

First Quarter 2019 Results

8th May 2019



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



ROVI – First Quarter 2019 Financial Results

ROVI reports operating revenue growth of 8%, underpinned by outstanding low-molecular-weight heparin franchise sales

- Operating revenue increased by 8% to 82.2 million euros in the first quarter of 2019, driven by the strength of the specialty pharmaceutical business, where sales rose 12%, strongly outperforming the market. Total revenue increased by 8% to 82.4 million euros in the first quarter of 2019.
- ➤ ROVI is upgrading its operating revenue guidance for the full year 2019, from high-single-digit growth rate to low-double-digit growth rate.
- ➤ In March 2018, ROVI announced Positive Topline Results from Phase 3 study of Doria®. These advanced final results show that primary and key secondary efficacy endpoints were achieved with both doses tested for the treatment of patients with acute exacerbation of schizophrenia. The application for registration with the FDA in USA is planned for the second half of 2019.
- ROVI launched its enoxaparin biosimilar in Germany in September 2017; in United Kingdom, Italy, Spain, France, Austria, Latvia and Estonia in 2018 and in Portugal and Costa Rica in the first quarter of 2019.
- As of 31st March 2019, all the European Union countries (25 countries) where ROVI had applied for the national registration of the enoxaparin biosimilar had approved such registration, except Luxembourg.
- ➤ Sales of the Low Molecular Weight Heparin (LMWH) franchise (enoxaparin biosimilar and Bemiparin) increased by 34% to 37.6 million euros in the first quarter of 2019. LMWH sales represented 46% of operating revenue in the first quarter of 2019 compared to 37% in the first quarter of 2018. Sales of the enoxaparin biosimilar amounted to 16.5 million euros in the first quarter of 2019 and sales of Bemiparin increased 4% to 17.6 million euros in Spain.
- ➤ Sales of Neparvis®, launched in December 2016, increased by 60% to 4.3 million euros in the first quarter of 2019.



- ➤ EBITDA increased by 17%, from 10.2 million euros in the first quarter of 2018 to 11.9 million euros in the first quarter of 2019, reflecting a 1.0 percentage point rise in the EBITDA margin to 14.4% in the first quarter of 2019.
- Net profit increased by 1%, from 6.8 million euros in the first quarter of 2018 to 6.9 million euros in the first quarter of 2019.

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

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said "in the first quarter of 2019, we reached 8% operating revenue growth mainly driven by the specialty pharmaceutical business strength, where sales rose by 12%. According to IQVIA, the Spanish innovative product market increased by 2% in the first quarter 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 4%. Likewise, we continue the national phase of the registration process of our Enoxaparin biosimilar in Europe, with its approval in 25 countries before 31st March 2019. ROVI has signed two important licensing agreements to distribute and market its Enoxaparin biosimilar, the first with Hikma Pharmaceuticals, who has the exclusive rights for 17 Middle East and North Africa countries and the second 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 quarter of 2019, when sales were 16.5 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 lowmolecular-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 Tetridar®, 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 will immediately have 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 are carrying out a Phase III trial with our ISM® technology (Risperidone ISM®) and published Positive Topline Results. We expect to file an NDA (New Drug Application) US Registration Dossier for the FDA (Food and Drug Administration), the second half 2019. We are also conducting a Phase I study for another candidate, Letrozole, 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

€ million	Q1 2019	Q1 2018	Growth	% Growth
Operating revenue	82.2	75.8	6.4	8%
Other income	0.2	0.2	0.0	-5%
Total revenue	82.4	76.0	6.4	8%
Cost of sales	-35.6	-32.2	-3.4	10%
Gross profit	46.8	43.8	3.0	7%
% margin	<i>57.0%</i>	<i>57.8%</i>		-0.8pp
R&D expenses	-6.9	-8.0	1.0	-13%
SG&A	-28.0	-25.6	-2.4	9%
Share of profit/loss of a joint				
venture	0.0	0.0	0.1	n.a.
EBITDA	11.9	10.2	1.7	17%
% margin	14.4%	<i>13.4%</i>		1.0pp
EBIT	7.5	7.3	0.3	4%
% margin	9.2%	9.6%		<i>-0.4pp</i>
Net profit	6.9	6.8	0.1	1%

Note: certain numerical figures included in this document have been rounded. Therefore, discrepancies in tables between totals and the sums of the amounts listed may occur due to such rounding.

