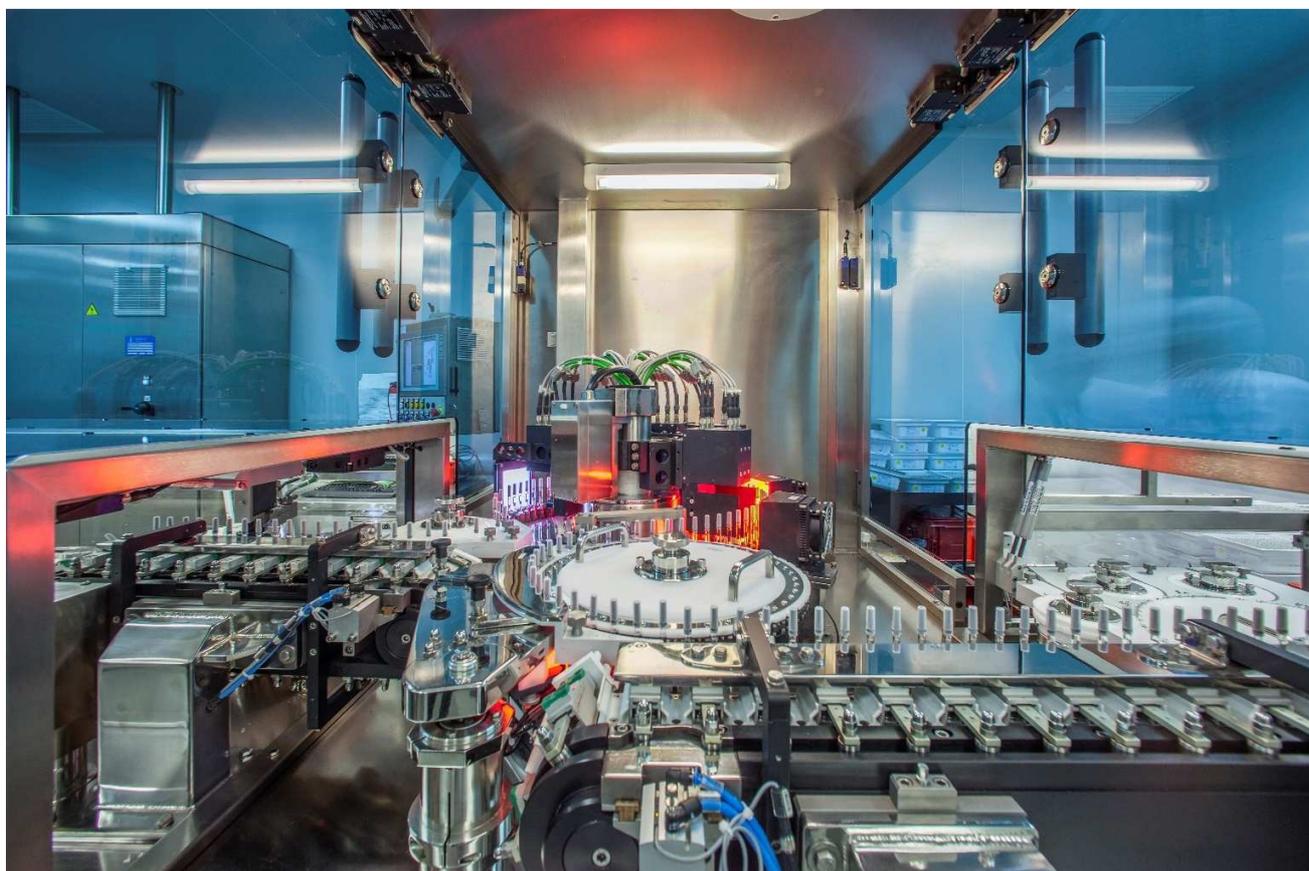




First Half 2019 Results

30th July 2019



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



ROVI – First Half 2019 Financial Results

ROVI reports operating revenue growth of 21% and EBITDA growth of 99%

- Operating revenue increased by 21% to 177.5 million euros in the first half of 2019, driven by the strength of the specialty pharmaceutical business, where sales rose 22%, strongly outperforming the market, and by the toll manufacturing business, which grew by 15%. Total revenue increased by 21% to 177.9 million euros in the first half of 2019.
- For the second time this year, ROVI is upgrading its operating revenue guidance for the full year 2019, from low-double-digit growth rate to high-double-digit growth rate.
- On July 5, 2019, ROVI informed about the conclusion of the PRISMA-3¹ and BORIS² studies, thus completing the Clinical Trial Program that will support the application for the marketing authorisation for Doria[®] for the treatment of schizophrenia in the European Union and United States, in a first phase, and, subsequently, in other countries.
- Preliminary data of the Letrozole ISM[®] phase I clinical trial (the LISA-1 study³) confirm that this ISM[®] formulation provides a prolonged release of letrozole which produces a sustained suppression of oestrogenic hormones.
- As of 30th June 2019, all the European Union countries (26 countries) where ROVI had applied for the national registration of the enoxaparin biosimilar had approved such registration.
- Sales of the Low Molecular Weight Heparin (LMWH) franchise (enoxaparin biosimilar and Bemiparin) increased by 43% to 81.7 million euros in the first half of 2019. LMWH sales represented 46% of operating revenue in the first half of 2019 compared to 39% in the first half of 2018. Sales of the enoxaparin

¹ <https://clinicaltrials.gov/ct2/show/NCT03160521>

² <https://clinicaltrials.gov/ct2/show/NCT03527186>

³ Evaluation of IM Letrozole ISM[®] Pharmacokinetics, Safety, and Tolerability in Healthy Post-menopausal Women (LISA-1). [Clinicaltrials.gov#NCT03401320](https://clinicaltrials.gov/ct2/show/NCT03401320) [<https://clinicaltrials.gov/ct2/show/NCT03401320>].



biosimilar increased four times to 36.5 million euros in the first half of 2019 and sales of Bemiparin increased 5% to 35.5 million euros in Spain.

