FINANCIAL RESULTS for the nine-month period ending 30th September

2021

03/11

KEY FIGURES

Summary

IN € MILLIONS	Nine-month period ending Sept. 30, **2021**	2020	Growth	% Growth
Operating revenue	463.5	302.1	161.4	53%
Gross profit	266.8	175.4	91.3	52%
EBITDA	139.5	69.7	69.9	100%
EBIT	123.3	55.3	68.0	123%
Net profit	98.9	46.8	52.1	111%
Capital Expenditure	22.0	16.9	5.1	30%
FCF	116.1	-21.5	137.6	n.a.
Gross profit as % of revenue	57.6%	58.1%		-0.5pp
EBITDA as % of revenue	30.1%	23.1%		7.0pp
EBIT as % of revenue	26.6%	18.3%		8.3pp
Net profit as % of revenue	21.3%	15.5%		5.8pp
Capex as % of revenue	4.7%	5.6%		-0.9pp
FCF as % of revenue	25.0%	-7.1%		32.2pp
	As of Sept. 30, 2021	As of Dec. 31, 2020		
Net debt (€ Millions)	-74.4	19.8	-94.2	n.a.
Net leverage ratio[1] (x)	-0.53	0.28	-0.82	n.a.

[1] *Net debt/EBITDA*

Non-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 the first nine months of 2021 and the comparative information for 2020 (balance sheet) and for the first nine months of 2020 (consolidated income statement and cash flow statement) are attached to this report (see Appendix 1).

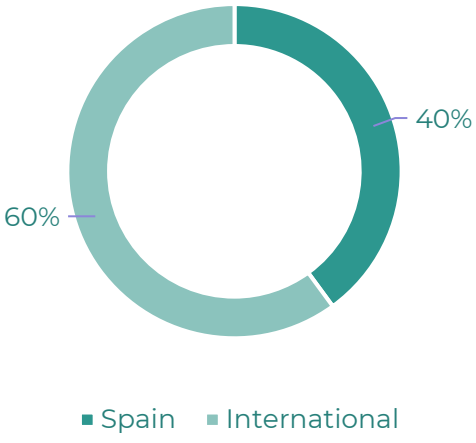
CONTENTS

HIGHLIGHTS 9M 2021

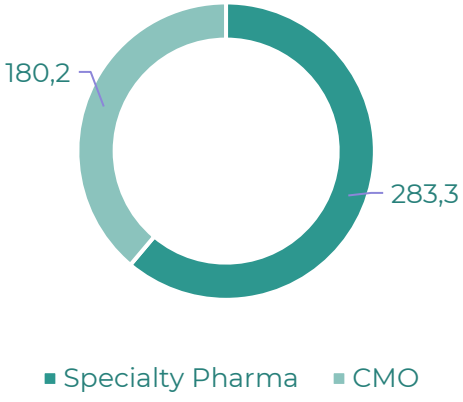
ROVI REPORTS OPERATING REVENUE GROWTH OF 53% AND DOUBLES ITS EBITDA

- Operating revenue increased by 53% to 463.5 million euros driven by (i) the strength of the contract manufacturing organization ("CMO") business, which grew by 187%, and (ii) the specialty pharmaceutical business, where sales rose 18%.
- Sales of the heparin franchise (Low Molecular Weight Heparins (LMWH) and other heparins) increased by 15% to 181.5 million euros. Sales of the enoxaparin biosimilar increased 17% to 89.9 million euros and sales of Bemiparin increased 13% to 86.3 million euros.
- EBITDA doubled to 139.5 million euros.
- Net profit increased by 111% to 98.9 million euros.
- ROVI's ESG aspects have been evaluated by Sustainalytics, having obtained an "ESG Risk Rating 2021" of 18.4, which places the company at low risk (between 10 and 20). ROVI has attained the second position out of 432 companies in the sub-industry "pharmaceuticals".
- ROVI General Shareholders Meeting approved the payment of a gross dividend of 0.3812 euros per share on 2020 earnings (+118%). This dividend was paid on July, 7th.

SALES BY REGION (%)



OPERATING REVENUE BY BUSINESS UNIT (€Mn)



OUTLOOK

For **2022**, ROVI expects a mid-single-digit growth rate for the operating revenue.

In July 2021, ROVI upgraded its operating revenue guidance for the full year 2021 from the higher end of the 20% to 30% range to the range between 35% and 40%. With the visibility that the Company has at this moment, ROVI is upgrading again its **2021 operating revenue guidance** from the range between 35% and 40% to the 40% and 45% range.

SHARE BUYBACK PROGRAM

Today, ROVI has informed the market that, effective as of this date, 3 November 2021, a share buyback program (the "Buyback Program") will commence, in accordance with the following terms (see further information on pages 25-26):

1. **Purpose and scope**: the Buyback Program'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, 3 November 2021, for a twelve-month period.
3. **Maximum monetary amount**: up to 125,000,000 euros.
4. **Maximum number of shares to be acquired**: 1,682,000 shares of the Company, representing approximately 3% of the Company's share capital.

