

# First Quarter 2021 Results

May 13<sup>th</sup>, 2021



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



# **ROVI** – First Quarter 2021 Financial Results

# **ROVI** reports operating revenue growth of 29% and EBITDA growth of 74%

- Operating revenue increased by 29% to 130.5 million euros in the first quarter of 2021, driven by (i) the strength of the toll manufacturing business, which grew by 179%, and (ii) the specialty pharmaceutical business, where sales rose 8%. Total revenue increased by 29% to 130.9 million euros in the first quarter of 2021.
- 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 the Moderna's COVID-19 vaccine. As a result of the expansion of the collaboration between ROVI and Moderna, for 2021 ROVI expects to achieve the higher end of this 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.
- Sales of the heparin franchise (Low Molecular Weight Heparins (LMWH) and other heparins) increased by 15% to 63.9 million euros in the first quarter of 2021. Heparin sales represented 49% of operating revenue in the first quarter of 2021 compared to 55% in the first quarter of 2020. Sales of LMWH (Enoxaparin biosimilar and Bemiparin) increased by 15% to 62.2 million euros in the first quarter of 2021. Sales of the enoxaparin biosimilar decreased 1% to 29.4 million euros in the first quarter of 2021 and sales of Bemiparin increased 35% to 32.8 million euros.
- Sales of Neparvis<sup>®</sup>, launched in December 2016, increased by 10% to 8.7 million euros in the first quarter of 2021.
- EBITDA increased by 74%, from 20.0 million euros in the first quarter of 2020 to 34.8 million euros in the first quarter of 2021, reflecting a 6.9 percentage point rise in the EBITDA margin to 26.7% in the first quarter of 2021.
- Net profit increased by 71%, from 13.9 million euros in the first quarter of 2020 to 23.8 million euros in the first quarter of 2021.



ROVI strengthens its collaboration with Moderna (i) in the fill-finish of the COVID-19 Vaccine Moderna by increasing its fill-finish capacity (see section 7.1), and (ii) for the manufacture of the active substance of this vaccine (see section 7.2). To this end, further industrial investments will be made in the ROVI Group's facilities in Madrid and Granada.

Madrid (Spain), 13<sup>th</sup> May 2021, 8:00 AM CET - ROVI released today its financial results for the first quarter of 2021.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said "At the time of presenting these results, it has been a little over a year 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 and, with the expansion of the agreement with Moderna, we will be also involved in the manufacture of the active substance. Mass vaccination programmes 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 guarter results, we achieved 29% operating revenue growth, mainly driven by the strength of the toll manufacturing business, which grew by 179% and by the specialty pharmaceutical business, where sales rose 8%. We forecast continued growth thanks to, among other factors, our flagship product, Bemiparin, which grew by 35%. Likewise, we are already marketing our enoxaparin biosimilar in 19 countries in the first quarter of 2021. We are in a phase of international expansion and hope that 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<sup>®</sup>, from Novartis, and Volutsa<sup>®</sup>, 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 toll manufacturing activities strategy towards high valueadded products, backed by the high degree of technological specialisation of our plants in differentiated niches, enabled our toll manufacturing business to increase 179% in the first quarter 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<sup>®</sup>). We are currently undergoing a regulatory process with our first candidate, Risperidone ISM<sup>®</sup>, based on our ISM<sup>®</sup> technology, in Europe and the United States in order to obtain the



marketing authorisation for Risperidone ISM<sup>®</sup> 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<sup>®</sup> technology".

# 1. Financial highlights

€ million	Q1 2021	Q1 2020	Growth	% Growth
Operating revenue	130.5	101.0	29.6	29%
Other income	0.3	0.3	0.1	23%
Total revenue	130.9	101.2	29.6	29%
Cost of goods sold	-60.8	-46.0	-14.7	32%
Gross profit	70.1	55.2	14.9	27%
% margin	53.7%	54.7%		-0.9pp
R&D expenses	-5.8	-4.5	-1.4	30%
SG&A	-29.5	-30.8	1.2	-4%
Share of profit of a joint venture	0.0	0.0	0.0	41%
EBITDA	34.8	20.0	14.8	74%
% margin	26.7%	19.8%		6.9pp
EBIT	29.6	15.1	14.5	96%
% margin	22.7%	15.0%		7.7pp
Net profit	23.8	13.9	9.9	71%

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



# 2. Performance of the Group

**Operating revenue** increased by 29% to 130.5 million euros in the first quarter of 2021, driven by the strength of the toll manufacturing business, which grew by 179%, and by the specialty pharmaceutical business, where sales rose 8%. Total revenue increased by 29% to 130.9 million euros in the first quarter of 2021.

