Nine-month period ending 30th September 2018 Results

6th November 2018

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

ROVI – Nine-month period ending 30th September 2018 Financial Results

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

- **Operating revenue increased by 8% to 218.9 million euros in the first nine months of 2018, driven by the strength of the specialty pharmaceutical business, where sales rose 15%, strongly outperforming the market. Total revenue increased by 8% to 220.0 million euros in the first nine months of 2018.**

- **In 2019, ROVI expects a high-single-digit growth rate for the operating revenue.**

- **ROVI is upgrading its operating revenue guidance for the full year 2018, from mid-single digit growth rate to high-single-digit growth rate. Guidance for Enoxaparin biosimilar sales remains unchanged, within a range of between 20 and 30 million euros, and is expected to be towards the higher end of the range.**

- **ROVI launched its enoxaparin biosimilar in Germany in September 2017, in the United Kingdom in March 2018, in Italy in April 2018, in Spain in September 2018 and in France in September 2018 (pursuant to an agreement with Biogaran).**

- **By 30th September 2018, the countries with the national registration approved of the Enoxaparin biosimilar are Germany, France, United Kingdom, Italy, Spain, Portugal, Belgium, Finland, Norway, Sweden, Austria, Hungary, Slovenia, Estonia, Latvia, Slovakia, Bulgaria, Romania, Croatia, Czech Republic, Denmark, Poland and Ireland.**

- **Sales of the Enoxaparin biosimilar amounted to 16.7 million euros in the first nine months of 2018.**

- **Sales of Bemiparin increased 11% in the nine-month period ending 30 September 2018 to 68.7 million euros with an outstanding performance in Spain (+21%).**

- **Sales of Volutsa®, increased by 25% to 8.2 million euros, and sales of Hirobriz® Breezhaler® and Ulunar® Breezhaler® increased by 9% to 11.4 million euros in the first nine months of 2018, compared to the same period the previous year.**

- **Sales of Neparvis®, launched in December 2016, increased 3.3 times to 9.3 million euros in the first nine months of 2018.**

- **In the nine-month period ending 30 September 2017, EBITDA was affected by non-recurring expenses of 1.1 million euros linked to a substantial change to Frosst Ibérica employees working conditions.**

- **EBITDA "Pre-R&D", calculated excluding R&D expenses in the first nine months of 2018 and 2017 and the impact of non-recurring expenses in the first nine months of 2018, increased by 13%, from 45.8 million euros in the first nine months of 2017 to 51.6 million euros in the first nine months of 2018, reflecting a 1.1 percentage point rise in the EBITDA margin to 23.6% in the first nine months of 2018.**

- **Net profit "Pre-R&D", calculated excluding R&D expenses in the first nine months of 2018 and 2017 and the impact of non-recurring expenses in the first nine months of 2018, increased by 13%, from 35.5 million euros in the first nine months of 2017 to 40.1 million euros in the first nine months of 2018.**

Madrid (Spain), 6th November 2018, 8:00 AM CET - ROVI released today its financial results for the first nine months of 2018.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said "*in the first nine months of 2018, we reached 8% operating revenue growth mainly driven by the specialty pharmaceutical business strength, where sales rose by 15%. According to QuintilesIMS, the Spanish innovative product market increased by 2% in the first nine months 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 21%. 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.
Likewise, we continue the national phase of the registration process of our Enoxaparin biosimilar in Europe, with its approval in 23 countries before 30th September 2018. 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 and Italy and have started commercialization in Spain and France, five of the top Enoxaparin markets in Europe (in terms of volume and value), with good sales prospects, as reflected in the first nine months of 2018, when sales were 16.7 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.
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 half of 2017 and published interim results that showed a positive outcome. We also started a new Phase I study for another candidate, Letrozole, in November 2017, reflecting our clear commitment to our ISM® technology. ROVI is currently undergoing a growth transformation and the capital increase recently executed underpins this next phase of growth".

1. Financial highlights

€ million	9M 2018	9M 2017	Growth	% Growth
Operating revenue	218.9	203.4	15.5	8%
Other income	1.1	1.1	0.1	5%
Total revenue	**220.0**	**204.5**	**15.5**	**8%**
Cost of sales	-89.3	-82.2	-7.1	9%
Gross profit	**130.7**	**122.3**	**8.4**	**7%**
% margin	*59.7%*	*60.1%*		-0.4pp
R&D expenses	-24,6	-18,9	-5,7	30%
SG&A	-79,1	-76,1	-2,9	4%
Other expenses	-1,1	-	-1,1	n.a.
Share of profit/loss of a joint venture	0,0	-0,3	0,3	-99%
EBITDA	**25,9**	**27,0**	**-1,0**	**-4%**
% margin	*11,9%*	*13,2%*		-1,4pp
EBIT	**17,1**	**18,1**	**-1,0**	**-6%**
% margin	*7,8%*	*8,9%*		-1,1pp
Net profit	**15,7**	**17,0**	**-1,4**	**-8%**