Juan López-Belmonte Encina, Chairman and Chief Executive Officer of ROVI, said *"At the time of presenting these results, it has been over a year and a half since the WHO declared the COVID-19 pandemic in March 2020. Since then, all our efforts have been directed towards protecting our employees and ensuring that patients who needed our medicines had them and were not affected by global lockdowns. Fortunately, it seems that in 2021 we are starting to see the light at the end of the tunnel thanks to the development of COVID-19 vaccines. One of those vaccines is the Moderna vaccine, in which ROVI is currently involved regarding its fill and finish. Mass vaccination programs are already in progress all around the globe and we are very proud for our work to contribute to this historic moment. Regarding ROVI's 2021 first nine months results, we achieved 53% operating revenue growth, mainly driven by the strength of the contract manufacturing organization ("CMO") business, which grew by 187% and by the specialty pharmaceutical business, where sales rose 18%. We forecast continued growth thanks to our flagship product, Bemiparin, which grew by 13%. Likewise, we are already marketing our enoxaparin biosimilar in 28 countries in the first nine months of 2021 and its sales increased 17%. 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 the good performance of 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 redirection of the contract manufacturing activities strategy towards high value-added products, backed by the high degree of technological specialisation of our plants in differentiated niches, enabled our CMO business to increase 187% in the first nine months of 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®). We are currently undergoing a regulatory process with our first candidate, Risperidone ISM®, based on our ISM® technology, in Europe and the United States to obtain the marketing authorization for Risperidone ISM® in both territories. We expect to launch this product on the market in 2022. We are also conducting a Phase I study for another candidate, Letrozole, for which preliminary data likewise show positive results, reflecting our clear commitment to our ISM® technology".

GROUP MANAGEMENT REPORT

for the nine-month period ending September 30th, 2021

INCOME STATEMENT

	Nine-month period ending Sept. 30,			
IN € MILLIONS	**2021**	2020	Growth	% Growth
Operating revenue	463.5	302.1	161.4	53%
Other income	1.0	0.9	0.1	13%
Total revenue	**464.5**	**303.0**	**161.5**	**53%**
Cost of goods sold	-197.7	-127.6	-70.2	55%
Gross profit	**266.8**	**175.4**	**91.3**	**52%**
% margin	*57.6%*	*58.1%*		-0.5pp
R&D expenses	-19.1	-15.6	-3.5	22%
SG&A	-108.3	-90.1	-18.2	20%
Share of profit of a joint venture	0.2	0.0	0.2	n.a.
EBITDA	**139.5**	**69.7**	**69.9**	**100%**
% margin	*30.1%*	*23.1%*		7.0pp
EBIT	**123.3**	**55.3**	**68.0**	**123%**
% margin	*26.6%*	*18.3%*		8.3pp
Finance Income/(Costs)	1.1	-1.0	2.1	n.a.
Profit before income tax	**124.3**	**54.3**	**70.1**	**129%**
Income tax	-25.4	-7.4	-18.0	n.a.
Effective tax	*20.4%*	*13.7%*		6.7pp
Net profit	**98.9**	**46.8**	**52.1**	**111%**

REVENUES

Total revenue by business unit

IN € MILLIONS	Nine-month period ending Sept. 30, 2021	2020	Growth	% Growth
Specialty pharmaceutical business	283.3	239.5	43.8	18%
CMO business	180.2	62.7	117.5	187%
Operating revenue	**463.5**	**302.1**	**161.4**	**53%**
Other income	1.0	0.9	0.1	13%
Total revenue	**464.5**	**303.0**	**161.5**	**53%**

Operating revenue increased by 53% to 463.5 million euros in the first nine months of 2021, driven by the strength of the contract manufacturing organisation business, which grew by 187%, and by the specialty pharmaceutical business, where sales rose 18%. **Total revenue** increased by 53% to 464.5 million euros in the first nine months of 2021.

Sales outside Spain increased by 96% to 275.9 million euros in the first nine months of 2021, 46.8 million euros (or 17%) 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 the first nine months of 2021 compared to 47% in the first nine months of 2020.

SPECIALTY PHARMACEUTICAL BUSINESS

Sales of the specialty pharmaceutical business

IN € MILLIONS	Nine-month period ending Sept. 30, 2021	2020	Growth	% Growth
Prescription-based pharmaceutical products	**256.6**	**216.8**	**39.7**	**18%**
LMWH franchise	176.2	153.1	23.1	15%
Biosimilar of enoxaparin	89.9	76.6	13.3	17%
Bemiparin (Hibor)	86.3	76.5	9.8	13%
Sales in Spain	51.8	50.4	1.4	3%
International sales	34.5	26.1	8.4	32%
Neparvis	27.7	21.6	6.1	28%
Ulunar & Hirobriz	7.1	8.7	-1.6	-19%
Volutsa	11.8	10.5	1.3	12%
Vytorin & Absorcol & Orvatez	20.3	22.0	-1.6	-7%
Medikinet & Medicebran	2.6	2.4	0.1	5%
Other products	21.3	19.8	1.4	7%
Discounts to the National Health System	-10.3	-21.3	11.0	-51%
Contrast agents and other hospital products	**25.8**	**22.1**	**3.7**	**17%**
OTC and Other	**0.9**	**0.5**	**0.4**	**78%**
Total specialty pharmaceutical business	**283.3**	**239.5**	**43.8**	**18%**

Sales of **prescription-based pharmaceutical** products rose 18% to 256.6 million euros in the first nine months of 2021.

Sales of the **heparin franchise** (Low Molecular Weight Heparins and other heparins) increased by 15% to 181.5 million euros in the first nine months of 2021. Heparin sales represented 39% of operating revenue in the first nine months of 2021 compared to 52% in the first nine months of 2020.

Heparin franchise

	Nine-month period ending Sept. 30,			
IN € MILLIONS	**2021**	2020	Growth	% Growth
LMWH franchise	176.2	153.1	23.1	15%
Biosimilar of enoxaparin	89.9	76.6	13.3	17%
Bemiparin (Hibor)	86.3	76.5	9.8	13%
Sales in Spain	51.8	50.4	1.4	3%
International sales	34.5	26.1	8.4	32%
Other heparins[1]	5.3	4.7	0.6	14%
Heparins franchise	**181.5**	**157.7**	**23.7**	**15%**

LOW MOLECULAR WEIGHT HEPARINS

Sales of **Low Molecular Weight Heparins** (LMWH) (Enoxaparin biosimilar and Bemiparin) increased by 15% to 176.2 million euros in the first nine months of 2021.