The consolidated financial statements of Grupo ROVI for the first quarter 2019 and the comparative information for 2018 (balance sheet) and for the first quarter 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 8% to 82.2 million euros in the first quarter of 2019, driven by the strength of the specialty pharmaceutical business, where sales rose 12%, strongly outperforming the market. Total revenue increased by 8% to 82.4 million euros in the first quarter of 2019.

<i>€ million</i>	Q1 2019	Q1 2018	% Growth
Specialty pharmaceutical business	71.4	63.8	12%
Toll manufacturing business	10.7	12.0	-11%
Total operating revenue	82.2	75.8	8%

Sales of **prescription-based pharmaceutical** products rose 12% to 62.7 million euros in the first quarter of 2019.

<i>€ million</i>	Q1 2019	Q1 2018	% Growth
Prescription-based pharmaceutical products	62.7	55.8	12%
Low Molecular Weight Heparins	37.6	28.1	34%
Enoxaparin biosimilar (Enoxaparin Becat)	16.5	4.1	n.a.
Bemiparin (Hibor)	21.1	24.0	-12%
Sales in Spain	17.6	16.9	4%
International sales	3.5	7.1	-50%
Neparvis	4.3	2.7	60%
Ulunar & Hirobriz	3.8	3.9	-2%
Volutsa	3.1	2.6	22%
Vytorin & Absorcol & Orvatez	7.3	13.0	-44%
Medikinet & Medicebran	2.1	2.0	6%
Other products	8.1	7.4	10%
Discounts to the National Health System	-3.6	-3.8	-4%
Contrast agents and other hospital products	8.2	7.5	8%
Non prescription pharmaceutical products			
("OTC") and Other	0.6	0.4	28%
Total specialty pharmaceutical business	71.4	63.8	12%

Sales of the **Low Molecular Weight Heparin (LMWH) franchise** (Enoxaparin biosimilar and Bemiparin) increased by 34% to 37.6 million euros in the first quarter of 2019. LMWH sales represented 46% of operating revenue in 2018 compared to 37% in the first quarter of 2018.

Sales of the **Enoxaparin biosimilar** amounted to 16.5 million euros in the first quarter 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 quarter of 2019.

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, had a positive performance in Spain (**Hibor**®) in the first quarter of 2019, with sales up 4% to 17.6 million euros. International sales of Bemiparin decreased by 50% to 3.5 million euros. This significant decrease was specifically linked to the first quarter of 2019 and ROVI expects international Bemiparin sales to remain stable in 2019. Bemiparin total sales decreased by 12% to 21.1 million euros in the first quarter 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, reached 4.3 million euros in the first quarter of 2019, compared to 2.7 million euros in the first quarter 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 3.8 million euros in the first quarter 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 22% to 3.1 million euros in the first guarter 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 44% to 7.3 million euros in the first quarter 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 8.2 million euros in the first quarter of 2018, an extraordinary rise of 89% 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 6% to 2.1 million euros in the first guarter of 2019.



According to IQVIA, Spanish innovative product market increased by 2% in the first quarter of 2019 compared to the same period of the previous year. Nevertheless, ROVI prescription-based pharmaceutical product sales rose 12% in the first quarter of 2019, beating the market by 10 percentage points.

Sales of **contrast imaging agents** and other hospital products increased by 8% to 8.2 million euros in the first quarter of 2019.

Sales of Perspirex® represented 55% of over-the counter pharmaceutical products ("OTC") and other sales in the first quarter of 2019. The distribution contract of Perspirex® will terminate on 30th June, 2019, then ROVI expects to stop distributing the product from this date.

Toll manufacturing sales decreased by 11% to 10.7 million euros in the first quarter of 2019 mainly because of the reduction of the oral forms business compared to the first quarter of 2018. Injectable business sales increased by 22% to 6.1 million euros in the first quarter of 2019 compared to the same period of the previous year. By the end of 2019, a mid-single-digit growth rate in toll manufacturing is expected.

€ million	Q1 2019	Q1 2018	% Growth
Injectable business	6.1	5.0	22%
Oral forms business (Frosst Ibérica)	4.6	7.0	-34%
Total toll manufacturing business	10.7	12.0	-11%

Sales outside Spain increased by 22% to 26.2 million euros in the first quarter of 2019, 9.8 million euros (or 38%) of which related to international subsidiaries, mainly due to recognition of Enoxaparin biosimilar sales. Sales outside Spain represented 32% of operating revenue in the first quarter of 2019 compared to 28% in the first quarter of 2018.

