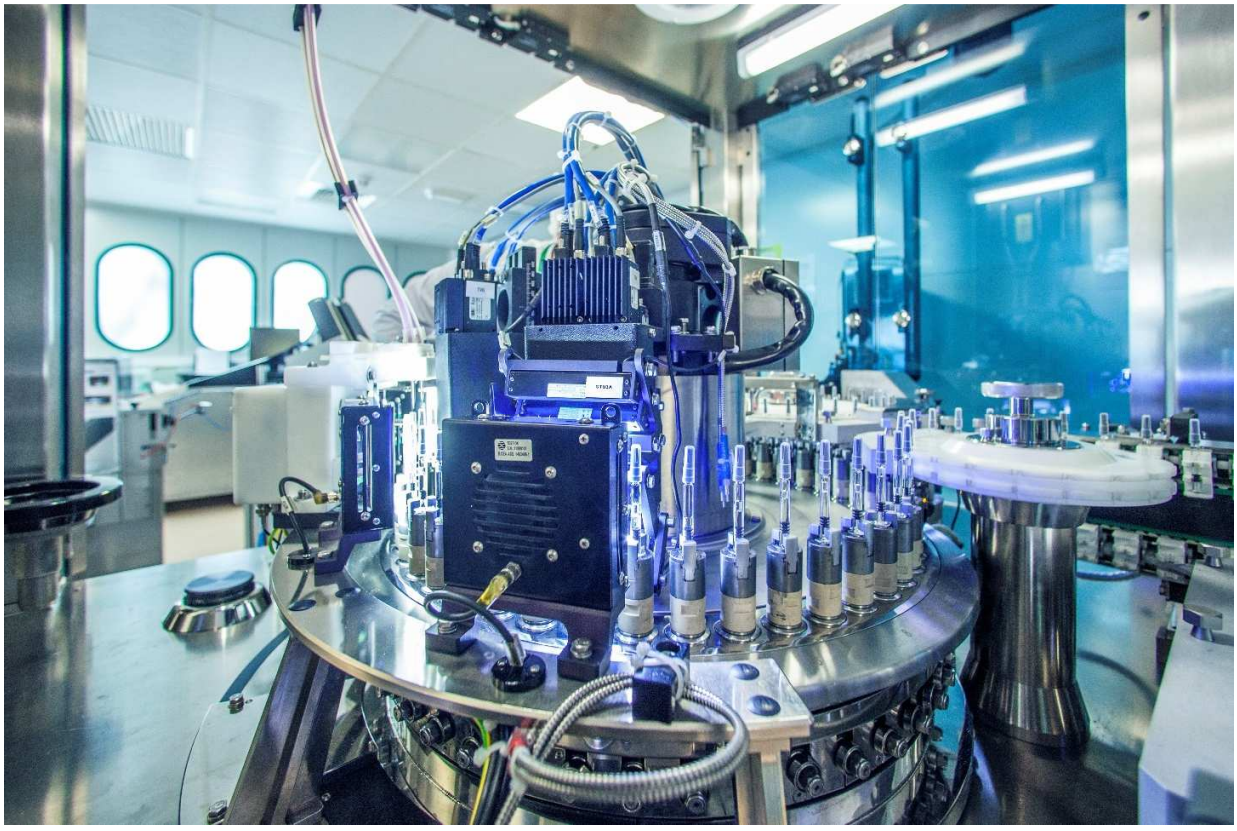
Full Year 2018 Results

26th February 2019



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

ROVI – Full Year 2018 Financial Results

ROVI reports operating revenue growth of 10%, underpinned by outstanding low-molecular-weight heparin franchise sales

- **Operating revenue increased by 10% to 303.2 million euros in 2018, driven by the strength of the specialty pharmaceutical business, where sales rose 16%, strongly outperforming the market. Total revenue increased by 10% to 304.8 million euros in 2018.**

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

- **In December 2018, all patients completed the double-blind (main) part of the "PRISMA 3" study of Risperidone ISM®. 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.**

- **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, in France in September 2018 (pursuant to an agreement with Biogaran) and in Austria, Latvia and Estonia in October 2018.**