€ million	Q1 2021	Q1 2020	% Growth
Specialty pharmaceutical business	95.0	88.2	8%
Toll manufacturing business	35.6	12.7	179%
Operating revenue	130.5	101.0	29%

Sales of **prescription-based pharmaceutical** products rose 8% to 86.2 million euros in the first quarter of 2021.

€ million	Q1 2021	Q1 2020	% Growth
Prescription-based pharmaceutical products	86.2	79.7	8%
LMWH franchise	62.2	53.9	15%
Biosimilar of enoxaparin	29.4	29.6	-1%
Bemiparin (Hibor)	32.8	24.3	35%
Sales in Spain	18.9	18.3	3%
International sales	13.9	6.0	132%
Neparvis	8.7	7.9	10%
Ulunar & Hirobriz	2.5	3.8	-35%
Volutsa	3.9	3.8	2%
Vytorin & Absorcol & Orvatez	6.8	9.5	-29%
Medikinet & Medicebran	0.9	1.1	-13%
Other products	6.5	7.5	-13%
Discounts to the National Health System	-5.3	-7.9	-32%
Contrast agents and other hospital products	8.5	8.3	2%
OTC and Other	0.3	0.2	34%
Total specialty pharmaceutical business	95.0	88.2	8%

Sales of the **heparin franchise** (Low Molecular Weight Heparins and other heparins) increased by 15% to 63.9 million euros in the first quarter of 2021. Heparin sales represented 49% of operating revenue in the first quarter of 2021 compared to 55% in in the first quarter of 2020.



€ million	Q1 2021	Q1 2020	% Growth
LMWH franchise	62.2	53.9	15%
Biosimilar of enoxaparin	29.4	29.6	-1%
Bemiparin (Hibor)	32.8	24.3	35%
Sales in Spain	18.9	18.3	3%
International sales	13.9	6.0	132%
Other heparins <sup>1</sup>	1.7	1.7	-1%
Heparins franchise	63.9	55.6	15%

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

Sales of **Low Molecular Weight Heparins (LMWH)** (Enoxaparin biosimilar and Bemiparin) increased by 15% to 62.2 million euros in the first quarter of 2021.

Sales of the **Enoxaparin biosimilar** decreased 1% to 29.4 million euros in the first quarter of 2021 mainly as a result of the high stocking of ROVI's partners and wholesalers during the first quarter of 2020 due to COVID-19. 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; and in South Africa, Israel, Peru, Holland, Panama and the Dominican Republic in 2020.

ROVI's low-molecular-weight heparin (LMWH), **Bemiparin**, showed a positive performance in the first quarter of 2021, with sales up 35% to 32.8 million euros. International sales of Bemiparin increased by 132% to 13.9 million euros. This increase was mainly linked to (i) the increase in sale prices to some partners due to the rise in LMWH raw material prices, and (ii) a high concentration of purchase orders from the Russian market, where the product was launched in 2020. This significant increase was specifically linked to the first quarter of 2021 and ROVI expects double digit sales increase for international Bemiparin in 2021. Sales of Bemiparin in Spain (**Hibor**<sup>®</sup>) increased 3% to 18.9 million euros in the first quarter of 2021 mainly due to a higher penetration of the product in the treatment segment.

Sales of **Neparvis**<sup>®</sup>, 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 10% to 8.7 million euros in the first quarter of 2021, compared to 7.9 million euros in the first quarter of 2020.

Sales of **Hirobriz® Breezhaler**<sup>®</sup> and **Ulunar® Breezhaler**<sup>®</sup>, 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 35% to 2.5 million euros in the first quarter of 2021, compared to 3.8 million euros



in the same period of the previous year, mainly due to Ulunar<sup>®</sup> Breezhaler<sup>®</sup> price reduction of 18% in the second quarter of 2020.

Sales of **Volutsa**<sup>®</sup>, 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 2% to 3.9 million euros in the first quarter of 2021.

Sales of **Vytorin®**, **Orvatez**<sup>®</sup> and **Absorcol**<sup>®</sup>, specialty products from Merck Sharp & Dohme ("MSD") indicated as adjunctive therapy to diet in patients with hypercholesterolemia, decreased by 29% to 6.8 million euros in the first quarter 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 **Medicebran**<sup>®</sup> and **Medikinet**<sup>®</sup>, 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, decreased by 13% to 0.9 million euros in the first quarter of 2021. In July 2019, Medikinet<sup>®</sup> (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 decreased by 5% in the first quarter of 2021 compared to the same period of the previous year. Nevertheless, ROVI prescription-based pharmaceutical product sales increased 8% in the first quarter of 2021, outperforming the market by 13 percentage points.

