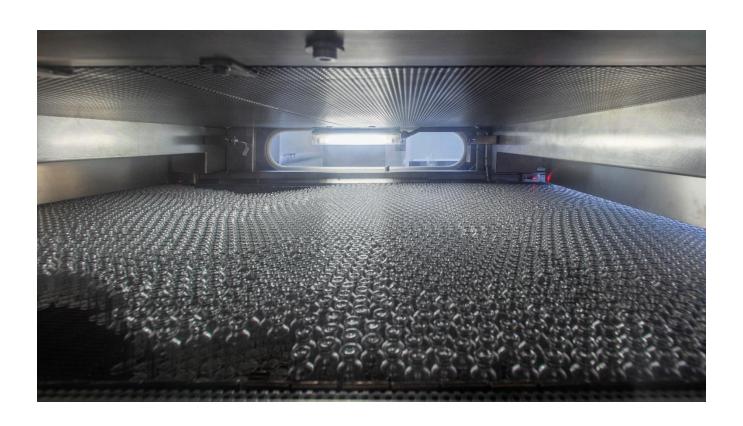


First Quarter 2018 Results

25th April 2018



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



ROVI – First Quarter 2018 Financial Results

ROVI reports operating revenue growth of 12% underpinned by outstanding Bemiparin sales

- Operating revenue increased by 12% to 75.8 million euros in the first quarter of 2018, driven by the strength of the specialty pharmaceutical business, where sales rose 23%, strongly outperforming the market. Total revenue increased by 12% to 76.0 million euros in the first quarter of 2018.
- ➤ In March 2018, ROVI commenced the marketing of Enoxaparin biosimilar in UK, one top Enoxaparin markets in Europe together with Germany where the company commenced marketing in September 2017.
- ➤ In April 2018, ROVI has signed a licensing agreement with Hikma Pharmaceuticals PLC, the quoted multinational pharmaceutical group (LSE: HIK), for the exclusive distribution and marketing of its Enoxaparin biosimilar in 17 MENA¹ (Middle East and North Africa) countries: Kingdom of Saudi Arabia, Jordan, Algeria, Egypt, Tunisia, Sudan, Syria, Yemen, Iraq, Oman, United Arab Emirates, Kuwait, Qatar, Bahrain, Libya, Palestine and Lebanon.
- By 31st March 2018, the countries with the national registration approved of the Enoxaparin biosimilar are Germany, France, United Kingdom, Italy, Norway, Sweden, Austria, Hungary, Slovenia, Estonia, Latvia, Slovakia, Bulgaria, Romania, Spain and Croatia.
- Sales of the Enoxaparin biosimilar amounted to 4.1 million euros in the first quarter of 2018.
- ➤ For 2018, ROVI expects a mid-single-digit growth rate for operating revenue with a range of 20-30 million-euro sales of Enoxaparin biosimilar, despite (i) a new reduction in sanitary expenditure from 6.0% to 5.8% of GDP expected for 2018, according to the 2018 Draft Budget Plan²; and (ii) 1-4% growth rate in spending on medicine in Spain to 2021 forecast by QuintilesIMS³.

¹ The agreement does not include Morocco and Lebanon has a semi-exclusive agreement.

² http://www.minhafp.gob.es/Documentacion/Publico/CDI/EstrategiaPoliticaFiscal/2018/PLAN_PRESUPUESTARIO_2018.pdf

³ Outlook for Global Medicines through 2021. Report by the QuintilesIMS Institute.



- ➤ Sales of Bemiparin increased 19% in the first quarter of 2018 to 24.0 million euros; this growth came from sales in Spain (20%) and from international sales (17%).
- ➤ Sales of Vytorin®, Orvatez® and Absorcol® had an outstanding performance with an increase of 47% to 13.0 million euros in the first quarter of 2018. In the second quarter of 2018, the active principle ezetimibe goes out of patent and a price reduction is expected in Absorcol®. However, generics formulated with ezetimibe and simvastatin have recently begun commercialization in the market, so ROVI is evaluating the most convenient way to protect his licensing rights.
- Sales of Volutsa[®], increased by 27% to 2.6 million euros, and sales of Hirobriz[®] Breezhaler[®] and Ulunar[®] Breezhaler[®] increased by 11% to 3.9 million euros in the first quarter of 2018, compared to the same period the previous year.
- > Sales of Neparvis[®], launched in December 2016, reached 2.7 million euros in the first quarter of 2018.
- ➤ EBITDA "Pre-R&D", calculated excluding R&D expenses in the first quarter of 2018 and 2017, increased by 10%, from 16.4 million euros in the first quarter of 2017 to 18.1 million euros in the first quarter of 2018, reflecting a 0.4 percentage point fall in the EBITDA margin to 23.9% in the first quarter of 2018. Likewise, recognising the same amount of R&D expenses in the first quarter of 2018 as in the first quarter of 2017, EBITDA would have increased by 17% to 12.0 million euros, reflecting a 0.6 percentage point rise in the EBITDA margin to 15.8% in the first quarter of 2018.
- Net profit "Pre-R&D", calculated excluding R&D expenses in the first quarter of 2018 and 2017, increased by 21%, from 12.0 million euros in the first quarter of 2017 to 14.6 million euros in the first quarter of 2018. Likewise, recognising the same amount of R&D expenses in the first quarter of 2018 as in the first quarter of 2017, net profit would have increased by 35% to 8.6 million euros.
- ➤ ROVI will propose to the Shareholders General Meeting a dividend of 0.1207 euros per share with dividend rights on 2017 earnings. This proposed dividend represents a 35% pay out.