- **As of 31st December 2018, all the European Union countries (24 countries) where ROVI had applied for the national registration of the enoxaparin biosimilar had approved such registration, except Greece and Luxembourg.**

- **Sales of the Low Molecular Weight Heparin (LMWH) franchise (enoxaparin biosimilar and Bemiparin) increased by 42% to 121.5 million euros in 2018. LMWH sales represented 40% of operating revenue in 2018 compared to 31% in 2017. Sales of the enoxaparin biosimilar amounted to 30.2 million euros in 2018 and sales of Bemiparin increased 9% in 2018 to 91.3 million euros with an outstanding performance in Spain (+15%).**

- **Sales of Neparvis®, launched in December 2016, increased 2.9 times to 13.6 million euros in 2018.**

- **Sales of Volutsa®, increased by 25% to 11.2 million euros, and sales of Hirobriz® Breezhaler® and Ulunar® Breezhaler® increased by 7% to 15.3 million euros in 2018, compared to the previous year.**

- **In 2018, 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 2018 and 2017 and the impact of non-recurring expenses in 2018, increased by 8%, from 58.2 million euros in 2017 to 63.0 million euros in 2018, reflecting a 0.3 percentage point fall in the EBITDA margin to 20.8% in 2018.**

- **Net profit "Pre-R&D", calculated excluding R&D expenses in 2018 and 2017 and the impact of non-recurring expenses in 2018, increased by 19%, from 45.0 million euros in 2017 to 53.8 million euros in 2018.**

- **As the Market was informed in a Relevant Event dated 24 September, 2018, ROVI will 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.**

Madrid (Spain), 26th February 2019, 8:00 AM CET - ROVI released today its financial results for 2018.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said "*in 2018, we reached 10% operating revenue growth mainly driven by the specialty pharmaceutical business strength, where sales rose by 16%. According to QuintilesIMS, the Spanish innovative product market increased by 2% in 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 15%. Likewise, we continue the national phase of the registration process of our Enoxaparin biosimilar in Europe, with its approval in 24 countries before 31st December 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, Italy, Spain and France, five of the top Enoxaparin markets in Europe (in terms of volume and value) and have started commercialization in Austria, Latvia and Estonia, with good sales prospects, as reflected in 2018,*

when sales were 30.2 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.

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 are carrying out a Phase III trial with our ISM® technology (Risperidone ISM®) and published interim results that showed a positive outcome. 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 recently executed underpins this next phase of growth".

1. Financial highlights

€ million	2018	2017	Growth	% Growth
Operating revenue	303.2	275.6	27.6	10%
Other income	1.6	1.8	-0.2	-10%
Total revenue	**304.8**	**277.4**	**27.4**	**10%**
Cost of sales	-128.6	-110.2	-18.4	17%
Gross profit	**176.2**	**167.2**	**8.9**	**5%**
% margin	*58.1%*	*60.7%*		*-2,6pp*
R&D expenses	-32.4	-28.3	-4.1	15%
SG&A	-113.2	-108.5	-4.7	4%
Other expenses	-1.1	-	-1.1	n.a.
Share of profit/loss of a joint venture	0.0	-0.6	0.6	-104%
EBITDA	**29.5**	**29.9**	**-0.4**	**-1%**
% margin	*9.7%*	*10.9%*		*-1,1pp*
EBIT	**17.5**	**18.4**	**-1.0**	**-5%**
% margin	*5.8%*	*6.7%*		*-0,9pp*
Net profit	**17.9**	**17.2**	**0.7**	**4%**

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 2018 and the comparative information for 2017 are attached to this report (see Appendix 1).

2. Performance of the Group

Operating revenue increased by 10% to 303.2 million euros in 2018, driven by the strength of the specialty pharmaceutical business, where sales rose 16%, strongly outperforming the market. Total revenue increased by 10% to 304.8 million euros in 2018.

€ million	2018	2017	% Growth
Specialty pharmaceutical business	248.6	214.6	16%
Toll manufacturing business	54.6	61.1	-11%
Total operating revenue	**303.2**	**275.6**	**10%**

Sales of **prescription-based pharmaceutical** products rose 18% to 216.8 million euros in 2018.