<i>€ million</i>	Q1 2019	Q1 2018	% Growth
Portugal	1.3	0.7	89%
Germany	3.9	4.1	-5%
Italy	3.5	0.8	n.a.
United Kingdom	1.1	0.0	n.a.
Total sales in the international subsidiaries	9.8	5.6	76%

Other income (subsidies) decreased by 5% to 0.2 million euros in the first quarter of 2019, compared to the same period of the previous year.



Gross profit increased by 7% to 46.8 million euros in the first quarter of 2019, the gross margin showing a decrease of 0.8 percentage points from 57.8% in the first quarter of 2018 to 57.0%, mainly due to (i) the increase of Enoxaparin biosimilar sales, which added lower margins in the first quarter of 2019 after the launch of the product in eight new markets; and (ii) the increase in the LMWH raw material prices, which, in the first quarter of 2019, were running around 30% over first quarter 2018 prices. ROVI expects this rising trend to continue during 2019.

Research and development expenses (R&D) decreased 13% to 6.9 million euros in the first quarter 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 March 31, 2019 were:

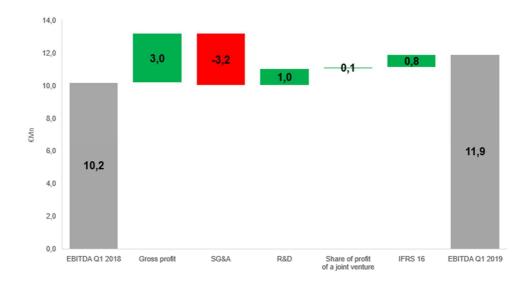
- Recognition of assets under the "Property, plant and equipment" caption (non-current assets) for an amount of 21.0 million euros.
- Increase in debt under the captions "Financial liabilities for non-current and current leases" of 18.9 million euros and 2.1 million euros, respectively.
- Lower operating expenses and, consequently, an increase of EBITDA of 0.8 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 0.7 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 9% to 28.0 million euros in the first quarter of 2019, mainly due to (i) international subsidiaries expenses which amounted to 1.9 million euros compared to 1.1 million euros in the first quarter 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.



€ million	Q1 2019	Q1 2018	% Growth
Personnel expenses	17.7	18.0	-2%
Other operating expenses (exc. R&D)	10.4	7.6	36%
Total SG&A expenses	28.0	25.6	9%
Expenses related to intern. subsidiaries	1.9	1.1	82%

EBITDA increased to 11.9 million euros in the first quarter of 2019, a rise of 17% compared to the same period of the previous year, reflecting a 1.0 percentage point increase in the EBITDA margin, which was up to 14.4% in the first quarter of 2019 from 13.4% in the first quarter of 2018.



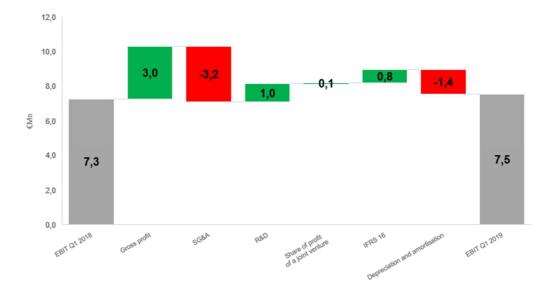
However, EBITDA "Pre-R&D", calculated excluding R&D expenses in the first quarters of 2019 and 2018, increased by 4%, from 18.1 million euros in the first quarter of 2018 to 18.8 million euros in the first quarter of 2019, reflecting a 1.1 percentage point fall in the EBITDA margin to 22.9% in the first quarter 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 quarter of 2019 as in the first quarter of 2018, EBITDA would have increased by 7% to 10.8 million euros, reflecting a 0.2 percentage point decline in the EBITDA margin to 13.2% in the first quarter of 2019, down from 13.4% in the first quarter of 2018 (see "Flat R&D costs" columns of the table below).