Sales of **contrast imaging agents** and other hospital products increased by 2% to 8.5 million euros in the first quarter of 2021. This small increase shows the slow rate at which the Spanish and Portuguese hospitals activity is recovering its pace.

**Toll manufacturing** sales increased by 179% to 35.6 million euros in the first quarter 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 toll manufacturing activities strategy towards high-value-added products.

ROVI strengthens its collaboration with Moderna (i) in the fill-finish of the COVID-19 Vaccine Moderna by increasing its fill-finish capacity (see section 7.1), and (ii) for the manufacture of the active substance of this vaccine (see section 7.2). To this end, further industrial investments will be made in the ROVI Group's facilities in Madrid and Granada.



Likewise, in the year 2021, ROVI expects the toll manufacturing business to increase by between 15% and 20%, including Moderna activities but excluding the production of the vaccine. Including the production of the vaccine, ROVI expects to approximately double 2020 toll manufacturing revenue.

**Sales outside Spain** increased by 68% to 68.3 million euros in the first quarter of 2021, 15.4 million euros (or 23%) of which related to international subsidiaries, mainly due to (i) the increase in Bemiparin international sales and (ii) the increase in the toll manufacturing business. Sales outside Spain represented 52% of operating revenue in the first quarter of 2021 compared to 40% in the first quarter of 2020.

**Other income** (subsidies) increased by 23% to 0.3 million euros in the first quarter of 2021, compared to the same period of the previous year.

**Gross profit** increased by 27% to 70.1 million euros in the first quarter of 2021, the gross margin showing a decrease of 0.9 percentage points from 54.7% in the first quarter of 2020 to 53.7% in the first quarter of 2021, mainly due to the 51% increase in the LMWH raw material cost of goods sold in the first quarter of 2021 compared to the same period last year. ROVI expects LMWH raw material prices to continue to decline in 2021. 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) increased 30% to 5.8 million euros in the first quarter of 2021. R&D expenses were mainly related to (i) the preparation to repeat the bioavailability study comparing multiple doses of Risperidone ISM<sup>®</sup> 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<sup>®</sup> Phase I trial; and (iii) the development of a new formulation of Risperidone ISM<sup>®</sup> for a 3-monthly injection.

**Selling, general and administrative expenses** (SG&A) decreased 4% to 29.5 million euros in the first quarter of 2021 mainly as a result of (i) a drop in promotion expenses (travel and congress expenses) incurred by the sales force, and (ii) the booking of 0.4 million euros in personnel and other expenses related to the COVID-19 measures implemented in the first quarter of 2021 compared to 1.0 million euros in the first quarter of 2020. Excluding expenses related to COVID-19, SG&A would have decreased by 2% to 29.2 million euros in the first quarter of 2021 compared to 29.7 million euros in the first queater of 2020.



€ million	Q1 2021	Q1 2020	% Variation
Employee benefit expenses (exc. R&D)	17,4	16,6	5%
Other operating expenses (exc. R&D)	12,1	14,1	-14%
Total SG&A expenses	29,5	30,8	-4%
Expenses related to international			
subsidiaries	2,5	2,4	4%
Expenses related to COVID-19	0,4	1,0	-64%
Total SG&A expenses excluding expenses related to COVID-19	29,2	29,7	-2%

**EBITDA** increased to 34.8 million euros in the first quarter of 2021, a rise of 74% compared to the same period of the previous year, reflecting a 6.9 percentage point increase in the EBITDA margin, which was up to 26.7% in the first quarter of 2021 from 19.8% in the first quarter of 2020.



However, EBITDA "Pre-R&D", calculated excluding R&D expenses in the first quarter of 2021 and in the first quarter of 2020, increased by 66%, from 24.5 million euros in the first quarter of 2020 to 40.6 million euros in the first quarter of 2021, reflecting a 6.9 percentage point rise in the EBITDA margin to 31.1% in the first quarter of 2021 (see "Pre-R&D costs" columns of the table below). Likewise, recognising the same amount of R&D expenses in the first quarter of 2021 as in the first quarter of 2020, EBITDA would have increased by 81% to 36.2 million euros, reflecting a 7.9 percentage point rise in the EBITDA margin to 27.7% in the first quarter

of 2021, up from 19.8% in the first quarter of 2020 (see "Flat R&D costs" columns of the table below).