€ million	2018	2017	% Growth
Prescription-based pharmaceutical products	**216.8**	**183.4**	**18%**
Low Molecular Weight Heparins	121.5	85.3	42%
Enoxaparin biosimilar (Enoxaparin Becat)	30.2	1.5	n.a.
Bemiparin (Hibor)	91.3	83.9	9%
Sales in Spain	67.4	58.8	15%
International sales	23.8	25.1	-5%
Neparvis	13.6	4.7	2.9x
Ulunar & Hirobriz	15.3	14.3	7%
Volutsa	11.2	9.0	25%
Vytorin & Absorcol & Orvatez	36.0	39.4	-9%
Medikinet & Medicebran	7.4	7.5	-2%
Exxiv	2.3	3.6	-35%
Other products	27.7	34.2	-19%
Discounts to the National Health System	-18.3	-14.7	24%
Contrast agents and other hospital products	**29.7**	**28.5**	**4%**
Non prescription pharmaceutical products ("OTC") and Other	**2.2**	**2.6**	**-17%**
Total specialty pharmaceutical business	**248.6**	**214.6**	**16%**

Sales of the **Low Molecular Weight Heparin (LMWH) franchise** (Enoxaparin biosimilar and Bemiparin) increased by 42% to 121.5 million euros in 2018. LMWH sales represented 40% of operating revenue in 2018 compared to 31% in 2017.

Sales of the **Enoxaparin biosimilar** amounted to 30.2 million euros in 2018. ROVI commenced the marketing of its Enoxaparin biosimilar in UK, Italy, Spain, France, Austria, Latvia and Estonia in 2018.

ROVI's low molecular weight heparin (LMWH), **Bemiparin,** had a positive performance in 2018, with sales up 9% to 91.3 million euros. Sales of Bemiparin in Spain (**Hibor®**) increased by 15% to 67.4 million euros, while international sales decreased by 5% to 23.8 million euros.

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 13.6 million euros in 2018, compared to 4.7 million euros in 2017.

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 7% to 15.3 million euros in 2018, compared to 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 11.2 million euros in 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, decreased by 9% to 36.0 million euros in 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 **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 7.4 million euros in 2018.

Sales of **Exxiv®**, a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 35% to 2.3 million euros in 2018, mainly due to a continued deceleration of the COX-2 market.

Corlentor® and **Thymanax®** products were not marketed by ROVI in 2018. In 2017 sales of Corlentor® and Thymanax® amounted to 2.5 million euros and 3.9 million euros respectively.
According to QuintilesIMS, Spanish innovative product market increased by 2% in 2018 compared to the previous year. Nevertheless, ROVI prescription-based pharmaceutical product sales rose 18% in the same period, beating the market by 16 percentage points.

As a member of Farmaindustria, a Spanish pharmaceutical industry association, ROVI is subject to a collaboration agreement entered into between Farmaindustria and the Spanish government in 2016. This agreement was renewed in December 2017. Pursuant to the agreement, in the event that public spending on drugs (excluding generics and biosimilars) increases at a rate in excess of the actual rate of growth of the Spanish gross domestic product (GDP), the pharmaceutical industry must reimburse the difference to the government through monetary payments. In 2018, the public spending growth rate was higher than the GDP growth rate and, therefore, the sales recorded by ROVI were 3.5 million euros lower than the actual sales (this amount is included in the "Discounts to the National Health System" line).

Sales of **contrast imaging agents** and other hospital products increased by 4% to 29.7 million euros in 2018.

Sales of **over-the-counter pharmaceutical products** ("OTC") **and other** decreased by 17% to 2.2 million euros in 2018 compared to the previous year.

Toll manufacturing sales decreased by 11% to 54.6 million euros in 2018 mainly because of the reduction of the injectable business compared to 2017, when exceptional high volumes were manufactured for some customers. Frosst Ibérica plant sales decreased by 1% to 25.9 million euros in 2018 compared to the previous year.

€ million	**2018**	**2017**	**% Growth**
Injectable business	28.6	34.9	-18%
Oral forms business (Frosst Ibérica)	25.9	26.2	-1%
Total toll manufacturing business	**54.6**	**61.1**	**-11%**

Sales outside Spain increased by 25% to 99.4 million euros in 2018, 27.1 million euros (or 27%) of which related to international subsidiaries, mainly due to recognition of Enoxaparin biosimilar sales. Sales outside Spain represented 33% of operating revenue in 2018 compared to 29% in 2017.