Sales of the **Enoxaparin biosimilar** increased 17% to 89.9 million euros in the first nine months of 2021 mainly as a result of (i) the launch of the product in nine new countries; in the first nine months of 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 in the first nine months of 2021.

Bemiparin showed a positive performance in the first nine months of 2021, with sales up 13% to 86.3 million euros. International sales of Bemiparin increased by 32% to 34.5 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) a high concentration of purchase orders from the Russian and Chinese markets. ROVI expects a double digit increase for international Bemiparin sales in 2021. Sales of Bemiparin in Spain (Hibor®) increased 3% to 51.8 million euros in the first nine months of 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 28% to 27.7 million euros in the first nine months of 2021, compared to 21.6 million euros in the first nine months of 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 12% to 11.8 million euros in the first nine months of 2021.

Sales of **Vytorin®**, **Orvatez**® and **Absorcol**®, specialty products from Merck Sharp & Dohme ("MSD") indicated as adjunctive therapy to diet in patients with hypercholesterolemia, decreased by 7% to 20.3 million euros in the first nine months of 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 19% to 7.1 million euros in the first nine months of 2021, compared to 8.7 million euros in the same period of 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 5% to 2.6 million euros in the first nine months of 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 3% in the first nine months of 2021 compared to the same period of the previous year. Nevertheless, ROVI prescription-based pharmaceutical product sales increased 18% in the first nine months of 2021, outperforming the market by 15 percentage points.

CONTRAST AGENTS AND OTHER HOSPITAL PRODUCTS

Sales of **contrast imaging agents and other hospital products** increased by 17% to 25.8 million euros in the first nine months of 2021. This increase shows the strong recovery of the Spanish and Portuguese hospital activity during this period after the effects of lockdowns during the pandemic.

CONTRACT MANUFACTURING ORGANISATION ("CMO") BUSINESS

CMO sales increased by 187% to 180.2 million euros in the first nine months of 2021 as a result 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 redirection of our contract manufacturing activities strategy towards high-value-added products.

Likewise, in the year 2021, ROVI expects the toll manufacturing business to increase by between 2 and 2.5 times, including production of the COVID-19 vaccine.

OTHER INCOME

Other income (subsidies) increased by 13% to 1.0 million euros in the first nine months of 2021, compared to the same period of the previous year.

COSTS

GROSS PROFIT

Gross profit increased by 52% to 266.8 million euros in the first nine months of 2021, the gross margin showing a decrease of 0.5 percentage points from 58.1% in the first nine months of 2020 to 57.6% in the first nine months of 2021, mainly due to the increase in the LMWH raw material cost of goods sold in the first nine months of 2021 compared to the same period last year. ROVI expects LMWH raw material prices to continue to decline in 2021 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 22% to 19.1 million euros in the first nine months of 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 20% to 108.3 million euros in the first nine months of 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 the Doria® launch in Europe. Expenses related to Covid-19 decreased to 1.4 million euros in the first nine months of 2021, from 3.1 million euros in the first nine months of 2020. Excluding expenses related to COVID-19, SG&A would have increased by 23% to 106.9 million euros in the first nine months of 2021, compared to 87.0 million euros in the first nine months of 2020.

SG&A expenses

	Nine-month period ending Sept. 30,			
IN € MILLIONS	**2021**	2020	Growth	% Growth
Employee benefit expenses (exc. R&D)	59.4	50.0	9.4	19%
Other operating expenses (exc. R&D)	48.9	40.1	8.8	22%
Total SG&A expenses	**108.3**	**90.1**	**18.2**	**20%**
Expenses related to international subsidiaries	7.5	5.6	1.8	33%
Expenses related to COVID-19	1.4	3.1	-1.7	-55%
Total SG&A expenses excluding expenses related to COVID-19	**106.9**	**87.0**	**19.9**	**23%**

DEPRECIATION

Depreciation and amortisation expenses increased by 13% to 16.2 million euros in the first nine months of 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 the first nine months of 2021 compared to -1.0 million euros (cost) in the first nine months of 2020, mainly due to the higher income related to exchange-rate derivative financial instruments.