- **Sales of Neparvis[®], launched in December 2016, increased by 63% to 9.6 million euros in the first half of 2019.**
- **EBITDA increased by 99%, from 13.3 million euros in the first half of 2018 to 26.5 million euros in the first half of 2019, reflecting a 5.8 percentage point rise in the EBITDA margin to 14.9% in the first half of 2019.**
- **Net profit increased by 114%, from 7.6 million euros in the first half of 2018 to 16.2 million euros in the first half of 2019.**

Madrid (Spain), 30th July 2019, 8:00 AM CET - ROVI released today its financial results for the first half of 2019.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said *"in the first half of 2019, we reached 21% operating revenue growth mainly driven by the strength of the specialty pharmaceutical business, where sales rose by 22%, and by the toll manufacturing business, which grew by 15%. According to IQVIA, the Spanish innovative product market increased by 2% in the first half of 2019. We forecast continued growth thanks to, among other factors, our flagship product, Bemiparin, which is contributing to our growth, especially in the domestic market with a sales increase of 5%. Likewise, we have finished the national phase of the registration process of our Enoxaparin biosimilar in Europe, with its approval in 26 countries, and we have signed agreements to distribute it in more than 85 countries outside Europe, including the agreements with Hikma Pharmaceuticals, who has the exclusive rights for 17 Middle East and North Africa countries and with Sandoz for 14 countries/regions. Likewise, we continue marketing in Germany, UK, Italy, Spain, France, Austria, Latvia and Estonia, and have started commercialisation in Portugal and Costa Rica, with good sales prospects, as reflected in the first half of 2019, when sales were 36.5 million euros. The Enoxaparin biosimilar represents an excellent growth opportunity for us considering the size of the European Enoxaparin market, which totals around 1 billion euros. In 2017, ROVI started its internationalisation process, setting up subsidiaries in the main European countries: Germany, United Kingdom, France, Italy and Poland. We are very excited about this new phase, in which we aim to become one of the leaders in the low-molecular-weight heparin field worldwide.*

Furthermore, we expect a number of factors to contribute to our growth in forthcoming years: (i) the strengthening of the osteoarticular franchise through the launch of Tetricid[®], from Teva, in Spain in the third quarter of 2019; (ii) the reinforcement of the cardiovascular franchise as a result of the launch of Neparvis[®], a product with high strategic value from Novartis, in Spain in December 2016; and (iii) our entry into the urology field through the launch of Volutsa[®], from



Astellas Pharma, in Spain in February 2015. These launches cover growing demand needs and we expect them to provide us with a sustainable and profitable growth opportunity in the future. In addition, recent product acquisitions such as Falithrom® and Polaramine® fully complements our existing portfolio and have already had a favourable impact on the company's profits. At the same time, we are confident of the potential of our current pipeline of R&D projects, making important investment efforts, since we trust they will be the company's growth engine in the future. We have high hopes of the potential of our long-acting injectable technology (ISM®). We have just concluded a Phase III trial with our ISM® technology (Risperidone ISM®) and published positive results. 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® technology. ROVI is currently undergoing a growth transformation and the capital increase executed in October 2018 underpins this next phase of growth".



1. Financial highlights

<i>€ million</i>	H1 2019	H1 2018	Growth	% Growth
Operating revenue	177.5	146.3	31.2	21%
Other income	0.4	0.8	-0.4	-50%
Total revenue	177.9	147.1	30.8	21%
Cost of sales	-76.1	-61.9	-14.1	23%
Gross profit	101.9	85.1	16.7	20%
<i>% margin</i>	<i>57.4%</i>	<i>58.2%</i>		<i>-0.8pp</i>
R&D expenses	-14.7	-16.8	2.0	-12%
SG&A	-60.7	-52.4	-8.3	16%
Other expenses	0.0	-2.6	2.6	n.a.
Share of profit/loss of a joint venture	0.0	0.0	0.0	-60%
EBITDA	26.5	13.3	13.1	99%
<i>% margin</i>	<i>14.9%</i>	<i>9.1%</i>		<i>5.8pp</i>
EBIT	17.7	7.5	10.3	138%
<i>% margin</i>	<i>10.0%</i>	<i>5.1%</i>		<i>4.9pp</i>
Net profit	16.2	7.6	8.6	114%

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 half 2019 and the comparative information for 2018 (balance sheet) and for the first half of 2018 (consolidated income statement and cash flow statement) are attached to this report (see Appendix 1).

2. Performance of the Group

Operating revenue increased by 21% to 177.5 million euros in the first half of 2019, driven by the strength of the specialty pharmaceutical business, where sales rose 22%, strongly outperforming the market, and by the toll manufacturing business, which grew by 15%. Total revenue increased by 21% to 177.9 million euros in the first half of 2019.

<i>€ million</i>	H1 2019	H1 2018	% Growth
Specialty pharmaceutical business	151.0	123.3	22%
Toll manufacturing business	26.5	23.0	15%
Total operating revenue	177.5	146.3	21%



Sales of **prescription-based pharmaceutical** products rose 24% to 132.5 million euros in the first half of 2019.

<i>€ million</i>	H1 2019	H1 2018	% Growth
Prescription-based pharmaceutical products	132.5	106.7	24%
Low Molecular Weight Heparins	81.7	57.2	43%
Enoxaparin biosimilar (Enoxaparin Becat)	36.5	8.9	n.a.
Bemiparin (Hibor)	45.2	48.3	-6%
Sales in Spain	35.5	33.9	5%
International sales	9.7	14.4	-33%
Neparvis	9.6	5.9	63%
Ulunar & Hirobriz	7.5	7.7	-2%
Volutsa	6.4	5.4	20%
Vytorin & Absorcol & Orvatez	15.4	19.6	-22%
Medikinet & Medicebran	4.0	3.9	2%
Other products	16.4	15.1	9%
Discounts to the National Health System	-8.6	-8.1	7%
Contrast agents and other hospital products	16.7	15.3	9%
Non prescription pharmaceutical products ("OTC") and Other	1.7	1.2	43%
Total specialty pharmaceutical business	151.0	123.3	22%

Sales of the **Low Molecular Weight Heparin (LMWH) franchise** (Enoxaparin biosimilar and Bemiparin) increased by 43% to 81.7 million euros in the first half of 2019. LMWH sales represented 46% of operating revenue in the first half of 2019 compared to 39% in the first half of 2018.

Sales of the **Enoxaparin biosimilar** increased four times to 36.5 million euros in the first half of 2019. ROVI commenced the marketing of its Enoxaparin biosimilar in Germany in 2017; in UK, Italy, Spain, France, Austria, Latvia and Estonia in 2018; and in Portugal and Costa Rica in the first half of 2019.

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, had a positive performance in Spain (**Hibor**[®]) in the first half of 2019, with sales up 5% to 35.5 million euros. International sales of Bemiparin decreased by 33% to 9.7 million euros. This significant decrease was specifically linked to the first half of 2019 and ROVI expects international Bemiparin sales to remain stable in 2019. Bemiparin total sales decreased by 6% to 45.2 million euros in the first half of 2019.

Sales of **Neparvis**[®], a specialty product from Novartis, launched in December 2016, indicated for the treatment of adult patients with symptomatic chronic heart failure and reduced ejection



fraction, increased 63% to 9.6 million euros in the first half of 2019, compared to 5.9 million euros in the first half of 2018.

