FINANCIAL RESULTS for the full year 2021

23/02/2022

KEY FIGURES

Summary

IN € MILLIONS	**2021**	2020	Growth	% Growth
Operating revenue	648.7	420.0	228.7	54%
Gross profit	386.2	242.5	143.7	59%
EBITDA	202.9	94.2	108.7	115%
EBIT	181.6	74.7	106.9	143%
Net profit	153.1	61.1	92.0	151%
Capital Expenditure	40.9	39.7	1.2	3%
FCF	108.6	7.3	101.4	n.a.
Gross profit as % of revenue	59.5%	57.7%		1.8pp
EBITDA as % of revenue	31.3%	22.4%		8.8pp
EBIT as % of revenue	28.0%	17.8%		10.2pp
Net profit as % of revenue	23.6%	14.5%		9.1pp
Capex as % of revenue	6.3%	9.5%		-3.1pp
FCF as % of revenue	16.7%	1.7%		15.0pp

	As of Dec. 31, 2021	As of Dec. 31, 2020		
Net debt (€m)	(27.4)	19.8	(47.2)	n.a.
Net leverage ratio (x)	(0.13)	0.21	(0.35)	n.a.

[1] *Net debt/EBITDA*

Audited figures

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 2021 and the comparative information for 2020 (balance sheet, consolidated income statement and cash flow statement) are attached to this report (see Appendix 1).

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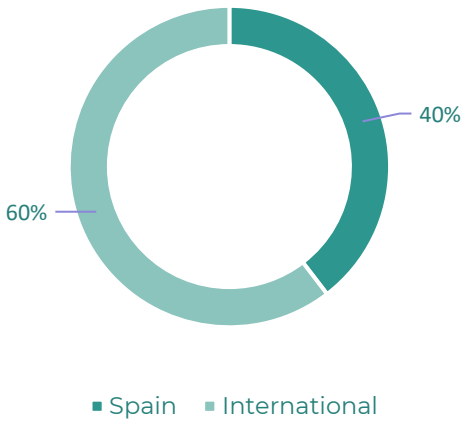
HIGHLIGHTS FY 2021

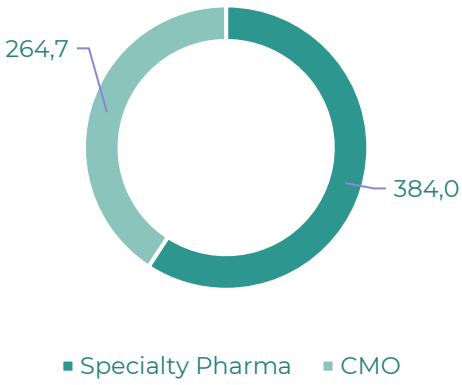
ROVI REPORTS OPERATING REVENUE GROWTH OF 54% AND NET PROFIT GROWTH OF 151%

- Operating revenue increased by 54% to 648.7 million euros driven by (i) the strength of the contract manufacturing organization ("CMO") business, which grew by 189%, and (ii) the specialty pharmaceutical business, where sales rose 17%.
- Sales of the heparin franchise (Low Molecular Weight Heparins (LMWH) and other heparins) increased by 16% to 242.0 million euros. Sales of the enoxaparin biosimilar increased 22% to 124.0 million euros and sales of Bemiparin increased 9% to 110.7 million euros.
- EBITDA increased by 115% to 202.9 million euros.
- Net profit increased by 151% to 153.1 million euros.
- ROVI and Moderna announced a long-term collaboration to increase capacities for the compounding, aseptic filling, inspection, labeling, and packaging of ROVI's facilities located in Madrid, San Sebastián de los Reyes and Alcalá de Henares. This new agreement, which has a term of ten years, includes a series of investments expected to allow the manufacturing capacity to increase across ROVI's facilities in Madrid, Spain.
- The European Commission has authorized the marketing of Okedi® (Risperidone ISM®) for the treatment of schizophrenia in adults for whom tolerability and effectiveness has been established with oral risperidone.
- ROVI will propose to the Shareholders General Meeting a dividend of 0.9556 euros per share with dividend rights on 2021 earnings. This proposed dividend would mean an increase of 151% compared to the dividend on 2020 earnings (€0.3812/share) and represents a 35% pay-out.

REVENUE BY REGION



REVENUE BY BUSINESS UNIT (€Mn)



OUTLOOK

For **2022**, ROVI is upgrading its operating revenue guidance from a mid-single-digit growth rate to the range between 15% and 20%, compared to the forecast provided to the market in November 2021.

END OF THE SHARE BUY-BACK PROGRAMME

On 22 February 2022, ROVI informed that the Board of Directors resolved to finalize the share buy-back programme launched by the Company as of 3 November 2021, having acquired 1,492,108 own shares, this is, 89% of the maximum number of shares to be acquired under the buy-back programme.

LAUNCHING OF A NEW SHARE BUY-BACK PROGRAMME

On 22 February 2022, ROVI informed the market that, effective as of today's date, 23 February, 2022, a new share buy-back programme (the "Buy-back Program") will commence under the following terms (see further information on pages 24-25):

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, increasing the remuneration of ROVI's shareholders by raising earnings per share.
2. **Term**: from today, 23 February 2022, for a six-month period.
3. **Maximum monetary amount**: up to 46,000,000 euros.
4. **Maximum number of shares to be acquired**: 560,700 shares of the Company, representing approximately 1% of the Company's share capital.

Juan López-Belmonte Encina, Chairman and Chief Executive Officer of ROVI, said *"We ended 2021 as we started it, immersed in the global vaccination campaign against COVID-19, in which ROVI is one of the protagonists. Never in the history of mankind has it been possible to vaccinate so many people in such a short time. 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. Thanks to vaccines, we expect to see the end of the pandemic and a progressive return to normality.*

The 2021 results are historic for ROVI and demonstrate our company's ability to continuously

adapt, compete and excel. We achieved 54% operating revenue growth, mainly driven by the strength of the contract manufacturing organization ("CMO") business, which grew by 189% and by the specialty pharmaceutical business, where sales rose 17%. We forecast continued growth thanks to our flagship product, Bemiparin, which grew by 9%. Likewise, we were already marketing our enoxaparin biosimilar in 32 countries in 2021 and its sales increased 22%. We are in a phase of international expansion and our enoxaparin biosimilar will enable us to be present in more than 120 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. Furthermore, we expect our specialty business in Spain, supported by a good performance by products such as Neparvis®, from Novartis, and Volutsa®, from Astellas, to provide us with a sustainable and profitable growth opportunity in the future. Furthermore, (i) the agreement signed with Moderna and (ii) the reorientation of the contract manufacturing activities strategy towards high-value-added products, backed by the high degree of technological specialization of our plants in differentiated niches, enabled our CMO business to increase 189% in 2021. At the same time, we are confident of the potential of our current pipeline of R&D projects, making important investment efforts, since we trust they will be the company's growth engine in the future. We have high hopes of the potential of our long-acting injectable technology (ISM®). In Europe, the European Commission has just authorized the marketing of our first candidate, Okedi®, a 4-weekly Risperidone LAI based on our ISM® technology for the treatment of schizophrenia, and we are currently undergoing a regulatory process in the United States to obtain the marketing authorization of this product. We expect to launch it on the market in 2022. We also obtained positive results in our Phase I study for another candidate, Letrozole-ISM®, and made significant progress in our quarterly Risperidone formulation, reflecting our clear commitment to our ISM® technology".

GROUP MANAGEMENT REPORT

for the annual period ending December 31th, 2021

INCOME STATEMENT

IN € MILLIONS	**2021**	2020	Growth	% Growth
Operating revenue	648.7	420.0	228.7	54%
Other income	1.3	1.2	0.2	15%
Total revenue	**650.0**	**421.1**	**228.9**	**54%**
Cost of goods sold	-263.9	-178.7	-85.2	48%
Gross profit	**386.2**	**242.5**	**143.7**	**59%**
% margin	*59.5%*	*57.7%*		1.8pp
R&D expenses	-27.4	-23.8	-3.6	15%
SG&A	-156.0	-124.4	-31.6	25%
Share of profit of a joint venture	0.2	0.0	0.2	n.a.
EBITDA	**202.9**	**94.2**	**108.7**	**115%**
% margin	*31.3%*	*22.4%*		8.8pp
EBIT	**181.6**	**74.7**	**106.9**	**143%**
% margin	*28.0%*	*17.8%*		10.2pp
Finance Income/(Costs)	1.1	-2.1	3.1	-151%
Profit before income tax	**182.6**	**72.6**	**110.0**	**152%**
Income tax	-29.6	-11.5	-18.0	156%
Effective tax	*16.2%*	*15.9%*		0.3pp
Net profit	**153.1**	**61.1**	**92.0**	**151%**

REVENUES

Total revenue by business unit

IN € MILLIONS	**2021**	2020	Growth	% Growth
Specialty pharmaceutical business	384.0	328.4	55.6	17%
CMO business	264.7	91.6	173.1	189%
Operating revenue	**648.7**	**420.0**	**228.7**	**54%**
Other income	1.3	1.2	0.2	15%
Total revenue	**650.0**	**421.1**	**228.9**	**54%**

Operating revenue increased by 54% to 648.7 million euros in 2021, driven by the strength of the contract manufacturing organisation business, which grew by 189%, and by the specialty pharmaceutical business, where sales rose 17%. **Total revenue** increased by 54% to 650.0 million euros in 2021.