€ million	**2018**	**2017**	**% Growth**
Portugal	2,6	2,5	6%
Germany	15,2	1,5	10,3x
Italy	8,1	-	n.a.
United Kingdom	1,2	-	n.a.
Total sales in the international subsidiaries	**27,1**	**4,0**	**6,8x**

Other income (subsidies) decreased by 10% to 1.6 million euros in 2018, compared to the previous year.

Gross profit increased by 5% to 176.2 million euros in 2018, the gross margin showing a decrease of 2.6 percentage points from 60.7% in 2017 to 58.1%, mainly due to (i) the drop in the injectable business, which had added higher margins in 2017; (ii) the increase of Enoxaparin biosimilar sales, which added lower margins in 2018 after the launch of the product in seven new markets; (iii) the 3.5 million euro reduction in sales recorded in connection with the agreement entered into between Farmaindustria and the Spanish government mentioned above and (iv) the increase in the LMWH raw material prices, which, in 2018, were running around 30% over 2017 prices. ROVI expects this rising trend to continue during 2019.

Research and development expenses (R&D) mainly related to ISM® technology platform rose 15% to 32.4 million euros in 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 113.2 million euros in 2018, mainly due to international subsidiaries expenses which amounted to 6.6 million euros compared to 1.6 million euros in 2017. Excluding expenses related to international subsidiaries, SG&A would have decreased by 0.2% in 2018. In 2019, expenses related to international subsidiaries are expected to be around 10 million euros.

€ million	**2018**	**2017**	**% Growth**
Personnel expenses	69.1	64.0	8%
Other operating expenses (exc. R&D)	44.1	44.5	-1%
Total SG&A expenses	**113.2**	**108.5**	**4%**
Expenses related to intern. subsidiaries	*6.6*	*1.6*	*4,0x*

In 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.

The press release on the results for the first half of 2018 included 1.5 million euros of non-recurring expenses relating to the capital increase (see section 6.3), which had not been executed as of the press release publication date. When it became known that the transaction would be successful, although before it was completed, 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. After completion of the capital increase in October 2018, these "prepaid expenses" and other expenses accrued up to 31 December 2018 (total gross expenses of 5.2 million euros; 3.9 million euros net of taxes) were recognised as "retained earnings and voluntary reserves".

EBITDA decreased to 29.5 million euros in 2018, a fall of 1% compared to the previous year, reflecting a 1.1 percentage point decrease in the EBITDA margin, which was down to 9.7% in 2018 from 10.9% in 2017. However, EBITDA "Pre-R&D", calculated excluding R&D expenses in 2018 and 2017 and the impact of non-recurring expenses in 2018, increased by 8%, from 58.2 million euros in 2017 to 63.0 million euros in 2018, reflecting a 0.3 percentage point fall in the EBITDA margin to 20.8% in 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 2018 as in 2017 and excluding the impact of non-recurring expenses in 2018, EBITDA would have increased by 16% to 34.7 million

euros, reflecting a 0.6 percentage point rise in the EBITDA margin to 11.5% in 2018, up from 10.9% in 2017 (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	**2018**	**2017**	**2018**	**2017**	**Chang**	**2018**	**2017**	**Chang**
Operat. revenue	303.2	275.6	303.2	275.6	10%	303.2	275.6	10%
Other income	1.6	1.8	1.6	1.8	-10%	1.6	1.8	-10%
Total revenue	**304.8**	**277.4**	**304.8**	**277.4**	**10%**	**304.8**	**277.4**	**10%**
Cost of sales	-128.6	-110.2	-128.6	-110.2	17%	-128.6	-110.2	17%
Gross profit	**176.2**	**167.2**	**176.2**	**167.2**	**5%**	**176.2**	**167.2**	**5%**
% margin	*58.1%*	*60.7%*	*58.1%*	*60.7%*	*-2.6pp*	*58.1%*	*60.7%*	*-2.6pp*
R&D expenses	-32.4	-28.3	**0.0**	**0.0**	n.a.	**-28.3**	-28.3	n.a.
SG&A	-113.2	-108.5	-113.2	-108.5	4%	-113.2	-108.5	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	-0.6	0.0	-0.6	-104%	0.0	-0.6	-104%
EBITDA	**29.5**	**29.9**	**63.0**	**58.2**	**8%**	**34.7**	**29.9**	**16%**
% margin	*9.7%*	*10.9%*	*20.8%*	*21.1%*	*-0.3pp*	*11.5%*	*10.9%*	*0.6pp*

Depreciation and amortisation expenses increased by 5% to 12.0 million euros in 2018, mainly due to the new property, plant and equipment and intangible assets purchases made during the last twelve months.