Sales of **Hirobriz**[®] **Breezhaler**[®] and **Ulunar**[®] **Breezhaler**[®], both inhaled bronchodilators from Novartis for patients with respiratory difficulties due to a pulmonary disease known as Chronic Obstructive Pulmonary Disease (COPD), launched in Spain in the fourth quarter of 2014, decreased by 2% to 7.5 million euros in the first half of 2019, compared to the same period of the previous year.

Sales of **Volutsa**[®], a specialty product from Astellas Pharma indicated for the treatment of moderate to severe storage symptoms and voiding symptoms associated with benign prostatic hyperplasia, launched in Spain in February 2015, increased by 20% to 6.4 million euros in the first half of 2019.

Sales of **Vytorin**[®], **Orvatez**[®] and **Absorcol**[®], the first of the five licenses of MSD, indicated as adjunctive therapy to diet in patients with hypercholesterolemia, decreased by 22% to 15.4 million euros in the first half of 2019. In the second quarter of 2018, the active principle ezetimibe went out of patent and the price of Absorcol[®] was reduced. Likewise, generics formulated with ezetimibe and simvastatin were marketed in the same period, so the price of Vytorin[®] was reduced to be competitive. In addition, sales of Orvatez[®] amounted to 12.5 million euros in the first half of 2018, an extraordinary rise of 29% compared to the same period of the previous year.

Sales of **Medicebran**[®] and **Medikinet**[®], specialty products from Medice indicated for the treatment of ADHD (Attention Deficit and Hyperactivity Disorder) in children and teenagers, launched in December 2013 and marketed on exclusivity basis by ROVI in Spain, increased by 2% to 4.0 million euros in the first half of 2019.

According to IQVIA, Spanish innovative product market increased by 2% in the first half of 2019 compared to the same period of the previous year. Nevertheless, ROVI prescription-based pharmaceutical product sales rose 24% in the first half of 2019, beating the market by 22 percentage points.

Sales of **contrast imaging agents** and other hospital products increased by 9% to 16.7 million euros in the first half of 2019.

Sales of Perspirex[®] represented 64% of over-the counter pharmaceutical products ("OTC") and other sales in the first half of 2019. The distribution contract of Perspirex[®] ended on 30th June, 2019 and, therefore, ROVI will stop distributing the product as from the third quarter of 2019. Therefore, ROVI has now fully divested the OTC division.



Toll manufacturing sales increased by 15% to 26.5 million euros in the first half of 2019 because of the good performance of the injectable business, where revenue increased by 53% to 15.2 million euros as a result of higher volumes manufactured for some customers. Frosst Ibérica plant sales decreased by 13% to 11.4 million euros in the first half of 2019 compared to the same period of the previous year. By the end of 2019, ROVI expects the toll manufacturing business to have grown from a high-single-digit rate to a low-double-digit rate.

<i>€ million</i>	H1 2019	H1 2018	% Growth
Injectable business	15.2	9.9	53%
Oral forms business (Frosst Ibérica)	11.4	13.1	-13%
Total toll manufacturing business	26.5	23.0	15%

Sales outside Spain increased by 48% to 63.2 million euros in the first half of 2019, 20.9 million euros (or 33%) of which related to international subsidiaries, mainly due to recognition of Enoxaparin biosimilar sales. Sales outside Spain represented 36% of operating revenue in the first half of 2019 compared to 29% in the first half of 2018.

Other income (subsidies) decreased by 50% to 0.4 million euros in the first half of 2019, compared to the same period of the previous year.

Gross profit increased by 20% to 101.9 million euros in the first half of 2019, the gross margin showing a decrease of 0.8 percentage points from 58.2% in the first half of 2018 to 57.4%, mainly due to (i) the increase of Enoxaparin biosimilar sales, which added lower margins in the first half of 2019 after the launch of the product in seven new markets; and (ii) the increase in the LMWH raw material prices, which, in the first half of 2019, were running around 35% over first half 2018 prices. ROVI expects this rising trend to continue during 2019.

Research and development expenses (R&D) decreased 12% to 14.7 million euros in the first half of 2019. R&D expenses were mainly related to the development of the Risperidone-ISM[®] Phase III trial and the Letrozole-ISM[®] Phase I trial.

On the 1st January, 2019, IFRS 16 "Leases" became effective. The new standard affects ROVI's financial statements.

The principal new feature of IFRS 16 is that there will be a single new accounting model for lessees, who will include all leases (with limited exceptions) in their statements of financial position with an impact similar to that of the present finance leases. IFRS states that lessees must recognise a financial liability for the present value of the payments to be made over the remaining life of the lease contract and an asset for the right of use of the underlying asset. Additionally, the lessee will recognise as an expense for amortisation of the asset and a financial

expense for the discounting of the lease liability, not recording the lease expense. The impacts of the application of IFRS 16 in ROVI as of June 30, 2019 were:

- Recognition of assets under the "Property, plant and equipment" caption (non-current assets) for an amount of 22.8 million euros.
- Increase in debt under the captions "Financial liabilities for non-current and current leases" of 19.1 million euros and 3.7 million euros, respectively.
- Lower operating expenses and, consequently, an increase of EBITDA of 1.6 million euros, since operating lease payments were recognized under the SG&A caption.
- Higher expense for the depreciation of the right-of-use asset of 1.5 million euros.
- An increase of 0.1 million euros in the finance costs of the lease liabilities.

Selling, general and administrative expenses (SG&A) increased 16% to 60.7 million euros in the first half of 2019, mainly due to (i) international subsidiaries expenses which amounted to 4.3 million euros compared to 2.6 million euros in the first half of 2018; and (ii) a larger volume of enoxaparin biosimilar production. In 2019, expenses related to international subsidiaries are expected to be around 10 million euros.

<i>€ million</i>	H1 2019	H1 2018	% Growth
Personnel expenses (exc. R&D)	32.8	30.2	9%
Other operating expenses (exc. R&D)	27.8	22.1	26%
Total SG&A expenses	60.7	52.4	16%
<i>Expenses related to intern. subsidiaries</i>	<i>4.3</i>	<i>2.6</i>	<i>70%</i>

In the first half of 2018, EBITDA was affected by non-recurring expenses of 2.6 million euros. 1.5 million euros of this amount were related to the study and analysis of the capital increase operation carried out in October 2018, while 1.1 million euros were linked to a substantial change to Frosst Ibérica employees working conditions. This change in working conditions was mainly related to the removal of the catering service, for which the employees were compensated with a sum similar to the costs that ROVI would have incurred in the following five-year period.