Sales outside Spain increased by 105% to 392.0 million euros in 2021, 64.4 million euros (or 16%) of which related to international subsidiaries, mainly due to (i) the increase in LMWH international sales and (ii) the increase in the contract manufacturing organisation business. Sales outside Spain represented 60% of operating revenue in 2021 compared to 46% in 2020.

SPECIALTY PHARMACEUTICAL BUSINESS

Sales of the specialty pharmaceutical business

IN € MILLIONS	**2021**	2020	Growth	% Growth
Prescription-based pharmaceutical products	**347.4**	**297.0**	**50.4**	**17%**
LMWH franchise	234.8	202.8	32.0	16%
Biosimilar of enoxaparin	124.0	101.4	22.7	22%
Bemiparin (Hibor)	110.7	101.4	9.3	9%
Sales in Spain	69.4	68.5	1.0	1%
International sales	41.3	33.0	8.3	25%
Neparvis	38.5	29.6	8.9	30%
Ulunar & Hirobriz	9.4	11.3	-1.9	-17%
Volutsa	16.3	14.2	2.0	14%
Vytorin & Absorcol & Orvatez	28.3	28.4	0.0	0%
Medikinet & Medicebran	3.6	3.5	0.1	4%
Other products	28.4	26.6	1.9	7%
Discounts to the National Health System	-11.9	-19.4	7.5	-39%
Contrast agents and other hospital products	**35.5**	**30.7**	**4.8**	**15%**
Other	**1.1**	**0.7**	**0.4**	**61%**
Total specialty pharmaceutical business	**384.0**	**328.4**	**55.6**	**17%**

Sales of **prescription-based pharmaceutical** products rose 17% to 347.4 million euros in 2021.

Sales of the **heparin franchise** (Low Molecular Weight Heparins and other heparins) increased by 16% to 24
2.0 million euros in 2021. Heparin sales represented 37% of operating revenue in 2021 compared to 50% in 2020.

IN € MILLIONS	2021	2020	Growth	% Growth
LMWH franchise	234.8	202.8	32.0	16%
Biosimilar of enoxaparin	124.0	101.4	22.7	22%
Bemiparin (Hibor)	110.7	101.4	9.3	9%
Sales in Spain	69.4	68.5	1.0	1%
International sales	41.3	33.0	8.3	25%
Other heparins[1]	7.3	6.5	0.8	12%
Heparins franchise	**242.0**	**209.3**	**32.7**	**16%**

LOW MOLECULAR WEIGHT HEPARINS

Sales of **Low Molecular Weight Heparins** (LMWH) (Enoxaparin biosimilar and Bemiparin) increased by 16% to 234.8 million euros in 2021.

Sales of the **Enoxaparin biosimilar** increased 22% to 124.0 million euros in 2021 mainly because of (i) the launch of the product in thirteen new countries in 2021 and (ii) the increase in the demand for the product in countries where we are already present. ROVI commenced the marketing of its Enoxaparin biosimilar in Germany in 2017; in UK, Italy, Spain, France, Austria, Latvia, and Estonia in 2018; in Portugal, Poland, Costa Rica, Finland, and Sweden in 2019; in South Africa, Israel, Peru, Holland, Panama, and the Dominican Republic in 2020; and in Canada, Malasya, Albania, North Macedonia, Guatemala, El Salvador, Honduras, Georgia, Bahamas, Jamaica, Gabon, Democratic Republic of Congo, and Trinidad and Tobago in 2021.

Bemiparin showed a positive performance in 2021, with sales up 9% to 110.7 million euros. International sales of Bemiparin increased by 25% to 41.3 million euros. This increase was mainly linked to (i) the increase in sale prices to some partners and wholesalers due to the rise in LMWH raw material prices; and (ii) the increase in sales in the Russian, Turkish and Chinese markets. Sales of Bemiparin in Spain (Hibor®) increased 1% to 69.4 million euros in 2021, mainly due to a higher penetration of the product in the treatment segment.

[1] *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 December 2016, indicated for the treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction, increased 30% to 38.5 million euros in 2021, compared to 29.6 million euros in 2020.

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, increased by 14% to 16.3 million euros in 2021.

Sales of **Vytorin®**, **Orvatez**® and **Absorcol**®, specialty products from Merck Sharp & Dohme ("MSD") indicated as adjunctive therapy to diet in patients with hypercholesterolemia, remained constant at 28.3 million euros in 2021. In the second quarter of 2020, Orvatez® price was reduced by 30% due to the entrance of hybrid products formulated with ezetimibe and atorvastatine.

Sales of **Hirobriz**® **Breezhaler**® and **Ulunar**® **Breezhaler**®, both inhaled bronchodilators from Novartis for patients with respiratory difficulties due to a pulmonary disease known as Chronic Obstructive Pulmonary Disease (COPD), launched in Spain in the fourth quarter of 2014, decreased 17% to 9.4 million euros in 2021, compared to 11.3 million euros in the previous year, mainly due to Ulunar® Breezhaler® price reduction of 18% in the second quarter of 2020.

Sales of **Medicebran**® and **Medikinet**®, specialty products from Medice indicated for the treatment of ADHD (Attention Deficit and Hyperactivity Disorder) in children and teenagers, launched in December 2013 and marketed on exclusivity basis by ROVI in Spain, increased by 4% to 3.6 million euros in 2021. In July 2019, Medikinet® (methylphenidate hydrochloride with a modified release) went out of protection for galenic innovation and its price was reduced by 50.3% on average.

According to IQVIA, Spanish innovative product market increased by 4% in 2021 compared to the previous year. Nevertheless, ROVI prescription-based pharmaceutical product sales increased 17% in 2021, outperforming the market by more than 13 percentage points.

CONTRAST AGENTS AND OTHER HOSPITAL PRODUCTS

Sales of **contrast imaging agents and other hospital products** increased by 15% to 35.5 million euros in 2021. This increase shows the strong recovery of the Spanish and Portuguese hospital activity in 2021 after the effects of lockdowns during the pandemic.

CONTRACT MANUFACTURING ORGANISATION ("CMO") BUSINESS

CMO sales increased by 189% to 264.7 million euros in the 2021 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.

Likewise, in 2022, ROVI expects the CMO business to increase by between 30% and 40%, including production of the COVID-19 vaccine.

OTHER INCOME

Other income (subsidies) increased by 15% to 1.3 million euros in 2021, compared to the previous year.

COSTS

GROSS PROFIT

Gross profit increased by 59% to 386.2 million euros in 2021, the gross margin showing an increase of 1.8 percentage points from 57.7% in 2020 to 59.5% in 2021, mainly because the increase in the CMO business contributed higher margins to group sales. This positive impact on the gross margin offset the increase in the LMWH cost of goods sold in 2021 compared to the previous year. ROVI expects LMWH raw material prices to continue to decline in 2022 as a result of the increase in the pig population in China. Nevertheless, despite the potential decrease in LMWH raw material prices, the impact on the gross margin will continue to be negative because of the long LMWH manufacturing process, in which the raw material currently being used, stocked for several months, was purchased at higher prices.

RESEARCH AND DEVELOPMENT EXPENSES

R&D expenses increased 15% to 27.4 million euros in 2021. R&D expenses were mainly related to (i) the repetition of the bioavailability study comparing multiple doses of Risperidone ISM® with oral risperidone, in response to the major observation of the Committee for Medicinal Products for Human Use (CHMP), (ii) the development of the Letrozole ISM® Phase I trial; and (iii) the development of a new formulation of Risperidone ISM® for a 3-monthly injection.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

SG&A expenses increased 25% to 156.0 million euros 2021 mainly as a result of (i) an increase in expenses related to the manufacture of the Moderna vaccine; and (ii) an increase in expenses due to the preparation of Okedi® launch in Europe. Expenses related to Covid-19 decreased to 1.6 million euros in 2021, from 4.0 million euros in 2020. Excluding expenses related to COVID-19, SG&A would have increased by 28% to 154.4 million euros in 2021, compared to 120.4 million euros in 2020.