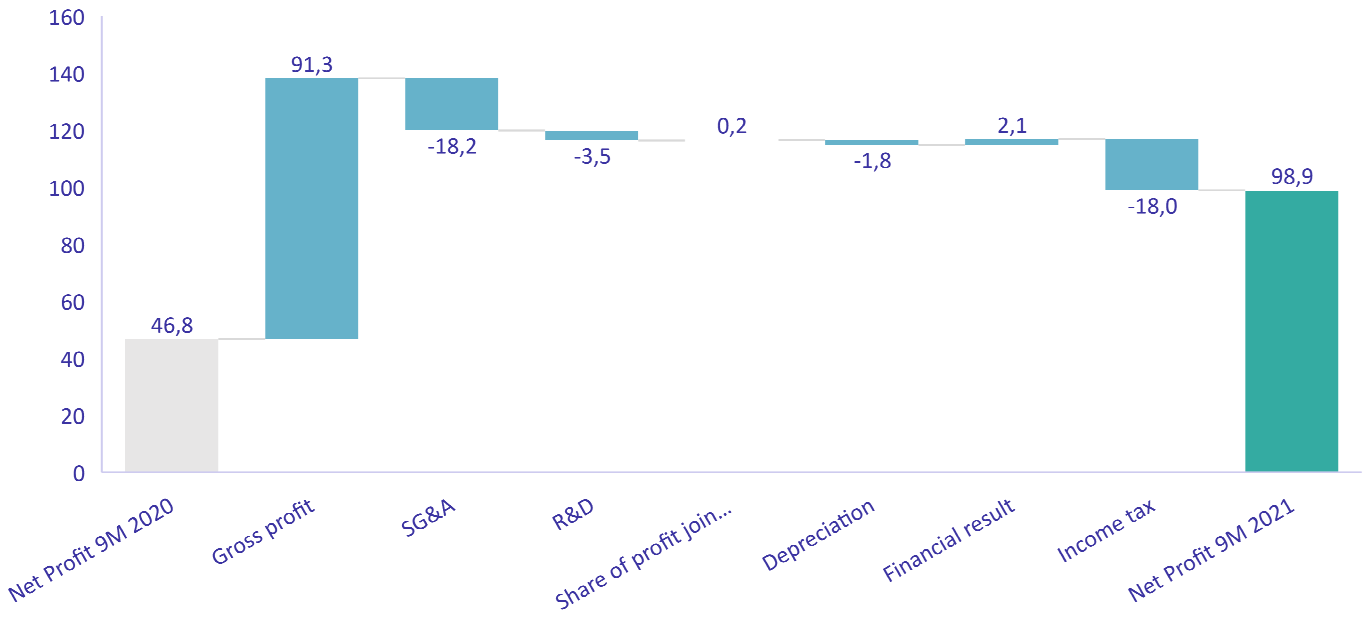
EFFECTIVE TAX RATE

The **effective tax rate** was 20.4% in the first nine months of 2021, compared to 13.7% in the first nine months of 2020, mainly due to the increase of the profit before income tax.

As of 30 September 2021, all the Group's negative tax bases, 18.6 million euros, had been used.

FINANCIAL PERFORMANCE

Million euros



EBITDA

EBITDA increased to 139.5 million euros in the first nine months of 2021, a rise of 100% compared to the same period of the previous year, reflecting a 7.0 percentage point increase in the EBITDA margin, which was up to 30.1% in the first nine months of 2021 from 23.1% in the first nine months of 2020. **EBITDA excluding expenses related to COVID-19** ("recurrent EBITDA") increased to 141.0 million euros in the first nine months of 2021, a rise of 94% compared to the same period of the previous year, reflecting a 6.3 percentage point increase in the recurrent EBITDA margin, which was up to 30.4% in the first nine months of 2021 from 24.1% in the first nine months of 2020.

EBIT

EBIT increased by 123% to 123.3 million euros in the first nine months of 2021, reflecting a 8.3 percentage point rise in the EBIT margin, which was up to 26.6% in the first nine months of 2021 from 18.3% in the first nine months of 2020.

NET PROFIT

Net profit increased by 111%, from 46.8 million euros in the first nine months of 2020 to 98.9 million euros in the first nine months of 2021.

PRE-R&D/FLAT R&D

EBITDA "Pre-R&D", calculated excluding R&D expenses in the first nine months of 2021 and in the first nine months of 2020, increased by 86%, from 85.3 million euros in the first nine months of 2020 to 158.6 million euros in the first nine months of 2021, reflecting a 6.0 percentage point rise in the EBITDA margin to 34.2% in the first nine months of 2021 (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 2021 as in the first nine months of 2020, EBITDA would have increased by 105% to 143.0 million euros, reflecting a 7.8 percentage point rise in the EBITDA margin to 30.9% in the first nine months of 2021, up from 23.1% in the first nine months of 2020 (see "Flat R&D costs" columns of the table below).

EBIT "pre-R&D", calculated excluding R&D expenses in the first nine months of 2021 and in the first nine months of 2020, increased by 101%, from 70.9 million euros in the first nine months of 2020 to 142.4 million euros in the first nine months of 2021, reflecting a 7.3 percentage point rise in the EBIT margin to 30.7% in the first nine months of 2021 (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 2021 as in the first nine months of 2020, EBIT would have increased by 129% to 126.8 million euros, reflecting a 9.1 percentage point rise in the EBIT margin to 27.4% in the first nine months of 2021, up from 18.3% in the first nine months of 2020 (see "Flat R&D costs" columns of the table below).

Net profit "pre-R&D", calculated excluding R&D expenses in the first nine months of 2021 and in the first nine months of 2020, increased by 89%, from 60.3 million euros in the first nine months of 2020 to 114.1 million euros in the first nine months of 2021 (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 2021 as in in the first nine months of 2020, net profit would have increased by 117% to 101.7 million euros (see "Flat R&D costs" columns of the table below).