EBIT decreased to 17.5 million euros in 2018, reflecting a 0.9 percentage point decrease in the EBIT margin, which was down to 5.8% in 2018 from 6.7% in 2017. However, EBIT "pre-R&D", calculated excluding R&D expenses in 2018 and 2017 and the impact of non-recurring expenses in 2018, increased by 9%, from 46.7 million euros in 2017 to 51.0 million euros in 2018, reflecting a 0.1 percentage point fall in the EBIT margin to 16.8% in 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 2018 as in 2017 and excluding the impact of non-recurring expenses in 2018, EBIT would have increased by 23% to 22.7 million euros, reflecting a 0.8 percentage point rise in the EBIT margin to 7.5% in 2018, up from 6.7% in 2017 (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	**2018**	**2017**	**2018**	**2017**	**Chang**	**2018**	**2017**	**Chang**
Operat. revenue	303.2	275.6	303.2	275.6	10%	303.2	275.6	10%
Other income	1.6	1.8	1.6	1.8	-10%	1.6	1.8	-10%
Total revenue	**304.8**	**277.4**	**304.8**	**277.4**	**10%**	**304.8**	**277.4**	**10%**
Cost of sales	-128.6	-110.2	-128.6	-110.2	17%	-128.6	-110.2	17%
Gross profit	**176.2**	**167.2**	**176.2**	**167.2**	**5%**	**176.2**	**167.2**	**5%**
% margin	*58.1%*	*60.7%*	*58.1%*	*60.7%*	*-2.6pp*	*58.1%*	*60.7%*	*-2.6pp*
R&D expenses	-32.4	-28.3	**0.0**	**0.0**	n.a.	**-28.3**	-28.3	n.a.
SG&A	-113.2	-108.5	-113.2	-108.5	4%	-113.2	-108.5	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	-0.6	0.0	-0.6	-104%	0.0	-0.6	-104%
EBITDA	**29.5**	**29.9**	**63.0**	**58.2**	**8%**	**34.7**	**29.9**	**16%**
% margin	*9.7%*	*10.9%*	*20.8%*	*21.1%*	*-0.3pp*	*11.5%*	*10.9%*	*0.6pp*
EBIT	**17.5**	**18.4**	**51.0**	**46.7**	**9%**	**22.7**	**18.4**	**23%**
% margin	*5.8%*	*6.7%*	*16.8%*	*16.9%*	*-0.1pp*	*7.5%*	*6.7%*	*0.8pp*

Financial expense decreased by 30% in 2018, compared to the previous year.

Financial income decreased by 83% in 2018, compared to 2017.

The **effective tax rate** was -7.3% in 2018, generating a positive income tax of 1.2 million euros, compared to 1.6% in 2017 (negative income tax of 0.3 million euros). 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 December 2018, 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.