Madrid (Spain), 25th April 2018, 8:00 AM CET - ROVI released today its financial results for the first quarter of 2018.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said "in the first guarter of 2018, we reached 12% operating revenue growth mainly driven by the specialty pharmaceutical business strength, where sales rose by 23%. According to QuintilesIMS, the Spanish innovative product market decreased by 1% in the first quarter of 2018. 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 20%. Furthermore, we expect a number of factors to contribute to our growth in forthcoming years: (i) 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; (ii) our entry into the respiratory market through Hirobriz® Breezhaler® and Ulunar® Breezhaler® from Novartis, launched in Spain in December 2014; (iii) our entry into the urology field through the launch of Volutsa®, from Astellas Pharma, in Spain in February 2015; and (iv) the strengthening of the hypercholesterolaemia franchise through the launch of Orvatez®, from Merck Sharp and Dohme (MSD), in Spain in June 2015. These launches cover growing demand needs and we expect them to provide us with a sustainable and profitable growth opportunity in the future. 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 started a Phase III trial with our ISM® technology in the second quarter of 2017 with the recruitment of the first patient and we shared the project update with the market. We also started a new Phase I study for another candidate, Letrozole, in November 2017. Likewise, we continue the national phase of the registration process of our Enoxaparin biosimilar in Europe, with its approval in 16 countries before 31st March 2018. ROVI has signed an important licensing agreement to distribute and market our Enoxaparin biosimilar with Hikma Pharmaceuticals, who has the exclusive rights for 17 Middle East and North Africa countries. Likewise, we continue marketing in Germany and have started commercialization in UK, two of the top Enoxaparin markets in Europe (in terms of volume and value), with good sales prospects, as reflected in the first quarter of 2018, when sales were 4 million euros. The Enoxaparin biosimilar represents an excellent growth opportunity for us considering the size of the European Enoxaparin market, which totals more than 1 billion euros. In 2017, ROVI started its internationalisation process, setting up subsidiaries in the main European countries: Germany, United Kingdom, France and Italy. 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".



1. Financial highlights

<i>€ million</i>	1Q 2018	1Q 2017	Growth	% Growth
Operating revenue	75.8	67.5	8.3	12%
Other income	0.2	0.3	-0.1	-27%
Total revenue	76.0	67.8	8.2	12%
Cost of sales	-32.2	-26.3	-5.9	23%
Gross profit	43.8	41.5	2.3	5%
% margin	<i>57.8%</i>	61.5%		<i>-3.7pp</i>
R&D expenses	-8.0	-6.2	-1.8	29%
Other SG&A	-25.6	-25.1	-0.6	2%
EBITDA	10.2	10.2	-0.1	-1%
% margin	<i>13.4%</i>	<i>15.2%</i>		<i>-1.8pp</i>
EBIT	7.3	7.3	0.0	0%
% margin	9.6%	10.8%		-1.2pp
Net profit	6.8	6.4	0.5	7%

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 2018 and the comparative information for 2017 (balance sheet) and for the first quarter of 2017 (consolidated income statement and cash flow statement) are attached to this report (see Appendix 1).

2. Performance of the Group

Operating revenue increased by 12% to 75.8 million euros in the first quarter of 2018, driven by the strength of the specialty pharmaceutical business, where sales rose 23%, strongly outperforming the market. Total revenue increased by 12% to 76.0 million euros in the first quarter of 2018.

€ million	1Q 2018	1Q 2017	% Growth
Specialty pharmaceutical business	63.8	51.9	23%
Toll manufacturing business	12.0	15.5	-23%
Royalties	0.0	0.0	-53%
Total operating revenue	75.8	67.5	12%

Sales of **prescription-based pharmaceutical** products rose 27% to 55.8 million euros in the first quarter of 2018.



<i>€ million</i>	1Q 2018	1Q 2017	% Growth
Prescription-based pharmaceutical products	55.8	43.9	27%
Bemiparin (Hibor)	24.0	20.1	19%
Sales in Spain	16.9	14.0	20%
International sales	7.1	6.1	17%
Enoxaparin biosimilar (Enoxaparin Becat)	4.1	-	n.a.
Vytorin & Absorcol & Orvatez	13.0	8.8	47%
Ulunar & Hirobriz	3.9	3.5	11%
Volutsa	2.6	2.0	27%
Medikinet & Medicebran	2.0	2.0	-1%
Neparvis	2.7	0.4	6.7x
Exxiv	0.6	1.2	-50%
Other	3.0	5.9	-48%
Contrast agents and other hospital products	7.5	7.4	2%
Non prescription pharmaceutical products ("OTC") and Other	0.4	0.6	-33%
Total specialty pharmaceutical business	63.8	51.9	23%

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, had a positive performance in the first quarter of 2018, with sales up 19% to 24.0 million euros. Sales of Bemiparin in Spain (**Hibor**®) increased by 20% to 16.9 million euros, while international sales increased by 17% to 7.1 million euros.