Pre-R&D/Flat R&D

	Nine-month period ended Sept. 30,							
	Reported		Pre-R&D costs			Flat R&D costs		
IN € MILLIONS	**2021**	2020	**2021**	2020	% Growth	**2021**	2020	% Growth
Operating revenue	463.5	302.1	463.5	302.1	53%	463.5	302.1	53%
Other income	1.0	0.9	1.0	0.9	13%	1.0	0.9	13%
Total revenue	**464.5**	**303.0**	**464.5**	**303.0**	**53%**	**464.5**	**303.0**	**53%**
Cost of sales	-197.7	-127.6	-197.7	-127.6	55%	-197.7	-127.6	55%
Gross profit	**266.8**	**175.4**	**266.8**	**175.4**	**52%**	**266.8**	**175.4**	**52%**
% margin	57.6%	58.1%	57.6%	58.1%	*-0.5pp*	57.6%	58.1%	*-0.5pp*
R&D expenses	-19.1	-15.6	0.0	0.0	n.a.	-15.6	-15.6	0%
SG&A	-108.3	-90.1	-108.3	-90.1	20%	-108.3	-90.1	20%
Share of profit of a joint venture	0.2	0.0	0.2	0.0	n.a.	0.2	0.0	n.a.
EBITDA	**139.5**	**69.7**	**158.6**	**85.3**	**86%**	**143.0**	**69.7**	**105%**
% margin	30.1%	23.1%	34.2%	28.2%	*6.0pp*	30.9%	23.1%	*7.8pp*
EBIT	**123.3**	**55.3**	**142.4**	**70.9**	**101%**	**126.8**	**55.3**	**129%**
% margin	26.6%	18.3%	30.7%	23.5%	*7.3pp*	27.4%	18.3%	*9.1pp*
Net profit	**98.9**	**46.8**	**114.1**	**60.3**	**89%**	**101.7**	**46.8**	**117%**
% margin	21.3%	15.5%	24.6%	20.0%	*4.7pp*	21.9%	15.5%	*6.4pp*

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 means an increase of 118% compared to the dividend on 2019 earnings (€0.1751/share) and represents a 35% pay out (vs 25% pay out last year). This dividend was paid on 7 July 2021.

FINANCIAL POSITION

Balance Sheet

IN € MILLIONS	Sept. 30, 2021	Dec. 31, 2020	Growth	% Growth
Assets				
Non-current assets	208.6	209.9	-1.3	-1%
Current assets	476.5	364.6	111.9	31%
Total assets	**685.1**	**574.4**	**110.6**	**19%**
Equity				
Capital and reserves attributable to shareholders of the company	**453.0**	**373.7**	**79.3**	**21%**
Liabilities				
Non-current liabilities	72.6	77.9	-5.3	-7%
Financial debt	66.7	68.4	-1.7	-3%
Current liabilities	159.4	122.9	36.5	30%
Financial debt	5.2	6.0	-0.8	-13%
Total liabilities	**232.0**	**200.7**	**31.3**	**16%**
Total equity and liabilities	**685.1**	**574.4**	**110.6**	**19%**

TOTAL ASSETS

ROVI's **total assets** increased by 19% from €574.4 million as of December 31, 2020 to €685.1 million as of September 30, 2021, mainly due to (i) an increase in cash and cash equivalents of 90.8 million euros in the first nine months of 2021; (ii) a rise in the "trade and other receivables" item of 33.2 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 9.8 million euros in the first nine months of 2021 (see "capital expenditure" in page 19).

As of 30 September 2021, **Social Security and Public Administrations total debt** with ROVI amounted to 11.6 million euros, from 9.4 million euros as of December 31, 2020, of which 5.3 million euros in Spain, 3.1 million euros in Portugal and 3.2 million euros in Italy.

EQUITY

ROVI's **equity** increased by 79.3 million euros to 453.0 million euros as of September 30, 2021. This increase resulted from the "profit for the period".

TOTAL LIABILITIES

ROVI's **total liabilities** increased by 16% from €200.7 million as of December 31, 2020 to €232.0 million as of September 30, 2021, mainly due to (i) an increase in the "contract liabilities" item of 17.6 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 September 30, 2021 and (ii) a rise of 10.1 million euros in the "trade and other payables" caption.

As of 30 September 2021, ROVI **total debt** decreased to 71.9 million euros. Debt with public administration, which is 0% interest rate debt, represented 15% of total debt as of 30 September 2021.

Total Debt

IN € THOUSANDS	**Sept. 30, 2021**	Dec. 31, 2020	Interest rate
Bank borrowings	45,000	45,000	0.297-0.681
Debt with public administration	10,774	10,972	0
Financial liabilities for leases	16,118	17,546	-
Derivative financial instruments	-	925	-
Total	**71,892**	**74,443**	

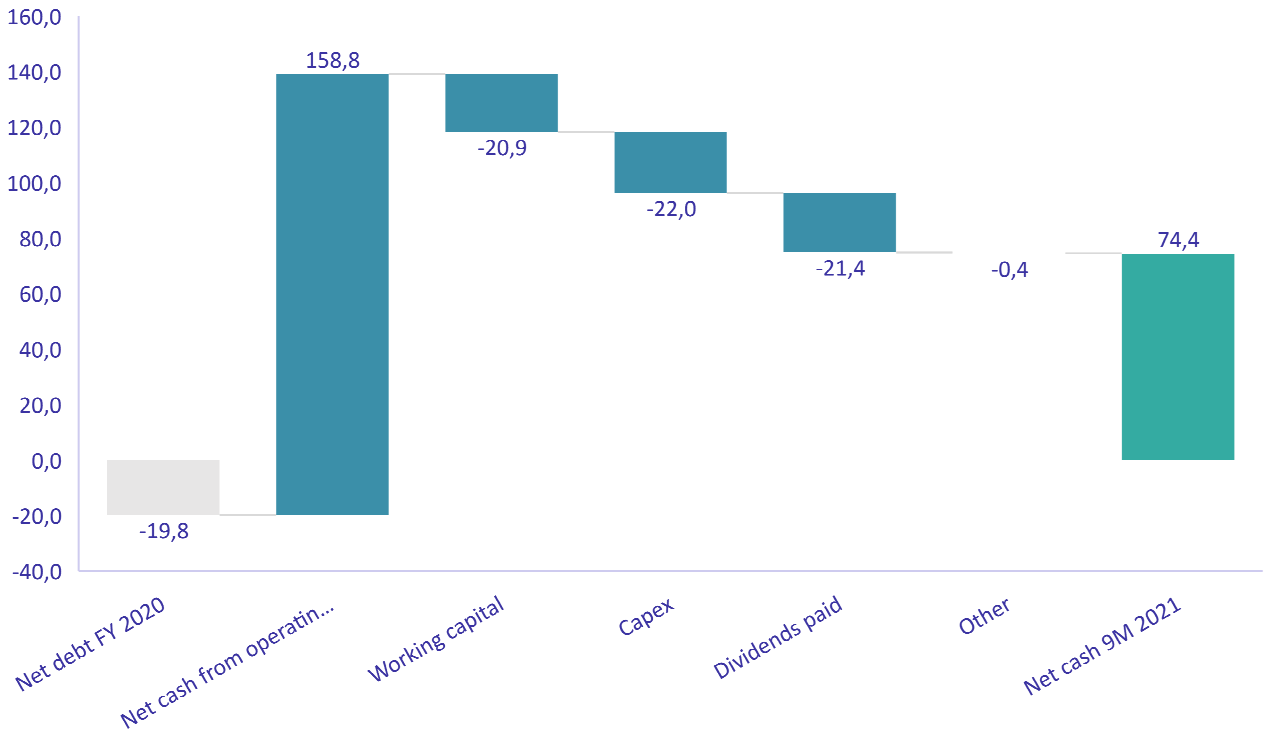
As of 30 September 2021, bank borrowings remained stable. In December 2017, ROVI announced the European Investment Bank (EIB) had granted it a loan to support its investments in Research, Development and Innovation. The loan was for 45 million euros. As of 30 September 2019, ROVI had drawn 45 million 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 October 2021) and 40 million euros at a fixed interest of 0.681%. The credit matures in 2029 and includes a grace period of 3 years.