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 4%, from 17.2 million euros in 2017 to 17.9 million euros in 2018. However, net profit "pre-R&D", calculated excluding R&D expenses in 2018 and 2017 and the impact of non-recurring expenses in 2018, increased by 19%, from 45.0 million euros in 2017 to 53.8 million euros in 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 2018 as in 2017 and excluding the impact of non-recurring expenses in 2018, net profit would have increased by 36% to 23.5 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	**2018**	**2017**	**2018**	**2017**	**Chang**	**2018**	**2017**	**Chang**
Operat. revenue	303.2	275.6	303.2	275.6	10%	303.2	275.6	10%
Other income	1.6	1.8	1.6	1.8	-10%	1.6	1.8	-10%
Total revenue	**304.8**	**277.4**	**304.8**	**277.4**	**10%**	**304.8**	**277.4**	**10%**
Cost of sales	-128.6	-110.2	-128.6	-110.2	17%	-128.6	-110.2	17%
Gross profit	**176.2**	**167.2**	**176.2**	**167.2**	**5%**	**176.2**	**167.2**	**5%**
% margin	*58.1%*	*60.7%*	*58.1%*	*60.7%*	*-2.6pp*	*58.1%*	*60.7%*	*-2.6pp*
R&D expenses	-32.4	-28.3	**0.0**	**0.0**	n.a.	**-28.3**	-28.3	n.a.
SG&A	-113.2	-108.5	-113.2	-108.5	4%	-113.2	-108.5	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	-0.6	0.0	-0.6	-104%	0.0	-0.6	-104%
EBITDA	**29.5**	**29.9**	**63.0**	**58.2**	**8%**	**34.7**	**29.9**	**16%**
% margin	*9.7%*	*10.9%*	*20.8%*	*21.1%*	*-0.3pp*	*11.5%*	*10.9%*	*0.6pp*
EBIT	**17.5**	**18.4**	**51.0**	**46.7**	**9%**	**22.7**	**18.4**	**23%**
% margin	*5.8%*	*6.7%*	*16.8%*	*16.9%*	*-0.1pp*	*7.5%*	*6.7%*	*0.8pp*
Net profit	**17,9**	**17,2**	**53,8**	**45,0**	**19%**	**23,5**	**17,2**	**36%**
% margin	*5,9%*	*6,3%*	*17,7%*	*16,3%*	*1,4pp*	*7,7%*	*6,3%*	*1,5pp*

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 2018. Total revenue increased by 10% 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 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 increase

In 2018, ROVI increased its equity by approximately 88 million euros (see section 6.3). Net expenses related to the transaction amounted to 3.9 million euros, resulting in a net capital increase of 84.1 million euros. As of the date of this press release, ROVI has used, among other uses, 22.5 million euros of these funds to acquire Falithrom® (see section 6.2) and Polaramine® (see section 6.1).

3.2 Capital expenditure

ROVI invested 17.4 million euros in 2018, compared to 15.5 million euros in 2017. Of this amount:

- 3.8 million euros corresponds to investment capex related to the injectable facility, versus 2.9 million euros in 2017;
- 2.8 million euros relates to investment capex regarding the San Sebastián de los Reyes plant, versus 4.8 million euros in 2017;
- 3.0 million euros were invested in the Granada facility, versus 1.6 million euros in 2017;
- 5.5 million euros were invested in the Alcalá de Henares (Frosst Ibérica) facility, versus 3.8 million euros in 2017; and
- 2.3 million euros relates to expenditure on maintenance and other capex, in line with the investment in 2017.

In 2018, ROVI invested 9.0 million euros in the acquisition of Falithrom® (see section 6.2). Likewise, ROVI recorded a 4.5 million euro investment related to enoxaparin biosimilar in 2017.

	2018	2017	% Growth
Injectable plant	3.8	2.9	33%
San Sebastián de los Reyes plant	2.8	4.8	-41%
Granada plant	3.0	1.6	85%
Alcalá de Henares plant (Frosst Ibérica)	5.5	3.8	45%
Expenditure on maintenance and other capex	2.3	2.3	-3%
Total Capex	**17.4**	**15.5**	**13%**
Acquisitions and capitalization of development expenses	*9.0*	*4.5*	

3.3 Debt

As of 31 December 2018, ROVI had total debt of 34.2 million euros. Debt with public administration, which is 0% interest rate debt, represented 34% of total debt as of 31 December 2018.

In thousand euros	31 December 18	31 December 17
Bank borrowings	22,716	30,938
Debt with public administration	11,508	12,299
Total	**34,224**	**43,237**

As of 31 December 2018, bank borrowings decreased by 8.2 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 December 2018, ROVI had drawn down 5 million euros against this credit line.

3.4 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 -17.8 million euros in 2018 compared to -1.6 million euros in 2017 mainly due to (i) the increase of 19.4 million euros in the "inventories" line in 2018, compared to an increase of 8.1 million euros in 2017; (ii) the increase in the "trade and other receivables" line of 10.4 million euros in 2018, compared to a decrease of 4.1 million euros in 2017; (iii) the increase of 15.2 million

euros in the "trade and other payables" item in 2018, compared to a decrease of 6.9 million euros in 2017; and (iv) the increase of 6.5 million euros in Capex.

