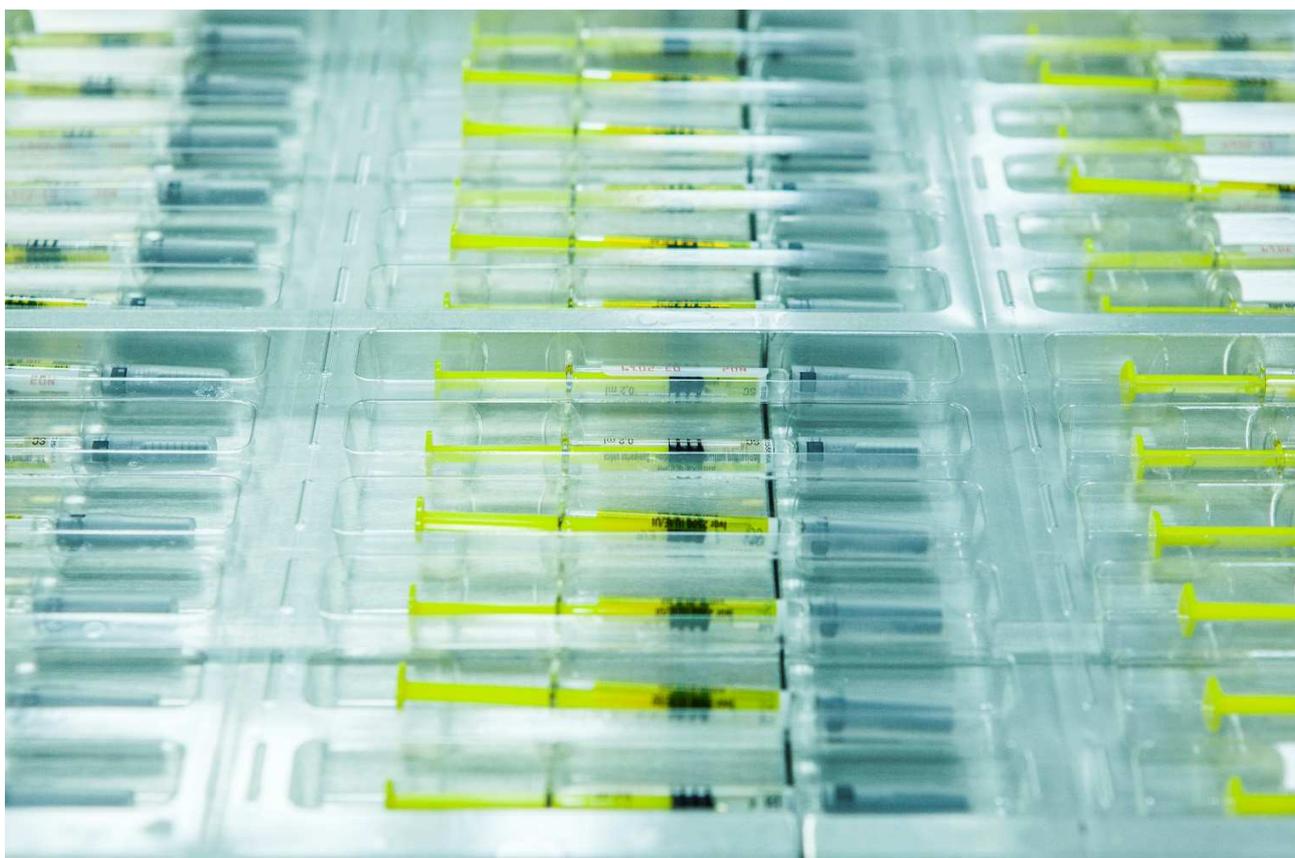




# Nine-month period ending 30<sup>th</sup> September 2020 Results

November 5<sup>th</sup>, 2020



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



## **ROVI – Nine-month period ending 30<sup>th</sup> September 2020 Financial Results**

# **ROVI reports operating revenue growth of 12% and net profit growth of 53%**

- **Operating revenue increased by 12% to 302.1 million euros in the first nine months of 2020, driven by (i) the strength of the specialty pharmaceutical business, where sales rose 6%, and by (ii) the toll manufacturing business, which grew by 38%. Total revenue increased by 12% to 303.0 million euros in the first nine months of 2020.**
- **For 2021, ROVI expects a mid-single-digit growth rate for the operating revenue, excluding the production of the Moderna's COVID-19 vaccine candidate. 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 the next year.**
- **For 2020, ROVI expects a mid-single-digit growth rate for the operating revenue.**
- **Sales of the heparin franchise (Low Molecular Weight Heparins (LMWH) and other heparins) increased by 26% to 157.7 million euros in the first nine months of 2020. Heparin sales represented 52% of operating revenue in the first nine months of 2020 compared to 46% in the first nine months of 2019. Sales of LMWH (Enoxaparin biosimilar and Bemiparin) increased by 25% to 153.1 million euros in the first nine months of 2020. Sales of the enoxaparin biosimilar increased 45% to 76.6 million euros in the first nine months 2020 and sales of Bemiparin increased 10% to 76.5 million euros.**
- **Sales of Neparvis<sup>®</sup>, launched in December 2016, increased by 42% to 21.6 million euros in the first nine months of 2020.**
- **EBITDA increased by 47%, from 47.5 million euros in the first nine months of 2019 to 69.7 million euros in the first nine months 2020, reflecting a 5.5 percentage point rise in the EBITDA margin to 23.1% in the first nine months of 2020.**



- **Net profit increased by 53%, from 30.7 million euros in the first nine months of 2019 to 46.8 million euros in the first nine months of 2020.**
- **ROVI's ESG (Environmental, Social and Governance) aspects have been evaluated by Sustanalytics, 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). ROVI has attained the second position out of 360 companies in the sub-industry "pharmaceuticals".**
- **ROVI filed its application for marketing authorisation for Doria® with the European health authority, the European Medicines Agency (EMA), through the Centralised Procedure on 27 December, 2019. After passing the validation phase satisfactorily, the dossier was admitted for evaluation on 30 January, 2020 and was released to the Stock Market through the publication of the material event with register number 286374 dated 31 January, 2020.**
- **ROVI General Shareholders Meeting, on 20 October, 2020, approved the payment of a gross dividend of 0.1751 euros per share on 2019 earnings. This dividend will be paid on 19 November, 2020; it means an increase of 119% on the dividend paid out of the 2018 profit (€0.0798/share) and represents a 25% pay-out.**
- **The General Assembly of Farmaindustria, the Spanish pharmaceutical industry association, has unanimously elected ROVI's CEO, Mr. Juan López-Belmonte, as the new president of the Association for the next two years.**

**Madrid (Spain), 5<sup>th</sup> November 2020, 8:00 AM CET** - ROVI released today its financial results for the first nine months of 2020.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said "first of all, I would like to thank health professionals around the world for their efforts in the face of this health crisis and express our condolences for the human losses it is causing. I would also like to thank all ROVI employees for their response to COVID-19. As a pharmaceutical company we are an essential company and the commitment of our staff has allowed us to operate normally. Regarding the first nine months of 2020 results, we reached 12% operating revenue growth, mainly driven by the strength of the specialty pharmaceutical business, where sales rose by 6%, and by the toll manufacturing business, which grew by 38%. We forecast continued growth thanks to, among other factors, our flagship product, Bemiparin, which grew by 10%. Likewise, we are already marketing our enoxaparin biosimilar in 18 countries and sales increased by 45% in the first nine months of 2020. 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, the redirection of the toll manufacturing activities strategy towards high value-added products, backed by the high degree of technological specialisation of our plants in differentiated niches, enabled our toll manufacturing business to increase 38% in the first nine months of 2020. Likewise, between 20% and 25% growth for the toll manufacturing business is expected in 2020. In addition, the agreement signed with Moderna makes us very proud to be part of the supply chain of its finished vaccine against COVID-19, once approved, and help address a solution for this pandemic that affects us all. 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 concluded a Phase III trial with our ISM<sup>®</sup> technology (Risperidone ISM<sup>®</sup>) and have filed the dossier in Europe, likewise planning filing in the United States for the last quarter of 2020. We are also conducting a Phase I study for another candidate, Letrozole, for which preliminary data also show positive results, reflecting our clear commitment to our ISM<sup>®</sup> technology".