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

The consolidated financial statements of Grupo ROVI for the first nine months of 2018 and the comparative information for 2017 (balance sheet) and for the first nine months 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 8% to 218.9 million euros in the first nine months of 2018, driven by the strength of the specialty pharmaceutical business, where sales rose 15%, strongly outperforming the market. Total revenue increased by 8% to 220.0 million euros in the first nine months of 2018.

€ million	9M 2018	9M 2017	% Growth
Specialty pharmaceutical business	180.3	157.2	15%
Toll manufacturing business	38.5	46.1	-16%
Royalties	0.1	0.1	-50%
Total operating revenue	**218.9**	**203.4**	**8%**

Sales of **prescription-based pharmaceutical** products rose 17% to 156.4 million euros in the first nine months of 2018.

€ million	**9M 2018**	**9M 2017**	**% Growth**
Prescription-based pharmaceutical products	**156.4**	**133.8**	**17%**
Bemiparin (Hibor)	68.7	61.7	11%
Sales in Spain	49.5	40.8	21%
International sales	19.2	20.9	-8%
Enoxaparin biosimilar (Enoxaparin Becat)	16.7	0.0	n.a.
Vytorin & Absorcol & Orvatez	28.0	28.9	-3%
Ulunar & Hirobriz	11.4	10.4	9%
Volutsa	8.2	6.5	25%
Medikinet & Medicebran	5.2	5.3	-2%
Neparvis	9.3	2.8	3,3x
Exxiv	1.8	2.9	-39%
Other products	20.6	26.1	-21%
Discounts to the National Health System	-13.5	-11.0	23%
Contrast agents and other hospital products	**22.2**	**21.4**	**4%**
Non prescription pharmaceutical products ("OTC") and Other	**1.7**	**2.1**	**-16%**
Total specialty pharmaceutical business	**180.3**	**157.2**	**15%**

ROVI's low molecular weight heparin (LMWH), **Bemiparin,** had a positive performance in the nine-month period ending 30 September 2018, with sales up 11% to 68.7 million euros. Sales of Bemiparin in Spain (**Hibor®**) increased by 21% to 49.5 million euros, while international sales decreased by 8% to 19.2 million euros.

Sales of the **Enoxaparin biosimilar** amounted to 16.7 million euros in the first nine months of 2018, 70% of which corresponds to sales in Germany and 16% corresponds to sales in Italy. In the first nine months of 2018, ROVI commenced the marketing of its Enoxaparin biosimilar in UK, Italy, Spain and France, and in October 2018 in Austria and Latvia.

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 3% to 28.0 million euros in the first nine months of 2018. 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 have recently been marketed, so the price of Vytorin® has been reduced to be competitive.

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 9% to 11.4 million euros in the first nine months of 2018, compared to the same half 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 25% to 8.2 million euros in the first nine months 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 2% to 5.2 million euros in the first nine months 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 9.3 million euros in the first nine months of 2018, compared to 2.8 million euros in the same period of 2017.

Sales of **Exxiv®**, a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 39% to 1.8 million euros in the first nine months of 2018, mainly due to a continued deceleration of the COX-2 market.

Corlentor® and **Thymanax®** products were not marketed by ROVI in the first nine months of 2018. In the first nine months of 2017 sales of Corlentor® and Thymanax® amounted to 2.6 million euros and 3.2 million euros respectively.

According to QuintilesIMS, Spanish innovative product market increased by 2% in the first nine months of 2018 compared to the same period the previous year. Nevertheless, ROVI prescription-based pharmaceutical product sales rose 17% in the same period, beating the market by 15 percentage points.

Also, prescription-based pharmaceutical market covering the 12-month period ending September 2018 increased by 2% compared to the same period the previous year. However, ROVI prescription-based pharmaceutical product sales rose 14% in the last year.

Sales of **contrast imaging agents** and other hospital products increased by 4% to 22.2 million euros in the first nine months of 2018.

Sales of **over-the-counter pharmaceutical products** ("OTC") **and other** decreased by 16% to 1.7 million euros in the first nine months of 2018 compared to the same period the previous year.