SG&A expenses

IN € MILLIONS	**2021**	2020	Change	% Change
Employee benefit expenses (exc. R&D)	81.4	67.4	14.0	21%
Other operating expenses (exc. R&D)	74.5	57.0	17.6	31%
Total SG&A expenses	**156.0**	**124.4**	**31.6**	**25%**
Expenses related to international subsidiaries	10.5	7.7	2.8	37%
Expenses related to COVID-19	1.6	4.0	-2.4	-61%
Total SG&A expenses excluding expenses related to COVID-19	**154.4**	**120.4**	**34.0**	**28%**

DEPRECIATION

Depreciation and amortisation expenses increased by 9% to 21.4 million euros in 2021, as a result of the new property, plant and equipment and intangible assets purchases made during the last twelve months.

NET FINANCE RESULT

Net finance result (income) amounted to 1.1 million euros in 2021 compared to (2.1) million euros (cost) in 2020, mainly due to the higher income related to exchange-rate derivative financial instruments.

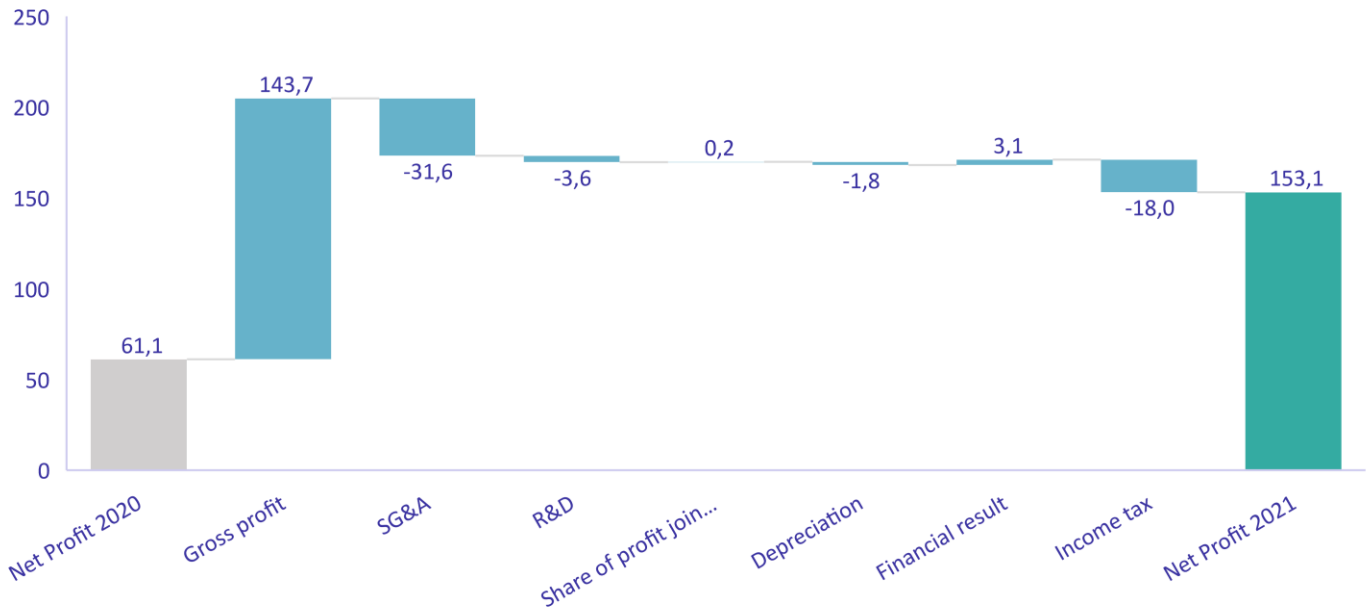
EFFECTIVE TAX RATE

The **effective tax rate** was 16.2% in 2021, compared to 15.9% in 2020, mainly due to the increase of the profit before income tax.

As of 31 December 2021, all the Group's negative tax bases had been used.

FINANCIAL PERFORMANCE

Million euros



EBITDA

EBITDA increased to 202.9 million euros in 2021, a rise of 115% compared to the previous year, reflecting a 8.8 percentage point increase in the EBITDA margin, which was up to 31.3% in 2021 from 22.4% in 2020. **EBITDA excluding expenses related to COVID-19** ("recurrent EBITDA") increased to 204.5 million euros in 2021, a rise of 108% compared to the previous year, reflecting a 8.1 percentage point increase in the recurrent EBITDA margin, which was up to 31.5% in 2021 from 23.4% in 2020.

EBIT

EBIT increased by 143% to 181.6 million euros in 2021, reflecting a 10.2 percentage point rise in the EBIT margin, which was up to 28.0% in 2021 from 17.8% in 2020.

NET PROFIT

Net profit increased by 151%, from 61.1 million euros in 2020 to 153.1 million euros in 2021.

PRE-R&D/FLAT R&D

EBITDA "Pre-R&D", calculated excluding R&D expenses in 2021 and 2020, increased by 95%, from 118.0 million euros in 2020 to 230.4 million euros in 2021, reflecting a 7.4 percentage point rise in the EBITDA margin to 35.5% in 2021 (see "Pre-R&D costs" columns of the table below). Likewise, recognising the same amount of R&D expenses in 2021 as in 2020, EBITDA would have increased by 119% to 206.6 million euros, reflecting a 9.4 percentage point rise in the EBITDA margin to 31.8% in 2021, up from 22.4% in 2020 (see "Flat R&D costs" columns of the table below).

EBIT "pre-R&D", calculated excluding R&D expenses in 2021 and 2020, increased by 112%, from 98.5 million euros in 2020 to 209.0 million euros in 2021, reflecting a 8.8 percentage point rise in the EBIT margin to 32.2% in 2021 (see "Pre-R&D costs" columns of the table below). Likewise, recognising the same amount of R&D expenses in 2021 as in 2020, EBIT would have increased by 148% to 185.2 million euros, reflecting a 10.8 percentage point rise in the EBIT margin to 28.6% in 2021, up from 17.8% in 2020 (see "Flat R&D costs" columns of the table below).

Net profit "pre-R&D", calculated excluding R&D expenses in 2021 and 2020, increased by 117%, from 81.1 million euros in 2020 to 176.1 million euros in 2021 (see "Pre-R&D costs" columns of the table below). Likewise, recognising the same amount of R&D expenses in 2021 as in 2020, net profit would have increased by 156% to 156.1 million euros (see "Flat R&D costs" columns of the table below).

Pre-R&D/Flat R&D

	Reported		Pre-R&D costs			Flat R&D costs		
IN € MILLIONS	**2021**	2020	**2021**	2020	% Growth	**2021**	2020	% Growth
Operating revenue	648.7	420.0	648.7	420.0	54%	648.7	420.0	54%
Other income	1.3	1.2	1.3	1.2	15%	1.3	1.2	15%
Total revenue	**650.0**	**421.1**	**650.0**	**421.1**	**54%**	**650.0**	**421.1**	**54%**
Cost of sales	-263.9	-178.7	-263.9	-178.7	48%	-263.9	-178.7	48%
Gross profit	**386.2**	**242.5**	**386.2**	**242.5**	**59%**	**386.2**	**242.5**	**59%**
% margin	59.5%	57.7%	59.5%	57.7%	*1.8pp*	59.5%	57.7%	*1.8pp*
R&D expenses	-27.4	-23.8	0.0	0.0	n.a.	-23.8	-23.8	0%
SG&A	-156.0	-124.4	-156.0	-124.4	25%	-156.0	-124.4	25%
Share of profit of a joint venture	0.2	0.0	0.2	0.0	n.a.	0.2	0.0	n.a.
EBITDA	**202.9**	**94.2**	**230.4**	**118.0**	**95%**	**206.6**	**94.2**	**119%**
% margin	31.3%	22.4%	35.5%	28.1%	*7.4pp*	31.8%	22.4%	*9.4pp*
EBIT	**181.6**	**74.7**	**209.0**	**98.5**	**112%**	**185.2**	**74.7**	**148%**
% margin	28.0%	17.8%	32.2%	23.4%	*8.8pp*	28.6%	17.8%	*10.8pp*
Net profit	**153.1**	**61.1**	**176.1**	**81.1**	**117%**	**156.1**	**61.1**	**156%**
% margin	23.6%	14.5%	27.1%	19.3%	*7.8pp*	24.1%	14.5%	*9.5pp*

DIVIDEND

ROVI General Shareholders Meeting, on 17 June 2021, approved the payment of a **gross dividend** of 0.3812 euros per share on 2020 earnings; it meant an increase of 118% compared to the dividend on 2019 earnings (€0.1751/share) and represented a 35% pay out (vs 25% pay out last year). This dividend was paid on 7 July 2021.

ROVI will pay a dividend of 0.9556 euros per share with dividend rights on 2021 earnings if the Shareholders General Meeting approves the application of the 2021 profit, under proposal of ROVI's Board of Directors. This proposed dividend would mean an increase of 151% compared to the dividend on 2020 earnings (€0.3812/share) and represents a 35% pay-out.