Sales of the **Enoxaparin biosimilar** in Germany and UK amounted to 4.1 million euros in the first guarter of 2018.

Sales of **Vytorin®**, **Orvatez®** and **Absorcol®**, the first of the five licenses of MSD, indicated as adjunctive therapy to diet in patients with hypercholesterolemia, increased by 47% to 13.0 million euros in the first quarter of 2018. In the second quarter of 2018, the active principle ezetimibe goes out of patent and a price reduction is expected in Absorcol®. However, generics formulated with ezetimibe and simvastatin have recently begun commercialization in the market, so ROVI is evaluating the most convenient way to protect his licensing rights.

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, increased by 11% to 3.9 million euros in the first quarter of 2018, compared to the same quarter 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 27% to 2.6 million euros in the first quarter of 2018.

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, decreased by 1% to 2.0 million euros in the first quarter of 2018.

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 2.7 million euros in the first quarter of 2018, compared to 0.4 million euros in the same period of 2017.

Sales of **Exxiv**®, a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 50% to 0.6 million euros in the first quarter of 2018, mainly due to a continued deceleration of the COX-2 market.

According to QuintilesIMS, Spanish innovative product market decreased by 1% in the first quarter of 2018 compared to the same period the previous year. Nevertheless, ROVI prescription-based pharmaceutical product sales rose 27% in the same period, beating the market by 28 percentage points.

Also, prescription-based pharmaceutical market covering the 12-month period ending March 2018 increased by 2% compared to the same period the previous year. However, ROVI prescription-based pharmaceutical product sales rose 8% in the last year.

For 2018, a new reduction in healthcare expenditure from 6.0% to 5.8% of GDP is expected (the lowest health spending forecast since 2007), according to the 2018 Draft Budget Plan¹, and a 1-4% growth rate in spending on medicine in Spain to 2021, is forecast by QuintilesIMS². Despite the difficult situation the Spanish pharmaceutical industry continues to go through, ROVI forecasts to continue to grow above the growth estimates of the pharmaceutical expenditure.

Sales of **contrast imaging agents** and other hospital products increased by 2% to 7.5 million euros in the first quarter of 2018.

Sales of **over-the-counter pharmaceutical products** ("OTC") **and other** decreased by 33% to 0.4 million euros in the first quarter of 2018 compared to the same period the previous year.

Toll manufacturing sales decreased by 23% to 12.0 million euros in the first quarter of 2018, compared to the same period the previous year, mainly because of the reduction of the

¹ http://www.minhafp.gob.es/Documentacion/Publico/CDI/EstrategiaPoliticaFiscal/2018/PLAN_PRESUPUESTARIO_2018.pdf

² Outlook for Global Medicines through 2021. Report by the QuintilesIMS Institute.



injectable business compared to Q1 2017, when exceptional high volumes were manufactured for some customers. Frosst Ibérica plant sales increased by 13% to 7.0 million euros in the first quarter of 2018 compared to the same period the previous year. By the end of 2018, a moderate decline in toll manufacturing is expected.

<i>€ million</i>	1Q 2018	1Q 2017	% Growth
Injectable business	5.0	9.3	-46%
Oral forms business (Frosst Ibérica)	7.0	6.2	13%
Total toll manufacturing business	12.0	15.5	-23%

Sales outside Spain increased by 8% to 21.5 million euros in the first quarter of 2018 compared to the same period the previous year mainly due to (i) the Bemiparin international sale increase; and (ii) the registration of Enoxaparin biosimilar sales. Sales outside Spain represented 28% of operating revenue in the first quarter of 2018, reflecting a 1.1 percentage point fall in the first quarter of 2018, compared to the first quarter of 2017.

Other income (subsidies) decreased by 27% to 0.2 million euros in the first quarter of 2018 from 0.3 million euros in the first quarter of 2017.

Gross profit increased by 5% to 43.8 million euros in the first quarter of 2018, reflecting a decrease of 3.7 percentage points in the gross margin to 57.8% from 61.5% in the first quarter of 2017, mainly due to the decrease of injectable business which adds higher margins. Sales of Enoxaparin biosimilar had a positive impact on first quarter of 2018, nevertheless some gross margin erosion is expected in the future, as the product will be launch in other markets.

Research and development expenses (R&D) mainly related to ISM® technology platform rose 29% to 8.0 million euros in the first quarter of 2018 mainly due to the development of the Risperidone-ISM® Phase III trial and the Letrozole-ISM® Phase I trial.

Selling, general and administrative expenses (SG&A) increased 2% to 25.6 million euros in the first quarter of 2018, compared to the same period the previous year, mainly due to international subsidiaries expenses, which amounted to 1.1 million euros.