	Reported		w/e	w/o R&D costs		Flat R&D costs		sts
€ million	Q1 2019	Q1 2018	Q1 2019	Q1 2018	Chang	Q1 2019	Q1 2018	Chang
Operat. revenue Other income	82.2 0.2	75.8 0.2	82.2 0.2	75.8 0.2	8% -5%	82.2 0.2	75.8 0.2	8% -5%
Total revenue	82.4	76.0	82.4	76.0	8%	82.4	76.0	8%
Cost of sales	-35.6	-32.2	-35.6	-32.2	10%	-35.6	-32.2	10%
Gross profit	46.8	43.8	46.8	43.8	7%	46.8	43.8	7%
% margin	<i>57.0%</i>	<i>57.8%</i>	<i>57.0%</i>	<i>57.8%</i>	-0,8pp	<i>57.0%</i>	<i>57.8%</i>	-0,8pp
R&D expenses	-6.9	-8.0	0.0	0.0	n.a.	-8.0	-8.0	n.a.
SG&A	-28.0	-25.6	-28.0	-25.6	9%	-28.0	-25.6	9%
Share of P/L of								
a JV	0.0	0.0	0.0	0.0	n.a.	0.0	0.0	n.a.
EBITDA	11.9	10.2	18.8	18.1	4%	10.8	10.2	7%
% margin	<i>14.4%</i>	<i>13.4%</i>	22.9%	23.9%	-1.1pp	<i>13.2%</i>	<i>13.4%</i>	-0.2pp

Depreciation and amortisation expenses increased by 50% to 4.3 million euros in the first quarter 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 4% to 7.5 million euros in the first quarter of 2019, reflecting a 0.4 percentage point decrease in the EBIT margin, which was down to 9.2% in the first quarter of 2019 from 9.6% in the first quarter of 2018.





However, EBIT "pre-R&D", calculated excluding R&D expenses in the first quarters of 2019 and 2018, decreased by 5%, from 15.2 million euros in the first quarter of 2018 to 14.4 million euros in the first quarter of 2019, reflecting a 2.5 percentage point fall in the EBIT margin to 17.6% in the first quarter 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 quarter of 2019 as in the first quarter of 2018, EBIT would have decreased by 11% to 6.5 million euros, reflecting a 1.7 percentage point decline in the EBIT margin to 7.9% in the first quarter of 2019, down from 9.6% in the first quarter of 2018 (see "Flat R&D costs" columns of the table below).

	Reported		w/	w/o R&D costs		Fla	t R&D co	sts
€ million	Q1 2019	Q1 2018	Q1 2019	Q1 2018	Chang	Q1 2019	Q1 2018	Chang
Operat. revenue	82.2	75.8	82.2	75.8	8%	82.2	75.8	8%
Other income	0.2	0.2	0.2	0.2	-5%	0.2	0.2	-5%
Total revenue	82.4	76.0	82.4	76.0	8%	82.4	76.0	8%
Cost of sales	-35.6	-32.2	-35.6	-32.2	10%	-35.6	-32.2	10%
Gross profit	46.8	43.8	46.8	43.8	7%	46.8	43.8	7%
% margin	<i>57.0%</i>	<i>57.8%</i>	<i>57.0%</i>	<i>57.8%</i>	-0,8pp	<i>57.0%</i>	<i>57.8%</i>	-0,8pp
R&D expenses	-6.9	-8.0	0.0	0.0	n.a.	-8.0	-8.0	n.a.
SG&A	-28.0	-25.6	-28.0	-25.6	9%	-28.0	-25.6	9%
Share of P/L of								
a JV	0.0	0.0	0.0	0.0	n.a.	0.0	0.0	n.a.
EBITDA	11.9	10.2	18.8	18.1	4%	10.8	10.2	7%
% margin	<i>14.4%</i>	13.4%	22.9%	23.9%	-1.1pp	13.2%	<i>13.4%</i>	-0.2pp
EBIT	7.5	7.3	14.4	15.2	-5%	6.5	7.3	-11%
% margin	9.2%	9.6%	<i>17.6%</i>	20.1%	<i>-2.5pp</i>	7.9%	9.6%	-1.7pp

As a result of the IFRS 16 application, **financial expense** increased by 18% in the first quarter of 2019, compared to the same period of the previous year.

Financial income decreased by 83% in the first quarter of 2019, compared to the first quarter of 2018.

The **effective tax rate** was 6.9% in the first quarter of 2019, compared to 2.6% in the first quarter of 2018. This favourable effective tax rate is due to the deduction of existing research and development expenses and the capitalisation of negative tax bases. As of 31 March 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 0.2 million euros in the first quarter of 2019.