FINANCIAL POSITION

Balance Sheet

IN € MILLIONS	Dec. 31, 2021	Dec. 31, 2020	Growth	% Growth
Assets				
Non-current assets	226.3	209.9	16.5	8%
Current assets	506.4	364.6	141.8	39%
Total assets	**732.7**	**574.4**	**158.2**	**28%**
Equity				
Capital and reserves attributable to shareholders of the company	**471.0**	**373.7**	**97.3**	**26%**
Liabilities				
Non-current liabilities	71.3	77.9	-6.5	-8%
Financial debt	66.7	68.4	-1.7	-2%
Current liabilities	190.4	122.9	67.5	55%
Financial debt	6.4	6.0	0.4	7%
Total liabilities	**261.7**	**200.7**	**61.0**	**30%**
Total equity and liabilities	**732.7**	**574.4**	**158.2**	**28%**

TOTAL ASSETS

ROVI's **total assets** increased by 28% from €574.4 million as of December 31, 2020 to €732.7 million as of December 31, 2021, mainly due to (i) an increase in cash and cash equivalents of 45.9 million euros in 2021; (ii) a rise in the "trade and other receivables" item of 73.8 million euros mainly as a result of an increase in invoices pending to be paid by Moderna; and (iii) an increase in the "property, plant and equipment" caption of 26.4 million euros in 2021 (see "capital expenditure" in page 19).

As of 31 December 2021, **Social Security and Public Administrations total debt** with ROVI amounted to 9.0 million euros, from 9.4 million euros as of December 31, 2020, of which 4.5 million euros in Spain, 2.0 million euros in Portugal and 2.5 million euros in Italy.

EQUITY

ROVI's **equity** increased by 97.3 million euros to 471.0 million euros as of December 31, 2021. This increase resulted from the "profit for the year".

TOTAL LIABILITIES

ROVI's **total liabilities** increased by 30% from €200.7 million as of December 31, 2020 to €261.7 million as of December 31, 2021, mainly due to (i) an increase in the "contract liabilities" item of 28.4 million euros, which mainly related to amounts billed to customers that had not yet been taken to profit and loss as service revenue as of December 31, 2021 and (ii) a rise of 33.8 million euros in the "trade and other payables" caption.

As of 31 December 2021, ROVI **total debt** decreased to 73.2 million euros. Debt with public administration, which is 0% interest rate debt, represented 15% of total debt as of 31 December 2021.

Total Debt

IN € THOUSANDS	**Dec. 31, 2021**	Dec. 31, 2020	Interest rate
Bank borrowings	44,821	45,000	0.297-0.681
Debt with public administration	10,661	10,972	0
Financial liabilities for leases	17,663	17,546	-
Derivative financial instruments	17	925	-
Total	**73,162**	**74,443**	

As of 31 December 2021, bank borrowings remained almost stable. 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 31 December 2021, 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 0.297% in January 2022) 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 4.8 million euros. The credit matures in 2029 and includes a grace period of 3 years.

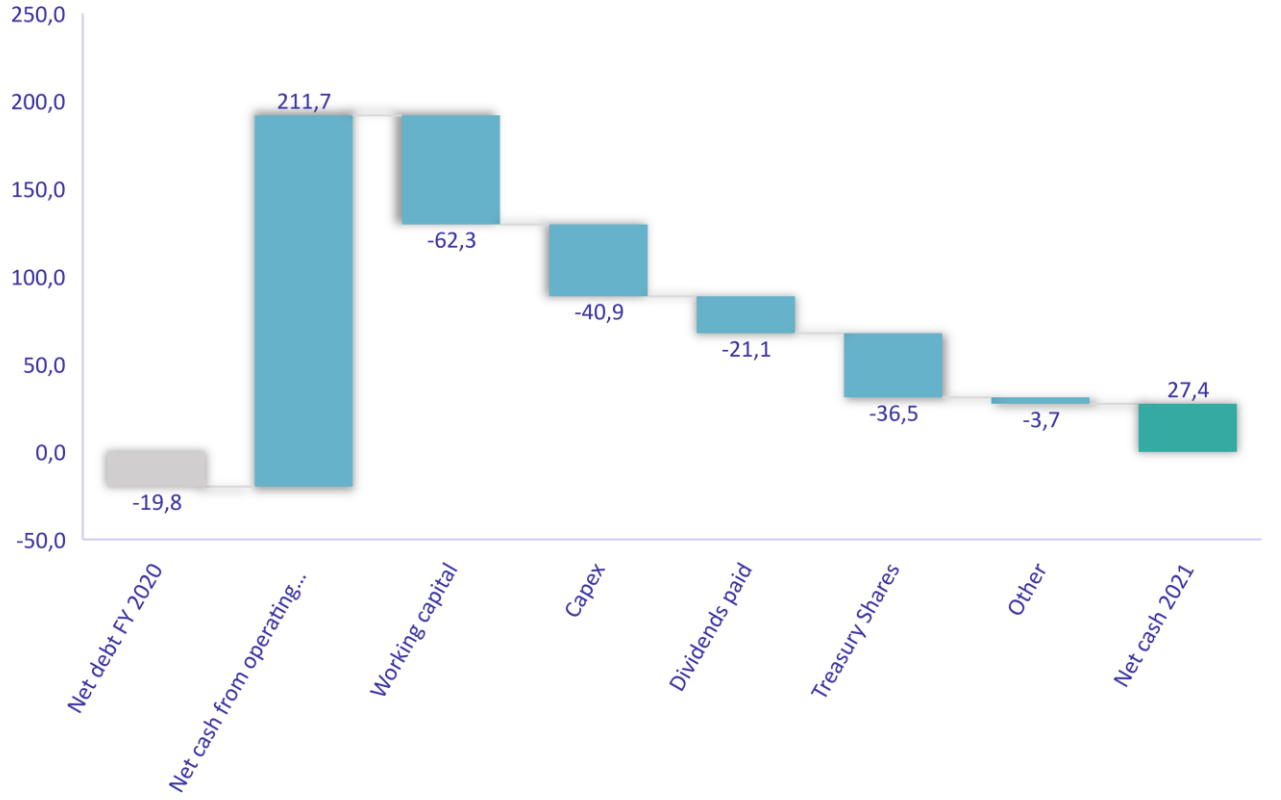
GROSS CASH POSITION AND NET DEBT

As of 31 December 2021, ROVI had a **gross cash position** of 100.5 million euros, compared to 54.6 million euros as of 31 December 2020, and **net cash** of 27.4 million euros (equity securities plus deposits plus financial derivatives plus cash and cash equivalents minus current and non-current financial debt), compared to **net debt** of 19.8 million euros as of 31 December 2020.

Net cash generated in operating activities amounted to 149.4 million euros in 2021, compared to 46.9 million euros in 2020. Net cash generated from operating activities

excluding changes in working capital increased 91% to 211.7 million euros in 2021 from 110.6 million euros in 2020.

Million euros



LIQUIDITY

Cash Flow

IN € MILLIONS	**2021**	2020	Growth	% Growth
Cash flow from operating activities	149.4	46.9	102.6	219%
Cash flow from investing activities	-40.8	-39.6	-1.2	3%
Cash flow from financing activities	-62.7	-21.5	-41.2	192%
Net increase/ (decrease) in cash	**45.9**	**-14.3**	**60.1**	**n.a.**
Cash at the beginning of the period	53.2	67.4	-14.3	-21%
Cash at the end of the period	**99.0**	**53.2**	**45.9**	**86%**

CASH FLOW FROM OPERATING ACTIVITIES

Cash flow from operating activities increased to 149.4 million euros in 2021 from 46.9 million euros in 2020. This increase was mainly due to:

- the increase of 110.0 million euros in profit before income tax
- the decrease of 23.4 million euros in the "inventory" item in 2021 compared to a decrease of 70.4 million euros in 2020;
- the booking of 34.4 million euros under the "Proceeds from CMO services" caption in 2021 relating to payments received but not yet allocated to the income statement, compared to the 21.6 million euros recognized in 2020; and
- the increase of 35.4 million euros in the "trade and other payables" item in 2021, compared to a decrease of 0.8 million euros in 2020.

These positive impacts were partially offset by:

- the decrease of 74.2 million euros in the "trade receivables" caption in 2021 compared to an increase of 7.5 million euros in 2020; and
- the decrease of 23.9 million euros in 2021 in the "income tax cash flow" caption compared to a decrease of 6.0 million euros in 2020.

CASH FLOW FROM INVESTING ACTIVITIES

ROVI invested 40.9 million euros in 2021, compared to 39.7 million euros in 2020.