€ million	1Q 2018	1Q 2017	% Growth
Personnel expenses	18.0	16.1	12%
Other operating expenses (exc. R&D)	7.6	9.0	-15%
Total SG&A expenses	25.6	25.1	2%
Expenses related to intern. subsidiaries	1.1	0.1	11x

EBITDA decreased to 10.2 million euros in the first quarter of 2018, a fall of 1% compared to the same period the previous year, reflecting a 1.8 percentage point decrease in the EBITDA margin, which was down to 13.4% in the first quarter of 2018 from 15.2% in the first quarter



of 2017. However, EBITDA "Pre-R&D", calculated excluding R&D expenses in the first quarter of 2018 and 2017, increased by 10%, from 16.4 million euros in the first quarter of 2017 to 18.1 million euros in the first quarter of 2018, reflecting a 0.4 percentage point fall in the EBITDA margin to 23.9% in the first quarter of 2018 (see "Pre-R&D costs" columns of the table below). Likewise, recognising the same amount of R&D expenses in the first quarter of 2018 as in the first quarter of 2017, EBITDA would have increased by 17% to 12.0 million euros, reflecting a 0.6 percentage point rise in the EBITDA margin to 15.8% in the first quarter of 2018, up from 15.2% in the first quarter of 2017 (see "Flat R&D costs" columns of the table below).

	Reported		Pre	Pre-R&D costs			Flat R&D costs	
€ million	1Q 2018	1Q 2017	1Q 2018	1Q 2017	Chang	1Q 2018	1Q 2017	Chang
Operat. revenue	75.8	67.5	75.8	67.5	12%	75.8	67.5	12%
Other income	0.2	0.3	0.2	0.3	-27%	0.2	0.3	-27%
Total revenue	76.0	67.8	76.0	67.8	12%	76.0	67.8	12%
Cost of sales	-32.2	-26.3	-32.2	-26.3	23%	-32.2	-26.3	23%
Gross profit	43.8	41.5	43.8	41.5	5%	43.8	41.5	5%
% margin	<i>57.8%</i>	61.5%	<i>57.8%</i>	61.5%	-3.7pp	<i>57.8%</i>	61.5%	-3.7pp
R&D expenses	-8.0	-6.2	0.0	0.0	n.a.	-6.2	-6.2	n.a.
Other SG&A	-25.6	-25.1	-25.6	-25.1	2%	-25.6	-25.1	2%
EBITDA	10.2	10.2	18.1	16.4	10%	12.0	10.2	17%
% margin	<i>13.4%</i>	<i>15.2%</i>	23.9%	<i>24.3%</i>	-0.4pp	<i>15.8%</i>	<i>15.2%</i>	0.6pp

Depreciation and amortisation expenses decreased by 2% to 2.9 million euros in the first quarter of 2018, mainly due to the decrease in new property, plant and equipment and intangible assets purchases made during the last twelve months.

EBIT remained flat in 7.3 million euros in the first quarter of 2018, reflecting a 1.2 percentage point decrease in the EBIT margin, which was down to 9.6% in the first quarter of 2018 from 10.8% in the first quarter of 2017. However, EBIT "pre-R&D", calculated excluding R&D expenses in the first quarter of 2018 and 2017, increased by 13%, from 13.5 million euros in the first quarter of 2017 to 15.2 million euros in the first quarter of 2018, reflecting a 0.1 percentage point rise in the EBIT margin to 20.1% in the first quarter of 2018 (see "Pre-R&D costs" columns of the table below). Likewise, recognising the same amount of R&D expenses in the first quarter of 2018 as in the first quarter of 2017, EBIT would have increased by 24% to 9.1 million euros, reflecting a 1.1 percentage point rise in the EBIT margin to 12.0% in the first quarter of 2018, up from 10.8% in the first quarter of 2017 (see "Flat R&D costs" columns of the table below).



	Repo	rted	Pre	e-R&D cos	sts	Fla	t R&D co	sts
<i>€ million</i>	1Q	1Q	1Q	1Q		1Q	1Q	
	2018	2017	2018	2017	Chang	2018	2017	Chang
Operat revenue	75.8	67.5	75.8	67.5	12%	75.8	67.5	12%
Operat. revenue					_		67.5	_
Other income	0.2	0.3	0.2	0.3	-27%	0.2	0.3	-27%
Total revenue	76.0	67.8	76.0	67.8	12%	76.0	67.8	12%
Cost of sales	-32.2	-26.3	-32.2	-26.3	23%	-32.2	-26.3	23%
Gross profit	43.8	41.5	43.8	41.5	5%	43.8	41.5	5%
% margin	<i>57.8%</i>	61.5%	<i>57.8%</i>	61.5%	<i>-3.7pp</i>	<i>57.8%</i>	61.5%	-3.7pp
R&D expenses	-8.0	-6.2	0.0	0.0	n.a.	-6.2	-6.2	n.a.
Other SG&A	-25.6	-25.1	-25.6	-25.1	2%	-25.6	-25.1	2%
EBITDA	10.2	10.2	18.1	16.4	10%	12.0	10.2	17%
% margin	<i>13.4%</i>	<i>15.2%</i>	23.9%	<i>24.3%</i>	-0.4pp	15.8%	<i>15.2%</i>	0.6pp
EBIT	7.3	7.3	15.2	13.5	13%	9.1	7.3	24%
% margin	9.6%	<i>10.8%</i>	20.1%	20.0%	0.1pp	12.0%	<i>10.8%</i>	1.1pp

Financial expense decreased by 4% in the first quarter of 2018, compared to the same period the previous year.