EBITDA increased to 26.5 million euros in the first half of 2019, a rise of 99% compared to the same period of the previous year, reflecting a 5.8 percentage point increase in the EBITDA margin, which was up to 14.9% in the first half of 2019 from 9.1% in the first half of 2018.



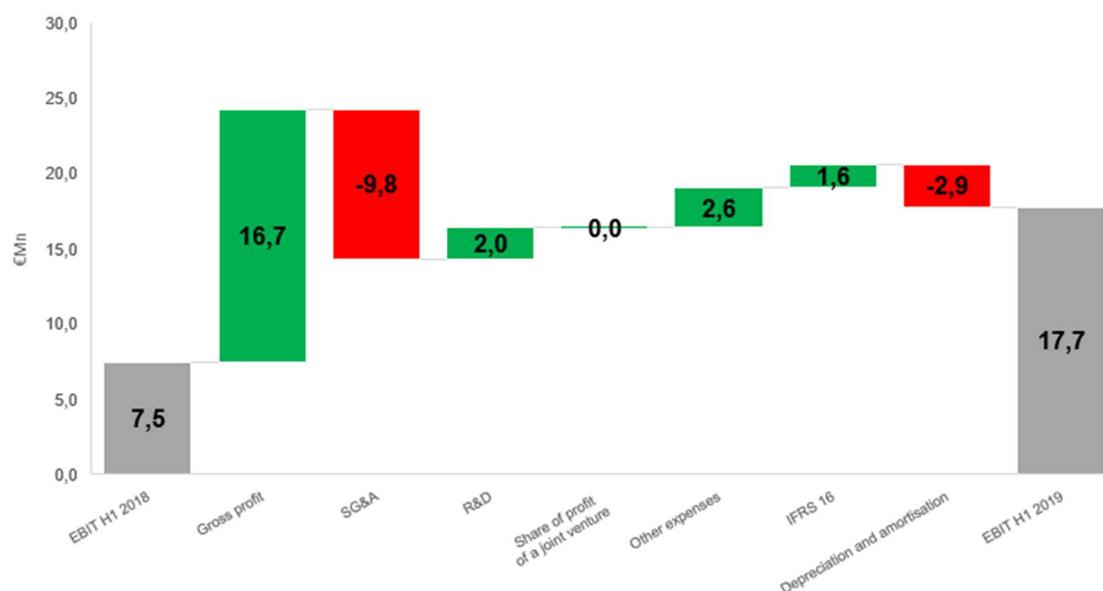
However, EBITDA “Pre-R&D”, calculated excluding R&D expenses in the first half of 2019 and 2018 and the impact of non-recurring expenses in the first half of 2018, increased by 26%, from 32.7 million euros in the first half of 2018 to 41.2 million euros in the first half of 2019, reflecting a 0.8 percentage point rise in the EBITDA margin to 23.2% in the first half of 2019 (see “w/o R&D costs” columns of the table below). Likewise, recognising the same amount of R&D expenses in the first half of 2019 as in the first half of 2018 and excluding the impact of non-recurring expenses in the first half of 2018, EBITDA would have increased by 53% to 24.4 million euros, reflecting a 2.8 percentage point rise in the EBITDA margin to 13.8% in the first half of 2019, up from 10.9% in the first half of 2018 (see “Flat R&D costs” columns of the table below).



<i>€ million</i>	Reported		w/o R&D costs			Flat R&D costs		
	H1 2019	H1 2018	H1 2019	H1 2018	Chang	H1 2019	H1 2018	Chang
Operat. revenue	177.5	146.3	177.5	146.3	21%	177.5	146.3	21%
Other income	0.4	0.8	0.4	0.8	-50%	0.4	0.8	-50%
Total revenue	177.9	147.1	177.9	147.1	21%	177.9	147.1	21%
Cost of sales	-76.1	-61.9	-76.1	-61.9	23%	-76.1	-61.9	23%
Gross profit	101.9	85.1	101.9	85.1	20%	101.9	85.1	20%
<i>% margin</i>	<i>57.4%</i>	<i>58.2%</i>	<i>57.4%</i>	<i>58.2%</i>	<i>-0,8pp</i>	<i>57.4%</i>	<i>58.2%</i>	<i>-0.8pp</i>
R&D expenses	-14.7	-16.8	0.0	0.0	n.a.	-16.8	-16.8	n.a.
SG&A	-60.7	-52.4	-60.7	-52.4	16%	-60.7	-52.4	16%
Other expenses	0.0	-2.6	0.0	0.0	n.a.	0.0	0.0	n.a.
Share of P/L of a JV	0.0	0.0	0.0	0.0	n.a.	0.0	0.0	n.a.
EBITDA	26.5	13.3	41.2	32.7	26%	24.4	16.0	53%
<i>% margin</i>	<i>14.9%</i>	<i>9.1%</i>	<i>23.2%</i>	<i>22.4%</i>	<i>0.8pp</i>	<i>13.8%</i>	<i>10.9%</i>	<i>2.8pp</i>

Depreciation and amortisation expenses increased by 49% to 8.7 million euros in the first half of 2019, as a result of the IFRS 16 application and the new property, plant and equipment and intangible assets purchases made during the last twelve months.

EBIT increased by 138% to 17.7 million euros in the first half of 2019, reflecting a 4.9 percentage point rise in the EBIT margin, which was up to 10.0% in the first half of 2019 from 5.1% in the first half of 2018.



However, EBIT “pre-R&D”, calculated excluding R&D expenses in the first half of 2019 and 2018 and the impact of non-recurring expenses in the first half of 2018, increased by 21%, from 26.9 million euros in the first half of 2018 to 32.5 million euros in the first half of 2019, reflecting a 0.1 percentage point fall in the EBIT margin to 18.3% in the first half of 2019 (see “w/o R&D costs” columns of the table below). Likewise, recognising the same amount of R&D expenses in the first half of 2019 as in the first quarter of 2018 and excluding the impact of non-recurring expenses in the first half of 2018, EBIT would have increased by 56% to 15.7 million euros, reflecting a 1.9 percentage point rise in the EBIT margin to 8.8% in the first half of 2019, up from 6.9% in the first half of 2018 (see “Flat R&D costs” columns of the table below).