GROSS CASH POSITION AND NET DEBT

As of 30 September 2021, ROVI had a **gross cash position** of 146.3 million euros, compared to 129.0 million euros as of 30 June 2021 and 54.6 million euros as of 31 December 2020, and net cash of 74.4 million euros (equity securities plus deposits plus financial derivatives plus cash and cash equivalents minus current and non-current financial debt), compared to 56.1 million euros as of 30 June 2021 and **net debt** of 19.8 million euros as of 31 December 2020.

Net cash generated in operating activities amounted to 137.9 million euros in the first nine months of 2021, compared to -4.7 million euros in the first nine months of 2020. Net cash generated from operating activities excluding changes in working capital increased 77% to 158.8 million euros in the first nine months of 2021 from 90.0 million euros in the first nine months of 2020.

Million euros



LIQUIDITY

Cash Flow

IN € MILLIONS	Nine-month period ending Sept. 30, 2021	2020	Growth	% Growth
Cash flow from operating activities	137.9	-4.7	142.6	n.a.
Cash flow from investing activities	-21.9	-16.9	-5.0	30%
Cash flow from financing activities	-25.3	-10.6	-14.6	137%
Net increase/ (decrease) in cash	**90.8**	**-32.1**	**122.9**	**n.a.**
Cash at the beginning of the period	53.2	67.4	-14.3	-21%
Cash at the end of the period	**144.0**	**35.3**	**108.7**	***n.a.***

CASH FLOW FROM OPERATING ACTIVITIES

Cash flow from operating activities increased to 137.9 million euros in the first nine months of 2021 from a negative result of 4.7 million euros in the first nine months of 2020. This increase was mainly due to:

- the increase of 70.1 million euros in profit before income tax

- the increase of 2.1 million euros in the "inventory" line item in the first nine months of 2021 (mainly because of lower heparin stock levels) compared to a decrease of 79.4 million euros in the first nine months of 2020;
- the booking of 21.5 million euros under the "Proceeds from toll manufacturing services" caption in the first nine months of 2021 relating to payments received but not yet allocated to the income statement, compared to the 18.1 million euros recognized in the first nine months of 2020; and
- the increase of 10.7 million euros in the "trade and other payables" item in the first nine months of 2021, compared to a decrease of 5.3 million euros in the first nine months of 2020.

These positive impacts were partially offset by:

- the decrease of 33.6 million euros in the "trade receivables" line in the first nine months of 2021 compared to a decrease of 9.9 million euros in the first nine months of 2020; and

CASH FLOW FROM INVESTING ACTIVITIES

ROVI invested 22.0 million euros in the first nine months of 2021, compared to 16.9 million euros in the first nine months of 2020.

Capital expenditure

	Nine-month period ending Sept. 30,			
IN € MILLIONS	**2021**	2020	Growth	% Growth
Madrid Injectable plant	1.4	1.3	0.1	9%
San Sebastián de los Reyes Injectable plant	1.3	1.2	0.0	2%
Granada plant	1.0	1.3	-0.3	-24%
Alcalá de Henares plant	2.6	2.2	0.4	18%
Expenditure on maintenance and other capex	1.4	1.4	0.0	1%
Maintenance Capex	**7.6**	**7.4**	**0.2**	**3%**
ISM industrialisation	3.5	5.2	-1.8	-34%
Escúzar plant	8.5	2.2	6.4	n.a.
New vial filling line & operations expansion	2.4	2.1	0.3	12%
Investment Capex	**14.4**	**9.5**	**4.9**	**51%**
Total Capex	**22.0**	**16.9**	**5.1**	**30%**

CASH FLOW FROM FINANCING ACTIVITIES

Cash flow from financing activities decreased to -25.3 million euros in the first nine months of 2021 from -10.6 million in the first nine months of 2020. This decrease was mainly attributable to the payment of the ordinary dividend on 2020 earnings of 21.4 million euros in the first nine months of 2021. The dividend on 2019 earnings was paid in November 2020.