3.5 Gross cash position and net debt

As a result of the capital increase carried out in October 2018, as of 31 December 2018, ROVI had a gross cash position of 97.0 million euros, compared to 18.9 million euros as of 30 September 2018 and 42.1 million euros as of 31 December 2017, and net cash of 62.8 million euros (equity securities plus deposits plus cash and cash equivalents minus current and non-current financial debt), compared to net debt of 20.6 million euros as of 30 September 2018 and net debt of 1.1 million euros as of 31 December 2017.

3.6 Working capital

The increase in working capital in 2018 was mainly due to (i) an increase of 19.4 million euros in the "inventories" line, mainly due to higher heparin stock levels in 2018; (ii) an increase of 10.4 million euros in the "trade and other receivables" line; (iii) an increase, in 2018, of 15.2 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) an increase of 54.8 million euros in the "cash and cash equivalents" item as a result of the capital raise completed in October 2018 (see section 6.3).

As of 31 December 2018, Social Security and Public Administrations total debt with ROVI amounted to 7.3 million euros, of which 4.6 million euros in Spain, 1.1 million euros in Portugal and 1.6 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. Research and Development update

ISM® technology platform

As previously informed, ROVI has progressed in the development of Risperidone ISM®, 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 Risperidone ISM®, ROVI started the pivotal phase III trial "PRISMA-3"[3] with the recruitment of the first patient in May 2017. After finishing the recruitment in September 2018, all patients completed the double-blind (main) part of the study in December 2018. 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 6.5).

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.

6. Key operating and financial events

6.1 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

[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].*

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.

6.2 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).

6.3 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 Risperidone ISM® and other expenses related to Risperidone ISM® 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.

6.4 ROVI has commenced the marketing of the Enoxaparin biosimilar in eight countries 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 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 2018, ROVI commenced the marketing of its Enoxaparin biosimilar in UK, Italy, Spain and France, Austria, Latvia and Estonia.

As of 31st December 2018, all the European Union countries where ROVI had applied for the national registration of the Enoxaparin biosimilar had approved such registration, except Greece and Luxembourg.

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 December 2018, ROVI has distribution and marketing agreements for the Enoxaparin biosimilar in 64 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.

6.5 ROVI updates the pivotal PRISMA 3 study of 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®, an independent Data Monitoring Committee has recommended to continue the clinical trial and not increasing the currently planned number of randomized patients.

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 Risperidone ISM® in patients with acute exacerbation of schizophrenia[2], having initiated patients' recruitment in May 2017, as previously informed the 25th of October 2017 on a relevant fact (number 257753).

[1] *The agreement does not include Morocco and Lebanon has a semi-exclusive agreement.*
[2] *https://clinicaltrials.gov/ct2/show/NCT03160521*

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.

In December 2018, all patients completed the double-blind (main) part of the study. 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.

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

For further enquiries, please contact:

Juan López-Belmonte Encina
Chief Executive Officer
+34 913756235
jlopez-belmonte@rovi.es
www.rovi.es

Javier López-Belmonte Encina
Chief Financial Officer
+34 913756266
javierlbelmonte@rovi.es
www.rovi.es

Marta Campos Martínez
Investor Relations
+34 912444422
mcampos@rovi.es
www.rovi.es

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 DECEMBER 2018 AND 31 DECEMBER 2017

(Thousands of euros)

	31 December 2018	31 December 2017
ASSETS		
Non-current assets		
Property, Plant and Equipment	95,837	89,056
Intangible assets	34,650	27,078
Investment in a joint venture	2,038	2,054
Deferred income tax assets	16,036	11,893
Equity securities	70	69
Financial receivables	65	65
	148,696	**130,215**
Current assets		
Inventories	94,861	75,492
Trade and other receivables	60,180	49,747
Current income tax assets	3,414	2,228
Financial derivatives	17	-
Prepaid expenses	21	-
Cash and cash equivalents	95,511	40,700
	254,004	**168,167**
Total assets	**402,700**	**298,382**