€ million	Reported		w/o R&D costs			Flat R&D costs		
	H1 2019	H1 2018	H1 2019	H1 2018	Chang	H1 2019	H1 2018	Chang
Operat. revenue	177.5	146.3	177.5	146.3	21%	177.5	146.3	21%
Other income	0.4	0.8	0.4	0.8	-50%	0.4	0.8	-50%
Total revenue	177.9	147.1	177.9	147.1	21%	177.9	147.1	21%
Cost of sales	-76.1	-61.9	-76.1	-61.9	23%	-76.1	-61.9	23%
Gross profit	101.9	85.1	101.9	85.1	20%	101.9	85.1	20%
<i>% margin</i>	<i>57.4%</i>	<i>58.2%</i>	<i>57.4%</i>	<i>58.2%</i>	<i>-0,8pp</i>	<i>57.4%</i>	<i>58.2%</i>	<i>-0.8pp</i>
R&D expenses	-14.7	-16.8	0.0	0.0	n.a.	-16.8	-16.8	n.a.
SG&A	-60.7	-52.4	-60.7	-52.4	16%	-60.7	-52.4	16%
Other expenses	0.0	-2.6	0.0	0.0	n.a.	0.0	0.0	n.a.
Share of P/L of a JV	0.0	0.0	0.0	0.0	n.a.	0.0	0.0	n.a.
EBITDA	26.5	13.3	41.2	32.7	26%	24.4	16.0	53%
<i>% margin</i>	<i>14.9%</i>	<i>9.1%</i>	<i>23.2%</i>	<i>22.4%</i>	<i>0.8pp</i>	<i>13.8%</i>	<i>10.9%</i>	<i>2.8pp</i>
EBIT	17.7	7.5	32.5	26.9	21%	15.7	10.1	56%
<i>% margin</i>	<i>10.0%</i>	<i>5.1%</i>	<i>18.3%</i>	<i>18.4%</i>	<i>-0.1pp</i>	<i>8.8%</i>	<i>6.9%</i>	<i>1.9pp</i>

As a result of the IFRS 16 application, **financial expense** increased by 14% in the first half of 2019, compared to the same period of the previous year.

Financial income decreased by 57% in the first half of 2019, compared to the first half of 2018.

The **effective tax rate** was 7.5% in the first half of 2019 (negative income tax of 1.3 million euros), compared to -7.4% in the first half of 2018 (positive income tax of 0.5 million euros), mainly due to the decrease in R&D expenses in the first half of 2019 in comparison with the same period of the previous year, which led to lower research and development tax credits.

As of 30 June 2019, negative tax bases of the Group amounted to 36.3 million euros, of which 1.4 million euros will be used in the 2018 income tax and 1.0 million euros in the first half of 2019.

Net profit increased by 114%, from 7.6 million euros in the first half of 2018 to 16.2 million euros in the first half of 2019. However, net profit "pre-R&D", calculated excluding R&D expenses in the first half of 2019 and 2018 and the impact of non-recurring expenses in the first half of 2018, increased by 5%, from 28.4 million euros in the first half of 2018 to 29.8



million euros in the first half of 2019 (see “w/o R&D costs” columns of the table below). Likewise, recognising the same amount of R&D expenses in the first half of 2019 as in the first half of 2018 and excluding the impact of non-recurring expenses in the first half of 2018, net profit would have increased by 37% to 14.3 million euros (see “Flat R&D costs” columns of the table below).

€ million	Reported		w/o R&D costs			Flat R&D costs		
	H1 2019	H1 2018	H1 2019	H1 2018	Chang	H1 2019	H1 2018	Chang
Operat. revenue	177.5	146.3	177.5	146.3	21%	177.5	146.3	21%
Other income	0.4	0.8	0.4	0.8	-50%	0.4	0.8	-50%
Total revenue	177.9	147.1	177.9	147.1	21%	177.9	147.1	21%
Cost of sales	-76.1	-61.9	-76.1	-61.9	23%	-76.1	-61.9	23%
Gross profit	101.9	85.1	101.9	85.1	20%	101.9	85.1	20%
% margin	57.4%	58.2%	57.4%	58.2%	-0,8pp	57.4%	58.2%	-0.8pp
R&D expenses	-14.7	-16.8	0.0	0.0	n.a.	-16.8	-16.8	n.a.
SG&A	-60.7	-52.4	-60.7	-52.4	16%	-60.7	-52.4	16%
Other expenses	0.0	-2.6	0.0	0.0	n.a.	0.0	0.0	n.a.
Share of P/L of a JV	0.0	0.0	0.0	0.0	n.a.	0.0	0.0	n.a.
EBITDA	26.5	13.3	41.2	32.7	26%	24.4	16.0	53%
% margin	14.9%	9.1%	23.2%	22.4%	0.8pp	13.8%	10.9%	2.8pp
EBIT	17.7	7.5	32.5	26.9	21%	15.7	10.1	56%
% margin	10.0%	5.1%	18.3%	18.4%	-0.1pp	8.8%	6.9%	1.9pp
Net profit	16.2	7.6	29.8	28.4	5%	14.3	10.4	37%
% margin	9.1%	5.2%	16.8%	19.4%	-2.6pp	8.0%	7.1%	0.9pp

ROVI General Shareholders Meeting, on 12 June 2018, approved the payment of a **gross dividend** of 0.0798 euros per share on 2018 earnings. This dividend was paid on 4th July 2019 and it represented a 25% pay-out.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that “we are very happy with the results of the first half of 2019. Total revenue increased by 21% thanks to the strength of our leading products, which continue to enjoy good sales prospects. The development of the Risperidone ISM[®] phase III, as well as the opening of subsidiaries for the marketing of our Enoxaparin biosimilar in the main European markets, required a significant investment effort from us. However, EBITDA margin increased in the first half of 2019, mainly as a result of the operating leverage contributed by our LMWH franchise and the expansion of our injectable toll manufacturing business. The capital increase carried out in October 2018 will enable us to



embrace the new phase of growth we are facing and keep our balance sheet strong to execute on 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 8.6 million euros in the first half of 2019, compared to 5.1 million euros in the first half of 2018. Of this amount:

- 0.8 million euros corresponds to investment capex related to the injectable facility, versus 0.9 million euros in the first half of 2018;
- 1.1 million euros relates to investment capex regarding the San Sebastián de los Reyes plant, versus 0.9 million euros in the first half of 2018;
- 2.4 million euros were invested in the Granada facility, versus 1.2 million euros in the first half of 2018;
- 2.5 million euros were invested in the Alcalá de Henares (Frosst Ibérica) facility, versus 1.2 million euros in the first half of 2018; and
- 1.8 million euros relates to expenditure on maintenance and other capex, versus 0.8 million euros in the first half of 2018.

In addition, in the first half of 2019, ROVI invested 13.5 million euros in the acquisition of Polaramine® (see section 6.4).

