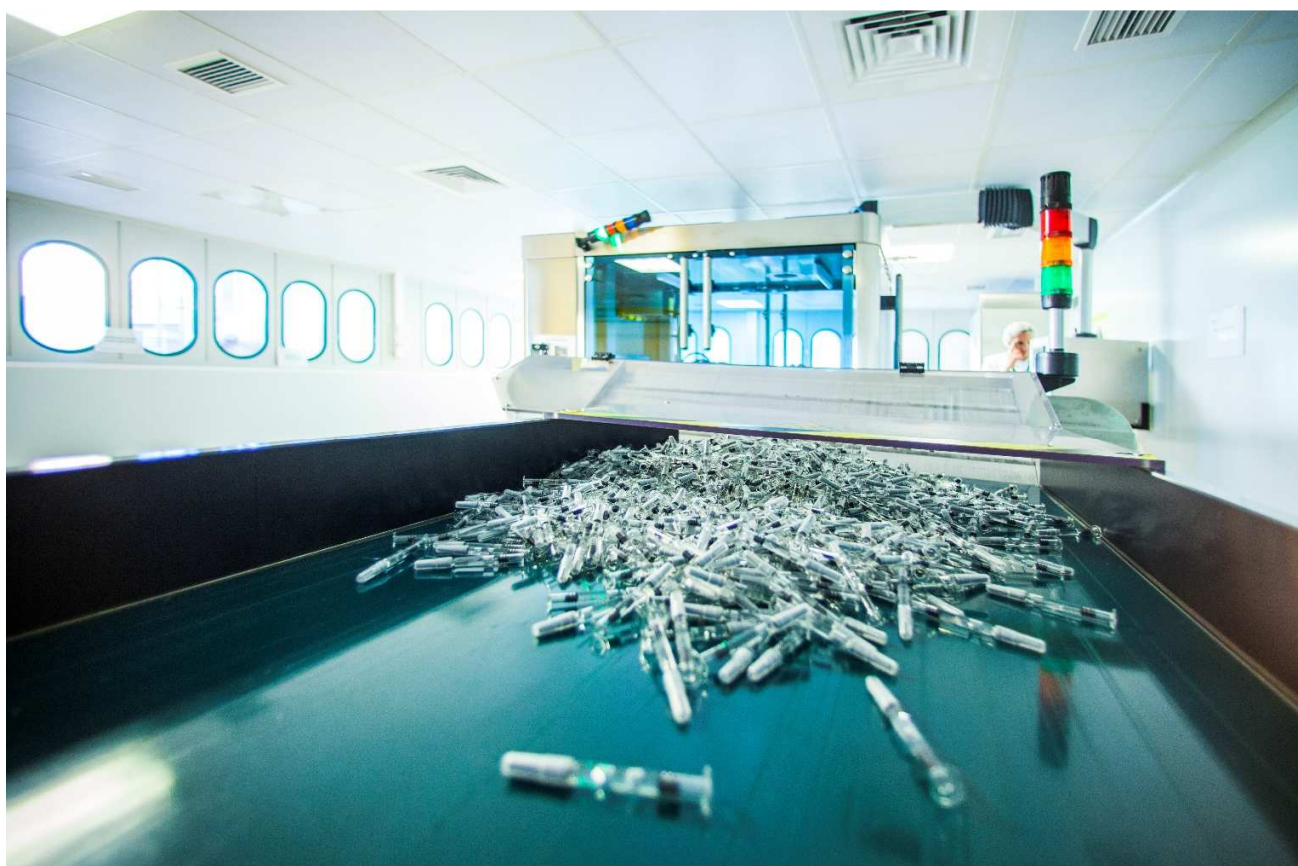




# First Half 2018 Results

26<sup>th</sup> July 2018



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



## **ROVI – First Half 2018 Financial Results**

# **ROVI reports operating revenue growth of 5% underpinned by outstanding Bemiparin sales**

- **Operating revenue increased by 5% to 146.3 million euros in the first half of 2018, driven by the strength of the specialty pharmaceutical business, where sales rose 14%, strongly outperforming the market. Total revenue increased by 5% to 147.1 million euros in the first half of 2018.**
- **In the first half of 2018, ROVI commenced the marketing of Enoxaparin biosimilar in UK and Italy, two top Enoxaparin markets in Europe together with Germany where the company commenced marketing in September 2017.**
- **In the first half of 2018, ROVI announced the signature of two licensing agreements for the distribution and marketing of its Enoxaparin biosimilar, the first with Hikma Pharmaceuticals for 17 MENA (Middle East and North Africa) countries and the second with Sandoz for 14 countries/regions.**
- **By 30<sup>th</sup> June 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 and Denmark.**
- **Sales of the Enoxaparin biosimilar amounted to 8.9 million euros in the first half of 2018.**
- **In 2018, ROVI expects a mid-single-digit growth rate for the operating revenue, with sales of its Enoxaparin biosimilar within a range of between 20 and 30 million euros.**
- **Sales of Bemiparin increased 13% in the first half of 2018 to 48.3 million euros; this growth came from sales in Spain (16%) and from international sales (7%).**
- **Sales of Vytorin<sup>®</sup>, Orvatez<sup>®</sup> and Absorcol<sup>®</sup> increased by 3% to 19.6 million euros in the first half of 2018. Sales of Volutsa<sup>®</sup>, increased by 25% to 5.4 million euros, and sales of Hirobriz<sup>®</sup> Breezhaler<sup>®</sup> and Ulunar<sup>®</sup> Breezhaler<sup>®</sup> increased by 9% to 7.7 million euros in the first half of 2018, compared to the same period the previous year.**