Toll manufacturing sales decreased by 16% to 38.5 million euros in the first nine months of 2018, compared to the same period the previous year, mainly because of the reduction of the injectable business compared to 9M 2017, when exceptional high volumes were manufactured for some customers. Frosst Ibérica plant sales decreased by 1% to 18.8 million euros in the first nine months of 2018 compared to the same period the previous year. By the end of 2018, a mid-teen decline (from 10-20%) in toll manufacturing is expected.

€ million	**9M 2018**	**9M 2017**	**% Growth**
Injectable business	19.8	27.1	-27%
Oral forms business (Frosst Ibérica)	18.8	18.9	-1%
Total toll manufacturing business	**38.5**	**46.1**	**-16%**

Sales outside Spain increased by 17% to 69.5 million euros in the first nine months of 2018 compared to the same period the previous year mainly due to the registration of Enoxaparin biosimilar sales. Sales outside Spain represented 32% of operating revenue in the first nine months of 2018 compared to 29% in the first nine months of 2017.

Other income (subsidies) increased by 5% to 1.1 million euros in the nine-month period ending 30 September 2018, compared to the same period the previous year.

Gross profit increased by 7% to 130.7 million euros in the first nine months of 2018, the gross margin showing a decrease of 0.4 percentage points from 60.1% in the first nine months of 2017 to 59.7%, mainly due to a drop in the injectable business, which added higher margins in the nine-month period ending 30 September 2017. However, the good performance of the injectable business in the third quarter of 2018 helped to recover, to a large extent, the margin decrease of 2.5 percentage points recorded in the first six months of the year. Sales of the Enoxaparin biosimilar had a positive impact in the first nine months of 2018; nevertheless some gross margin erosion is expected in the future, as the product will be launched in other markets.

Research and development expenses (R&D) mainly related to ISM® technology platform rose 30% to 24.6 million euros in the first nine months 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 4% to 79.1 million euros in the nine-month period ending 30 September 2018, mainly due to international subsidiaries expenses which amounted to 4.1 million euros compared to 1.0 million euros in the first nine

months of 2017. Excluding expenses related to international subsidiaries, SG&A would have decreased by 0.2% in the nine-month period ending 30 September 2018.

€ million	**9M 2018**	**9M 2017**	**% Growth**
Personnel expenses	51,3	47,0	9%
Other operating expenses (exc. R&D)	27,8	29,1	-4%
Total SG&A expenses	**79,1**	**76,1**	**4%**
Expenses related to intern. subsidiaries	*4.1*	*1.0*	*3.9x*

In the first nine months of 2018, EBITDA was affected by non-recurring expenses of 1.1 million euros, 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.

In the press release on the results for the first half of 2018, 1.5 million euros of non-recurring expenses related to the capital increase, which had not been executed as of the press release publication date, were included. Once the success of the transaction was known, said expenses (1.5 million euros), as well as other expenses accrued up to 30 September 2018 (total gross expenses of 2.0 million euros; 1.5 million euros net of taxes), were recognised as "prepaid expenses" in the balance sheet assets. These "prepaid expenses" will be recognised as equity after completion of the capital increase on 5 October 2018.

EBITDA decreased to 25.9 million euros in the first nine months of 2018, a fall of 4% compared to the same period the previous year, reflecting a 1.4 percentage point decrease in the EBITDA margin, which was down to 11.9% in the first nine months of 2018 from 13.2% in the first nine months of 2017. However, EBITDA "Pre-R&D", calculated excluding R&D expenses in the first nine months of 2018 and 2017 and the impact of non-recurring expenses in the first nine months of 2018, increased by 13%, from 45.8 million euros in the first nine months of 2017 to 51.6 million euros in the first nine months of 2018, reflecting a 1.1 percentage point rise in the EBITDA margin to 23.6% in the first nine months of 2018 (see "w/o R&D costs and one-off" columns of the table below). Likewise, recognising the same amount of R&D expenses in the first nine months of 2018 as in the first nine months of 2017 and excluding the impact of non-recurring expenses in the first nine months of 2018, EBITDA would have increased by 21% to 32.7 million euros, reflecting a 1.7 percentage point rise in the EBITDA margin to 15.0% in the first nine months of 2018, up from 13.2% in the first nine months of 2017 (see "Flat R&D costs and w/o one-off" columns of the table below).