Financial income decreased by 45% in the first quarter of 2018, compared to the first quarter of 2017, due to the reduction of delay interests from Court decisions related to pending invoices due for collection from Public Administration in 2017.

The **effective tax rate** was 2.6% in the first quarter of 2018 compared to 8.5% in the first quarter of 2017. This favourable effective tax rate is due to the deduction of existing research and development expenses and the capitalisation of negative tax bases from Frosst Ibérica, S.A. As of 31 March 2018, Frosst Ibérica negative tax bases amounted to 35.1 million euros, of which 1.5 million euros will be used in the 2017 income tax and 0.6 million euros in the first quarter of 2018.

However, ROVI expects to maintain a mid-single-digit effective tax rate for the foreseeable future.

Net profit increased by 7%, from 6.4 million euros in the first quarter of 2017 to 6.8 million euros in the first quarter of 2018. However, net profit of the "pre-R&D", calculated excluding R&D expenses in the first quarter of 2018 and 2017, increased by 21%, from 12.0 million euros in the first quarter of 2017 to 14.6 million euros in the first quarter of 2018 (see "pre-R&D costs" columns of the table below). Likewise, recognising the same amount of R&D expenses in the first quarter of 2018 as in the first quarter of 2017, net profit would have increased by 35% to 8.6 million euros (see "Flat R&D costs" columns of the table below).



	Repo	rted	Pre	Pre-R&D costs		Fla	t R&D co	sts
€ million	1Q 2018	1Q 2017	1Q 2018	1Q 2017	Chang	1Q 2018	1Q 2017	Chang
Operat. revenue Other income	75.8 0.2	67.5 0.3	75.8 0.2	67.5 0.3	12% -27%	75.8 0.2	67.5 0.3	12% -27%
Total revenue Cost of sales	76.0 -32.2	67.8 -26.3	76.0 -32.2	67.8 -26.3	12% 23%	76.0 -32.2	67.8 -26.3	12% 23%
Gross profit % margin	43.8 <i>57.8%</i>	41.5 61.5%	43.8 <i>57.8%</i>	41.5 61.5%	5% -3.7pp	43.8 57.8%	41.5 61.5%	5% -3.7pp
R&D expenses Other SG&A	-8.0 -25.6	-6.2 -25.1	0.0 -25.6	0.0 -25.1	n.a. 2%	- 6.2 -25.6	-6.2 -25.1	n.a. 2%
EBITDA % margin	10.2 13.4%	10.2 15.2%	18.1 23.9%	16.4 24.3%	10% -0.4pp	12.0 15.8%	10.2 15.2%	17% 0.6pp
EBIT <u>% margin</u>	7.3 9.6%	7.3 10.8%	15.2 20.1%	13.5 20.0%	13% 0.1pp	9.1 12.0%	7.3 10.8%	24% 1.1pp
Net profit % margin	6.8 9.0%	6.4 9.4%	14.6 19.3%	12.0 <i>17.8%</i>	21% 1.4pp	8.6 11.3%	6.4 9.4%	35% 1.9pp

ROVI will pay a **dividend** of 0.1207 euros per share with dividend rights on 2017 earnings if the Shareholders General Meeting approves the application of the 2017 profit, under proposal of ROVI's Board of Directors. This proposed dividend represents a 35% pay out.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that "we are happy with the results of the first quarter of 2018. Total revenue increased by 12% thanks to the strength of our leading products, which continue to enjoy good sales prospects. The commencement 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 2018 EBITDA figure. However, the EBITDA "pre-R&D" increased by 10% reflecting the good performance of the traditional business. We continue to have a strong balance sheet and an excellent cash-generating capacity, which allow us to finance organic growth through the launch of new products, such as Neparvis®, Volutsa®, Ulunar® and Orvatez®, and to be in a strong position to benefit in the current operating environment, as we will pay special attention to potential opportunities to expand our sales base and improve the utilisation of our asset base".



3. Balance Sheet items

3.1 Capital expenditure

ROVI invested 2.5 million euros in the first quarter of 2018, compared to 3.1 million euros in the first quarter of 2017. Of this amount:

- 0.2 million euros corresponds to investment capex related to the injectable facility, versus
 0.5 million euros in the first quarter of 2017;
- 0.5 million euros relates to investment capex regarding the San Sebastián de los Reyes plant, versus 0.1 million euros in the first guarter of 2017;
- 1.4 million euros were invested in the Granada and Alcalá de Henares (Frosst Ibérica) facilities, versus 0.1 million euros in the first guarter of 2017; and
- 0.4 million euros relates to expenditure on maintenance and other capex, versus 2.4 million euros in the first quarter of 2017.