	Reported		Pre-R&D costs			Fla	t R&D c	osts
€ million	Q1	Q1	Q1	Q1	%	Q1	Q1	%
	2021	2020	2021	2020	Growth	2021	2020	Growth
Operating revenue	130.5	101.0	130.5	101.0	29%	130.5	101.0	29%
Other income	0.3	0.3	0.3	0.3	23%	0.3	0.3	23%
Total revenue	<b>130.9</b>	<b>101.2</b>	<b>130.9</b>	<b>101.2</b>	<b>29%</b>	<b>130.9</b>	<b>101.2</b>	<b>29%</b>
Cost of sales	-60.8	-46.0	-60.8	-46.0	32%	-60.8	-46.0	32%
Gross profit	70.1	55.2	70.1	55.2	27%	70.1	55.2	27%
% <i>margin</i>	<i>53.7%</i>	<i>54.7%</i>	<i>53.7%</i>	54.7%	<i>-0.9pp</i>	<i>53.7%</i>	<i>54.7%</i>	<i>-0.9pp</i>
R&D expenses	-5.8	-4.5	<b>0.0</b>	<mark>0.0</mark>	n.a.	- <b>4.5</b>	-4.5	n.a.
SG&A	-29.5	-30.8	-29.5	-30.8	-4%	-29.5	-30.8	-4%
Other expenses	0.0	0.0	0.0	0.0	41%	0.0	0.0	41%
EBITDA	<b>34.8</b>	<b>20.0</b>	<b>40.6</b>	<b>24.5</b>	<b>66%</b>	<b>36.2</b>	<b>20.0</b>	<b>81%</b>
% margin	26.7%	19.8%	<i>31.1%</i>	24.2%	<i>6.9pp</i>	27.7%	19.8%	<i>7.9pp</i>

**EBITDA excluding expenses related to COVID-19** ("recurrent EBITDA") increased to 35.2 million euros in the first quarter of 2021, a rise of 68% compared to the same period of the previous year, reflecting a 6.2 percentage point increase in the recurrent EBITDA margin, which was up to 26.9% in the first quarter of 2021 from 20.8% in the first quarter of 2020.

**Depreciation and amortisation expenses** increased by 8% to 5.2 million euros in the first quarter of 2021, as a result of the new property, plant and equipment and intangible assets purchases made during the last twelve months.

**EBIT** increased by 96% to 29.6 million euros in the first quarter of 2021, reflecting a 7.7 percentage point rise in the EBIT margin, which was up to 22.7% in the first quarter of 2021 from 15.0% in the first quarter of 2020.





However, EBIT "pre-R&D", calculated excluding R&D expenses in the first quarter of 2021 and in the first quarter of 2020, increased by 81%, from 19.6 million euros in the first quarter of 2020 to 35.4 million euros in the first quarter of 2021, reflecting a 7.7 percentage point rise in the EBIT margin to 27.2% in the first quarter of 2021 (see "Pre-R&D costs" columns of the table below). Likewise, recognising the same amount of R&D expenses in the first quarter of 2021 as in the first quarter of 2020, EBIT would have increased by 105% to 31.0 million euros, reflecting a 8.7 percentage point rise in the EBIT margin to 23.7% in the first quarter of 2021, up from 15.0% in the first quarter of 2020 (see "Flat R&D costs" columns of the table below).

	Repo	orted	Pre	e-R&D co	osts	Fla	t R&D co	osts
€ million	Q1 2021	Q1 2020	Q1 2021	Q1 2020	% Growth	Q1 2021	Q1 2020	% Growth
Operating revenue	130.5	101.0	130.5	101.0	29%	130.5	101.0	29%
Other income Total revenue	0.3 <b>130.9</b>	0.3 <b>101.2</b>	0.3 <b>130.9</b>	0.3 <b>101.2</b>	<u>23%</u> <b>29%</b>	0.3 <b>130.9</b>	0.3 <b>101.2</b>	<u>23%</u> <b>29%</b>
Cost of sales	-60.8	-46.0	-60.8	-46.0	32%	-60.8	-46.0	32%
Gross profit	70.1	55.2	70.1	55.2	27%	70.1	55.2	27%
% margin	53.7%	54.7%	53.7%	54.7%	-0.9pp	53.7%	54.7%	-0.9pp
R&D expenses	-5.8	-4.5	0.0	0.0	n.a.	-4.5	-4.5	n.a.
SG&A	-29.5	-30.8	-29.5	-30.8	-4%	-29.5	-30.8	-4%
Share of profit of								
a joint venture	0.0	0.0	0.0	0.0	41%	0.0	0.0	41%
EBITDA	34.8	20.0	40.6	24.5	66%	36.2	20.0	81%
% margin	26.7%	19.8%	31.1%	24.2%	6.9pp	27.7%	19.8%	7.9pp
EBIT	29.6	15.1	35.4	19.6	81%	31.0	15.1	105%
% margin	22.7%	15.0%	27.2%	19.4%	7.7pp	23.7%	15.0%	8.7pp

**Net finance result** (cost) amounted to 0.2 million euros in the first quarter of 2021 compared to 0.3 million euros (income) in the first quarter of 2020, mainly due to the lower income related to exchange-rate derivative financial instruments.