€ million	Reported		w/o R&D costs and one-off			Flat R&D costs and w/o one-off		
	9M 2018	**9M 2017**	**9M 2018**	**9M 2017**	**Chang**	**9M 2018**	**9M 2017**	**Chang**
Operat. revenue	218.9	203.4	218.9	203.4	8%	218.9	203.4	8%
Other income	1.1	1.1	1.1	1.1	5%	1.1	1.1	5%
Total revenue	**220.0**	**204.5**	**220.0**	**204.5**	**8%**	**220.0**	**204.5**	**8%**
Cost of sales	-89.3	-82.2	-89.3	-82.2	9%	-89.3	-82.2	9%
Gross profit	**130.7**	**122.3**	**130.7**	**122.3**	**7%**	**130.7**	**122.3**	**7%**
% margin	*59.7%*	*60.1%*	*59.7%*	*60.1%*	*-0.4pp*	*59.7%*	*60.1%*	*-0.4pp*
R&D expenses	-24.6	-18.9	**0.0**	**0.0**	n.a.	**-18.9**	-18.9	n.a.
SG&A	-79.1	-76.1	-79.1	-76.1	4%	-79.1	-76.1	4%
Other expenses	-1.1	0.0	**0.0**	0.0	n.a.	**0.0**	0.0	n.a.
Share of P/L of a JV	0.0	-0.3	0.0	-0.3	-99%	0.0	-0.3	-99%
EBITDA	**25.9**	**27.0**	**51.6**	**45.8**	**13%**	**32.7**	**27.0**	**21%**
% margin	*11.9%*	*13.2%*	*23.6%*	*22.5%*	*1.1pp*	*15.0%*	*13.2%*	*1.7pp*

Depreciation and amortisation expenses increased by 0.3% to 8.9 million euros in the nine-month period ending 30 September 2018, mainly due to the decrease in new property, plant and equipment and intangible assets purchases made during the last twelve months.

EBIT decreased to 17.1 million euros in the nine-month period ending 30 September 2018, reflecting a 1.1 percentage point decrease in the EBIT margin, which was down to 7.8% in the first nine months of 2018 from 8.9% in the first nine months of 2017. However, EBIT "pre-R&D", calculated excluding R&D expenses in the first nine months of 2018 and 2017 and the impact of non-recurring expenses in the first nine months of 2018, increased by 16%, from 37.0 million euros in the first nine months of 2017 to 42.8 million euros in the first nine months of 2018, reflecting a 1.3 percentage point rise in the EBIT margin to 19.5% in the first nine months of 2018 (see "w/o R&D costs and one-off" columns of the table below). Likewise, recognising the same amount of R&D expenses in the first nine months of 2018 as in the first nine months of 2017 and excluding the impact of non-recurring expenses in the first nine months of 2018, EBIT would have increased by 32% to 23.9 million euros, reflecting a 2.0 percentage point rise in the EBIT margin to 10.9% in the first nine months of 2018, up from 8.9% in the first nine months of 2017 (see "Flat R&D costs and w/o one-off" columns of the table below).

€ million	Reported		w/o R&D costs and one-off			Flat R&D costs and w/o one-off		
	9M 2018	**9M 2017**	**9M 2018**	**9M 2017**	**Chang**	**9M 2018**	**9M 2017**	**Chang**
Operat. revenue	218.9	203.4	218.9	203.4	8%	218.9	203.4	8%
Other income	1.1	1.1	1.1	1.1	5%	1.1	1.1	5%
Total revenue	**220.0**	**204.5**	**220.0**	**204.5**	**8%**	**220.0**	**204.5**	**8%**
Cost of sales	-89.3	-82.2	-89.3	-82.2	9%	-89.3	-82.2	9%
Gross profit	**130.7**	**122.3**	**130.7**	**122.3**	**7%**	**130.7**	**122.3**	**7%**
% margin	*59.7%*	*60.1%*	*59.7%*	*60.1%*	*-0.4pp*	*59.7%*	*60.1%*	*-0.4pp*
R&D expenses	-24.6	-18.9	**0.0**	**0.0**	n.a.	**-18.9**	-18.9	n.a.
SG&A	-79.1	-76.1	-79.1	-76.1	4%	-79.1	-76.1	4%
Other expenses	-1.1	0.0	**0.0**	0.0	n.a.	**0.0**	0.0	n.a.
Share of P/L of a JV	0.0	-0.3	0.0	-0.3	-99%	0.0	-0.3	-99%
EBITDA	**25.9**	**27.0**	**51.6**	**45.8**	**13%**	**32.7**	**27.0**	**21%**
% margin	*11.9%*	*13.2%*	*23.6%*	*22.5%*	*1.1pp*	*15.0%*	*13.2%*	*1.7pp*
EBIT	**17.1**	**18.1**	**42.8**	**37.0**	**16%**	**23.9**	**18.1**	**32%**
% margin	*7.8%*	*8.9%*	*19.5%*	*18.2%*	*1.3pp*	*10.9%*	*8.9%*	*2.0pp*

Financial expense decreased by 14% in the nine-month period ending 30 September 2018, compared to the same period the previous year.