	1Q 2018	1Q 2017	% Growth
Injectable plant	0.2	0.5	-57%
San Sebastián de los Reyes plant	0.5	0.1	4x
Granada & Alcalá de Henares plants (Frosst Ibérica)	1.4	0.1	20x
Expenditure on maintenance and other capex	0.4	2.4	-83%
Total Capex	2.5	3.1	-19%

3.2 Debt

As of 31 March 2018, ROVI had total debt of 40.4 million euros. Debt with public administration, which is 0% interest rate debt, represented 30% of total debt as of 31 March 2017.

In thousand euros	31 March 18	31 December 17
Bank borrowings	28,424	30,938
Debt with public administration	11,996	12,299
Total	40,420	43,237

As of 31 March 2018, bank borrowings decreased by 2.5 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.



3.3 Free cash flow

Free cash flow (net cash generated (used) from operating activities minus (plus) property, plant and equipment and intangible assets purchases (sales) plus interest received) increased to 1.1 million euros in the first quarter of 2018 compared to -11.3 million euros in the first quarter of 2017 mainly due to (i) the increase of 4.9 million euros in the "trade and other payables" item in the first quarter of 2018, compared to a decrease of 9.9 million euros in the first quarter of 2017; (ii) the increase of 5.2 million euros in the "trade and other receivables" item in the first quarter of 2018, compared to an increase of 5.6 million euros in the first quarter of 2017; and (iii) the decrease of 0.6 million euros in capex.

3.4 Gross cash position and net debt

As of 31 March 2018, ROVI had gross cash position of 40.4 million euros, compared to 42.1 million euros as of 31 December 2017, and net debt of 0.01 million euros (available-for-sale financial assets plus deposits plus cash and cash equivalents minus short term and long term financial debt), compared to net debt of 1.1 million euros as of 31 December 2017.

3.5 Working capital

The increase in working capital in the first quarter of 2018 was mainly due to (i) an increase in the "inventories" line of 6.3 million euros mainly due to higher heparin stock levels in the first quarter of 2018; (ii) an increase in the "trade and other payables" line of 4.9 million euros; (iii) an increase in the "trade and other receivables" line of 5.2 million euros; and (iv) a decrease in the "cash and cash equivalents" item of 1.7 million euros.

As of 31 March 2018, Social Security and Public Administrations total debt with ROVI amounted to 5.2 million euros, of which 3.7 million euros in Spain and the other 1.5 million euros in Portugal.

4. Guidance for 2018

In 2018, ROVI expects a mid-single digit growth rate for the operating revenue with a range of 20 to 30 million-euro sales of Enoxaparin biosimilar, despite (i) a new reduction in health expenditure from 6.0% to 5.8% of GDP expected for 2018 (the lowest health spending forecast since 2007), according to the 2018 Draft Budget Plan¹, and (ii) 1-4% growth rate in spending on medicine in Spain to 2021 forecast by QuintilesIMS².

¹ http://www.minhafp.gob.es/Documentacion/Publico/CDI/EstrategiaPoliticaFiscal/2018/PLAN_PRESUPUESTARIO_2018.pdf

² Outlook for Global Medicines through 2021. Report by the QuintilesIMS Institute.



ROVI expects its growth drivers to be Bemiparin, the latest license agreements (Neparvis®, Volutsa®, Orvatez® and Ulunar®), the Enoxaparin biosimilar, its existing portfolio of specialty pharmaceuticals, new product distribution licenses and new contracts in the toll manufacturing area.

In 2018, the active principle ezetimibe goes out of patent and a price reduction is expected in Absorcol®.

Likewise, ROVI expects to stop distributing Merus Labs products (Sintrom[®], Salagen[®], Cordiplast[®] and Estraderm[®]) as of the fourth quarter of 2018.

5. Research and Development update

ISM® technology platform

As previously informed, ROVI has progressed in the development of DORIA®, the first candidate for its leading-edge drug delivery technology, ISM®, for a prolonged release of risperidone, a well-stablished second-generation antipsychotic medicine.

After successfully finishing the phase I & II program^{1,2} of DORIA[®], ROVI started the pivotal phase III trial "PRISMA-3"³ with the recruitment of the first patient in May 2017. An update of the project with details of the design and cost of Phase III was released, together with a presentation to analysts on 24th October 2017 (see section 6.3).

On the other hand, ROVI continues with the first Phase I clinical trial⁴ of Letrozol ISM[®] initiated in November 2017. Letrozol ISM[®] is a long-acting injectable aromatase inhibitor intended for the treatment of hormone-dependent breast cancer.

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¹ Llaudó J, et al. Phase I, open-label, randomized, parallel study to evaluate the pharmacokinetics, safety, and tolerability of one intramuscular injection of risperidone ISM at different dose strengths in patients with schizophrenia or schizoaffective disorder (PRISMA-1). Int Clin Psychopharmacol. 2016;31(6):323-31.

² Carabias LA, et al. A phase II study to evaluate the pharmacokinetics, safety, and tolerability of Risperidone ISM multiple intramuscular injections once every 4 weeks in patients with schizophrenia. Int Clin Psychopharmacol. 2017 Nov 3. doi: 10.1097/YIC.0000000000000203. [Epub ahead of print]

³ 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].