The **effective tax rate** was 19.1% in the first quarter of 2021, compared to 9.6% in the first quarter of 2020, mainly due to the increase of the profit before income tax.

As of 31 March 2021, negative tax bases of the Group amounted to 25.5 million euros, of which 9.4 million euros will be used in the full year 2020 income tax and 4.2 million euros will be used in the first quarter of 2021. All negative tax bases were recognised as assets as of 31 December 2019.

**Net profit** increased by 71%, from 13.9 million euros in the first quarter of 2020 to 23.8 million euros in the first quarter of 2021. However, net profit "pre-R&D", calculated excluding R&D expenses in the first quarter of 2021 and in the first quarter of 2020, increased by 59%, from 18.0 million euros in the first quarter of 2020 to 28.6 million euros in the first quarter of 2021 (see "Pre-R&D costs" columns of the table below). Likewise, recognising the same amount of R&D expenses in the first quarter of 2021 as in in the first quarter of 2020, net profit would have increased by 79% to 24.9 million euros (see "Flat R&D costs" columns of the table below).



	Repo	orted	Pre	e-R&D co	osts	Fla	t R&D co	osts
€ million	Q1 2021	Q1 2020	Q1 2021	Q1 2020	% Growth	Q1 2021	Q1 2020	% Growth
Operating revenue	130.5	101.0	130.5	101.0	29%	130.5	101.0	29%
Other income	0.3	0.3	0.3	0.3	23%	0.3	0.3	23%
Total revenue	130.9	101.2	130.9	101.2	<b>29%</b>	130.9	101.2	<b>29%</b>
Cost of sales	-60.8	-46.0	-60.8	-46.0	32%	-60.8	-46.0	32%
Gross profit	70.1	55.2	70.1	55.2	27%	70.1	55.2	27%
% margin	53.7%	54.7%	53.7%	54.7%	-0.9pp	53.7%	54.7%	-0.9pp
R&D expenses	-5.8	-4.5	0.0	0.0	n.a.	-4.5	-4.5	n.a.
SG&A	-29.5	-30.8	-29.5	-30.8	-4%	-29.5	-30.8	-4%
Share of profit of								
a joint venture	0.0	0.0	0.0	0.0	41%	0.0	0.0	41%
EBITDA	34.8	20.0	40.6	24.5	66%	36.2	20.0	81%
% margin	26.7%	19.8%	31.1%	24.2%	6.9рр	27.7%	<i>19.8%</i>	7.9рр
EBIT	29.6	15.1	35.4	19.6	81%	31.0	15.1	105%
% margin	22.7%	15.0%	27.2%	19.4%	7.7pp	23.7%	15.0%	8.7pp
Net profit	23.8	13.9	28.6	18.0	59%	24.9	13.9	<b>79%</b>
% margin	18.3%	13.8%	21.9%	17.8%	4.1pp	19.1%	13.8%	5.3pp

ROVI will pay a **dividend** of 0.3812 euros per share with dividend rights on 2020 earnings if the Shareholders General Meeting approves the application of the 2020 profit, under proposal of ROVI's Board of Directors. This proposed dividend would mean an increase of 118% compared to the dividend on 2019 earnings ( $\in 0.1751$ /share) and represents a 35% pay out (vs 25% pay out last year).

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that "*we are very happy with the results of the first quarter of 2021. We have been able to deliver an operating revenue growth of 29% in a difficult environment thanks to the strength of our toll manufacturing business, which continue to enjoy good sales prospects, and an EBITDA margin rise of 6.9 percentage points mainly as a result of the operating leverage contribution of our toll manufacturing business, the good performance of our LMWH division, and the decrease in operating expenses mainly as a result of the reduction of product promotion. ROVI's commitment to innovation is reflected in the figures of the first quarter 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".* 



# 3. Balance Sheet items

# 3.1 Capital expenditure

ROVI invested 3.9 million euros in the first quarter of 2021, compared to 3.0 million euros in the first quarter of 2020. Of the amount invested:

- 0.1 million euros corresponds to capex related to the Madrid injectables facility, versus 0.6 million euros in the first quarter of 2020;
- 1.8 million euros were invested in the San Sebastián de los Reyes plant (of which 0.4 million euros relates to maintenance capex and 1.4 million euros relates to investment capex), versus 0.3 million euros in the first quarter of 2020;
- 0.04 million euros were invested in the Granada facility, versus 0.2 million euros in the first quarter of 2020;
- 0.1 million euros were invested in the Alcalá de Henares facility, versus 0.2 million euros in the first quarter of 2020;
- 0.5 million euros corresponds to the ISM<sup>®</sup> industrialization, versus 1.0 million euros in the first quarter of 2020;
- 0.9 million euros relates to investment capex regarding the Escúzar plant (the second heparin plant in Granada) versus 0.2 million euros invested in the first quarter of 2020; and
- 0.4 million euros relates to expenditure on maintenance and other capex, versus 0.5 million euros in the first quarter of 2020.