## 1. Financial highlights

<i>€ million</i>	<b>9M 2020</b>	<b>9M 2019</b>	<b>Growth</b>	<b>% Growth</b>
Operating revenue	302.1	270.8	31.4	12%
Other income	0.9	0.8	0.1	9%
<b>Total revenue</b>	<b>303.0</b>	<b>271.6</b>	<b>31.4</b>	<b>12%</b>
Cost of sales	-127.6	-114.6	-13.0	11%
<b>Gross profit</b>	<b>175.4</b>	<b>157.0</b>	<b>18.4</b>	<b>12%</b>
<i>% margin</i>	<i>58.1%</i>	<i>58.0%</i>		<i>0.1pp</i>
R&D expenses	-15.6	-21.4	5.8	-27%
SG&A	-90.1	-88.0	-2.2	2%
Share of profit/loss of a joint venture	-0.0	-0.1	0.1	-76%
<b>EBITDA</b>	<b>69.7</b>	<b>47.5</b>	<b>22.1</b>	<b>47%</b>
<i>% margin</i>	<i>23.1%</i>	<i>17.6%</i>		<i>5.5pp</i>
<b>EBIT</b>	<b>55.3</b>	<b>34.1</b>	<b>21.2</b>	<b>62%</b>
<i>% margin</i>	<i>18.3%</i>	<i>12.6%</i>		<i>5.7pp</i>
<b>Net profit</b>	<b>46.8</b>	<b>30.7</b>	<b>16.1</b>	<b>53%</b>



*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 2020 and the comparative information for 2019 (balance sheet) and for the first nine months of 2019 (consolidated income statement and cash flow statement) are attached to this report (see Appendix 1).

## 2. Performance of the Group

**Operating revenue** increased by 12% to 302.1 million euros in the first nine months of 2020, driven by the strength of the specialty pharmaceutical business, where sales rose 6% and by the toll manufacturing business, which grew by 38%. Total revenue increased by 12% to 303.0 million euros in the first nine months of 2020.

<i>€ million</i>	<b>9M 2020</b>	<b>9M 2019</b>	<b>% Growth</b>
Specialty pharmaceutical business	239.5	225.4	6%
Toll manufacturing business	62.7	45.4	38%
<b>Operating revenue</b>	<b>302.1</b>	<b>270.8</b>	<b>12%</b>

Sales of **prescription-based pharmaceutical** products rose 9% to 216.8 million euros in the first nine months of 2020.



<i>€ million</i>	<b>9M 2020</b>	<b>9M 2019</b>	<b>% Growth</b>
<b>Prescription-based pharmaceutical products</b>	<b>216.8</b>	<b>199.2</b>	<b>9%</b>
LMWH franchise	153.1	122.6	25%
Biosimilar of enoxaparin	76.6	52.9	45%
Bemiparin (Hibor)	76.5	69.8	10%
Sales in Spain	50.4	51.5	-2%
International sales	26.1	18.2	43%
Neparvis	21.6	15.2	42%
Ulunar & Hirobriz	8.7	11.0	-20%
Volutsa	10.5	9.7	8%
Vytorin & Absorcol & Orvatez	22.0	23.2	-5%
Medikinet & Medicebran	2.4	4.8	-49%
Other products	19.8	25.5	-22%
Discounts to the National Health System	-21.3	-12.9	65%
<b>Contrast agents and other hospital products</b>	<b>22.1</b>	<b>24.3</b>	<b>-9%</b>
<b>OTC and Other</b>	<b>0.5</b>	<b>1.9</b>	<b>-72%</b>
<b>Total specialty pharmaceutical business</b>	<b>239.5</b>	<b>225.4</b>	<b>6%</b>

Sales of the **heparin franchise** (Low Molecular Weight Heparins and other heparins) increased by 26% to 157.7 million euros in the first nine months of 2020. Heparin sales represented 52% of operating revenue in the first nine months of 2020 compared to 46% in the first nine months of 2019.

<i>€ million</i>	<b>9M 2020</b>	<b>9M 2019</b>	<b>% Growth</b>
LMWH franchise	153.1	122.6	25%
Biosimilar of enoxaparin	76.6	52.9	45%
Bemiparin (Hibor)	76.5	69.8	10%
Sales in Spain	50.4	51.5	-2%
International sales	26.1	18.2	43%
Other heparins <sup>1</sup>	4.7	3.0	57%
<b>Heparins franchise</b>	<b>157.7</b>	<b>125.6</b>	<b>26%</b>

<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 25% to 153.1 million euros in the first nine months of 2020.

Sales of the **Enoxaparin biosimilar** increased 45% to 76.6 million euros in the first nine months of 2020. 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, Panama and the Dominican Republic in the first nine months of 2020.

ROVI's low-molecular-weight heparin (LMWH), **Bemiparin**, showed a positive performance during the first nine months of 2020, with sales up 10% to 76.5 million euros. International sales of Bemiparin increased by 43% to 26.1 million euros. This significant increase was mainly linked to the increase in transfer prices to some partners due to the rise in LMWH raw material prices. ROVI expects international Bemiparin sales to increase by between 15% and 20% in 2020. Sales of Bemiparin in Spain (**Hibor**<sup>®</sup>) decreased 2% to 50.4 million euros in the first nine months of 2020 due to the significant reduction in the number of surgical operations performed during the period of lockdown.

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 42% to 21.6 million euros in the first nine months of 2020, compared to 15.2 million euros in the first nine months of 2019.

Sales of **Hirobriz**<sup>®</sup> **Breezhaler**<sup>®</sup> and **Ulunar**<sup>®</sup> **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 20% to 8.7 million euros in the first nine months of 2020, compared to 11.0 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 first nine months 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 8% to 10.5 million euros in the first nine months of 2020.

Sales of **Vytorin**<sup>®</sup>, **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 5% to 22.0 million euros in the first nine months of 2020. In this period, Orvatez<sup>®</sup> 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 49% to 2.4 million euros in the first nine months of 2020. 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 increased by 3% in the first nine months of 2020 compared to the same period of the previous year. Nevertheless, ROVI prescription-based pharmaceutical product sales increased 9% during the first nine months of the year, outperforming the market by 6 percentage points.

As a member of Farmaindustria, the Spanish pharmaceutical industry association, ROVI is subject to the collaboration agreement signed between Farmaindustria and the Spanish government in 2016. The parties have undertaken to work together to develop a new 2020 implementation agreement. Negotiations have not yet begun, and the company is unable to anticipate the final terms that the parties may agree on.

Sales of **contrast imaging agents** and other hospital products decreased by 9% to 22.1 million euros in the first nine months of 2020. This fall is mainly due to the significant reduction in the number of diagnostic tests performed during the period of lockdown. Sales of contrast imaging agents and other hospital products increased by 26% in the third quarter of 2020 compared to the second quarter of 2020 and by 2% in the third quarter of 2020 compared to the third quarter of 2019.