Financial income decreased by 74% in the nine-month period ending 30 September 2018, compared to the first half of 2017.

The **effective tax rate** was 4.7% in the nine-month period ending 30 September 2018 compared to 2.3% in the first nine months of 2017. This favourable effective tax rate is due to the deduction of existing research and development expenses, 5.7 million euros higher in this period compared to the same period of 2017, and the capitalisation of negative tax bases from Frosst Ibérica, S.A., Rovi GmbH, the German franchise, and Rovi Biotech, S.R.L., the Italian franchise. As of 30 September 2018, negative tax bases of the Group amounted to 35.0 million euros, of which 1.0 million euros will be used in the first nine months of 2018.

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. 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 decreased by 8%, from 17.0 million euros in the first nine months of 2017 to 15.7 million euros in the first nine months of 2018. However, net profit "pre-R&D", calculated excluding R&D expenses in the first nine months of 2018 and 2017 and the impact of non-recurring expenses in the first nine months of 2018, increased by 13%, from 35.5 million euros in the first nine months of 2017 to 40.1 million euros in the first nine months of 2018 (see "w/o R&D costs and one-off" columns of the table below). Likewise, recognising the same amount of R&D expenses in the first nine months of 2018 as in the first nine months of 2017 and excluding the impact of non-recurring expenses in the first nine months of 2018, net profit would have increased by 30% to 22.1 million euros (see "Flat R&D costs and w/o one-off" columns of the table below).

	Reported		w/o R&D costs and one-off			Flat R&D costs and w/o one-off		
€ million	**9M 2018**	**9M 2017**	**9M 2018**	**9M 2017**	**Chang**	**9M 2018**	**9M 2017**	**Chang**
Operat. revenue	218.9	203.4	218.9	203.4	8%	218.9	203.4	8%
Other income	1.1	1.1	1.1	1.1	5%	1.1	1.1	5%
Total revenue	**220.0**	**204.5**	**220.0**	**204.5**	**8%**	**220.0**	**204.5**	**8%**
Cost of sales	-89.3	-82.2	-89.3	-82.2	9%	-89.3	-82.2	9%
Gross profit	**130.7**	**122.3**	**130.7**	**122.3**	**7%**	**130.7**	**122.3**	**7%**
% margin	*59.7%*	*60.1%*	*59.7%*	*60.1%*	*-0.4pp*	*59.7%*	*60.1%*	*-0.4pp*
R&D expenses	-24.6	-18.9	**0.0**	**0.0**	n.a.	**-18.9**	-18.9	n.a.
SG&A	-79.1	-76.1	-79.1	-76.1	4%	-79.1	-76.1	4%
Other expenses	-1.1	0.0	**0.0**	0.0	n.a.	**0.0**	0.0	n.a.
Share of P/L of a JV	0.0	-0.3	0.0	-0.3	-99%	0.0	-0.3	-99%
EBITDA	**25.9**	**27.0**	**51.6**	**45.8**	**13%**	**32.7**	**27.0**	**21%**
% margin	*11.9%*	*13.2%*	*23.6%*	*22.5%*	*1.1pp*	*15.0%*	*13.2%*	*1.7pp*
EBIT	**17.1**	**18.1**	**42.8**	**37.0**	**16%**	**23.9**	**18.1**	**32%**
% margin	*7.8%*	*8.9%*	*19.5%*	*18.2%*	*1.3pp*	*10.9%*	*8.9%*	*2.0pp*
Net profit	**15.7**	**17.0**	**40.1**	**35.5**	**13%**	**22.1**	**17.0**	**30%**
% margin	*7.2%*	*8.4%*	*18.3%*	*17.4%*	*0.9pp*	*10.1%*	*8.4%*	*1.7pp*

ROVI General Shareholders Meeting, on 29 May 2018, approved the payment of a **gross dividend** of 0.1207 euros per share on 2017 earnings. This dividend was paid on 5th July 2018 and it represented a 35% pay-out.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that "*we are very happy with the results of the first nine months of 2018. 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 nine months 2018 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 9.3 million euros in the first nine months of 2018, compared to 8.1 million euros in the first nine months of 2017. Of this amount:

- 1.9 million euros corresponds to investment capex related to the injectable facility, versus 1.5 million euros in the first nine months of 2017;
- 1.3 million euros relates to investment capex regarding the San Sebastián de los Reyes plant, versus 1.7 million euros in the first nine months of 2017;
- 2.2 million euros were invested in the Granada facility, versus 0.7 million euros in the first nine months of 2017;
- 2.3 million euros were invested in the Alcalá de Henares (Frosst Ibérica) facility, versus 1.2 million euros in the first nine months of 2017; and
- 1.6 million euros relates to expenditure on maintenance and other capex, versus 3.0 million euros in the first nine months of 2017 (including capex related to the biosimilar of enoxaparin).