€ million	Q1 2021	Q1 2020	% Growth
Injectable plant	0.1	0.6	-89%
San Sebastián de los Reyes plant	0.4	0.3	17%
Granada plant	0.0	0.2	-78%
Alcalá de Henares plant (Frosst Ibérica)	0.1	0.2	-37%
Expenditure on maintenance and other capex	0.4	0.5	-21%
Maintenance Capex	1.0	1.8	-46%
ISM industrialisation	0.5	1.0	-49%
Escúzar plant	0.9	0.2	n.a.
New vial filling line	1.4	-	n.a.
Investment Capex	2.9	1.2	142%
Total Capex	3.9	3.0	29%



# 3.2 Debt

As of 31 March 2021, ROVI total debt decreased to 72.7 million euros. Debt with public administration, which is 0% interest rate debt, represented 15% of total debt as of 31 March 2021.

In thousand euros	31 March 21	30 December 20	Interest rate (%)
Bank borrowings	45,000	45,000	0.290-0.681
Debt with public administration	10,943	10,972	0
Financial liabilities for leases	16,615	17,546	-
Derivative financial instruments	160	925	-
Total	72,718	74,443	

As of 31 March 2021, bank borrowings remained stable. In December 2017, ROVI announced the European Investment Bank (EIB) 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 at a variable interest rate of Euribor at 3 months + 0.844%. The latest interest rate paid was 0.290% (April 2021). The credit matures in 2029, includes a grace period of 3 years with a fixed interest of 0.681%.

Likewise, since the beginning of the COVID-19 crisis, ROVI has signed credit policies for an amount of 45 million euros, in order to ensure the company's liquidity. As of 31 March 2021, ROVI had not used these credit policies. Thus, the Group is in a comfortable position to meet its payment obligations, debt maturities and any additional cash needs in the short and medium term.

# 3.3 Free cash flow

Free cash flow (net cash generated (used) from operating activities minus (plus) property, plant and equipment and intangible assets purchases (sales) plus interest received) increased to 20.8 million euros in the first quarter of 2021 compared to -3.1 million euros in the first quarter of 2020 mainly due to (i) the increase of 14.1 million euros in profit before income tax; (ii) the increase of 10.7 million euros in the "inventory" line item in the first quarter of 2021 (mainly as a result of lower heparin stock levels) compared to a decrease of 34.0 million euros in the first quarter of 2020; and (iii) the booking of 5.6 million euros in the "Proceeds from toll manufacturing services" line mainly due to payments received that are pending to be allocated to the income statement. These positive impacts were partially offset by (i) the decrease of 16.1 million euros in the "trade receivables" line in the first quarter of 2021 compared to a decrease of 2.5 million euros in the first quarter of 2020; and (ii) the decrease of 10.8 million euros in the "trade and other payables" item in the first quarter of 2021, compared to an increase of 8.9 million euros in the first quarter of 2020.



# 3.4 Gross cash position and net debt

As of 31 March 2021, ROVI had a gross cash position of 74.1 million euros, compared to 54.6 million euros as of 31 December 2020, and net cash of 1.4 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 24.7 million euros in the first quarter of 2021, compared to -0.2 million euros in the first quarter of 2020. Net cash generated from operating activities excluding changes in working capital increased 50% to 41.0 million euros in the first quarter of 2021 from 27.3 million euros in the first quarter of 2020.

# 3.5 Working capital

Figures included in the balance sheet showed an increase in working capital in the first quarter of 2021 mainly due to (i) an increase of 16.1 million euros in the "trade and other receivables" line; (ii) a decrease of 10.2 million euros in the "trade and other payables" line; (iii) a decrease



of 8.7 million euros in the "inventories" line, mainly due to lower heparin stock in the first quarter of 2021; and (iv) an increase of 19.5 million euros in the "cash and cash equivalents" item.

As of 31 March 2021, Social Security and Public Administrations total debt with ROVI amounted to 10.1 million euros, of which 4.9 million euros in Spain, 3.3 million euros in Portugal and 1.9 million euros in Italy.