- **Sales of Neparvis<sup>®</sup>, launched in December 2016, reached 5.9 million euros in the first half of 2018.**
- **In the first half of 2018, EBITDA was affected by non-recurring expenses of 2.6 million euros. 1.5 million euros of this amount were related to the study and analysis of potential corporate operations, while 1.1 million euros were linked to a substantial change to Frosst Ibérica employees working conditions.**
- **EBITDA "Pre-R&D", calculated excluding R&D expenses in the first half of 2018 and 2017 and the impact of non-recurring expenses in the first half of 2018, decreased by 1%, from 33.0 million euros in the first half of 2017 to 32.7 million euros in the first half of 2018, reflecting a 1.4 percentage point fall in the EBITDA margin to 22.4% in the first half of 2018.**
- **Net profit "Pre-R&D", calculated excluding R&D expenses in the first half of 2018 and 2017 and the impact of non-recurring expenses in the first half of 2018, increased by 17%, from 24.3 million euros in the first half of 2017 to 28.4 million euros in the first half of 2018.**

**Madrid (Spain), 26<sup>th</sup> July 2018, 8:00 AM CET** - ROVI released today its financial results for the first half of 2018.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said *"in the first half of 2018, we reached 5% operating revenue growth mainly driven by the specialty pharmaceutical business strength, where sales rose by 14%. According to QuintilesIMS, the Spanish innovative product market increased by 2% in the first half 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 16%. 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<sup>®</sup>, a product with high strategic value from Novartis, in Spain in December 2016; (ii) our entry into the respiratory market through Hirobriz<sup>®</sup> Breezhaler<sup>®</sup> and Ulunar<sup>®</sup> Breezhaler<sup>®</sup> from Novartis, launched in Spain in December 2014; (iii) our entry into the urology field through the launch of Volutsa<sup>®</sup>, from Astellas Pharma, in Spain in February 2015; and (iv) the strengthening of the hypercholesterolaemia franchise through the launch of Orvatez<sup>®</sup>, 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 21 countries before 30<sup>th</sup> June 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 and have started commercialization in UK and Italy, three of the top Enoxaparin markets in Europe (in terms of volume and value), with good sales prospects, as reflected in the first half of 2018, when sales were 8.9 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 with the recruitment of the first patient 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”.*

## 1. Financial highlights

<i>€ million</i>	<b>1H 2018</b>	<b>1H 2017</b>	<b>Growth</b>	<b>% Growth</b>
Operating revenue	146.3	138.8	7.6	5%
Other income	0.8	0.7	0.1	11%
<b>Total revenue</b>	<b>147.1</b>	<b>139.4</b>	<b>7.6</b>	<b>5%</b>
Cost of sales	-61.9	-55.2	-6.7	12%
<b>Gross profit</b>	<b>85.1</b>	<b>84.2</b>	<b>0.9</b>	<b>1%</b>
<i>% margin</i>	<i>58.2%</i>	<i>60.7%</i>		<i>-2.5pp</i>
R&D expenses	-16.8	-9.4	-7.4	79%
SG&A	-52.4	-50.9	-1.5	3%
Other expenses	-2.6	-	-2.6	n.a.
Share of profit/loss of a joint venture	0.0	-0.3	0.3	-91%
<b>EBITDA</b>	<b>13.3</b>	<b>23.6</b>	<b>-10.3</b>	<b>-44%</b>
<i>% margin</i>	<i>9.1%</i>	<i>17.0%</i>		<i>-7.9pp</i>
<b>EBIT</b>	<b>7.5</b>	<b>17.7</b>	<b>-10.3</b>	<b>-58%</b>
<i>% margin</i>	<i>5.1%</i>	<i>12.8%</i>		<i>-7.7pp</i>
<b>Net profit</b>	<b>7.6</b>	<b>15.8</b>	<b>-8.2</b>	<b>-52%</b>

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



The consolidated financial statements of Grupo ROVI for the first half 2018 and the comparative information for 2017 (balance sheet) and for the first half 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 5% to 146.3 million euros in the first half of 2018, driven by the strength of the specialty pharmaceutical business, where sales rose 14%, strongly outperforming the market. Total revenue increased by 5% to 147.1 million euros in the first half of 2018.