While the Risperidone-ISM® Phase III trial is ongoing, adding higher R&D expenses, ROVI expects a very beneficial effective tax rate to be applicable, which could cause the income tax item to be positive income. Notwithstanding, when the R&D expenses are normalised after completion of the Phase III trial, the company expects the effective tax rate to be in mid-single-digit numbers (i.e. between 0 and 10%) in the following years.

Net profit increased by 1%, from 6.8 million euros in the first quarter of 2018 to 6.9 million euros in the first quarter of 2019. However, net profit "pre-R&D", calculated excluding R&D expenses in the first quarters of 2019 and 2018, decreased by 9%, from 14.6 million euros in the first quarter of 2018 to 13.3 million euros in the first quarter 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 quarter of 2019 as in the first quarter of 2018, net profit would have decreased by 13% to 5.9 million euros (see "Flat R&D costs" columns of the table below).

	Reported		w/o R&D costs		Flat	t R&D cos	sts	
€ million	Q1	Q1	Q1	Q1		Q1	Q1	
E IIIIIIOII	2019	2018	2019	2018	Chang	2019	2018	Chang
Operat. revenue	82.2	75.8	82.2	75.8	8%	82.2	75.8	8%
Other income	0.2	0.2	0.2	0.2	-5%	0.2	0.2	-5%
Total revenue	82.4	76.0	82.4	76.0	8%	82.4	76.0	8%
Cost of sales	-35.6	-32.2	-35.6	-32.2	10%	-35.6	-32.2	10%
Gross profit	46.8	43.8	46.8	43.8	7%	46.8	43.8	7%
% margin	<i>57.0%</i>	<i>57.8%</i>	<i>57.0%</i>	<i>57.8%</i>	-0,8pp	<i>57.0%</i>	<i>57.8%</i>	-0,8pp
R&D expenses	-6.9	-8.0	0.0	0.0	n.a.	-8.0	-8.0	n.a.
SG&A	-28.0	-25.6	-28.0	-25.6	9%	-28.0	-25.6	9%
Share of P/L of								
a JV	0.0	0.0	0.0	0.0	n.a.	0.0	0.0	n.a.
EBITDA	11.9	10.2	18.8	18.1	4%	10.8	10.2	7 %
% margin	<i>14.4%</i>	<i>13.4%</i>	22.9%	23.9%	<i>-1.1pp</i>	13.2%	<i>13.4%</i>	-0.2pp
EBIT	7.5	7.3	14.4	15.2	-5%	6.5	7.3	-11%
% margin	9.2%	9.6%	17.6%	20.1%	<i>-2.5pp</i>	7.9%	9.6%	-1.7pp
Net profit	6.9	6.8	13.3	14.6	-9%	5.9	6.8	-13%
% margin	8.4%	9.0%	<i>16.2%</i>	19.3%	-3.0pp	7.2%	9.0%	-1.8pp

In line with the Company's announcement in the Relevant Event dated 24 September, 2018 (concerning the capital increase carried out in September 2018), which stated that ROVI's Board of Directors had agreed to reflect on a possible adjustment of the present dividend distribution policy in order to maintain the Company's growth strategy, the Board of Directors has decided to put a proposal to the General Shareholders' Meeting to allocate the 2018 profit to, firstly, the reserves item on the Company's statement of financial position and, secondly, the distribution



of a dividend of 0.0798 euros per share entitled to receive it, which would entail the distribution of approximately 25% of the consolidated net profit for 2018 (in comparison with the 35% of the consolidated net profit that ROVI has been distributing as a dividend over recent years).

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that "we are very happy with the results of the first quarter of 2019. Total revenue increased by 8% 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, which was reflected in the first quarter of 2019 EBITDA figure. The capital increase carried out in October 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 3.3 million euros in the first quarter of 2019, compared to 2.5 million euros in the first quarter of 2018. Of this amount:

- 0.3 million euros corresponds to investment capex related to the injectable facility, versus
 0.2 million euros in the first quarter of 2018;
- 0.1 million euros relates to investment capex regarding the San Sebastián de los Reyes plant, versus 0.5 million euros in the first quarter of 2018;
- 0.6 million euros were invested in the Granada facility, versus 0.9 million euros in the first quarter of 2018;
- 1.3 million euros were invested in the Alcalá de Henares (Frosst Ibérica) facility, versus
 0.4 million euros in the first quarter of 2018; and
- 1.0 million euros relates to expenditure on maintenance and other capex, versus 0.4 million euros in the first quarter of 2018.