# 4. Guidance for 2021

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 the Moderna's COVID-19 vaccine. As a result of the expansion of the collaboration between ROVI and Moderna, for 2021 ROVI expects to achieve the higher end of this range.

The Company forecasts that it will continue to grow at a much higher rate than the Spanish pharmaceutical market expenditure in the first three months of 2021, which, according to the Ministry of Health, Consumption and Social Welfare, showed a growth rate of -5.0%.

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.

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

# 5. Research and Development update

# ISM<sup>®</sup> technology platform

Risperidone ISM<sup>®</sup> is the first ROVI's product based in its leading-edge drug delivery technology, ISM<sup>®</sup>. It is a novel investigational antipsychotic for the treatment of schizophrenia with oncemonthly 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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.

On the other hand, as previously informed, the Risperidone ISM<sup>®</sup> dossier is mainly supported by the pivotal clinical trial "PRISMA-3"<sup>1</sup> whose results were published in November of 2020 in the medical journal *npj Schizophrenia*<sup>2</sup>. The PRISMA-3 study demonstrated that Risperidone ISM<sup>®</sup> 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<sup>®</sup> represents an effective therapeutic strategy in schizophrenia patients who are admitted to hospital with an acute episode with severe or moderate psychotic symptoms<sup>2</sup>.

The company also announced in July 2019 the completion of an open-label extension (12 additional months) of the PRISMA-3 study<sup>3</sup>, which is also included in the Risperidone ISM<sup>®</sup> dossier and further supports the long-term use of Risperidone ISM<sup>®</sup>.

<sup>&</sup>lt;sup>1</sup> Study to Evaluate the Efficacy and Safety of Risperidone In Situ Microparticles<sup>®</sup> (ISM<sup>®</sup>) 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").

<sup>&</sup>lt;sup>2</sup> Correll, C.U., Litman, R.E., Filts, Y. et al. Efficacy and safety of once-monthly Risperidone ISM® in schizophrenic patients with an acute exacerbation. npj Schizophr 6, 37 (2020). <u>https://doi.org/10.1038/s41537-020-00127-y</u>.

<sup>&</sup>lt;sup>3</sup> 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").



Furthermore, the company continues the clinical development of Letrozole ISM<sup>®</sup>, which represents the second candidate using the ROVI's ISM<sup>®</sup> 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 study<sup>1</sup>) of Letrozole ISM<sup>®</sup> 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<sup>®</sup> formulation provides a prolonged release of letrozole which produces a sustained suppression of oestrogenic hormones. The company is planning in the first half of 2021 to discuss with regulatory authorities 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<sup>®</sup> for a 3-monthly injection, which would complement the current formulation of Risperidone ISM<sup>®</sup> for the maintenance treatment of patients with clinically stable schizophrenia. This development is still in an initial phase.

# 6. ESG (Environmental, Social and Governance) Risk Rating 2020

In August 2020, ROVI's ESG aspects were evaluated by Sustainalytics, a Global Leader in ESG & Corporate Governance, having obtained an "ESG Risk Rating 2020" of 21.8, which places the company at medium risk (between 20 and 30).

The company is at medium risk of experiencing material financial impacts from ESG factors, due to its medium exposure and strong management of material ESG issues. Furthermore, the company has not experienced significant controversies.

ROVI attained the **second position** out of 360 companies in the sub-industry "pharmaceuticals". The "pharmaceutical industry" includes biotech, phamaceutical and laboratory equipment companies and the "pharmaceutical sub-industry" includes only pharmaceutical companies.

<sup>&</sup>lt;sup>1</sup> Evaluation of IM Letrozole ISM<sup>®</sup> 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").



# 7. Key operating and financial events

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

ROVI announced (by publication of the inside information number 858 dated 29<sup>th</sup> of April of 2021) that it will strengthen 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.

# 7.2 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 12<sup>th</sup> 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.



# 7.3 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 2<sup>sd</sup> of March of 2021) that it has 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 on the basis of 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<sup>®</sup>, 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<sup>®</sup>. 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<sup>®</sup> Platform technology, a leading-edge line of research in the field of prolonged drug release with proven advantages. For more information, please visit <u>www.rovi.es</u>

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# Forward-looking statements

This news release contains forward-looking statements. Such forward looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition, performance, or achievements of ROVI or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward looking statements. The statements in this press release represent ROVI's expectations and beliefs as of the date of this press release. ROVI anticipates that subsequent events and developments may cause these expectations and beliefs to change. However, while ROVI may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing ROVI's expectations or beliefs as of any date subsequent to 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 MARCH 2021 AND 31 DECEMBER 2020