Javier López-Belmonte Encina, First Vice-President and Chief Financial Officer of ROVI, said "We are very happy with the results of the first nine months of 2021. We have been able to deliver operating revenue growth of 53% 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 7.0 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 the first nine months of 2021. We are entering into 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 expects a mid-single-digit growth rate for the operating revenue.

In February 2021, ROVI announced it expected the operating revenue for the full year 2021 to increase between 20% and 30%, including the production of Moderna's COVID-19 vaccine. As a result of the expansion of the collaboration between ROVI and Moderna, in May the Company announced that, for 2021, they expected to achieve the higher end of this range. In July, ROVI upgraded its operating revenue guidance for the full year 2021 from the higher end of the 20% to 30% range to the range between 35% and 40%. With the visibility that the Company has at this moment, ROVI is upgrading its **2021 operating revenue guidance** from the range between 35% and 40% to the 40% and 45% range.

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 and the next one.

The Company forecasts that it will continue to grow at a much higher rate than the Spanish pharmaceutical market expenditure in the first nine months of 2021, which, according to the Ministry of Health, Consumption and Social Welfare, showed a growth rate of 5.1%.

ROVI expects its growth drivers to be 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

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 Risperidone ISM® with the European Medicines Agency (EMA). 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).

In March 2021, ROVI informed about the request of a "clock stop" in the Risperidone ISM® authorization process to provide answers within the framework of the centralized registration procedure. The purpose of said clock stop is to have sufficient time to repeat 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), which states that the study must be performed using the European reference product. The current Risperidone ISM® dossier already includes a clinical bioavailability trial using the oral risperidone drug marketed in the United States (USA). ROVI expected that the trial using the US reference product would be valid for Europe since the two products (the oral risperidone medicine marketed in the European Union and the one marketed in the U.S.) can be considered bioequivalent based on in vitro and in vivo studies that ROVI had carried out and presented to the European Medicines Agency (EMA). ROVI estimates that in November 2021 it will be able

to provide the additional clinical data requested and thus restart the regulatory process for the EMA to complete its evaluation.

ROVI has been informed of the delay in the decision on the granting of marketing authorisation for 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. Furthermore, on 24 September, 2021, ROVI received a Complete Response Letter from the FDA with outstanding questions on the Risperidone ISM® dossier. The Company has either answered them or will be answering them in the near future 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.

On the other hand, 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. According to the authors of the article, Risperidone ISM® represents an effective therapeutic strategy in schizophrenia patients who are admitted to hospital with an acute episode with severe or moderate psychotic symptoms[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®.

Besides, during the 8th European Conference on Schizophrenia Research (ECSR) held on 23-25 September 2021[5], three communications were presented, providing further clinical data of Risperidone ISM®:

- Robert E. Litman, et al. Personal And Social Functioning In Patients With Schizophrenia Treated With Once-Monthly Risperidone ISM® [oral presentation #O-06-003].
- Christoph U. Correll, et al. Risperidone ISM® Efficacy In Schizophrenia Patients With Severe Psychotic Symptoms During An Acute Exacerbation [poster #220].

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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, 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.

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

- 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].

Furthermore, the company continues the clinical development of Letrozole ISM®, which represents the second candidate using the ROVI's ISM® technology platform. This new investigational medicine is, to ROVI's best knowledge, the first long-acting injectable aromatase inhibitor intended for the treatment of hormone-dependent breast cancer. The first phase I clinical trial (the LISA-1 study6) of Letrozole ISM® is currently ongoing and due to the study design ("dose escalation") and its exploratory nature, the finalisation date cannot be anticipated. Nevertheless, preliminary data 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 has recently started 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 still in an initial phase.

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 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.

[6] *Evaluation of IM Letrozole ISM® Pharmacokinetics, Safety, and Tolerability in Healthy Post-menopausal Women (LISA-1). Clinicaltrials.gov#NCT03401320 [https://clinicaltrials.gov/ct2/show/NCT03401320]. This clinical program has had the support of the Industrial Technological Development Centre ("CDTI").*

KEY OPERATING AND FINANCIAL EVENTS

ROVI Share Buyback Program

Today, ROVI has informed the market (by publication of inside information) that, effective as of today's date, 3 November 2021, a share buyback program (the "Buyback Program") will commence, in accordance with the following terms:

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

2. **Term**: from today, 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.

   Nevertheless, the Buyback Program will terminate before the end of the referred period upon acquisition of the maximum number of shares authorized by the Board of Directors or if the maximum monetary amount of the Buyback Program is reached. Moreover, ROVI reserves the right to terminate the Buyback Program before the end of the referred 12-month period if any other circumstance that makes it advisable occurs.

3. **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.
   The maximum monetary amount of the Buyback Program may be reduced in the amount applied by the Company, during its term, to the acquisition of own shares on the block trades market or over the counter for the same purpose, which will be notified to the market in the periodic other relevant information notices informing of the transactions carried out under the Buyback Program.

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

   The maximum number of shares to be acquired under the Buyback Program may also be reduced if, during its term, acquisitions of own shares on the block trades market or over the counter are carried out for the same purpose, which will be

notified to the market in the periodic other relevant information notices informing of the transactions carried out under the Buyback Program.

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

The Buyback Program shall be managed by Bestinver, S.V., S.A., that will manage the Buyback Program by making its decisions regarding the implementation of the purchases of ROVI's shares and their price and volume conditions independently.

During the term of the Buyback Program the transactions regulated under the liquidity agreement entered into between ROVI and Renta 4 Banco, S.A. on 8 May 2019 will be suspended, in accordance with Circular 1/2017 of 26 April, of the Spanish National Securities Market Commission, pursuant to the provisions of rule 5, section c). The aforementioned transactions will resume once the Buyback Program ends.