Capital expenditure

IN € MILLIONS	**2021**	2020	Growth	% Growth
Madrid Injectable plant	2.9	3.2	-0.3	-10%
San Sebastián de los Reyes Injectable plant	2.0	2.7	-0.7	-27%
Granada plant	1.4	2.4	-1.0	-42%
Alcalá de Henares plant	4.2	3.8	0.5	12%
Expenditure on maintenance and other capex	3.3	2.0	1.3	66%
Maintenance Capex	**13.8**	**14.0**	**-0.2**	**-2%**
ISM industrialisation	5.5	9.7	-4.2	-44%
Escúzar plant	18.8	10.1	8.7	n.a.
New vial filling line & operations expansion	2.9	5.9	-3.0	-51%
Investment Capex	**27.2**	**25.7**	**1.5**	**6%**
Total Capex	**40.9**	**39.7**	**1.2**	**3%**

CASH FLOW FROM FINANCING ACTIVITIES

Cash flow from financing activities decreased to -62.7 million euros in 2021 from -21.5 million in 2020. This decrease was mainly attributable to (i) the payment of the ordinary dividend on 2020 earnings of 21.1 million euros in 2021 (compared to the dividend on 2019 earnings of 9.7 million euros) and (ii) ROVI's share buyback program that started in November 2021.

Javier López-Belmonte Encina, First Vice-President and Chief Financial Officer of ROVI, said "We are very happy with the results of 2021. We have been able to deliver operating revenue growth of 54% in a difficult environment thanks to the strength of our contract manufacturing organization business, which continues to enjoy good sales prospects, and an EBITDA margin rise of 8.8 percentage points, mainly as a result of the operating leverage contribution of our CMO business, the good performance of our LMWH division, and the recovery of the specialty pharma business. ROVI's commitment to innovation is reflected in the figures of 2021. We are in a new phase of growth and we expect our robust balance sheet to allow us to take advantage of other opportunities to expand our sales base and improve the utilization of our asset base".

OUTLOOK

For **2022**, ROVI is upgrading its operating revenue guidance from a mid-single-digit growth rate to the range between 15% and 20%, compared to the forecast provided to the market in November 2021.

Notwithstanding, given the uncertainties associated to the development of the COVID-19 pandemic (which ROVI will continue to monitor closely), it is not yet possible to make a precise assessment of the impact that the pandemic will have on this year.

The Company forecasts that it will continue to grow at a much higher rate than the Spanish pharmaceutical market expenditure in 2021, which, according to the Ministry of Health, Consumption and Social Welfare, showed a growth rate of 6.1%.

ROVI expects its growth drivers to be the launch of Okedi® in Europe, Bemiparin, the license agreements, such as Neparvis® and Volutsa®, the Enoxaparin biosimilar, its existing portfolio of specialty pharmaceuticals, the agreement with Moderna and new contracts in the toll manufacturing area.

R&D UPDATE

ISM® technology platform

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

In January 2020, ROVI announced the commencement of the centralised procedure for registration of Okedi® with the European Medicines Agency (EMA). In March 2021, ROVI informed about the request of a "clock stop" in the Okedi® authorization process to provide answers within the framework of the centralized registration procedure. The purpose of said clock stop was to have sufficient time to repeat the bioavailability study comparing multiple doses of Okedi® with oral risperidone from EU source, in response to the major observation of the Committee for Medicinal Products for Human Use (CHMP), which states that the study must be performed using the European reference product. The original Okedi® dossier already included a clinical bioavailability trial using the oral risperidone drug marketed in the United States (USA). Thereafter, at the planned date, ROVI submitted the required answers and additional clinical data to the CHMP. On 16 December 2021, the CHMP adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Okedi®. Finally, on 15 February 2022, the European Commission authorized 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 could be launched in Europe in the second quarter of 2022.

Likewise, at its Capital Markets Day held on 24 November 2020, ROVI announced the filing of an NDA (New Drug Application), i.e. a registration dossier to obtain marketing authorisation in the USA, with the FDA (Food and Drug Administration). ROVI was informed of the delay in the decision on the granting of marketing authorisation for Risvan® (Risperidone ISM®) by the U.S. Food and Drug Administration ("FDA"). The FDA will be taking a number of actions, including an in-situ inspection of the European production plant where the product is manufactured, located in Madrid (Spain). The grant of the marketing authorisation for Risvan® by the FDA is subject to the result of this inspection. Furthermore, on 24 September 2021, ROVI received a Complete Response Letter from the FDA with outstanding questions on the Risvan® dossier. The Company has already answered them since, in its letter, the FDA recognises that it did

not review some of the responses submitted during the evaluation process. ROVI expects its responses to clarify the outstanding questions. In the Complete Response Letter, the FDA states that, due to the exceptional situation caused by the pandemic which has prevented the inspection from taking place within the term defined in the Filing Communication Letter, all the responses to outstanding questions will be evaluated in accordance with the timeline described in the "*2020 Guidance for Industry Review Timelines for Applicant Reponses to Complete Response Letters When a Facility Assessment Is Needed During the COVID-19 Public Health Emergency*", with an estimated review time of 6 months as of the submission of the responses to the questions raised in the Complete Response Letter.

As previously informed, the Risperidone ISM® dossier is mainly supported by the pivotal clinical trial "PRISMA-3"[2] whose results were published in November of 2020 in the medical journal *npj Schizophrenia*[3]. The PRISMA-3 study demonstrated that Risperidone ISM® provides rapid and progressive reduction of symptoms in patients with acutely exacerbated schizophrenia without need of oral risperidone supplementation or loading doses[2].

The company also announced in July 2019 the completion of an open-label extension (12 additional months) of the PRISMA-3 study[4], which is also included in the Risperidone ISM® dossier and further supports the long-term use of Risperidone ISM®. The results of this part of the PRISMA-3 study have been recently published in the medical journal *Schizophrenia Research*. In this article the authors conclude that Risperidone ISM® is an effective, safe, and well-tolerated long-term treatment of schizophrenia in adults, regardless of the initial disease severity or whether patients were previously treated with Risperidone ISM® during an acute exacerbation or switched from stable doses of oral risperidone[5].

Besides, several communications were presented at two international congresses, providing further clinical data of Risperidone ISM®:

- 8th European Conference on Schizophrenia Research (ECSR) held on 23-25 September 2021[6]:
  - Robert E. Litman, et al. Personal And Social Functioning In Patients With Schizophrenia Treated With Once-Monthly Risperidone ISM® [oral presentation #O-06-003].

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[2] Study to Evaluate the Efficacy and Safety of Risperidone In Situ Microparticles® (ISM®) in Patients With Acute Schizophrenia (PRISMA-3). Clinicaltrials.gov#NCT03160521 [https://clinicaltrials.gov/show/NCT03160521]. This clinical program has had the support of the Industrial Technological Development Centre ("CDTI").

[3] Correll CU, Litman RE, Filts Y, et al. Efficacy and safety of once-monthly Risperidone ISM® in schizophrenic patients with an acute exacerbation. NPJ Schizophr. 2020;6(1):37. https://doi.org/10.1038/s41537-020-00127-y.

[4] Study to Evaluate the Efficacy and Safety of Risperidone ISM® in Patients With Acute Schizophrenia: Open Label Extension (PRISMA-3_OLE). Clinicaltrials.gov# NCT03870880 [https://clinicaltrials.gov/ct2/show/NCT03870880]. This clinical program has had the support of the Industrial Technological Development Centre ("CDTI").

[5] 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. 2022;239:83-91. https://doi.org/10.1016/j.schres.2021.11.030.

[6] 8th European Conference on Schizophrenia Research. Virtual meeting, 23-25 September 2021. [https://www.schizophrenianet.eu/portal/start.html].

  - Christoph U. Correll, et al. Risperidone ISM® Efficacy In Schizophrenia Patients With Severe Psychotic Symptoms During An Acute Exacerbation [poster #220].
  - Christoph U. Correll, et al. Efficacy Of Once-Monthly Risperidone ISM® In Schizophrenia Patients With A Psychotic Relapse Who Were Previously Treated With Either Risperidone Or Another Antipsychotic [poster #219].
- 34th European College of Neuropsychopharmacology (ECNP) congress held on 2-5 October 2021[7]:
  - Robert E. Litman, et al. Risperidone ISM® effect size evaluation: post-hoc findings from the Prisma-3 phase III study [poster #0839].

Furthermore, another article has been recently published in the journal *Drug Design, Development and Therapy* about a comparative bioavailability clinical trial of Risperidone ISM® and oral risperidone. The authors concluded that direct switch after 24 hours from the last oral risperidone dose to Risperidone ISM® treatment may be done in schizophrenia patients with no time lag, maintaining steady-state levels of the active moiety throughout the treatment without the need for oral supplementation or loading doses.[8]

In addition, the company continues with the clinical development of Letrozole ISM®, which represents the second candidate using ROVI's ISM® technology platform. This new investigational medicine is, to the best of ROVI's knowledge, the first long-acting injectable aromatase inhibitor intended for the treatment of hormone-dependent breast cancer. ROVI has obtained positive results that confirm that this ISM® formulation provides a prolonged release of letrozole which produces a sustained suppression of oestrogenic hormones. The company has initiated discussions with the FDA to review these results, as well as the next steps for continuing the clinical development of this novel long-acting injectable aromatase inhibitor.