(Thousands of euros) \* <u>Non-audited figures</u>

	31 March 2020	31 December 2020
ASSETS		
Non-current assets		
Property Plant and Equipment	154,962	155,395
Intangible assets	40,522	41,413
Investment in a joint venture	1,860	1,812
Deferred income tax assets	7,760	11,105
Equity securities	71	71
Financial receivables	65	65
	205,240	209,861
Current assets		
Inventories	218,494	227,199
Trade and other receivables	92,479	76,401
Current income tax assets	1,857	7,803
Prepaid expenses	695	13
Cash and cash equivalents	72,617	53,162
	386,142	364,578
Total assets	591,382	574,439



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

(Thousands of euros) \* <u>Non-audited figures</u>

	31 March 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	(23,876)	(20,185)
Retained earnings and voluntary reserves	305,712	241,158
Profit for the period	23,838	61,057
Other reserves	(3)	(3)
Total equity	397,344	373,700
LIABILITIES		
Non-current liabilities		
Financial debt	67,383	68,421
Deferred income tax liabilities	311	929
Contract liabilities	5,389	5,788
Deferred income	2,613	2,712
	75,696	77,850
Current liabilities		
Financial debt	5,335	6,022
Current income tax liabilities	1,097	-
Trade and other payables	81,178	91,364
Contract liabilities	30,247	25,005
Deferred income	485	498
	118,342	122,889
Total liabilities	194,038	200,739
Total equity and liabilities	591,382	574,439



## LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED INCOME STATEMENTS FOR THE THREE-MONTH PERIODS ENDING 31 MARCH 2021 AND 31 MARCH 2020

(Thousands of euros) \* <u>Non-audited figures</u>

	Three-month periods ending 31 March	
	2021	2020
Revenue	130,547	100,964
Changes in inventories of finished goods and work in progress	(16,848)	11,685
Raw materials and consumables used	(43,902)	(57,732)
Personnel expenses	(20,120)	(18,684)
Other operating expenses	(15,241)	(16,562)
Amortisation	(5,200)	(4,835)
Recognition of government grants on non-financial non-current		
assets and other	322	261
Share of profits of joint venture	48	34
OPERATING PROFIT	29,606	15,131
Finance income	-	2
Finance costs	(244)	(462)
Impairment and gain or loss on measurement of financial		
instruments	123	615
Exchange difference	(34)	114
FINANCE INCOME/(COSTS) - NET	(155)	269
PROFIT BEFORE INCOME TAX	29,451	15,400
Income tax	(5,613)	(1,481)
PROFIT FOR THE PERIOD	23,838	13,919



## LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED CASH FLOW STATEMENTS FOR THE THREE-MONTH PERIODS ENDING 31 MARCH 2021 AND 31 MARCH 2020

(Thousands of euros) \*<u>Non-audited figures</u>

Thousands of euros) · <u>Non-addited figures</u>	Three-month periods ending 31 March	
	2021	2020
Cash flows from operating activities		
Profit before tax	29,451	15,400
Adjustments for non-monetary transactions:		
Amortisation	5,200	4,835
Finance income	(0)	(2)
Valuation allowance	(2,070)	1,284
Adjustments for changes in value of derivatives	(766)	(350)
Gain or loss on derecognition of financial assets and liabilities	643	(265)
Finance expenses	244	348
Grants, income from distribution licenses and other deferred incomes	(706)	(415)
Other current assets (prepaid expenses)	(682)	-
Share of profit of joint venture	(48)	(34)
Changes in working capital:		
Trade and other receivables	(16,138)	(2,477)
Inventories	10,661	(33,951)
Trade and other payables	(10,810)	8,934
Other collections and payments:		
Proceeds from toll manufacturing services	5,613	-
Proceeds from distribution licenses	25	400
Income tax cash flow	4,069	6,260
Interest payments	(4)	(120)
Net cash generated from (used in) operating activities	24,682	(153)
Cash flows from investing activities	<i>i</i> =	
Purchases of intangible assets	(51)	(10)
Purchases of property, plant and equipment	(3,825)	(2,986)
Proceeds from sale of property, plant and equipment	-	14
Interest received	-	2
Net cash generated from (used in) investing activities	(3,876)	(2,980)
Cash flows from financing activities		(0.054)
Repayments of financial debt	(1,455)	(8,351)
Proceeds from financial debt	389	-
Interest paid	(72)	(9)
Purchase of treasury shares	(14,053)	(4,368)
Reissue of treasury shares	13,840	4,373
Net cash generated from (used in) financing activities	(1,351)	(8,355)
Net (decrease) increase in cash and cash equivalents	19,455	(11,488)
Cash and cash equivalents at the beginning of the period	53,162	<u>67,426</u>
Cash and cash equivalents at the end of the period	72,617	55,938