	9M 2018	9M 2017	% Growth
Injectable plant	1.9	1.5	26%
San Sebastián de los Reyes plant	1.3	1.7	-24%
Granada plant	2.2	0.7	203%
Alcalá de Henares plant (Frosst Ibérica)	2.3	1.2	104%
Expenditure on maintenance and other capex	1.6	3.0	-47%
Total Capex	**9.3**	**8.1**	**15%**

3.2 Debt

As of 30 September 2018, ROVI had total debt of 39.5 million euros. Debt with public administration, which is 0% interest rate debt, represented 31% of total debt as of 30 September 2018.

In thousand euros	**30 September 18**	**31 December 17**
Bank borrowings	27,127	30,938
Debt with public administration	12,391	12,299
Total	**39,518**	**43,237**

As of 30 September 2018, bank borrowings decreased by 3.8 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 September 2018, ROVI had drawn down 5 million euros against this credit line.

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 -13.2 million euros in the first nine months of 2018 compared to -2.1 million euros in the first nine months of 2017 mainly due to (i) the increase of 27.1 million euros in the "inventories" line in the first nine months of 2018, compared to an increase of 6.4 million euros in the first nine months of 2017; (ii) the increase in the "trade and other receivables" line of 10.6 million euros in the first nine months of 2018, compared to a decrease of 5.7 million euros in the first nine months of 2017; (iii) the increase of 10.5 million euros in the "trade and other payables" item in the first nine months of 2018, compared to a decrease of 19.8 million euros in the first nine months of 2017; (iv) the registration of 1.5 million euros of "other current assets (prepaid expenses)" related to the capital increase in the first nine months of 2018; (v) the increase of 1.2 million euros in Capex; and (vi) the decrease of 1.0 million euros in profit before income tax.

3.4 Gross cash position and net debt

As of 30 September 2018, ROVI had gross cash position of 18.9 million euros, compared to 42.1 million euros as of 31 December 2017, and net debt of 20.6 million euros (equity securities plus

deposits plus cash and cash equivalents minus short term and long term financial debt), compared to 1.1 million euros as of 31 December 2017.

3.5 Working capital

The increase in working capital in the first nine months of 2018 was mainly due to (i) an increase of 27.1 million euros in the "inventories" line, mainly due to higher heparin stock levels in the first nine months of 2018; (ii) an increase of 10.6 million euros in the "trade and other receivables" line; (iii) an increase, in the first nine months of 2018, of 10.5 million euros in the "trade and other payables" line, partly due to the inclusion of 3.5 million euros in this period, in accordance with the rules of the new IFRS 15, that were recognised as of December 31, 2017 as "provisions for other liabilities and charges", and (iv) a decrease of 23.2 million euros in the "cash and cash equivalents" item.

As of 30 September 2018, Social Security and Public Administrations total debt with ROVI amounted to 6.6 million euros, of which 3.9 million euros in Spain, 1.6 million euros in Portugal and 1.1 million euros in Italy.

4. Guidance for 2019

In 2019, ROVI expects **a high single digit growth rate for the operating revenue**. The Company forecasts that it will continue to grow at a higher rate than Spanish pharmaceutical market expenditure in the first nine months of 2018, which, according to the Ministry of Health, Consumption and Social Welfare, showed a growth rate of 3%.

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.

5. Guidance for 2018

ROVI is upgrading its operating revenue guidance for the full year 2018, from mid-single digit growth rate to high-single-digit growth rate. Guidance for Enoxaparin biosimilar sales remains unchanged, within a range of between 20 and 30 million euros, and is expected to be towards the higher end of the range.

This upgrade is mainly due to the excellent 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 fourth quarter of 2018 but will finally continue to distribute them for 2018 and will probably stop distributing them as of the first half of 2019.

6. 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. In September 2018 patients' recruitment of the double-blind (main) part of the study has already finished. Therefore, 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 7.3).

On the other hand, in November 2017 ROVI started the clinical development of Letrozole ISM®, the first long-acting injectable aromatase inhibitor intended for the treatment of hormone-dependent breast cancer. The first phase I clinical trial, the LISA-1 study[4], is currently ongoing; this is an open-label, dose escalation study to evaluate the pharmacokinetics, safety and tolerability of single intramuscular injections of Letrozole ISM® at different strengths in healthy post-menopausal women.