Lastly, ROVI's R&D team is progressing in the development of a new formulation of Risperidone ISM® for a 3-monthly injection, which would complement the current formulation of Risperidone ISM® for the maintenance treatment of patients with clinically stable schizophrenia. This development is currently undergoing regulatory toxicity studies needed to conduct a Phase I clinical trial in humans.

ESG

In August 2021, ROVI's ESG aspects were evaluated by Sustainalytics, a Global Leader in ESG & Corporate Governance, having obtained an "ESG Risk Rating 2020" of 18.4, which places the company at low risk (between 10 and 20). This rating improves by 3.4 points

[7] *34th ECNP congress. Lisbon (Portugal), 2-5 October 2021 [https://www.ecnp.eu/Congress2021/ECNPcongress].*
[8] *Walling DP, Hassman HA, Anta L, et al. The Steady-State Comparative Bioavailability of Intramuscular Risperidone ISM and Oral Risperidone: An Open-Label, One-Sequence Study. Drug Des Devel Ther. 2021;15:4371-4382. [https://doi.org/10.2147/dddt.s332026]*

the one achieved in the previous year (21.8), when the company reached a medium risk position (between 20 and 30 points).

ROVI attains the second position out of 432 companies in the sub-industry "pharmaceuticals" and 17th out of a total of 896 companies in the "pharmaceutical industry", which includes biotech, pharmaceutical and laboratory equipment companies.

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

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

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

KEY OPERATING AND FINANCIAL EVENTS

ROVI New Share Buy-back Programme

ROVI announced (by publication of the inside information number 1308 dated 22 February 2022) the end of the share buy-back programme, effective as of 3 November 2021, and the launching of a new share buy-back programme, effective as of today, 23 February 2022.

End of the share buy-back programme

ROVI informs that, yesterday, the Board of Directors resolved to finalize the share buy-back programme launched by the Company as of 3 November 2021, having acquired 1,492,108 own shares, this is, 89% of the maximum number of shares to be acquired under the buy-back programme.

After the transactions disclosed on 21 February 2022 by means of a relevant information notice (number 14160), the Company has not carried any transactions under the referred programme.

Launching of a new share buy-back programme

ROVI further informs that the Company will launch, effective as of today, 23 February 2022, a new share buy-back program (the "Buy-back Program"), in accordance with the following terms:

(i) Purpose and scope: the Buy-back Program's purpose is to redeem own shares of ROVI (share capital reduction) and, at the same time, to contribute to ROVI's shareholders remuneration by increasing earnings per share.

(ii) Term: from today, 23 February 2022, and for a period of 6 months.

(iii) Maximum monetary amount: up to 46,000,000 euros.

(iv) Maximum number of shares to be acquired: 560,700 shares of the Company, representing approximately 1% of the Company's share capital as of today.

(v) 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 Continuous Market of the Spanish Stock Exchanges during the twenty trading days prior to the date of the purchase.

Moderna and ROVI expand long-term collaboration for the manufacture of mRNA medicines over the next ten years

ROVI announced (by publication of the inside information number 1299 dated 16th of February of 2022) a long-term collaboration with Moderna to increase capacities for the compounding, aseptic filling, inspection, labelling, and packaging of ROVI's facilities located in Madrid, San Sebastián de los Reyes and Alcalá de Henares.

This new agreement, which has a term of ten years, includes a series of investments expected to allow the manufacturing capacity to increase across ROVI's facilities in Madrid, Spain. In addition to producing Moderna's COVID-19 vaccine, ROVI's platform could also be utilized to service future Moderna mRNA vaccine candidates.

"*ROVI has been a pivotal partner in supporting the manufacturing of our COVID-19 mRNA vaccine for countries outside of the U.S., and this long-term agreement expands our partnership and allows for further scale-up for future mRNA medicines*," said Juan Andres, Moderna's Chief Technical Operations and Quality Officer.

Mr. Juan López-Belmonte Encina, ROVI's Chairman and Chief Executive Officer, said: "*We are delighted to expand our collaboration with Moderna and become a long-term manufacturing partner. At ROVI we are working to contribute all our experience as a high-technological-value contract manufacturer of injectables to the solution of this pandemic and we are confident of our ability to take part in the manufacturing of new mRNA candidates in the future.*"

Moderna and ROVI are expected to finalize details of this agreement in the first quarter of 2022.

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

ROVI announced (by publication of the relevant information number 14055 dated 15th of February of 2022) that the European Commission has authorised the marketing of Okedi® (Risperidone ISM®) for the treatment of schizophrenia in adults for whom tolerability and effectiveness has been established with oral risperidone.

Risperidone ISM® is a prolonged-release injectable antipsychotic developed and patented by ROVI for the treatment of schizophrenia in adults for whom tolerability and effectiveness has been established with oral risperidone, since, as of the first injection, it 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[9]. 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 acute exacerbation of schizophrenia. The primary efficacy endpoint, the PANSS 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. Significantly improved mean changes for the secondary endpoint, the CGI-S 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. 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 long-term, 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[10].

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[9] *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*

[10] *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.*

"*We are very excited about the European Commission's approval of Risperidone ISM® because we think our medicine will be able to contribute to the clinical management of schizophrenia patients. Likewise, we hope to launch the product in Europe in the second quarter of 2022*", commented Juan López-Belmonte Encina, ROVI's Chairman and Chief Executive Officer.

Regarding other territories, ROVI filed the application for marketing authorisation of Risperidone ISM® with the United State Health authorities, the U.S. Food and Drug Administration ("FDA") on 24 November, 2020 and the dossier is currently being reviewed by the FDA. Recently, the FDA informed ROVI of a delay in making a decision on the grant of said marketing authorisation.

ROVI receives the positive opinion of the CHMP on Okedi® as a treatment for schizophrenia

ROVI announced (by publication of the relevant information number 13249 dated 17th of December of 2021) that the Committee for Medical Products for Human Use (CHMP) of the European Medicines Agency had recommended the approval of Okedi® (Risperidone ISM®) for the treatment of schizophrenia.

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

The positive opinion of the CHMP is based on the positive results of the pivotal PRISMA-3 study on the efficacy and safety of Risperidone ISM® in schizophrenia patients[11].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 acute exacerbation of schizophrenia. The primary efficacy endpoint, the PANSS 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. Significantly improved mean changes for the secondary endpoint, the CGI-S 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. 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

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[11] *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

completed the double-blind period were offered the opportunity to continue in a long-term, open-label 12-month extension phase with once-monthly 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. The objective of the study extension phase is to check the safety, tolerability and durability of the long-term effect of Risperidone ISM®12.

"*We are very satisfied to receive the favourable recommendation for Risperidone ISM® announced by the CHMP because we believe that our product can contribute to the clinical management of schizophrenia patients*", commented Juan López-Belmonte Encina, ROVI's Chairman and Chief Executive Officer.

Regarding other territories, ROVI filed the application for marketing authorisation of Risperidone ISM® with the United State Health authorities, the U.S. Food and Drug Administration ("FDA") on 24 November, 2020 and the dossier is currently being reviewed by the FDA. Recently, the FDA informed ROVI of a delay in making a decision on the grant of said marketing authorisation.

ROVI Share Buyback Program

ROVI informed the market (by publication of inside information number 1143 dated 3rd of November of 2021) that, effective as of 3 November 2021, a share buyback program (the "Buyback Program") commenced, in accordance with the following terms:

(vi) **Purpose and scope**: the Buyback Program's purpose is to redeem own shares of ROVI (share capital reduction) and, at the same time, to contribute to ROVI's shareholders remuneration by increasing earnings per share.

(vii) **Term**: from 3 November 2021, date of publication of the communication of the approval and effectiveness of the Buyback Program, and for a period of 12 months.

(viii) **Maximum monetary amount**: up to 125,000,000 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.

(ix) **Maximum number of shares to be acquired**: 1,628,000 shares of the Company, representing approximately 3% of the Company's share capital.

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[12] *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.*

(x) **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 is 25% of the average daily volume of ROVI's shares on the Continuous Market of the Spanish Stock Exchanges during the twenty trading days prior to the date of the purchase.

The FDA delays its decision on Risperidone ISM®

ROVI announced (by publication of the relevant information number 12278 dated 21st of October of 2021) that it had been informed of the delay in the decision on the granting of marketing authorisation for Risvan® (Risperidone ISM®) by the U.S. Food and Drug Administration ("FDA"). The FDA will be taking a number of actions, including an in-situ inspection of the European production plant where the product is manufactured, located in Madrid (Spain). The grant of the marketing authorisation for Risperidone ISM® by the FDA is subject to the result of this inspection.