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

(Thousands of euros)

	31 December 2018	31 December 2017
EQUITY		
Capital and reserves attributable to shareholders of the company		
Share capital	3,364	3,000
Share premium	87,636	-
Legal reserve	600	600
Treasury shares	(8,812)	(8,407)
Retained earnings and voluntary reserves	186,792	179,255
Profit for the period	17,895	17,241
Other reserves	(3)	(2)
Total equity	**287,472**	**191,687**
LIABILITIES		
Non-current liabilities		
Financial debt	16,589	27,029
Deferred income tax liabilities	1,243	1,438
Contract liabilities	6,263	-
Deferred income	3,621	5,005
	27,716	**33,472**
Current liabilities		
Financial debt	17,635	16,208
Trade and other payables	68,165	52,942
Contract liabilities	1,159	-
Deferred income	553	565
Provisions for other liabilities and charges	-	3,508
	87,512	**73,223**
Total liabilities	**115,228**	**106,695**
Total equity and liabilities	**402,700**	**298,382**

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED INCOME STATEMENTS FOR THE FULL YEARS 2018 AND 2017

(Thousands of euros)

	Full Year	
	2018	**2017**
Revenue	303,203	275,649
Changes in inventories of finished goods and work in progress	9,050	8,873
Raw materials and consumables used	(137,662)	(119,065)
Employee benefit expenses	(70,180)	(63,990)
Work performed by the Company on its assets	-	2,057
Other operating expenses	(76,496)	(74,809)
Amortisation and depreciation	(12,044)	(11,479)
Recognition of government grants on non-financial non-current assets and other	1,587	1,773
Share in profits of joint venture	24	(567)
OPERATING PROFIT	**17,482**	**18,442**
Finance income	16	93
Finance costs	(712)	(1,013)
Impairment and gain or loss on measurement of financial instruments	(23)	-
Exchange difference	(83)	-
FINANCE COSTS - NET	**(802)**	**(920)**
PROFIT BEFORE INCOME TAX	**16,680**	**17,522**
Income tax	1,215	(281)
PROFIT FOR THE PERIOD	**17,895**	**17,241**

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED CASH FLOW STATEMENTS FOR THE FULL YEARS 2018 AND 2017
(Thousands of euros)

	Full Year	
	2018	**2017**
Cash flows from operating activities		
Profit before tax	16,680	17,522
Adjustments for non-monetary transactions:		
Amortisation	12,044	11,479
Finance income	(16)	(93)
Valuation allowance	1,766	(1,437)
Adjustments for changes in value of derivatives	33	-
Finance expense	712	1,013
Net changes in provisions	-	630
Grant on non-financial assets and income from distribution	(1,806)	(2,012)
Profit for creation of joint venture	(10)	-
Share of profit of joint venture	(24)	567
Changes in working capital:		
Trade and other receivables	(9,605)	3,534
Inventories	(21,348)	(6,454)
Other current assets (prepaid expenses)	(21)	-
Trade and other payables	6,540	(6,910)
Other collections and payments:		
Proceeds from distribution licenses and other deferred revenue	6,727	87
Income tax cash flow	(3,141)	113
Net cash generated from (used in) operating activities	**8,531**	**18,039**
Cash flows from investing activities		
Purchases of intangible assets	(10,069)	(5,012)
Purchases of property, plant and equipment	(16,390)	(14,932)
Proceeds from sale of property, plant and equipment	62	25
Proceeds from sale of shares in joint venture	50	450
Interest received	105	285
Net cash generated from (used in) investing activities	**(26,242)**	**(19,184)**
Cash flows from financing activities		
Repayments of financial debt	(16,230)	(13,084)
Proceeds from financial debt	7,043	22,350
Interest paid	(187)	(253)
Purchase of treasury shares	(1,138)	(532)
Reissue of treasury shares	986	1,011
Dividends paid	(5,952)	(9,025)
Capital increase	88,000	-
Net cash generated from (used in) financing activities	**72,522**	**467**
Net (decrease) increase in cash and cash equivalents	**54,811**	**(678)**
Cash and cash equivalents at the beginning of the period	**40,700**	**41,378**
Cash and cash equivalents at the end of the period	**95,511**	**40,700**