[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] *Anta L, Llaudó J, Ayani I, Martínez J, Litman RE, Gutierro I. 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. 2018;33(2):79-87.*

[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). Clinicaltrials.gov#NCT03401320 [https://clinicaltrials.gov/ct2/show/NCT03401320].*

7. Key operating and financial events

7.1 ROVI has increased its equity by approximately 88 million euros

ROVI informed (by publication of the relevant fact number 270159 dated 4th of October of 2018) that the Board of Directors adopted a resolution to increase the share capital of ROVI by means of monetary contributions through the issue of new ordinary shares with a nominal value of €0.06 each (the "Initial Offer Shares") (the "Capital Increase"), which may be increased by a number of new ordinary shares representing up to 10% of the number of Initial Offer Shares that are issued (the "Option Shares" and, together with the Initial Offer Shares, the "Offer Shares") to cover over-allotments (if any) which may be made in connection with the offering of the Initial Offer Shares and short positions resulting from stabilization transactions. The final number of Offer Shares has led to the raising of approximately 88 million euros (share capital and issue premium).

The proceeds obtained from the sale of the Offer Shares are to be used to partly finance the Phase III clinical testing of Doria® (formerly Risperidone ISM®) and other expenses related to Doria® until its commercialization, if approved, to finance, in whole or in part, the Phase I clinical testing of Letrozol ISM®, to support the ongoing marketing of its enoxaparin biosimilar Becat® and for general corporate purposes, which may include acquisitions.

7.2 ROVI has commenced the marketing of the Enoxaparin biosimilar in Germany, UK, Italy, Spain and France and has reached distribution and marketing agreements with Hikma and Sandoz

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 half 2017, and it continued during the rest of the year and the first nine months 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 the first nine months of 2018, ROVI commenced the

marketing of its Enoxaparin biosimilar in UK, Italy, Spain and France, and in October 2018 in Austria and Latvia.

As of 30th September 2018, the countries with the registration national phase approved are Germany, France, United Kingdom, Italy, Spain, Portugal, Belgium, Finland, Norway, Sweden, Austria, Hungary, Slovenia, Estonia, Latvia, Slovakia, Bulgaria, Romania, Croatia, Czech Republic, Denmark, Poland and Ireland.

In April 2018, ROVI 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 MENA[1] (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.

Likewise, in June 2018 ROVI announced the signature of a licensing agreement with Sandoz, a division of Novartis AG and a global leader in generic pharmaceuticals and biosimilars, to distribute and market its enoxaparin biosimilar in 14 countries/regions (Australia, New Zealand, Philippines, Hong Kong, Singapore, Vietnam, Malaysia, Canada, South Africa, Brazil, Colombia, Argentina, Mexico and Central America). Under the terms of the agreement, Sandoz has the exclusive rights for three of these countries, which are Hong Kong, Singapore and Vietnam.

In September 2018, ROVI announced it had signed an agreement with Biogaran SAS, the leading French pharmaceutical company in biosimilar generic medicines and a subsidiary of Servier laboratories, for the semi-exclusive marketing of its enoxaparin biosimilar in France.

Besides Europe, by September 2018, ROVI has distribution and marketing agreements for the Enoxaparin biosimilar in 60 countries.

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.

7.3 ROVI updates the pivotal PRISMA 3 study of DORIA® (Risperidone ISM®)

ROVI informed that after a prespecified Interim Analysis on the pivotal PRISMA-3 study for the once-monthly injectable formulation of Risperidone ISM®, DORIA®, an independent Data Monitoring Committee has recommended to continue the clinical trial and not increasing the currently planned number of randomized patients.

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

The PRISMA-3 study is a multicentre, randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy and safety of monthly intramuscular injections of DORIA® in patients with acute exacerbation of schizophrenia[1], having initiated patients' recruitment in May 2017, as previously informed the 25th of October 2017 on a relevant fact (number 257753).

As expected, ROVI carried out one unblinded interim analysis that was planned to be conducted when approximately 50% of randomized patients have either reached study day 85 or withdrawn from the study to re-estimate the sample size required for the final analysis. In this sense, an independent Data Monitoring Committee received unblinded results from this interim analysis and communicated to ROVI the blinded outcome, concluding that the clinical trial can continue and an increase of the study sample size is not needed.

On September 2018 patients' recruitment of the double-blind (main) part of the study has already finished. 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.