In addition, in the first quarter of 2019, ROVI invested 13.5 million euros in the acquisition of Polaramine® (see section 6.3).



	Q1 2019	Q1 2018	% Growth
Injectable plant	0.3	0.2	20%
San Sebastián de los Reyes plant	0.1	0.5	-75%
Granada plant	0.6	0.9	-34%
Alcalá de Henares plant (Frosst Ibérica)	1.3	0.4	216%
Expenditure on maintenance and other capex	1.0	0.4	154%
Total Capex	3.3	2.5	33%
Acquisitions	13.5	_	n.a

3.2 Debt

As a result of the IFRS 16 application, as of 31 March 2019, ROVI total debt increased to 50.8 million euros. Debt with public administration, which is 0% interest rate debt, represented 23% of total debt as of 31 March 2019.

In thousand euros	31 March 19	31 December 18
Bank borrowings	18,297	22,716
Debt with public administration	11,448	11,508
Financial liabilities for leases	21,008	-
Total	50,753	34,224

As of 31 March 2019, bank borrowings decreased by 4.4 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 31 March 2019, ROVI had drawn down 5 million euros against this credit line.

Financial liabilities for leases reached 21.0 million euros in the first quarter 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 -19.0 million euros in the first quarter of 2019 compared to 1.1 million euros in the first quarter of 2018 mainly due to (i) the increase of 14.3 million euros in Capex mainly as a result of the acquisition of Polaramine[®]; (ii) the increase of 13.4 million euros in the "inventories" line in the first quarter of 2019, compared to an increase of 6.3 million euros in the first quarter of 2018;



and (iii) the increase of 2.0 million euros in the "trade and other payables" item in the first quarter of 2019, compared to an increase of 4.9 million euros in the first quarter of 2018. The "trade and other receivables" line increased by 2.3 million euros in the first quarter of 2019, compared to an increase of 5.2 million euros in the first quarter of 2018.

3.4 Gross cash position and net debt

As a result of the IFRS 16 application in the first quarter of 2019, as of 31 March 2019, ROVI had a gross cash position of 72.8 million euros, compared to 97.0 million euros as of 31 December 2018, and net cash of 22.0 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 quarter of 2019 was mainly due to (i) an increase of 13.4 million euros in the "inventories" line, mainly due to higher heparin stock levels in the first quarter of 2019; (ii) an increase of 2.3 million euros in the "trade and other receivables" line; (iii) an increase of 2.0 million euros in the "trade and other payables" line; and (iv) a decrease of 24.2 million euros in the "cash and cash equivalents" item partially as a result of the acquisition of Polaramine[®] (13.5 million euros).

As of 31 March 2019, Social Security and Public Administrations total debt with ROVI amounted to 7.2 million euros, of which 3.8 million euros in Spain, 1.8 million euros in Portugal and 1.6 million euros in Italy.

4. Guidance for 2019

ROVI is upgrading its operating revenue guidance for the full year 2019, from high-single-digit growth rate to low-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 two 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 first half of 2019 but will finally continue to distribute them for the third quarter of 2019. In addition, ROVI announced the acquisition of Falithrom® (see section 6.4) and Polaramine® (see section 6.3) in



January and February 2019 respectively and the distribution agreement of Tetridar[®] (see section 6.1) in April 2019. Revenue related to these three products were not included in the guidance published on the nine-month period ending 30th September 2018 financial results press release.

ROVI expects its growth drivers to be Bemiparin, the latest license agreements (Tetridar®, Neparvis®, Volutsa®, Orvatez® and Ulunar®), 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®. On 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. Consequently, the company plans to file an NDA (New Drug Application) US Registration Dossier for the FDA (Food and Drug Administration), the second half 2019 (see section 6.2).

Besides, the first phase I clinical trial (the LISA-1 study²) of Letrozole ISM[®], is still ongoing. This new investigational medicine is the second candidate on clinical development using the Rovi's ISM[®] technology platform, which represents, to our best knowledge, the first long-acting injectable aromatase inhibitor intended for the treatment of hormone-dependent breast cancer.

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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].

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].



6. Key operating and financial events

6.1 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.

6.2 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 19^{th} 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.

6.3 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.