**Toll manufacturing** sales increased by 38% to 62.7 million euros in the first nine months of 2020 as a result of the redirection of our toll manufacturing activities strategy towards high-value-added products.

In November 2019, the toll manufacturing management units, ROVI Contract Manufacturing and Frosst Ibérica, merged into a single entity, ROVI Pharma Industrial Services, which furnishes manufacturing services with the highest degree of quality and competitiveness. The total integration of the production processes is expected to allow the company to attain greater synergies and levels of efficiency in its industrial operations.

ROVI has started to carry on some activities linked to preparing the plant for the COVID-19 vaccine production under the agreement with Moderna, but no income was booked in the third quarter of 2020. Nevertheless, ROVI expects to start booking income related to these activities in the fourth quarter of 2020.

Likewise, by the end of 2020, ROVI expects the toll manufacturing business to have increased by between 20% and 25%, excluding the activities related to the Moderna agreement.



**Sales outside Spain** increased by 39% to 140.7 million euros in the first nine months of 2020, 40,5 million euros (or 29%) of which related to international subsidiaries, mainly due to recognition of Enoxaparin biosimilar sales. Sales outside Spain represented 47% of operating revenue in the first nine months of 2020 compared to 37% in the first nine months of 2019.

**Other income** (subsidiaries) increased by 9% to 0.9 million euros in the first nine months of 2020, compared to the same period of the previous year.

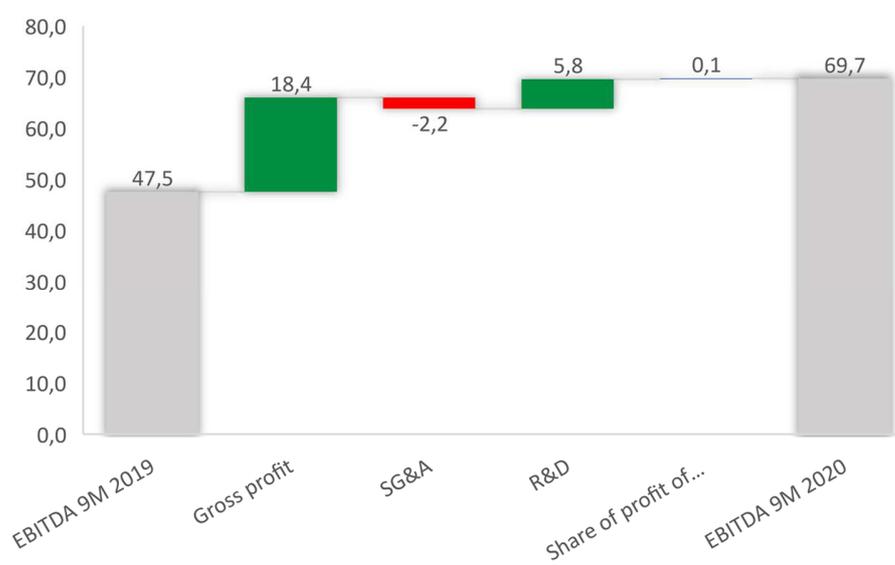
**Gross profit** increased by 12% to 175.4 million euros in the first nine months of 2020, the gross margin showing an increase of 0.1 percentage points from 58.0% in the first nine months of 2019 to 58.1%, mainly due to (i) the increase in toll manufacturing sales contributing higher margins to group sales; (ii) the increase in Bemiparin prices in hospitals due to rises in both LMWH raw material prices (caused by the African swine fever) and the demand for the product in hospitals to treat COVID-19; (iii) the improvement in enoxaparin margins in Spain, counteracting the drop in the margin on international sales of enoxaparin; and (iv) the end of the marketing of the Norgine B.V. product portfolio (Sintrom<sup>®</sup>, Salagen<sup>®</sup>, Cordiplast<sup>®</sup> and Estradem<sup>®</sup>), which had lower margins than the group. These factors with a positive impact on the gross margin offset the 37% increase in the LMWH raw material prices in the first nine months of 2020 compared to the same period last year. ROVI expects LMWH raw material prices to remain stable or even to begin a change of trend during the second half of 2020. 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 used, stocked for several months, was purchased at higher prices.

**Research and development expenses** (R&D) decreased 27% to 15.6 million euros in the first nine months of 2020. R&D expenses were mainly related to (i) the preparation of the Doria<sup>®</sup> registration dossier to be submitted to the U.S. Food and Drug Administration (FDA); (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. ROVI expects R&D expenses to decrease for the full year by between 15% and 20%.

**Selling, general and administrative expenses** (SG&A) increased 2% to 90.1 million euros in the first nine months of 2020, mainly due to the booking of 3.1 million euros in personnel and other expenses related to the COVID-19 measures implemented (see section 7.2). Excluding expenses related to COVID-19, SG&A would have decreased by 1% to 87.0 million euros in the first nine months of 2020 mainly as result of a drop in (i) promotion expenses (travel and congress expenses) incurred by the sales force; and (ii) expenses of international subsidiaries (including Portugal), which amounted to 5.6 million euros, compared to 6.5 million euros in the first nine months of 2019, mainly because of the COVID-19 pandemic. In 2020, expenses related to international subsidiaries are expected to be around 9 million euros.

	<b>9M 2020</b>	<b>9M 2019</b>	<b>% Growth</b>
Personnel expenses (exc. R&D)	50.0	48.8	3%
Other operating expenses (exc. R&D)	40.1	39.1	2%
<b>Total SG&amp;A expenses</b>	<b>90.1</b>	<b>88.0</b>	<b>2%</b>
<i>Expenses related to international subsidiaries</i>	<i>5.6</i>	<i>6.5</i>	<i>-14%</i>
<i>Expenses related to COVID-19</i>	<i>3.1</i>	<i>-</i>	<i>n.a.</i>
<b>Total SG&amp;A expenses excluding expenses related to COVID-19</b>	<b>87.0</b>	<b>88.0</b>	<b>-1%</b>

**EBITDA** increased to 69.7 million euros in the first nine months of 2020, a rise of 47% compared to the same period of the previous year, reflecting a 5.5 percentage point increase in the EBITDA margin, which was up to 23.1% in the first nine months of 2020 from 17.6% in the first nine months of 2019.



However, EBITDA "Pre-R&D", calculated excluding R&D expenses in the first nine months of 2020 and 2019, increased by 24%, from 68.9 million euros in the first nine months of 2019 to 85.3 million euros in the first nine months of 2020, reflecting a 2.8 percentage point rise in the EBITDA margin to 28.2% in the first nine months of 2020 (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 2020 as in the first nine months of 2019, EBITDA would have increased by 34% to 63.9 million euros, reflecting a 3.6 percentage point rise in the EBITDA margin to 21.1% in the first nine months of 2020, up from 17.6% in the first nine months of 2019 (see "Flat R&D costs" columns of the table below).