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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[1] *https://clinicaltrials.gov/ct2/show/NCT03160521*

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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 SEPTEMBER 2018 AND 31 SEPTEMBER 2017

(Thousands of euros)

	30 September 2018	31 December 2017
ASSETS		
Non-current assets		
Property, Plant and Equipment	90,592	89,056
Intangible assets	25,993	27,078
Investment in a joint venture	2,011	2,054
Deferred income tax assets	13,547	11,893
Equity securities	69	69
Financial receivables	65	65
	132,277	**130,215**
Current assets		
Inventories	102,555	75,492
Trade and other receivables	60,393	49,747
Current income tax assets	1,950	2,228
Prepaid expenses	1,509	-
Cash and cash equivalents	17,474	40,700
	183,881	**168,167**
Total assets	**316,158**	**298,382**

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS AS OF 30 SEPTEMBER 2018 AND 31 DECEMBER 2017

(Thousands of euros)

	30 September 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	(8,698)	(8,407)
Retained earnings and voluntary reserves	190,551	179,255
Profit for the period	15,651	17,241
Other reserves	(3)	(2)
Total equity	**201,101**	**191,687**
LIABILITIES		
Non-current liabilities		
Financial debt	20,640	27,029
Deferred income tax liabilities	1,157	1,438
Contract liabilities	3,659	-
Deferred income	3,762	5,005
	29,218	**33,472**
Current liabilities		
Financial debt	18,878	16,208
Trade and other payables	63,413	52,942
Contract liabilities	2,915	-
Deferred income	633	565
Provisions for other liabilities and charges	-	3,508
	85,839	**73,223**
Total liabilities	**115,057**	**106,695**
Total equity and liabilities	**316,158**	**298,382**

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED INCOME STATEMENTS FOR THE NINE-MONTH PERIODS ENDING 30 SEPTEMBER 2018 AND 30 SEPTEMBER 2017

(Thousands of euros)

	Nine-month periods ending 30 September	
	2018	**2017**
Revenue	218,885	203,409
Changes in inventories of finished goods and work in progress	4,644	8,351
Raw materials and consumables used	(93,938)	(90,561)
Employee benefit expenses	(52,364)	(47,049)
Other operating expenses	(52,402)	(47,975)
Amortisation	(8,871)	(8,847)
Recognition of government grants on non-financial non-current assets and other	1,122	1,068
Share of profit of joint venture	(3)	(292)
OPERATING PROFIT	**17,073**	**18,104**
Finance income	24	92
Finance costs	(666)	(771)
FINANCE COSTS - NET	**(642)**	**(679)**
PROFIT BEFORE INCOME TAX	**16,431**	**17,425**
Income tax	(780)	(405)
PROFIT FOR THE PERIOD	**15,651**	**17,020**

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED CASH FLOW STATEMENTS FOR THE NINE-MONTH PERIODS ENDING 30 SEPTEMBER 2018 AND 30 SEPTEMBER 2017
(Thousands of euros)

	Nine-month periods ending 30 September	
	2018	**2017**
Cash flows from operating activities		
Profit before income tax	16,431	17,425
Adjustments for non-monetary transactions:		
Amortisation	8,871	8,847
Finance income	(24)	(92)
Valuation allowance	462	1,670
Finance expense	666	771
Net changes in provisions	-	813
Grant on non-financial assets and income from distribution	(1,182)	(1,189)
Profit for creation of joint venture	(10)	-
Share of profit of joint venture	3	292
Changes in working capital:		
Trade and other receivables	(10,138)	5,002
Inventories	(27,706)	(7,980)
Other current assets (prepaid expenses)	(2,008)	-
Trade and other payables	6,968	(19,857)
Other collections and payments:		
Proceeds from distribution licenses	5,720	87
Income tax cash flow	(2,073)	62
Net cash generated from (used in) operating activities	**(4,020)**	**5,851**
Cash flows from investing activities		
Purchases of intangible assets	(756)	(2,537)
Purchases of property, plant and equipment	(8,578)	(5,552)
Proceeds from sale of property, plant and equipment	12	-
Proceeds from sale of shares in joint venture	50	450
Interest received	113	133
Net cash generated from (used in) investing activities	**(9,159)**	**(7,506)**
Cash flows from financing activities		
Repayments of financial debt	(10,756)	(8,963)
Proceeds from financial debt	6,961	22,190
Interest paid	(145)	(188)
Purchase of treasury shares	(699)	(394)
Reissue of treasury shares	544	828
Dividends paid	(5,952)	(9,025)
Net cash generated from (used in) financing activities	**(10,047)**	**4,448**
Net (decrease) increase in cash and cash equivalents	**(23,226)**	**2,793**
Cash and cash equivalents at the beginning of the period	**40,700**	**41,378**
Cash and cash equivalents at the end of the period	**17,474**	**44,171**