	H1 2019	H1 2018	% Growth
Injectable plant	0.8	0.9	-16%
San Sebastián de los Reyes plant	1.1	0.9	18%
Granada plant	2.4	1.2	102%
Alcalá de Henares plant (Frosst Ibérica)	2.5	1.2	n.a.
Expenditure on maintenance and other capex	1.8	0.8	n.a.
Total Capex	8.6	5.1	69%
<i>Acquisitions</i>	<i>13.5</i>	-	<i>n.a.</i>



3.2 Debt

As a result of the IFRS 16 application, as of 30 June 2019, ROVI total debt increased to 49.1 million euros. Debt with public administration, which is 0% interest rate debt, represented 25% of total debt as of 30 June 2019.

<i>In thousand euros</i>	30 June 19	31 December 18
Bank borrowings	13,871	22,716
Debt with public administration	12,383	11,508
Financial liabilities for leases	22,819	-
Total	49,073	34,224

As of 30 June 2019, bank borrowings decreased by 8.8 million euros due to debt amortization. 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 is for 45 million euros. ROVI may draw down this amount during a period of 24 months as from signature of the contract and the loan will mature in 2029. The loan provides for a three-year grace period and financial conditions (i.e. applicable interest rates, repayment periods, etc.) favorable to ROVI. As of 30 June 2019, ROVI had drawn down 5 million euros against this credit line.

Financial liabilities for leases reached 22.8 million euros in the first half of 2019 as a result of the IFRS 16 application.

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) decreased to -19.4 million euros in the first half of 2019 compared to -5.8 million euros in the first half of 2018 mainly due to (i) the increase of 17.0 million euros in Capex mainly as a result of the acquisition of Polaramine®; (ii) the increase of 26.9 million euros in the "inventories" line in the first half of 2019, compared to an increase of 15.9 million euros in the first half of 2018; (iii) the increase of 10.0 million euros in the "trade and other receivables" item in the first half of 2019, compared to an increase of 7.4 million euros in the first half of 2018; (iv) the increase of 21.2 million euros in the "trade and other payables" item in the first half of 2019, compared to an increase of 18.4 million euros in the first half of 2018; and (v) the increase of 10.4 million euros in profit before income tax.



3.4 Gross cash position and net debt

As a result of the IFRS 16 application in the first half of 2019, as of 30 June 2019, ROVI had a gross cash position of 68.1 million euros, compared to 97.0 million euros as of 31 December 2018, and net cash of 19.1 million euros (equity securities plus deposits plus cash and cash equivalents minus current and non-current financial debt), compared to 62.8 million euros as of 31 December 2018.

3.5 Working capital

The decrease in working capital in the first half of 2019 was mainly due to (i) an increase of 26.9 million euros in the "inventories" line, mainly due to higher heparin stock levels in the first half of 2019; (ii) an increase of 10.0 million euros in the "trade and other receivables" line; (iii) an increase of 21.2 million euros in the "trade and other payables" line; and (iv) a decrease of 28.8 million euros in the "cash and cash equivalents" item partially as a result of the acquisition of Polaramine® (13.5 million euros).

As of 30 June 2019, Social Security and Public Administrations total debt with ROVI amounted to 11.0 million euros, of which 5.5 million euros in Spain, 3.1 million euros in Portugal and 2.4 million euros in Italy.

4. Guidance for 2019

For the second time this year, ROVI is upgrading its operating revenue guidance for the full year 2019, from low-double-digit growth rate to high-double-digit growth rate. The Company forecasts that it will continue to grow at a higher rate than Spanish pharmaceutical market expenditure in the first five months of 2019, which, according to the Ministry of Health, Consumption and Social Welfare, showed a growth rate of 3%.

This upgrade is mainly due to the positive performance of Bemiparin in Spain and the good prospects for Enoxaparin biosimilar sales. Likewise, ROVI expected to stop distributing Merus Labs products (Sintrom®, Salagen®, Cordiplast® and Estraderm®) as of the third quarter of 2019 but will finally continue to distribute them for the fourth quarter of 2019.

ROVI expects its growth drivers to be Bemiparin, the latest license agreements (Tetridar®, Neparvis®, Volutsa® and Orvatez®), the Enoxaparin biosimilar, its existing portfolio of specialty pharmaceuticals, new products recently acquired (Falithrom® and Polaramine®) and new contracts in the toll manufacturing area.



5. Research and Development update

ISM[®] technology platform

ROVI has made meaningful progress in the development of its long-acting injectable (LAI) antipsychotic Risperidone ISM[®], the first candidate for its leading-edge drug delivery technology, ISM[®]. In March 2019, the company announced topline results from the pivotal study of Risperidone ISM[®] "PRISMA-3"¹, 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 (see section 6.3). Besides, the company very recently announced the completion of the Clinical Trial Program that will support the application for marketing authorization for Doria[®] for the treatment of schizophrenia (see section 6.1).

Furthermore, ROVI informs of the decision to expand its industrial capabilities for the manufacture of Doria[®] 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[®], which will require the installation of a specific filling machine. As a result, ROVI will prioritize the submission of the Doria[®] dossier in Europe, which it plans to file by 1Q2020; consequently, filing in the USA has been rescheduled for 2020.

Lastly, as previously informed, the company started the human testing with Letrozole ISM[®], which represents the second candidate on clinical development using the Rovi's ISM[®] 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 study²) of Letrozole ISM[®] is currently ongoing and due to the study design ("dose escalation") and its exploratory nature, the finalisation date cannot be anticipated. Nevertheless, preliminary data confirm that this ISM[®] formulation provides a prolonged release of letrozole which produces a sustained suppression of oestrogenic hormones. The company will be gathering more clinical data from this trial during the following months to better characterise the pharmacological profile of Letrozole ISM[®]; 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.

¹ Study to Evaluate the Efficacy and Safety of Risperidone In Situ Microparticles[®] (ISM[®]) in Patients With Acute Schizophrenia (PRISMA-3). [Clinicaltrials.gov#NCT03160521](https://clinicaltrials.gov/show/NCT03160521) [<https://clinicaltrials.gov/show/NCT03160521>].

² Evaluation of IM Letrozole ISM[®] Pharmacokinetics, Safety, and Tolerability in Healthy Post-menopausal Women (LISA-1). [Clinicaltrials.gov#NCT03401320](https://clinicaltrials.gov/ct2/show/NCT03401320) [<https://clinicaltrials.gov/ct2/show/NCT03401320>].