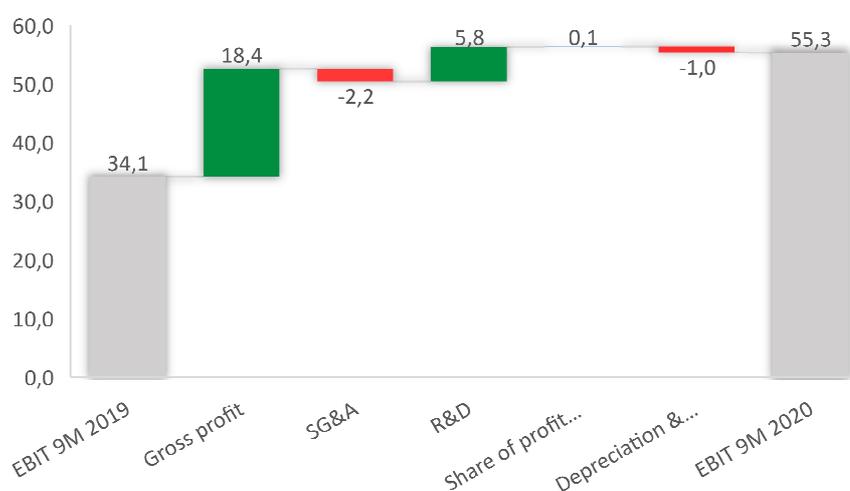


€ million	Reported		Pre-R&D costs			Flat R&D costs		
	9M 2020	9M 2019	9M 2020	9M 2019	% Growth	9M 2020	9M 2019	% Growth
Operating revenue	302.1	270.8	302.1	270.8	12%	302.1	270.8	12%
Other income	0.9	0.8	0.9	0.8	9%	0.9	0.8	9%
<b>Total revenue</b>	<b>303.0</b>	<b>271.6</b>	<b>303.0</b>	<b>271.6</b>	<b>12%</b>	<b>303.0</b>	<b>271.6</b>	<b>12%</b>
Cost of sales	-127.6	-114.6	-127.6	-114.6	11%	-127.6	-114.6	11%
<b>Gross profit</b>	<b>175.4</b>	<b>157.0</b>	<b>175.4</b>	<b>157.0</b>	<b>12%</b>	<b>175.4</b>	<b>157.0</b>	<b>12%</b>
<i>% margin</i>	<i>58.1%</i>	<i>58.0%</i>	<i>58.1%</i>	<i>58.0%</i>	<i>0.1pp</i>	<i>58.1%</i>	<i>58.0%</i>	<i>0.1pp</i>
R&D expenses	-15.6	-21.4	<b>0.0</b>	<b>0.0</b>	n.a.	<b>-21.4</b>	<b>-21.4</b>	0%
SG&A	-90.1	-88.0	-90.1	-88.0	2%	-90.1	-88.0	2%
Other expenses	0.0	-0.1	0.0	-0.1	-76%	0.0	-0.1	-76%
<b>EBITDA</b>	<b>69.7</b>	<b>47.5</b>	<b>85.3</b>	<b>68.9</b>	<b>24%</b>	<b>63.9</b>	<b>47.5</b>	<b>34%</b>
<i>% margin</i>	<i>23.1%</i>	<i>17.6%</i>	<i>28.2%</i>	<i>25.5%</i>	<i>2.8pp</i>	<i>21.1%</i>	<i>17.6%</i>	<i>3.6pp</i>

**EBITDA excluding expenses related to COVID-19** (“recurrent EBITDA”) increased to 72.8 million euros in the first nine months of 2020, a rise of 53% compared to the same period of the previous year, reflecting a 6.5 percentage point increase in the recurrent EBITDA margin, which was up to 24.1% in the first nine months of 2020 from 17.6% in the first nine months of 2019.

**Depreciation and amortisation expenses** increased by 7% to 14.4 million euros in the first nine months of 2020, as a result of the new property, plant and equipment and intangible assets purchases made during the last twelve months.

**EBIT** increased by 62% to 55.3 million euros in the first nine months of 2020, reflecting a 5.7 percentage point rise in the EBIT margin, which was up to 18.3% in the first nine months of 2020 from 12.6% in the first nine months of 2019.



However, EBIT “pre-R&D”, calculated excluding R&D expenses in the first nine months of 2020 and 2019, increased by 28%, from 55.5 million euros in the first nine months of 2019 to 70.9 million euros in the first nine months of 2020, reflecting a 3.0 percentage point rise in the EBIT margin to 23.5% in the first nine months of 2020 (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 2020 as in the first nine months of 2019, EBIT would have increased by 45% to 49.5 million euros, reflecting a 3.8 percentage point rise in the EBIT margin to 16.4% in the first nine months of 2020, up from 12.6% in the first nine months of 2019 (see “Flat R&D costs” columns of the table below).



<i>€ million</i>	Reported		Pre-R&D costs			Flat R&D costs		
	9M 2020	9M 2019	9M 2020	9M 2019	% Growth	9M 2020	9M 2019	% Growth
Operating revenue	302.1	270.8	302.1	270.8	12%	302.1	270.8	12%
Other income	0.9	0.8	0.9	0.8	9%	0.9	0.8	9%
<b>Total revenue</b>	<b>303.0</b>	<b>271.6</b>	<b>303.0</b>	<b>271.6</b>	<b>12%</b>	<b>303.0</b>	<b>271.6</b>	<b>12%</b>
Cost of sales	-127.6	-114.6	-127.6	-114.6	11%	-127.6	-114.6	11%
<b>Gross profit</b>	<b>175.4</b>	<b>157.0</b>	<b>175.4</b>	<b>157.0</b>	<b>12%</b>	<b>175.4</b>	<b>157.0</b>	<b>12%</b>
<i>% margin</i>	<i>58.1%</i>	<i>58.0%</i>	<i>58.1%</i>	<i>58.0%</i>	<i>0.1pp</i>	<i>58.1%</i>	<i>58.0%</i>	<i>0.1pp</i>
R&D expenses	-15.6	-21.4	<b>0.0</b>	<b>0.0</b>	n.a.	<b>-21.4</b>	<b>-21.4</b>	0%
SG&A	-90.1	-88.0	-90.1	-88.0	2%	-90.1	-88.0	2%
Share of profit of a joint venture	0.0	-0.1	0.0	-0.1	-76%	0.0	-0.1	-76%
<b>EBITDA</b>	<b>69.7</b>	<b>47.5</b>	<b>85.3</b>	<b>68.9</b>	<b>24%</b>	<b>63.9</b>	<b>47.5</b>	<b>34%</b>
<i>% margin</i>	<i>23.1%</i>	<i>17.6%</i>	<i>28.2%</i>	<i>25.5%</i>	<i>2.8pp</i>	<i>21.1%</i>	<i>17.6%</i>	<i>3.6pp</i>
<b>EBIT</b>	<b>55.3</b>	<b>34.1</b>	<b>70.9</b>	<b>55.5</b>	<b>28%</b>	<b>49.5</b>	<b>34.1</b>	<b>45%</b>
<i>% margin</i>	<i>18.3%</i>	<i>12.6%</i>	<i>23.5%</i>	<i>20.5%</i>	<i>3.0pp</i>	<i>16.4%</i>	<i>12.6%</i>	<i>3.8pp</i>

**Net finance result** amounted to -1.0 million euros (cost) in the first nine months of 2020 compared to 0.1 million euros (income), mainly due to the loss related to exchange-rate derivative financial instruments.

The **effective tax rate** was 13.7% in the first nine months of 2020, compared to 10.3% in the first nine months of 2019, mainly due to (i) the increase of the profit before income tax; (ii) the recognition in 2019 of negative tax bases ROVI had the right to use; and (iii) the decrease of research and development tax credits in the first nine months of 2020 as a result of the decrease in R&D expenses in the first nine months of 2020 compared to the same period of the previous year.

As of 30 September 2020, negative tax bases of the Group amounted to 26.4 million euros, of which 6.8 million euros will be used in the first nine months of 2020.