⁴ Evaluation of IM Letrozole ISM® Pharmacokinetics, Safety, and Tolerability in Healthy Post-menopausal Women (LISA-1). [https://clinicaltrials.gov/ct2/show/NCT03401320?term=letrozole&rank=4].



6. Key operating and financial events

6.1 ROVI has commenced the marketing of the Enoxaparin biosimilar in Germany and UK, and has reached a distribution and marketing agreement with Hikma

ROVI informed (by publication of the relevant fact number 249265 dated 7th of March of 2017) that the decentralised procedure used for the Company to submit, in 26 countries of the European Union, the marketing authorization application of a low molecular weight heparin (Enoxaparin biosimilar) was completed with positive outcome.

In the mentioned decentralised procedure, Germany has acted as Reference Member State (RMS). The national phase of the registration process, which is expected to be completed with the granting by the competent local authorities of the marketing authorisation in each concerned country, was initiated in the first quarter 2017, and it continued during the rest of the year and the first quarter of 2018.

In September 2017, ROVI informed by publication of a relevant fact (number 256121) about the commencement of marketing of Enoxaparin biosimilar in Germany, the first European country where ROVI launches its biosimilar and one of the top Enoxaparin countries in Europe (in terms of volume and value). In March 2018, ROVI commenced the marketing of Enoxaparin biosimilar in UK.

As of 31st March 2018, the countries with the registration national phase approved are Germany, France, United Kingdom, Italy, Norway, Sweden, Austria, Hungary, Slovenia, Estonia, Latvia, Slovakia, Bulgaria, Romania, Spain and Croatia.

In April 2018, ROVI has signed a licensing agreement with Hikma Pharmaceuticals PLC, the quoted multinational pharmaceutical group (LSE: HIK), for the exclusive distribution and marketing of its Enoxaparin biosimilar in 17 MENA¹ (Middle East and North Africa) countries: Kingdom of Saudi Arabia, Jordan, Algeria, Egypt, Tunisia, Sudan, Syria, Yemen, Iraq, Oman, United Arab Emirates, Kuwait, Qatar, Bahrain, Libya, Palestine and Lebanon.

By April 2018, ROVI has distribution and marketing agreements for the Enoxaparin biosimilar in 29 countries: Kingdom of Saudi Arabia, Jordan, Algeria, Egypt, Tunisia, Sudan, Syria, Yemen, Iraq, Oman, United Arab Emirates, Kuwait, Qatar, Bahrain, Libya, Palestine, Lebanon, Costa Rica, Panamá, Morocco, Serbia, Montenegro, Israel, West Bank, Gaza, Brunei, Austria, Estonia and Latvia.

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¹ The agreement does not include Morocco and Lebanon has a semi-exclusive agreement.



ROVI will regularly update the milestones considered relevant in this process of marketing authorisation as the schedule of the registration of the medicinal product progresses in each country.

6.2 ROVI updates the Phase III-PRISMA 3 project of Risperidone ISM®, called DORIA®

On 24th of October 2017, the company released a relevant fact (number 257683) updating the evolution of Phase III-PRISMA 3 of Risperidone ISM[®], called DORIA[®].

As mentioned before, in May 2017, ROVI began a Phase III study for a long-acting injectable (LAI) based in the ISM® technology patented by ROVI, to treat schizophrenia called DORIA® (previously Risperidone ISM®).

Schizophrenia diagnosed disorders affects around 3 million patients (Source IMS) in US and Europe, and although it has no cure, there are effective treatments to control symptoms. These treatments use Second-Generation of Antipsychotics (SGA) medications with a predictable efficacy and safety profile, and risperidone is the most used active principle.

ROVI has developed DORIA®, and expects a good evolution in Phase III, as the Active Principle is one of the most prescribed for schizophrenic patients (risperidone) and ISM® technology has been proved in Phase I&II studies.

Long-acting injectables (LAIs) are becoming the goal standard for schizophrenia compared to oral treatments, and with DORIA[®], ROVI is aiming to play a relevant role in the US and Europe Schizophrenia LAIs market, with an estimated total value in 2021 of 3.4 billion dollars (2.5 billion dollars in US and 930 million dollars in Top-5 Europe) (IMS Source).

The strategic drivers of DORIA® are:

- Long acting injectable (LAI) based on the ISM® technology developed by ROVI.
- LAI is becoming the goal standard for Schizophrenia.
- A good pharmacological profile providing a rapid onset allowing a once monthly injection without oral supplementation and loading dose.
- One monthly represents a fully medically supervised patient: eradicates all potential issues that may arise with an oral product.
- A monthly injection provides a better control of patients avoiding relapses.
- One monthly ensures a relapse rate improvement which on a pharmacoeconomic basis that justifies a cost effective of LAIs.

ROVI will regularly update the milestones considered relevant in this Phase III-PRISMA 3 process.