6. Key operating and financial events

6.1 ROVI announces completion of the Clinical Trial Program that will support the application for marketing authorization for Doria® for the treatment of schizophrenia

ROVI informed (by publication of the relevant fact number 279907 dated 5th of July of 2019) about the conclusion of the PRISMA-3¹ and BORIS² studies, thus completing the Clinical Research Program for Risperidone ISM®, in which more than 679 subjects participated. All the data collected and analyzed in this Program will be included in the registration dossier to apply for marketing authorization for Doria® for the treatment of schizophrenia in the European Union and United States, in a first phase, and, subsequently, in other countries.

As the company announced on 19 March, 2019, the final results of the pivotal PRISMA-3 clinical study confirm the superiority of Risperidone ISM®, a novel investigational antipsychotic for the treatment of schizophrenia with once-monthly injections, in comparison with the placebo. The prespecified primary efficacy endpoint in the study was the mean total score on the Positive and Negative Syndrome Scale (PANSS) after twelve weeks. The reductions in comparison with the baseline values obtained in the PANSS with monthly doses of 75 mg or 100 mg of Risperidone ISM® were statistically higher than those observed with placebo ($p < 0.0001$).

Likewise, both dosage strengths of Risperidone ISM® (75 mg and 100 mg, once monthly) showed reductions that were statistically higher than those of the placebo ($p < 0.0001$) in the total score on the Clinician Global Impression-Severity (CGI-S) scale, at week 12, which was the prespecified key secondary efficacy endpoint in the study.

Additionally, ROVI will include long-term safety data on more than 100 patients exposed to at least one year of treatment with Doria® in the registration dossier, as recommended in the International Conference on Harmonization (ICH) Guideline E1.

Lastly, ROVI has also announced the completion of the BORIS clinical trial, aimed to compare the bioavailability of multiple doses of oral risperidone with multiple doses of Risperidone ISM® in stable schizophrenic patients. The results of this study will provide support to the registration of Doria® with the FDA (Food and Drug Administration) and EMA (European Medicines Agency) as a hybrid application^{3,4}, i.e. based partly on own studies and partly on previously done with reference medicine.

“After successfully completing the Doria® Clinical Trial Program, we are now closer to marketing it and hope to file an application for marketing authorization for Doria® with the EMA and FDA

¹ <https://clinicaltrials.gov/ct2/show/NCT03160521>

² <https://clinicaltrials.gov/ct2/show/NCT03527186>

³ NDA 505(b)(2) Section of Federal Food, Drug, and Cosmetic Act

⁴ Hybrid Application, Article 10(3) – Directive 2001/83/EC



in the very near future”, said Juan López-Belmonte, ROVI’s CEO. “Once again, I want to thank all the patients, their caregivers and the investigators for their participation in this extensive clinical program and we hope that we will soon be able to contribute to the therapeutic arsenal to combat this severe, chronic and disabling disease”.

6.2 ROVI will market TEVA’s osteoporosis treatment for adults Tetridar® (teriparatide) in Spain

ROVI informed (by publication of the relevant fact number 276997 dated 11th of April of 2019) about the future marketing of Teva Pharmaceutical Industries Ltd. (TEVA)’s medicine Tetridar® (teriparatide) for the treatment of osteoporosis in adults in Spain.

Tetridar®, an injection containing the active substance teriparatide, is used to increase bone strength and reduce the risk of fracture by stimulating bone formation.

Marketing of this pharmaceutical by ROVI is expected to commence in the third quarter of 2019. Under the agreement between the two companies, ROVI will be responsible for the promotion and distribution of Tetridar® in Spanish territory for a five-year period as of the date on which marketing commences, which may subsequently be extended for a further five years.

Osteoporosis is a disease that weakens bones and makes them fragile. This disease is especially frequent in post-menopausal women, but may also affect men. In addition, osteoporosis often occurs in patients treated with corticosteroids.

According the data of the specialised healthcare management consultant Iqvia, in the twelve months up to February 2019 (MAT February 2019), sales of the original teriparatide molecule in Spain totalled 69.2 million euros.

6.3 ROVI Announces Positive Topline Results from Phase 3 study of Doria® in Patients with Schizophrenia

ROVI informed (by publication of the relevant fact number 276197 dated 19th of March of 2019) about topline results from the pivotal study PRISMA-3, a multicenter, randomized, placebo-controlled phase 3 trial of Doria® (Risperidone ISM®), a novel investigational once-monthly injectable antipsychotic for the treatment of schizophrenia. In this study, patients treated with once-monthly doses of either 75 mg or 100 mg of Doria®, obtained statistically significant reductions from baseline ($p < 0.0001$) compared to placebo in the Positive and Negative Syndrome Scale (PANSS) total score at week 12, which was the prespecified primary efficacy endpoint in the trial. As expected, the final clinical report will be available by June 2019.

“The positive results of the PRISMA-3 study provide the clinical evidence that Risperidone ISM® allows for a meaningful control of schizophrenia symptoms in patients with an acute illness



exacerbation, using once-monthly injection and without needing loading doses or oral supplementation” stated Christoph Correll, M.D., Professor of Psychiatry and Molecular Medicine at the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell in Hempstead, New York. “In view of these results that also documented a favorable safety profile consistent with data known from oral risperidone, I believe that Risperidone ISM[®], if approved, may represent a first-line therapeutic option for those schizophrenia patients in whom prescribers, patients and families consider risperidone to be the treatment of choice”.

Both doses of Risperidone ISM[®] (once-monthly 75 mg and 100 mg), compared to placebo, also showed statistically significant improvement ($p < 0.0001$) in the total score of the Clinical Global Impressions-Severity scale (CGI-S) at 12 weeks, which was the pre-specified key secondary efficacy endpoint in the study.

" It is a great satisfaction to have obtained such good and robust efficacy and safety results with Doria[®], which we consequently hope will allow us to make rapid progress with the registration in the US and Europe," said Juan Lopez-Belmonte, CEO of ROVI. "We want to especially thank patients, their caregivers and investigators for their participation in the study, since they have allowed us to get closer to being able to offer a novel therapeutic option that can help improve the management of schizophrenia, a still all too often serious, chronic and disabling disease".

Based on these positive results, and the remaining data of the product, ROVI is progressing in its plans to submit an NDA (New Drug Application) to the FDA (Food and Drug Administration) in the second half of 2019.

6.4 ROVI acquires rights to Dexchlorpheniramine Maleate in the Spanish and French markets

ROVI informed (by publication of the relevant fact number 274737 dated 15th of February of 2019) that it has reached an agreement with a subsidiary of Merck Sharp and Dohme ("MSD") whereby it acquires certain rights to MSD's dexchlorpheniramine maleate product line in Spain and France, allowing it to distribute this product directly in Spain in its different pharmaceutical forms (tablets, syrup and ampoules, marketed under the brand name POLARAMINE[®], and cream, marketed under the brand name POLARACREM[™]) and, in France, in its injectable form (ampoules).