**Net profit** increased by 53%, from 30.7 million euros in the first nine months of 2019 to 46.8 million euros in the first nine months of 2020. However, net profit "pre-R&D", calculated excluding R&D expenses in the first nine months of 2020 and 2019, increased by 21%, from 49.9 million euros in the first nine months of 2019 to 60.3 million euros in the first nine months of 2020 (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 2020 as in the first nine months of 2019,



net profit would have increased by 36% to 41.8 million euros (see “Flat R&D costs” columns of the table below).

€ million	Reported		Pre-R&D costs			Flat R&D costs		
	9M 2020	9M 2019	9M 2020	9M 2019	% Growth	9M 2020	9M 2019	% Growth
Operating revenue	302.1	270.8	302.1	270.8	12%	302.1	270.8	12%
Other income	0.9	0.8	0.9	0.8	9%	0.9	0.8	9%
<b>Total revenue</b>	<b>303.0</b>	<b>271.6</b>	<b>303.0</b>	<b>271.6</b>	<b>12%</b>	<b>303.0</b>	<b>271.6</b>	<b>12%</b>
Cost of sales	-127.6	-114.6	-127.6	-114.6	11%	-127.6	-114.6	11%
<b>Gross profit</b>	<b>175.4</b>	<b>157.0</b>	<b>175.4</b>	<b>157.0</b>	<b>12%</b>	<b>175.4</b>	<b>157.0</b>	<b>12%</b>
<i>% margin</i>	<i>58.1%</i>	<i>58.0%</i>	<i>58.1%</i>	<i>58.0%</i>	<i>0.1pp</i>	<i>58.1%</i>	<i>58.0%</i>	<i>0.1pp</i>
R&D expenses	-15.6	-21.4	<b>0.0</b>	<b>0.0</b>	n.a.	<b>-21.4</b>	<b>-21.4</b>	0%
SG&A	-90.1	-88.0	-90.1	-88.0	2%	-90.1	-88.0	2%
Share of profit of a joint venture	0.0	-0.1	0.0	-0.1	-76%	0.0	-0.1	-76%
<b>EBITDA</b>	<b>69.7</b>	<b>47.5</b>	<b>85.3</b>	<b>68.9</b>	<b>24%</b>	<b>63.9</b>	<b>47.5</b>	<b>34%</b>
<i>% margin</i>	<i>23.1%</i>	<i>17.6%</i>	<i>28.2%</i>	<i>25.5%</i>	<i>2.8pp</i>	<i>21.1%</i>	<i>17.6%</i>	<i>3.6pp</i>
<b>EBIT</b>	<b>55.3</b>	<b>34.1</b>	<b>70.9</b>	<b>55.5</b>	<b>28%</b>	<b>49.5</b>	<b>34.1</b>	<b>45%</b>
<i>% margin</i>	<i>18.3%</i>	<i>12.6%</i>	<i>23.5%</i>	<i>20.5%</i>	<i>3.0pp</i>	<i>16.4%</i>	<i>12.6%</i>	<i>3.8pp</i>
<b>Net profit</b>	<b>46.8</b>	<b>30.7</b>	<b>60.3</b>	<b>49.9</b>	<b>21%</b>	<b>41.8</b>	<b>30.7</b>	<b>36%</b>
<i>% margin</i>	<i>15.5%</i>	<i>11.3%</i>	<i>20.0%</i>	<i>18.4%</i>	<i>1.5pp</i>	<i>13.8%</i>	<i>11.3%</i>	<i>2.5pp</i>

ROVI General Shareholders Meeting, on 20 October 2020, approved the payment of a gross dividend of 0.1751 euros per share on 2019 earnings; it means an increase of 119% on the dividend paid out of the 2018 profit (€0.0798/share) and represents approximately a 25% payout. This dividend will be paid on 19 November 2020.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that “we are very happy with the results for the first nine months of 2020. We have been able to deliver an operating revenue growth of 12% in a difficult environment thanks to the strength of our leading products, which continue to enjoy good sales prospects, and an EBITDA margin rise of 5.5 percentage points mainly as a result of the operating leverage contribution of our LMWH division, the expansion of our injectables toll manufacturing business and the reduction in operating expenses as a result of the absence of promotion during the lockdown period. ROVI’s commitment to innovation is reflected in the figures for the first nine months of 2020. 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 16.9 million euros in the first nine months of 2020, compared to 14.3 million euros in the first nine months of 2019. Of the amount invested:

- 1.3 million euros corresponds to capex related to the Madrid injectables facility, versus 0.7 million euros in the first nine months of 2019;
- 3.3 million euros were invested in the San Sebastián de los Reyes plant (of which 1.2 million euros relates to maintenance capex and 2.1 million euros relates to investment capex), versus 2.5 million euros in the first nine months of 2019;
- 1.3 million euros were invested in the Granada facility, versus 3.8 million euros in the first nine months of 2019;
- 2.2 million euros were invested in the Alcalá de Henares facility, versus 3.9 million euros in the first nine months of 2019;
- 5.2 million euros corresponds to the ISM<sup>®</sup> industrialization, versus 1.0 million euros in the first nine months of 2019;
- 2.2 million euros relates to investment capex regarding the Escúzar plant (the second heparin plant in Granada) versus 0.7 million euros invested in the first nine months of 2019 (linked to the bought of land for the plant construction); and
- 1.4 million euros relates to expenditure on maintenance and other capex, versus 1.8 million euros in the first nine months of 2019.

In addition, in the first nine months of 2019, ROVI invested 13.5 million euros in the acquisition of Polaramine<sup>®</sup>.



	<b>9M 2020</b>	<b>9M 2019</b>	<b>% Growth</b>
Madrid injectables plant	1.3	0.7	94%
San Sebastián de los Reyes injectables plant	1.2	2.5	-50%
Granada plant	1.3	3.8	-66%
Alcalá de Henares plant (Frosst Ibérica)	2.2	3.9	-44%
Expenditure on maintenance and other capex	1.4	1.8	-24%
<b>Total maintenance capex</b>	<b>7.4</b>	<b>12.6</b>	<b>-42%</b>
ISM industrialisation	5.2	1.0	n.a.
Escúzar plant	2.2	0.7	n.a.
San Sebastián de los Reyes injectables plant	2.1	-	n.a.
<b>Total investment capex</b>	<b>9.5</b>	<b>1.7</b>	<b>5.6x</b>
<b>Total capex</b>	<b>16.9</b>	<b>14.3</b>	<b>18%</b>
<i>Acquisitions</i>	-	13.5	

### 3.2 Debt

As of 30 September 2020, ROVI total debt decreased to 74.9 million euros. Debt with public administration, which is 0% interest rate debt, represented 15% of total debt as of 30 September 2020.