About ROVI

ROVI is a fully integrated Spanish specialty pharmaceutical company engaged in the research, development, in-licensing, manufacturing and marketing of small molecule and specialty biologic drugs. The Company has a diversified portfolio of products that it markets in Spain through its specialized sales force, calling on specialist physicians, hospitals and pharmacies. ROVI's portfolio of 30 principal marketed products is currently anchored by the internallydeveloped, second generation low molecular weight heparin, Bemiparin. ROVI's research and development pipeline is focused primarily on the expansion of applications, indications and alternative mechanisms of action for the heparin-derived products glycosaminoglycans and on the development of new controlled release mechanisms based on ISM® technology, with the aim of obtaining new pharmaceutical products that enable the regular administration of formulations which are administered daily in chronic and prolonged treatments. ROVI manufactures the active biological ingredient (Bemiparin) for its principal proprietary products and for injectable pharmaceutical products developed by its in-house research team, and utilizes its state-of-the-art filling and packaging capabilities to provide a broad array of toll manufacturing services to leading international pharmaceutical companies, primarily in the area of pre-filled syringes. In addition, ROVI provides contract manufacturing and packaging services of solid oral pharmaceutical dosage forms, using the most enhanced technology, Roller Compaction. Additional information about ROVI is available on the company's website: 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 2018 AND 31 DECEMBER 2017

	31 March 2018	31 December 2017
ASSETS		
Non-current assets		
Property, Plant and Equipment	89,129	89,056
Intangible assets	26,589	27,078
Investment in a joint venture	2,039	2,054
Deferred income tax assets	12,411	11,893
Available-for-sale financial assets	69	69
Financial receivables	65	65
	130,302	130,215
Current assets		
Inventories	81,784	75,492
Trade and other receivables	54,985	49,747
Current income tax assets	1,283	2,228
Cash and cash equivalents	38,965	40,700
	177,017	168,167
Total assets	307,319	298,382



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS AS OF 31 MARCH 2018 AND 31 DECEMBER 2017

	31 March 2018	31 December 2017
EQUITY		
Capital and reserves attributable to		
shareholders of the company		
Share capital	3,000	3,000
Legal reserve	600	600
Treasury shares	(8,383)	(8,407)
Retained earnings and voluntary reserves	196,573	179,255
Profit for the period	6,838	17,241
Reserve for available-for-sale assets	(3)	(2)
Total equity	198,625	191,687
LIABILITIES		
Non-current liabilities		
Financial debt	22,285	27,029
Deferred income tax liabilities	1,194	1,438
Deferred revenues	5,029	5,005
	28,508	33,472
Current liabilities		
Financial debt	18,135	16,208
Trade and other payables	57,881	52,942
Deferred revenues	633	565
Provisions for other liabilities and charges	3,537	3,508
	80,186	73,223
Total liabilities	108,694	106,695
Total equity and liabilities	307,319	298,382



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED INCOME STATEMENTS FOR THE THREE-MONTH PERIODS ENDING 31 MARCH 2018 AND 31 MARCH 2017

	Three-month periods ending 31 March	
	2018	2017
Revenue	75,768	67,460
Cost of sales	(32,217)	(26,269)
Employee benefit expenses	(18,004)	(16,083)
Other operating expenses	(15,599)	(15,169)
Amortisation	(2,896)	(2,941)
Recognition of government grants on non financial non-		
current assets and other	225	310
OPERATING PROFIT	7,277	7,308
Finance income	6	11
Finance costs	(245)	(254)
FINANCE COSTS - NET	(239)	(243)
Share of profit of a joint venture	(15)	(96)
PROFIT BEFORE INCOME TAX	7,023	6,969
Income tax	(185)	(595)
PROFIT FOR THE PERIOD	6,838	6,374



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED CASH FLOW STATEMENTS FOR THE THREE-MONTH PERIODS ENDING 31 MARCH 2018 AND 31 MARCH 2017

indusands of euros)		1
	Three-month periods ending 31 March	
	2018	2017
Cash flows from operating activities		
Profit before income tax	7,023	6,969
Adjustments for non-monetary transactions:		
Amortisation	2,896	2,941
Interest income	(6)	(11)
Impairment	1.352	261
Interest expense	245	254
Net changes in provisions	29	36
Grant for non-financial fixed assets and income from distribution	(256)	(353)
Share of profit of a joint venture	15	96
Changes in working capital:		
Trade and other receivables	(5,208)	(5,198)
Inventories	(7,511)	(5,024)
Trade and other payables	4,939	(9,938)
Other collections and payments:		
Proceeds from distribution licenses	20	(30)
Income tax cash flow	(3)	1,746
Net cash generated (used) from operating activities	3.535	(8,251)
Cash flows from investing activities		
Purchases of intangible assets	(118)	(2,319)
Purchases of property, plant and equipment	(2,374)	(757)
Proceeds from sale of property, plant and equipment	12	-
Interest received	94	6
Net cash generated (used) in investing activities	(2,386)	(3,070)
Cash flows from financing activities		
Repayments of financial debt	(2,935)	(2,803)
Proceeds from financial debt	4	20,224
Interest paid	(54)	(56)
Purchase of treasury shares	(207)	(167)
Reissue of treasury shares	308	407
Net cash generated (used) in financing activities	(2,884)	17,605
Net (decrease)/increase in cash and cash equivalents	(1,735)	6,284
Cash and cash equivalents at beginning of the year	40,700	41,378
Cash and cash equivalents at end of the year	38,965	47,662