The delay in the inspection of the manufacturing facilities has been caused by the restrictions on movement due to COVID-19 and, thus, the FDA has not yet fixed the inspection date.

ROVI filed the application for marketing authorisation for Risvan® with the FDA on 24 November, 2020. On 24 September, 2021, ROVI received a Complete Response Letter from the FDA with outstanding questions on the Risvan® dossier. The Company has provided full response on 17th January 2022. ROVI expects its responses to clarify the outstanding questions.

In the Complete Response Letter, the FDA states that, due to the exceptional situation caused by the pandemic which has prevented the inspection from taking place within the term defined in the Filing Communication Letter, all the responses to outstanding questions will be evaluated in accordance with the timeline described in the "2020 Guidance for Industry Review Timelines for Applicant Reponses to Complete Response Letters When a Facility Assessment Is Needed During the COVID-19 Public Health Emergency", with an estimated review time of 6 months as of the submission of the responses to the questions raised in the Complete Response Letter.

ROVI informs about the joint statement from Moderna and Takeda on the investigation of suspended lots of the vaccine

ROVI, as an entity participating in the manufacturing process of Moderna's vaccine against COVID-19, and in relation to the notification of particulate matter having been seen in certain drug product vials of the vaccine distributed in Japan, informed (by publication of the relevant information number 11466 dated 1st of September of 2021) about the joint statement from Moderna and Takeda on the investigation of suspended lots of the vaccine published on that date.

Working with the Ministry of Health, Labour and Welfare (MHLW), Moderna, the vaccine manufacturer, ROVI Pharma Industrial Services, S.A. in Spain, Moderna's European contract manufacturing organization, and Takeda, the authorized distributor, conducted a thorough investigation, which included:

- Identification of the root cause of the particles and the corrective and preventive actions being taken;
- An assessment of the nature of a particle from one vial from Lot 3004667; and
- An associated medical safety assessment, to determine if the identified particle poses a health or safety risk.

Root Cause Investigation, and Corrective and Preventive Actions

Three lots of the Moderna COVID-19 Vaccine (Lots 3004667, 3004734 and 3004956) were suspended following reports from vaccination sites of a potential foreign particulate substance observed in unused vials from Lot 3004667.

According to the root cause analysis report, conducted by ROVI, the most probable cause of the particulates identified in lot 3004667 is related to friction between two pieces of metal installed in the stoppering module of the production line due to an incorrect set-up. The two pieces are the star-wheel and the stoppers feeding device piece which feeds stoppers into the star-wheel. It is believed that this condition occurred during the assembling of the line prior to production of batch 3004667 and was a result of improper alignment during a line changeover before starting this batch. Based on the analysis conducted by ROVI, the manufacturing issue only impacted the lots that were included in the suspension. The following steps had been taken by ROVI to correct and prevent future defects:

- Full inspection of the manufacturing line;
- Improving standard operating procedure for changeover of manufacturing line; and
- Setting alert inspection limits in the automatic visual inspection, as an internal process control.

Takeda, as the Japan Marketing Authorization Holder, was planning to initiate the recall of the three suspended lots 3004667, 3004734, and 3004956 from the market as of September 2, 2021, in consultation with MHLW and Osaka Prefecture. Moderna as the Global Marketing Authorization Holder was in full agreement with this decision.

Preliminary Particulate Analysis

According to Moderna's independent analysis, the particle from lot 3004667 had been thoroughly analyzed and was confirmed to be grade 316 stainless steel. This is consistent with the root cause determination described above. Grade 316 is a high grade of stainless steel commonly used in manufacturing and in food processing.

Current Medical Safety Assessment

After a health assessment conducted by Moderna and Takeda, the rare presence of stainless steel particles in the Moderna COVID-19 vaccine does not pose an undue risk to patient safety and it does not adversely affect the benefit/risk profile of the product. Metallic particles of this size injected into a muscle may result in a local reaction, but are unlikely to result in other adverse reactions beyond the local site of the injection. Stainless steel is routinely used in heart valves, joint replacements and metal sutures and staples. As such, it is not expected that injection of the particles identified in these lots in Japan would result in increased medical risk.

Investigation of Two Deaths Following Administration of Vaccine

At this time, there is no evidence that the two tragic deaths following administration of the Moderna COVID-19 vaccine (from lot 3004734) were in any way related to administration of the vaccine. The relationship is currently considered to be coincidental. It is important to conclude a formal investigation to confirm this. The investigation is being conducted with the greatest sense of urgency, transparency and integrity and is of the highest priority.

To date, more than 200 million doses of the Moderna COVID-19 vaccine had been administered to more than 110 million individuals in 45 countries, representing a critical component of the global fight against COVID-19.

ROVI informs on the evolution of the investigation of particulate matter having been seen in certain drug product vials of the Moderna COVID-19 vaccine distributed in Japan

ROVI, as an entity participating in the manufacturing process of Moderna's vaccine against COVID-19, and in relation to the notification of particulate matter having been seen in certain drug product vials of the vaccine distributed in Japan, announced (by publication of the relevant information number 11399 dated 29th of August of 2021) that the investigation on this event continued to be conducted to determine what happened in the drug product fill/finish manufacturing process of the related batch. As reported publicly by the laboratory owning the vaccine, Moderna, and the company in charge of distributing the vaccine in Japan, Takeda, unfortunately, the death of two individuals who had received the Moderna COVID-19 vaccine had been reported. There is no evidence up-to-date that these deaths are caused by the Moderna covid-19 vaccine. In any event, there is a formal investigation underway to determine whether there is any connection. As recently reported, the detection of this particulate matter in certain drug product vials is an event that is in the process of being investigated by ROVI in coordination with Moderna, Takeda and the health authorities. ROVI will continue to proactively assist in the investigation of this matter, waiting for its finalisation and the publishing of the relevant conclusions by Moderna and Takeda.

ROVI informs on the notification of particulate matter having been seen in certain drug product vials of the Moderna's COVID-19 vaccine distributed in Japan

ROVI, as an entity participating in the manufacturing process of Moderna's vaccine against COVID-19, and in relation to the notification of particulate matter having been seen in certain drug product vials of the vaccine distributed in Japan, announced (by publication of the relevant information number 11377 dated 26th of August of 2021) that it was conducting an investigation on this event, following the standard procedure for these cases.

The detection of this particulate matter referred to certain vials of one product lot distributed exclusively in Japan. ROVI, as well as Moderna and Takeda, the company distributing the referred vaccine in Japan, are working with health authorities in order to clarify and solve, if applicable, this incident

The origin of this manufacturing incident may be in one of ROVI's manufacturing lines. ROVI is working in order to provide with all the information and assistance that may be needed to progress with the investigation. As a precaution, this lot and two adjacent lots had been put on hold.

To date, no safety or efficacy issues have been identified in relation to the vaccine, as Moderna and Japanese authorities have reported.

Mr. Juan López-Belmonte Encina has been appointed as new Chairman of the Board of Directors of ROVI

ROVI announced (by publication of the inside information register No. 991 dated 16 July, 2021) that, subsequent to the death of its chairman Mr Juan López-Belmonte López (communicated as stated in point 7.2 below), the Board of Directors of ROVI had unanimously decided, acting on a proposal and report from the Appointments and Remuneration Committee, to appoint the current Chief Executive Officer, Mr Juan López-Belmonte Encina, as the new chairman of ROVI's Board of Directors. He will combine this position with his current post as Chief Executive Officer.

The Board of Directors has expressed the profound gratitude and respect of the Company and all of its employees towards the former Chairman, Mr. Juan López-Belmonte López. The Appointments and Remunerations Committee has considered that according to the career of Mr. Juan López-Belmonte Encina it is clear that he has unquestionable knowledge to perform the functions as Chairman of the Board, as well as a deep and extensive expertise in the Company, the Rovi Group and the sector in which it develops its activity, making him the suitable candidate to occupy such position. As indicated, Mr. Juan López-Belmonte Encina will continue to act also as a Chief Executive Officer. It was hereby stated that the Company has already appointed a lead independent director, Mr. Marcos Peña Pinto, among its independent directors.

The President of the Board of Directors of Laboratorios Farmacéuticos Rovi, S.A., Mr. Juan López-Belmonte López, passed away

ROVI announced (by publication of the relevant information number 10575 dated 13th of July of 2021) that the President of the Board of Directors of Laboratorios Farmacéuticos Rovi, S.A., Mr. Juan López-Belmonte López, passed away.

The First Vice President of the Board, Mr. Javier López-Belmonte Encina, exercised the functions of the presidency until the appointment of the new President in accordance with the provided succession plans and corporate procedures.

The Company will always be grateful for the commendable work carried out by its President and it will honour his example.