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 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 Risperidone ISM® 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 Risperidone ISM® dossier. The Company has either answered them or will be answering them in the near future 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.

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, have conducted a thorough investigation, which includes:

- 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 have 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, is 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 is in full agreement with this decision.

Preliminary Particulate Analysis

According to Moderna's independent analysis, the particle from lot 3004667 has been thoroughly analyzed and is 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 have been administered to more than 110 million individuals in 45 countries, representing a critical component of the global fight against COVID-19.

For additional updates and resources about the COVID-19 vaccine program in Japan please go to the official COVID-19 information center.

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 58 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 30 SEPTEMBER 2021 AND 31 DECEMBER 2020

IN € MILLIONS	30 September 2021	31 December 2020
ASSETS		
Non-current assets		
Property Plant and Equipment	165,191	155,395
Intangible assets	38,887	41,413
Investment in a joint venture	2,006	1,812
Deferred income tax assets	2,343	11,105
Equity securities	72	71
Financial receivables	65	65
	208,564	**209,861**
Current assets		
Inventories	220,769	227,199
Trade and other receivables	109,590	76,401
Current income tax assets	6	7,803
Derivative financial instrument	813	-
Prepaid expenses	1,363	13
Cash and cash equivalents	143,961	53,162
	476,502	**364,578**
Total assets	**685,066**	**574,439**

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS AS OF 30 SEPTEMBER 2021 AND 31 DECEMBER 2020

IN € MILLIONS	30 September 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	(28,720)	(20,185)
Retained earnings and voluntary reserves	291,143	241,158
Profit for the period	98,938	61,057
Other reserves	(2)	(3)
Total equity	**453,032**	**373,700**
LIABILITIES		
Non-current liabilities		
Financial debt	66,678	68,421
Deferred income tax liabilities	727	929
Contract liabilities	2,692	5,788
Deferred income	2,503	2,712
	72,600	**77,850**
Current liabilities		
Financial debt	5,214	6,022
Trade and other payables	101,430	91,364
Current income tax liabilities	6,601	-
Contract liabilities	45,704	25,005
Deferred income	485	498
	159,434	**122,889**
Total liabilities	**232,034**	**200,739**
Total equity and liabilities	**685,066**	**574,439**

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED INCOME STATEMENTS FOR THE NINE-MONTH PERIODS ENDING 30 SEPTEMBER 2021 AND 30 SEPTEMBER 2020

	Nine-month periods ending 30 September	
IN € MILLIONS	**2021**	2020
Revenue	463,501	302,143
Changes in inventories of finished goods and work in progress	5,912	29,862
Raw materials and consumables used	(203,642)	(157,442)
Personnel expenses	(65,641)	(55,328)
Other operating expenses	(61,772)	(50,389)
Amortisation	(16,248)	(14,411)
Recognition of government grants on non-financial non-current assets and other	985	873
Share of profits of joint venture	194	(32)
OPERATING PROFIT	**123,289**	**55,276**
Finance income	66	3
Finance costs	(672)	(757)
Impairment and gain or loss on measurement of financial instruments	1,793	(354)
Exchange difference	(127)	95
FINANCE INCOME/(COSTS) - NET	**1,060**	**(1,013)**
PROFIT BEFORE INCOME TAX	**124,349**	**54,263**
Income tax	(25,411)	(7,438)
PROFIT FOR THE PERIOD	**98,938**	**46,825**

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED CASH FLOW STATEMENTS FOR THE NINE-MONTH PERIODS ENDING 30 SEPTEMBER 2021 AND 30 SEPTEMBER 2020

	Nine-month periods ending 30 September	
IN € MILLIONS	**2021**	2020
Cash flows from operating activities		
Profit before tax	124,349	54,263
Adjustments for non-monetary transactions:		
Amortisation	16,248	14,411
Finance income	(66)	(98)
Valuation allowance	4,319	546
Adjustments for changes in value of derivatives	(1,738)	335
Gain or loss on derecognition of financial assets and liabilities	(55)	19
Finance expenses	672	757
Grants, income from distribution licenses and other deferred incomes	(4,198)	(2,683)
Other current assets (prepaid expenses)	(1,350)	(28)
Share of profit of joint venture	(194)	32
Share-based payments	1,403	-
Changes in working capital:		
Trade and other receivables	(33,601)	(9,896)
Inventories	2,083	(79,414)
Trade and other payables	10,657	(5,296)
Other collections and payments:		
Proceeds from toll manufacturing services	21,508	18,054
Proceeds from distribution licenses	373	1,113
Income tax cash flow	(2,458)	3,289
Interest payments	(4)	(57)
Net cash generated from (used in) operating activities	**137,948**	**(4,653)**
Cash flows from investing activities		
Purchases of intangible assets	(267)	(90)
Purchases of property, plant and equipment (usage rights not included)	(21,714)	(16,778)
Proceeds from sale of property, plant and equipment	33	14
Interest received	66	3
Net cash generated from (used in) investing activities	**(21,882)**	**(16,851)**
Cash flows from financing activities		
Repayments of financial debt	(4,377)	(11,087)
Proceeds from financial debt	867	428
Interest paid	(216)	(226)
Purchase of treasury shares	(36,876)	(20,297)
Reissue of treasury shares	36,708	20,543
Dividends paid	(21,373)	-
Net cash generated from (used in) financing activities	**(25,267)**	**(10,639)**
Net (decrease) increase in cash and cash equivalents	**90,799**	**(32,143)**
Cash and cash equivalents at the beginning of the period	**53,162**	**67,426**
Cash and cash equivalents at the end of the period	**143,961**	**35,283**