This line of products belongs to a group of medicines known as antihistamines used for symptomatic treatment of seasonal and perennial allergic rhinitis; vasomotor rhinitis; allergic conjunctivitis; mild, uncomplicated allergic cutaneous manifestations of urticaria or angioedema; and reactions to blood or plasma. It is also indicated, together with adrenalin or other appropriate measures, for treatment of anaphylactic reactions after the acute manifestations



have been controlled. These products often relieve cutaneous manifestations such as allergic eczema, atopic and contact dermatitis, insect bites, dermographisms and drug reactions. According to MSD, net sales of these products in Spain and France, were approximately 6.3 million US dollars in 2017.

ROVI will pay MSD 13.5 million euros for the product.

Under this agreement, this line of products will be marketed directly by ROVI in Spain in its different pharmaceutical forms and, in France, in its injectable form, when the administrative procedures to authorise the transfer of the marketing authorisations have been concluded at the Spanish Medicines Agency and the French Agency for the Safety of Medicines and Health Products.

6.5 ROVI acquires Falithrom® for the German market

ROVI informed (by publication of the relevant fact number 273591 dated 9th of January of 2019) about the acquisition of Falithrom®, which was owned by Hexal AG ("Hexal"), a company belonging to the Sandoz division of Novartis, to be directly marketed by ROVI in Germany.

Falithrom® is used for the prevention and treatment of thromboembolic disease including venous thrombosis, thromboembolism, and pulmonary embolism as well as for the prevention of ischemic stroke in patients with atrial fibrillation (AF).

According to IQVIA, the 2017 net sales of the product in Germany totalled around 3.5 million euros. ROVI will pay Hexal nine million euros for the product.

Under this agreement, Falithrom® will be directly marketed by ROVI in Germany as soon as the administrative processes to authorize the transfer of the marketing authorization are completed before the Federal Institute for Drugs and Medical Devices (BfArM).

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 and France 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

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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.



APPENDIX 1

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS AS OF 30 JUNE 2019 AND 31 DECEMBER 2018

(Thousands of euros)

	30 June 2019	31 December 2018
ASSETS		
Non-current assets		
Property, Plant and Equipment	121,064	95,837
Intangible assets	47,012	34,650
Investment in a joint venture	2,028	2,038
Deferred income tax assets	12,018	16,036
Equity securities	70	70
Financial receivables	65	65
	182,257	148,696
Current assets		
Inventories	121,734	94,861
Trade and other receivables	70,218	60,180
Current income tax assets	8,107	3,414
Financial derivatives	122	17
Prepaid expenses	3	21
Cash and cash equivalents	66,680	95,511
	266,864	254,004
Total assets	449,121	402,700



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS AS OF 30 JUNE 2019 AND 31 DECEMBER 2018

(Thousands of euros)

	30 June 2019	31 December 2018
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	600
Treasury shares	(9,183)	(8,812)
Retained earnings and voluntary reserves	200,659	186,792
Profit for the period	16,161	17,895
Other reserves	(3)	(3)
Total equity	299,307	287,472
LIABILITIES		
Non-current liabilities		
Financial debt	34,459	16,589
Deferred income tax liabilities	726	1,243
Contract liabilities	6,317	6,263
Deferred income	3,399	3,621
	44,901	27,716
Current liabilities		
Financial debt	14,614	17,635
Trade and other payables	89,402	68,165
Contract liabilities	317	1,159
Deferred income	580	553
	104,913	87,512
Total liabilities	149,814	115,228
Total equity and liabilities	449,121	402,700



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED INCOME STATEMENTS FOR THE SIX-MONTH PERIODS ENDING 30 JUNE
2019 AND 30 JUNE 2018

(Thousands of euros)

	Six-month period ending 30 June	
	2019	2018
Revenue	177,536	146,309
Changes in inventories of finished goods and work in progress	20,880	8,719
Raw materials and consumables used	(96,938)	(70,662)
Employee benefit expenses	(36,753)	(36,266)
Other operating expenses	(38,632)	(35,513)
Amortisation and depreciation	(8,715)	(5,858)
Recognition of government grants on non-financial non-current assets and other	374	754
Share in profits of joint venture	(10)	(25)
OPERATING PROFIT	17,742	7,458
Finance income	3	7
Finance costs	(452)	(438)
Impairment and gain or loss on measurement of financial instruments	134	-
Exchange difference	37	-
FINANCE COSTS - NET	(278)	(431)
PROFIT BEFORE INCOME TAX	17,464	7,027
Income tax	(1,303)	523
PROFIT FOR THE PERIOD	16,161	7,550



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED CASH FLOW STATEMENTS FOR THE SIX-MONTH PERIODS ENDING 30
JUNE 2019 AND 30 JUNE 2018

(Thousands of euros)

	Six-month period ending 30 June	
	2019	2018
Cash flows from operating activities		
Profit before tax	17,464	7,027
Adjustments for non-monetary transactions:		
Amortisation	8,715	5,858
Finance income	(40)	(7)
Valuation allowance	917	2,226
Adjustments for changes in value of financial instruments	(134)	-
Result from derecognition of financial assets and liabilities	29	-
Finance expense	452	438
Grants, income from distribution licenses and other deferred incomes	(1,305)	(792)
Share of profit of joint venture	10	25
Changes in working capital:		
Trade and other receivables	(9,640)	(7,068)
Inventories	(28,251)	(18,234)
Other current assets (prepaid expenses)	17	-
Trade and other payables	16,746	8,854
Other collections and payments:		
Proceeds from distribution licenses	143	2,910
Interest payment	(14)	-
Income tax cash flow	(2,495)	(2,074)
Net cash generated from (used in) operating activities	2,614	(837)
Cash flows from investing activities		
Purchases of intangible assets	(14,281)	(369)
Purchases of property, plant and equipment	(7,789)	(4,695)
Proceeds from sale of property, plant and equipment	-	12
Interest received	40	95
Net cash generated from (used in) investing activities	(22,030)	(4,957)
Cash flows from financing activities		
Repayments of financial debt	(11,037)	(6,677)
Proceeds from financial debt	1,516	1,933
Interest paid	(60)	(103)
Purchase of treasury shares	(1,631)	(490)
Reissue of treasury shares	1,797	397
Net cash generated from (used in) financing activities	(9,415)	(4,940)
Net (decrease) increase in cash and cash equivalents	(28,831)	(10,734)
Cash and cash equivalents at the beginning of the period	95,511	40,700
Cash and cash equivalents at the end of the period	66,680	29,966