6.4 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 31 MARCH 2019 AND 31 DECEMBER 2018

	31 March 2019	31 December 2018
ASSETS		
Non-current assets		
Property, Plant and Equipment	117,283	95,837
Intangible assets	47,395	34,650
Investment in a joint venture	2,076	2,038
Deferred income tax assets	15,247	16,036
Equity securities	71	70
Financial receivables	65	65
	182,137	148,696
Current assets		
Inventories	108,309	94,861
Trade and other receivables	62,456	60,180
Current income tax assets	3,428	3,414
Financial derivatives	-	17
Prepaid expenses	27	21
Cash and cash equivalents	71,308	95,511
-	245,528	254,004
Total assets	427,665	402,700



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

	31 March 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	600	600
Treasury shares	(8,968)	(8,812)
Retained earnings and voluntary reserves	204,926	186,792
Profit for the period	6,897	17,895
Other reserves	(3)	(3)
Total equity	294,452	287,472
LIABILITIES		
Non-current liabilities		
Financial debt	33,300	16,589
Deferred income tax liabilities	800	1,243
Contract liabilities	6,186	6,263
Deferred income	3,529	3,621
	43,815	27,716
Current liabilities		
Financial debt	17,453	17,635
Trade and other payables	70,125	68,165
Contract liabilities	1,237	1,159
Deferred income	583	553
	89,398	87,512
Total liabilities	133,213	115,228
Total equity and liabilities	427,665	402,700



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED INCOME STATEMENTS FOR THE THREE-MONTH PERIODS ENDING 31 MARCH 2019 AND 31 MARCH 2018

	Three-month periods ending 31 March	
	2019	2018
Revenue	82,154	75,768
Changes in inventories of finished goods and work in progress	13,160	(4,702)
Raw materials and consumables used	(48,737)	(27,515)
Employee benefit expenses	(17,690)	(18,004)
Other operating expenses	(17,270)	(15,599)
Amortisation and depreciation	(4,336)	(2,896)
Recognition of government grants on non-financial non-current assets and other	213	225
Share in profits of joint venture	38	(15)
OPERATING PROFIT	7,532	7,262
Finance income	1	6
Finance costs	(215)	(245)
Impairment and gain or loss on measurement of financial		
instruments	(17)	-
Exchange difference	108	-
FINANCE COSTS - NET	(123)	(239)
PROFIT BEFORE INCOME TAX	7,409	7,023
Income tax	(512)	(185)
PROFIT FOR THE PERIOD	6,897	6,838



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED CASH FLOW STATEMENTS FOR THE THREE-MONTH PERIODS ENDING 31 MARCH 2019 AND 31 MARCH 2018

Thousands of euros)		
	Three-month periods ending 31 March	
	2019	2018
Cash flows from operating activities		
Profit before tax	7,409	7,023
Adjustments for non-monetary transactions:		
Amortisation	4,336	2,896
Finance income	(1)	(6)
Valuation allowance	(612)	1,352
Adjustments for changes in value of derivatives	17	-
Finance expense	107	245
Net changes in provisions	-	29
Grant on non-financial assets and income from distribution	(279)	(256)
Share of profit of joint venture	(38)	15
Changes in working capital:		
Trade and other receivables	(1,681)	(5,208)
Inventories	(13,174)	(7,511)
Other current assets (prepaid expenses)	(6)	-
Trade and other payables	1,872	4,939
Other collections and payments:	66	20
Proceeds from distribution licenses and other deferred revenue	66	20
Income tax cash flow	(181)	(3)
Other payments	(14) (2,179)	2 525
Net cash generated from (used in) operating activities Cash flows from investing activities	(2,179)	3,535
Purchases of intangible assets	(13,683)	(118)
Purchases of property, plant and equipment	(3,128)	(2,374)
Proceeds from sale of property, plant and equipment	(3,120)	12
Interest received	1	94
Net cash generated from (used in) investing activities	(16,810)	(2,386)
Cash flows from financing activities	(20/020/	(=/555)
Repayments of financial debt	(5,353)	(2,935)
Proceeds from financial debt	-	4
Interest paid	(34)	(54)
Purchase of treasury shares	(9 4 0)	(207)
Reissue of treasury shares	1,113	308
Net cash generated from (used in) financing activities	(5,214)	(2,884)
Net (decrease) increase in cash and cash equivalents	(24,203)	(1,735)
Cash and cash equivalents at the beginning of the period	95,511	40,700
Cash and cash equivalents at the end of the period	71,308	38,965