<i>In thousand euros</i>	<b>30 September 20</b>	<b>31 December 19</b>	<b>Interest rate (%)</b>
Bank borrowings (EIB)	45,000	52,116	0.408-0.681
Debt with public administration	11,093	11,689	0
Financial liabilities for leases	18,344	20,871	-
Derivative financial instruments	464	129	-
<b>Total</b>	<b>74,901</b>	<b>84,805</b>	

As of 30 September 2020, bank borrowings decreased by 7.1 million euros. 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 5 million euros against this credit line at a variable interest rate of Euribor at 3 months + 0.844%. The latest interest rate paid was 0.408% (October 2020). As of 31 December 2019, ROVI had drawn the remaining 40 million euros. 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 30 September 2020, ROVI had not used these credit policies. Thus, the Group is in a comfortable position to



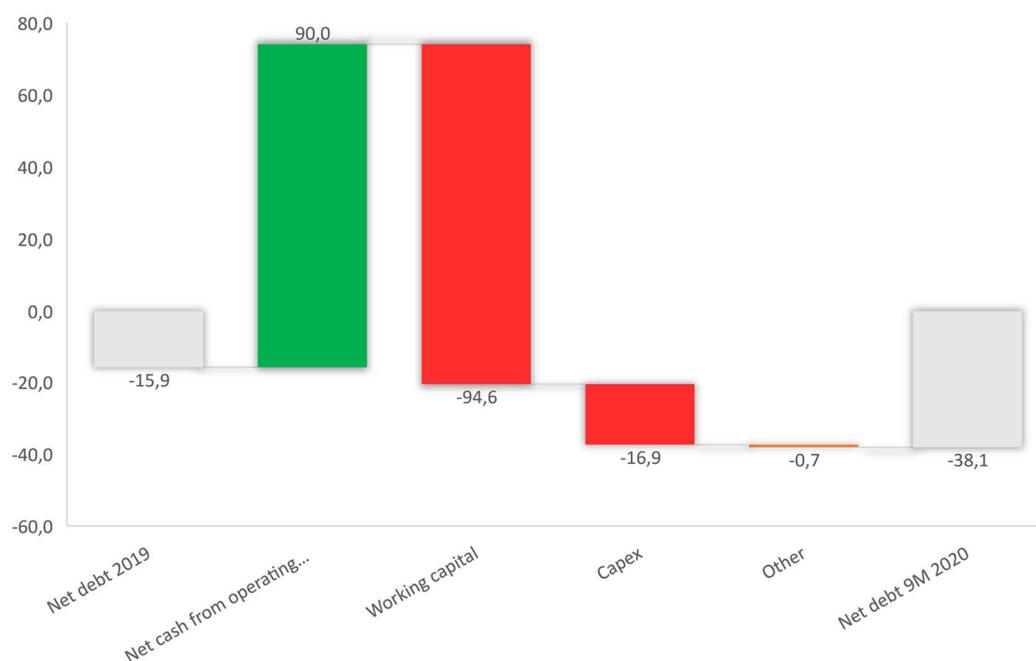
meet its payment obligations, debt maturities and any additional cash needs in the short and medium term.

### **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 -21.5 million euros in the first nine months of 2020 compared to -34.2 million euros in the first nine months of 2019 mainly due to (i) the decrease of 11.0 million euros in Capex mainly as a result of the acquisition of Polaramine® in the first nine months of 2019; (ii) the increase of 16.2 million euros in the "Proceeds from distribution licenses" line mainly due to the payments received because of some activities carried out under the agreement with Moderna; and (iii) the increase of 20.0 million euros in profit before income tax. These positive impacts were partially offset by (i) the increase of 79.4 million euros in the "inventories" line in the first nine months of 2020 (mainly as a result of higher heparin stock levels) compared to an increase of 54.7 million euros in the first nine months of 2019; and (ii) the decrease of 5.3 million euros in the "trade and other payables" item in the first nine months of 2020, compared to an increase of 12.2 million euros in the first nine months of 2019.

### **3.4 Gross cash position and net debt**

As of 30 September 2020, ROVI had a gross cash position of 36.8 million euros, compared to 68.9 million euros as of 31 December 2019, and net debt of 38.1 million euros (equity securities plus deposits plus financial derivatives plus cash and cash equivalents minus current and non-current financial debt), compared to 15.9 million euros as of 31 December 2019.



Net cash used in operating activities amounted to -4.7 million euros in the first nine months of 2020, compared to -6.4 million euros in the first nine months of 2019. Net cash generated from operating activities excluding changes in working capital increased 88% to 90.0 million euros in the first nine months of 2020, from 47.8 million euros in the first nine months of 2019.

### 3.5 Working capital

Figures included in the balance sheet showed an increase in working capital in the first nine months of 2020 mainly due to (i) an increase of 78.8 million euros in the “inventories” line, mainly due to higher heparin stock levels in the first nine months of 2020; (ii) an increase of 10.4 million euros in the “trade and other receivables” line; (iii) a decrease of 5.4 million euros in the “trade and other payables” line; and (iv) a decrease of 32.1 million euros in the “cash and cash equivalents” item.

Despite the significant increase in the first nine months of 2020 “inventories” line, heparin stock levels were lower in the third quarter of 2020 than in the second quarter of 2020.

As of 30 September 2020, Social Security and Public Administrations total debt with ROVI amounted to 13.9 million euros, of which 6.8 million euros in Spain, 4.1 million euros in Portugal and 3.0 million euros in Italy.

#### 4. Guidance for 2021

In 2021, ROVI expects **a mid-single-digit growth rate for the operating revenue**, excluding the production of the Moderna's COVID-19 vaccine candidate. The Company forecasts that it will continue to grow at a higher rate than the Spanish pharmaceutical market expenditure in the first nine months of 2020, which, according to the Ministry of Health, Consumption and Social Welfare, showed a growth rate of 2.9%.

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 next year.

Likewise, the potential increase in the discounts to the National Health System as a result of the COVID-19 impact may affect attainment of these growth forecasts.

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, the launch of Doria<sup>®</sup> in Europe, and new contracts in the toll manufacturing area.

#### 5. Research and Development update

##### ISM<sup>®</sup> technology platform

As the company informed (by publication of the material event number 286374 dated 31<sup>st</sup> of January of 2020), a very important milestone was achieved with its long-acting injectable (LAI) antipsychotic Doria<sup>®</sup> (Risperidone ISM<sup>®</sup>). After the conclusion of the validation phase, the European health authorities have commenced the assessment process to grant marketing authorisation for this first product based in its leading-edge drug delivery technology, ISM<sup>®</sup>. In March 2019, the company announced topline results from the pivotal study of Risperidone ISM<sup>®</sup> "PRISMA-3"<sup>1</sup>, which showed that primary and key secondary efficacy endpoints were achieved with both doses tested for the treatment of patients with acute exacerbation of schizophrenia. Besides, in July 2019, the company announced the completion of the Clinical Trial Program that will support the application for marketing authorization for Doria<sup>®</sup> for the treatment of

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<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) [<https://clinicaltrials.gov/show/NCT03160521>]. This clinical program has had the support of the Industrial Technological Development Centre ("CDTI").



schizophrenia. In addition, an open-label extension of the PRISMA-3 study<sup>1</sup> has already finished, which will provide clinical data on the long-term use of Risperidone ISM<sup>®</sup> (12 additional months).

Furthermore, ROVI informed of the decision to expand its industrial capabilities for the manufacture of Doria<sup>®</sup> with the incorporation of a second line for the manufacture of the syringe containing the solvent. The addition of this second line also provides the company with the necessary flexibility to the company to initiate the preparation of the industrial filling processes of Letrozole ISM<sup>®</sup>, which will require the installation of a specific filling machine. As a result, ROVI has prioritized the submission of the Doria<sup>®</sup> dossier in Europe (already done) and subsequently, filing in the USA, targeting the second half of 2020.

On the other hand, the company already announced the commencement of 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 our 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>2</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 will be gathering more clinical data from this trial during the following months to better characterise the pharmacological profile of Letrozole ISM<sup>®</sup>; afterwards, in 2020, ROVI is planning 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 Doria<sup>®</sup> for the maintenance treatment of patients with clinically stable schizophrenia. This development is still in an initial phase.

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<sup>1</sup> Study to Evaluate the Efficacy and Safety of Risperidone ISM<sup>®</sup> in Patients With Acute Schizophrenia: Open Label Extension (PRISMA-3\_OLE). [Clinicaltrials.gov# NCT03870880](https://clinicaltrials.gov/ct2/show/NCT03870880) [<https://clinicaltrials.gov/ct2/show/NCT03870880>]. This clinical program has had the support of the Industrial Technological Development Centre ("CDTI").