ROVI increases its fill-finish capacity for the COVID-19 Vaccine Moderna

ROVI announced (by publication of the inside information number 858 dated 29th of April of 2021) that it strengthened its collaboration in the fill-finish of the COVID-19 Vaccine Moderna by increasing its fill-finish capacity. To this end, further industrial investments will be made in the ROVI Group's facility in Madrid (Spain).

These investments consist of the installation of two new production lines and equipment for compounding, filling, automatic visual inspection, labelling and packaging that will provide additional fill-finish capacity for the COVID-19 Vaccine Moderna, intended to supply markets outside the United States. These lines, located at ROVI's facility in San Sebastián de los Reyes (Madrid), will come into operation in the fourth quarter of 2021 and be fully operational in the first half of 2022 and will more than double the number of vials for which there is fill-finish capacity at this facility.

ROVI participates in the manufacture of the active substance of Moderna's COVID-19 vaccine

ROVI announced (by publication of the inside information number 837 dated 12th of April of 2021) that they will strengthen their collaboration for the manufacture of the active substance of the COVID-19 Vaccine Moderna. To this end, further industrial investment will be made in the ROVI Group's facility in Granada (Spain).

This investment consists of the installation of a new line supporting production phases of the active substance of the mRNA vaccine, which are prior and additional to the compounding and fill-finish of the vaccine. This line will have a production capacity equivalent to more than 100 million doses per year and is expected to begin to supply markets outside the United States in the third quarter of 2021.

With this addition, ROVI will extend the activities it performs in the manufacturing process of the COVID-19 Vaccine Moderna: it will take part in the manufacture of the

active substance, as well as the compounding, filling and final packaging before the vaccine is distributed for administration to patients.

ROVI has requested to European Medicines Agency (EMA) to “stop the clock” on Day 181 of the Doria® authorisation process.

ROVI announced (by publication of the inside information number 781 dated 2sd of March of 2021) that it had requested to European Medicines Agency (EMA) to “stop the clock” on Day 181 of the authorisation process to provide responses within the framework of the centralised registration procedure.

The purpose of said clock stop is to have sufficient time to repeat the bioavailability study comparing multiple doses of Doria® with oral risperidone, in response to the major observation of the Committee for Medicinal Products for Human Use (CHMP), which states that the study must be performed using the European reference product. The current dossier of Doria® already includes a clinical trial of bioavailability using the oral risperidone medicine marketed in the United States.

ROVI expected the trial using the U.S.A. reference product to be valid for Europe because the two products -the oral risperidone medicine marketed in the European Union and the one marketed in the U.S.A.- can be considered bioequivalents based on the in vitro and in vivo studies that ROVI had conducted and submitted to the EMA. Indeed, the therapeutic indication in schizophrenia for oral risperidone was supported by the same efficacy clinical trials in both territories.

ROVI considers that the additional clinical information requested can be provided in November this year 2021, thus resuming the regulatory process and enabling the EMA to complete its evaluation. Additionally, the EMA includes a second major observation in its Day 180 evaluation, aimed to prevent possible problems related to the lack of flexibility in interrupting the treatment with a long-acting formulation, as well as other minor observations that will be answered on Day 181 of the procedure.

ROVI does not foresee any additional information requirements from the EMA and aspires to obtain the indication of “treatment of schizophrenia in adults”, which would mean that Doria®, due to its unique pharmacokinetic profile, would not only be indicated for the maintenance treatment of stabilised patients, but could also be used in unstable patients with moderate to severe symptoms who require a fast and prolonged-acting product like Doria®. It would be the only long-acting injectable atypical antipsychotic with said indication in the European Union.

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 marketed in 59 countries all over the world, should be highlighted. Likewise, in 2017, ROVI commenced the marketing of its enoxaparin biosimilar in Europe, developed in-house. ROVI continues to develop the ISM® Platform technology, a leading-edge line of research in the field of prolonged drug release with proven advantages. For more information, please visit www.rovi.es

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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.

Alternative performance measures

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

APPENDIX 1

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS AS OF 31 DECEMBER 2021 AND 31 DECEMBER 2020

IN € THOUSANDS	31 December 2021	31 December 2020
ASSETS		
Non-current assets		
Property Plant and Equipment	181,775	155,395
Intangible assets	38,558	41,413
Investment in a joint venture	1,994	1,812
Deferred income tax assets	3,850	11,105
Equity securities	72	71
Financial receivables	65	65
	226,314	**209,861**
Current assets		
Inventories	245,473	227,199
Trade and other receivables	150,172	76,401
Current income tax assets	9,891	7,803
Prepaid expenses	1,791	13
Cash and cash equivalents	99,035	53,162
	506,362	**364,578**
Total assets	**732,676**	**574,439**

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS AS OF 31 DECEMBER 2021 AND 31 DECEMBER 2020

IN € THOUSANDS	31 December 2021	31 December 2020
EQUITY		
Capital and reserves attributable to shareholders of the company		
Share capital	3,364	3,364
Share premium	87,636	87,636
Legal reserve	673	673
Treasury shares	(66,121)	(20,185)
Retained earnings and voluntary reserves	292,349	241,158
Profit for the year	153,077	61,057
Other reserves	(2)	(3)
Total equity	**470,976**	**373,700**
LIABILITIES		
Non-current liabilities		
Financial debt	66,745	68,421
Deferred income tax liabilities	776	929
Contract liabilities	1,460	5,788
Deferred income	2,331	2,712
	71,312	**77,850**
Current liabilities		
Financial debt	6,417	6,022
Trade and other payables	125,173	91,364
Deferred income tax liabilities	681	-
Contract liabilities	57,632	25,005
Deferred income	485	498
	190,388	**122,889**
Total liabilities	**261,700**	**200,739**
Total equity and liabilities	**732,676**	**574,439**

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED INCOME STATEMENTS FOR 2021 AND 2020

IN € THOUSANDS	**2021**	2020
Revenue	648,677	419,961
Changes in inventories of finished goods and work in progress	782	17,659
Raw materials and consumables used	(264,637)	(196,311)
Personnel expenses	(89,803)	(74,429)
Other operating expenses	(93,502)	(73,706)
Amortisation	(21,364)	(19,593)
Impairment of non-current assets	(95)	(56)
Recognition of government grants on non-financial non-current assets and other	1,334	1,157
Share of profits of joint venture	182	(31)
OPERATING PROFIT	**181,574**	**74,651**
Finance income	68	4
Finance costs	(905)	(1,072)
Impairment and gain or loss on measurement of financial instruments	2,069	(1,041)
Exchange difference	(178)	39
FINANCE INCOME/(COSTS) - NET	**1,054**	**(2,070)**
PROFIT BEFORE INCOME TAX	**182,628**	**72,581**
Income tax	(29,551)	(11,524)
PROFIT FOR THE YEAR	**153,077**	**61,057**

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED CASH FLOW STATEMENTS FOR 2021 AND 2020

IN € THOUSANDS	2021	2020
Cash flows from operating activities		
Profit before tax	182,628	72,581
Adjustments for non-monetary transactions:		
Amortisation	21,364	19,593
Finance income	(68)	(43)
Valuation allowance	4,885	1,772
Adjustments for changes in value of derivatives	(908)	796
Gain or loss on derecognition of financial assets and liabilities	(1,161)	245
Finance expenses	905	1,072
Grants, income from distribution licenses and other deferred incomes	(6,473)	(2,101)
Other current assets (prepaid expenses)	(1,778)	(10)
Share of profit of joint venture	(182)	31
Share-based payments	1,403	-
Changes in working capital:		
Trade and other receivables	(74,187)	7,468
Inventories	(23,427)	(70,398)
Trade and other payables	35,358	(811)
Other collections and payments:		
Proceeds from CMO services	34,429	21,617
Proceeds from distribution licenses	518	1,253
Income tax cash flow	(23,861)	(6,038)
Interest payments	(4)	(151)
Net cash generated from (used in) operating activities	**149,441**	**46,876**
Cash flows from investing activities		
Purchases of intangible assets	(722)	(355)
Purchases of property, plant and equipment (usage rights not included)	(40,218)	(39,337)
Proceeds from sale of property, plant and equipment	33	63
Interest received	68	4
Net cash generated from (used in) investing activities	**(40,839)**	**(39,625)**
Cash flows from financing activities		
Repayments of financial debt	(6,192)	(13,179)
Proceeds from financial debt	1,340	1,430
Interest paid	(288)	(299)
Purchase of treasury shares	(78,785)	(37,255)
Reissue of treasury shares	42,328	37,488
Dividends paid	(21,132)	(9,700)
Net cash generated from (used in) financing activities	**(62,729)**	**(21,515)**
Net (decrease) increase in cash and cash equivalents	**45,873**	**(14,264)**
Cash and cash equivalents at the beginning of the year	**53,162**	**67,426**
Cash and cash equivalents at the end of the year	**99,035**	**53,162**