<sup>2</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) [<https://clinicaltrials.gov/ct2/show/NCT03401320>]. This clinical program has had the support of the Industrial Technological Development Centre ("CDTI").



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

ROVI's ESG aspects have been 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 has attained the **second position** out of 360 companies in the sub-industry "pharmaceuticals". The "pharmaceutical industry" includes biotech, pharmaceutical and laboratory equipment companies and the "pharmaceutical sub-industry" includes only pharmaceutical companies.

## 7. Key operating and financial events

### 7.1 Moderna and ROVI Announce Collaboration for Outside the United States Fill-Finish Manufacturing of Moderna's COVID-19 Vaccine Candidate

ROVI informed (by publication of the inside information with register number 322 dated 9 July, 2020) of the collaboration with Moderna, Inc. (Nasdaq: MRNA), a clinical stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines, for large-scale, commercial fill-finish manufacturing of Moderna's mRNA COVID-19 vaccine candidate (mRNA-1273) at ROVI's facility in Madrid, Spain.

As part of the agreement, ROVI will provide vial filling and packaging capacity by procuring a new production line and equipment for compounding, filling, automatic visual inspection and labeling to support production of hundreds of millions of doses of the vaccine candidate intended in principle to supply markets outside of the U.S. starting in early 2021. ROVI will also hire additional staffing required to support manufacturing operations and production.

*"Moderna is committed to helping address the COVID-19 crisis. We are pleased to partner with ROVI to potentially supply hundreds of millions of doses of finished mRNA-1273, once approved, and help address the need for a vaccine against COVID-19 around the world,"* said Juan Andrés, Moderna's Chief Technology Operations and Quality Officer. *"ROVI's experience as a global manufacturer of drug product and expertise in fill-finish will be an important partnership for us to establish dedicated supply chains that can meet the needs of different countries and regions. I am delighted to be working with ROVI again".*

*"We are very happy about the collaboration with Moderna, whose vaccine against COVID-19 is one of the frontrunners in the race to solve this health crisis. We would be thrilled for ROVI to form part of the solution to this pandemic that is affecting all of us and to support Moderna in supplying it on a wide scale. Our proven experience and capabilities as a toll manufacturer of injectables has allowed us to reach this agreement, which would help strengthen our manufacturing area and would, in all probability, provide us with a significant growth opportunity in the area. Likewise, I would like to thank the Ministry of Health and the Spanish Medicines Agency for making themselves available and providing their support, which has been of fundamental importance, during this entire process",* said Juan López-Belmonte, Chief Executive Officer of ROVI.

## **7.2 ROVI informs on the impact of COVID-19 on the company's activities**

ROVI reports (by publication of the relevant information number 1365 dated 2<sup>nd</sup> of April of 2020) that, since the beginning of the propagation of COVID-19, the company has been executing the contingency plans necessary to guarantee the health and safety of its employees and those who work with it, as well as to ensure the continuity of the business and fulfil its responsibility to supply medicines to the hospitals of Spain and Europe.

To this end, the company has adopted a number of initiatives in line with the recommendations made by the authorities. Among them, we highlight the fact that ROVI has reduced the processes that must be performed in person at its facilities to a minimum. Thus, a significant part of the workforce is working from a distance. In the cases where home working is not possible, particularly at the manufacturing plants, ROVI is keeping all its production activities at a kind of normal activity level, with the relevant safety measures, in order to ensure that its medicines continue to be available to patients during the health crisis.

ROVI considers that it is extremely important to keep its manufacturing plants in operation in order to fulfil its responsibility as a pharmaceutical manufacturer. Therefore, the company wishes to acknowledge the commitment and responsibility shown by those of its employees who are physically present at work every day and, for these employees, has approved a bonus of 20% of their salary corresponding to the duration of the State of Alarm decreed by the Spanish government. Likewise, in order to work with the greatest safety and maintain the continuity of the production activities, ROVI recommends avoiding the use of public transport for travelling to the plants and assumes the cost of private transport and parking spaces for those employees who so require.

ROVI's sales behaved in line with company's expectations in the first nine months of 2020. As a consequence, the company confirms the growth forecasts reported previously for 2020, which placed growth in operating revenue in mid-single-digit figures, i.e. from 0% to 10%.

Notwithstanding, given the uncertainties associated to the development of the current situation (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 the current year.

Regarding the possible impact of COVID-19 on each one of the areas of the company, the following may be highlighted:

1. The World Health Organisation (WHO) has recommended ROVI's low-molecular-weight heparins (LMWHs), Bemiparin (Hibor®) and the Enoxaparin biosimilar, sales of which accounted for 47% of the company's operating revenue in 2019, as essential medicines for people hospitalised in intensive care units due to COVID-19. For this reason, in view of the habitual use of the product in hospitalised patients, the company believes that there will be a rise in LMWH sales in hospitals during the period of the health crisis. On the other hand, ROVI expects that the significant reduction in the number of surgical operations performed during the period of confinement may, likewise, affect the division's sales. The industrial shutdown that took place in China at the beginning of the year and the current shutdown in Europe, combined with the evolution of African swine fever in China, confirm the price increase in sodium heparin for this first part of the year.
2. A majority of ROVI's innovative products are indicated for the treatment of chronic diseases and therefore, consumption of these products should remain stable in the short term. However, the confinement measures, which favour the habit of staying at home, combined with the fact that it is impossible for the sales force to promote the products among health professionals, could provoke a slowdown in the sales of the pharmaceutical specialities division if the isolation measures adopted in the health crisis were to be prolonged.
3. As we have mentioned previously, as of today's date, production activities remain at normal capacity at all the plants, although productivity has been impaired by the various preventive measures concerning sanitisation and safety in relation to COVID-19. ROVI is very proud and satisfied with its employees' response to this crisis. However, the current situation and its potential impact is so unpredictable and volatile that the foregoing assessment of the plants' operations could be affected in the event of infections within their workforces.
4. R&D activities are continuing and, as of today's date, ROVI is not aware that there will be any kind of delay in the approval process for Doria® in Europe or registration of the medicine in the United States. Notwithstanding, the company understands that the efforts of the European Medicines Agency are currently focused on COVID-19 and does not rule out delays in the approval process for the medicine under the current circumstances. Likewise, for registration of the medicine in the United States, the company depends on third-party assistance, which means that ROVI cannot be certain

that the registration application will not be filed later the date reported previously (second half of 2020).

ROVI is continuing with its transformation process and the execution of its strategic plan. To date, the impact of the health crisis has not changed the Group's plans. Said strategic plan focuses on (i) the expansion of its enoxaparin biosimilar, with which it aspires to become a benchmark player in the low-molecular-weight heparin sub-market, and (ii) Doria® and Letrozol®, both of which are candidates that validate its extended-release drug delivery system, ISM®.

ROVI is also contributing to the provision of new solutions that help to improve the health situation of society overall and has taken the necessary steps to donate a million surgical masks and a thousand special protection suits to the Ministry of Health, Consumption and Social Welfare, taking account of the difficulties that the National Health System is having in accessing individual protection equipment at the present time. With this contribution, ROVI wishes to assist in the indispensable work carried out by the health professionals who are working nonstop to combat the COVID-19 pandemic in Spain.

ROVI wishes a swift recovery to all those affected by coronavirus and sends special recognition to the health professionals, the State security forces and all the other professionals who, in order to protect all of us, are on the battlefield in the fight against the virus. Likewise, ROVI would like to thank all its employees for their commitment, responsibility, involvement and determination, especially those who continue to travel to its work centres every day.

### **7.3 ROVI announces the commencement of the assessment process to obtain marketing authorisation for Doria® in the European Union**

ROVI informed (by publication of the material event number 286374 dated 31<sup>st</sup> of January of 2020) that, after the conclusion of the validation phase, the European health authorities have commenced the assessment process to grant marketing authorisation for Doria®, a long-acting anti-psychotic injection for the treatment of schizophrenia, based on the ISM® technology patented by ROVI, in the European Union (EU).

ROVI filed its application for marketing authorisation for Doria® with the European health authorities, the European Medicines Agency (EMA), through the Centralised Procedure on 27 December, 2019. After passing the validation phase satisfactorily, the dossier was admitted for evaluation on 30 January, 2020.

It is forecast that the assessment phase of the Centralised Procedure used by the Company to register this medicine in the EU may take around one year. It should, however, be noted that the assessment process is subject to interruptions and delays in the event that the European



health authorities require additional information. Likewise, mention should be made of the fact that the outcome of the registration process (which may be positive or negative) cannot be known until it has concluded.

ROVI will continue to provide information on the milestones deemed significant in this authorisation as the calendar for registration of the medicine in the European Union advances, as well as the registration of the same medicine with the U.S. Food and Drug Administration (FDA), which it is planned to commence in the second half of 2020.

*"We are continuing to progress with the approval phase of Doria® and are now closer to marketing it. We have confidence in the product's potential and hope that we will soon be able to offer a therapeutic alternative for the treatment of this chronic, serious and progressive disorder",* said Juan López-Belmonte, ROVI's Chief Executive Officer.

## **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 56 countries all over the world, should be highlighted. Likewise, in 2017, ROVI commenced the marketing of its enoxaparin biosimilar, developed in-house, in Europe. 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](http://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 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 30 SEPTEMBER 2020 AND 31 DECEMBER 2019

(Thousands of euros)

	30 September 2020	31 December 2019
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, Plant and Equipment	136,862	131,608
Intangible assets	42,268	45,079
Investment in a joint venture	1,811	1,843
Deferred income tax assets	13,783	14,660
Equity securities	69	71
Financial receivables	65	65
	<b>194,858</b>	<b>193,326</b>
<b>Current assets</b>		
Inventories	237,645	158,811
Trade and other receivables	91,989	81,541
Current income tax assets	1,906	10,104
Prepaid expenses	33	3
Cash and cash equivalents	35,283	67,426
	<b>366,856</b>	<b>317,885</b>
<b>Total assets</b>	<b>561,714</b>	<b>511,211</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS AS OF 30 SEPTEMBER 2020 AND 31 DECEMBER 2019**

(Thousands of euros)

	<b>30 September 2020</b>	<b>31 December 2019</b>
<b>EQUITY</b>		
<b>Capital and reserves attributable to shareholders of the company</b>		
Share capital	3,364	3,364
Share premium	87,636	87,636
Legal reserve	673	673
Treasury shares	(15,728)	(10,341)
Retained earnings and voluntary reserves	246,691	201,784
Profit for the period	46,825	39,273
Other reserves	(4)	(3)
<b>Total equity</b>	<b>369,457</b>	<b>322,386</b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>		
Financial debt	68,898	72,104
Deferred income tax liabilities	2,724	1,078
Contract liabilities	5,959	5,793
Deferred income	2,861	3,141
	<b>80,442</b>	<b>82,116</b>
<b>Current liabilities</b>		
Financial debt	6,003	12,701
Current tax liabilities	3	-
Trade and other payables	86,544	91,914
Contract liabilities	18,757	1,566
Deferred income	508	528
	<b>111,815</b>	<b>106,709</b>
<b>Total liabilities</b>	<b>192,257</b>	<b>188,825</b>
<b>Total equity and liabilities</b>	<b>561,714</b>	<b>511,211</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED INCOME STATEMENTS FOR THE NINE-MONTH PERIODS ENDING 30**  
**SEPTEMBER 2020 AND 30 SEPTEMBER 2019**

**(Thousands of euros)**

	<b>Nine-month periods ending 30 September</b>	
	<b>2020</b>	<b>2019</b>
Revenue	302,143	270,783
Changes in inventories of finished goods and work in progress	29,862	24,717
Raw materials and consumables used	(157,442)	(139,272)
Personnel expenses	(55,328)	(54,611)
Other operating expenses	(50,389)	(54,734)
Amortisation	(14,411)	(13,436)
Recognition of government grants on non-financial non-current assets and other	873	799
Share of profits of joint venture	(32)	(136)
<b>OPERATING PROFIT</b>	<b>55,276</b>	<b>34,110</b>
Finance income	3	5
Finance costs	(757)	(644)
Impairment and gain or loss on measurement of financial instruments	(354)	774
Exchange difference	95	(26)
<b>FINANCE INCOME/(COSTS) - NET</b>	<b>(1,013)</b>	<b>109</b>
<b>PROFIT BEFORE INCOME TAX</b>	<b>54,263</b>	<b>34,219</b>
Income tax	(7,438)	(3,537)
<b>PROFIT FOR THE PERIOD</b>	<b>46,825</b>	<b>30,682</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED CASH FLOW STATEMENTS FOR THE NINE-MONTH PERIODS ENDING 30**  
**SEPTEMBER 2020 AND 30 SEPTEMBER 2019**

(Thousands of euros)

	<b>Nine-month periods</b>	
	<b>ending 30 September</b>	
	<b>2020</b>	<b>2019</b>
<b>Cash flows from operating activities</b>		
Profit before tax	54,263	34,219
<b>Adjustments for non-monetary transactions:</b>		
Amortisation	14,411	13,436
Finance income	(98)	(5)
Valuation allowance	546	1,578
Adjustments for changes in value of derivatives	335	(774)
Gain or loss on derecognition of financial assets and liabilities	19	-
Finance expenses	757	670
Grants, income from distribution licenses and other deferred incomes	(2,683)	(1,849)
Other current assets (prepaid expenses)	(28)	18
Share of profit of joint venture	32	136
<b>Changes in working capital:</b>		
Trade and other receivables	(9,896)	(11,715)
Inventories	(79,414)	(54,692)
Trade and other payables	(5,296)	12,163
<b>Other collections and payments:</b>		
Proceeds from distribution licenses	19,167	2,944
Income tax cash flow	3,289	(2,496)
Other payments	(57)	(14)
<b>Net cash generated from (used in) operating activities</b>	<b>(4,653)</b>	<b>(6,381)</b>
<b>Cash flows from investing activities</b>		
Purchases of intangible assets	(90)	(14,362)
Purchases of property, plant and equipment	(16,778)	(13,471)
Proceeds from sale of property, plant and equipment	14	-
Interest received	3	5
<b>Net cash generated from (used in) investing activities</b>	<b>(16,851)</b>	<b>(27,828)</b>
<b>Cash flows from financing activities</b>		
Repayments of financial debt	(11,087)	(16,122)
Proceeds from financial debt	428	1,721
Interest paid	(226)	(80)
Purchase of treasury shares	(20,297)	(2,736)
Reissue of treasury shares	20,543	2,860
Dividends paid	-	(4,420)
<b>Net cash generated from (used in) financing activities</b>	<b>(10,639)</b>	<b>(18,777)</b>
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(32,143)</b>	<b>(52,986)</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>67,426</b>	<b>95,511</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>35,283</b>	<b>42,525</b>