<i>€ million</i>	<b>1H 2018</b>	<b>1H 2017</b>	<b>% Growth</b>
Specialty pharmaceutical business	123.2	107.8	14%
Toll manufacturing business	23.0	30.9	-25%
Royalties	0.0	0.1	-57%
<b>Total operating revenue</b>	<b>146.3</b>	<b>138.8</b>	<b>5%</b>

Sales of **prescription-based pharmaceutical** products rose 17% to 106.7 million euros in the first half of 2018.

<i>€ million</i>	<b>1H 2018</b>	<b>1H 2017</b>	<b>% Growth</b>
<b>Prescription-based pharmaceutical products</b>	<b>106.7</b>	<b>91.4</b>	<b>17%</b>
Bemiparin (Hibor)	48.3	42.6	13%
Sales in Spain	33.9	29.1	16%
International sales	14.4	13.5	7%
Enoxaparin biosimilar (Enoxaparin Becat)	8.9	-	n.a.
Vytorin & Absorcol & Orvatez	19.6	19.0	3%
Ulunar & Hirobriz	7.7	7.0	9%
Volutsa	5.4	4.3	25%
Medikinet & Medicebran	3.9	4.1	-3%
Neparvis	5.9	1.5	3,9x
Exxiv	1.2	2.3	-47%
Other products	13.8	18.1	-24%
Discounts to the National Health System	-8.1	-7.4	9%
<b>Contrast agents and other hospital products</b>	<b>15.3</b>	<b>14.8</b>	<b>4%</b>
<b>Non prescription pharmaceutical products ("OTC") and Other</b>	<b>1.2</b>	<b>1.6</b>	<b>-22%</b>
<b>Total specialty pharmaceutical business</b>	<b>123.2</b>	<b>107.8</b>	<b>14%</b>





ROVI's low molecular weight heparin (LMWH), **Bemiparin**, had a positive performance in the first half of 2018, with sales up 13% to 48.3 million euros. Sales of Bemiparin in Spain (**Hibor**<sup>®</sup>) increased by 16% to 33.9 million euros, while international sales increased by 7% to 14.4 million euros.

Sales of the **Enoxaparin biosimilar** amounted to 8.9 million euros in the first half of 2018, 86% of which corresponds to sales in Germany and 11% corresponds to sales in Italy.

Sales of **Vytorin**<sup>®</sup>, **Orvatez**<sup>®</sup> and **Absorcol**<sup>®</sup>, the first of the five licenses of MSD, indicated as adjunctive therapy to diet in patients with hypercholesterolemia, increased by 3% to 19.6 million euros in the first half of 2018. In the second quarter of 2018, the active principle ezetimibe went out of patent and the price of Absorcol<sup>®</sup> was reduced. Likewise, generics formulated with ezetimibe and simvastatin have recently been marketed, so the price of Vytorin<sup>®</sup> has been reduced to be competitive. However, Vytorin<sup>®</sup> is patent protected until April 2019, then ROVI is evaluating the most convenient way to protect its licensing rights.

Sales of **Hirobriz**<sup>®</sup> **Breezhaler**<sup>®</sup> and **Ulunar**<sup>®</sup> **Breezhaler**<sup>®</sup>, 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 7.7 million euros in the first half of 2018, compared to the same half the previous year.

Sales of **Volutsa**<sup>®</sup>, 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 5.4 million euros in the first half of 2018.

Sales of **Medicebran**<sup>®</sup> and **Medikinet**<sup>®</sup>, 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 3% to 3.9 million euros in the first half of 2018.

Sales of **Neparvis**<sup>®</sup>, 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 5.9 million euros in the first half of 2018, compared to 1.5 million euros in the same period of 2017.

Sales of **Exxiv**<sup>®</sup>, a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 47% to 1.2 million euros in the first half of 2018, mainly due to a continued deceleration of the COX-2 market.



**Corlantor®** and **Thymanax®** products were not marketed by ROVI in the first half of 2018. In the first half of 2017 sales of Corlantor® and Thymanax® amounted to 2.6 million euros and 2.2 million euros respectively.

According to QuintilesIMS, Spanish innovative product market increased by 2% in the first half 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 June 2018 increased by 2% compared to the same period the previous year. However, ROVI prescription-based pharmaceutical product sales rose 10% in the last year.

Sales of **contrast imaging agents** and other hospital products increased by 4% to 15.3 million euros in the first half of 2018.

Sales of **over-the-counter pharmaceutical products** ("OTC") and **other** decreased by 22% to 1.2 million euros in the first half of 2018 compared to the same period the previous year.

**Toll manufacturing** sales decreased by 25% to 23.0 million euros in the first half of 2018, compared to the same period the previous year, mainly because of the reduction of the injectable business compared to H1 2017, when exceptional high volumes were manufactured for some customers. Frosst Ibérica plant sales increased by 1% to 13.1 million euros in the first half 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.

<i>€ million</i>	<b>1H 2018</b>	<b>1H 2017</b>	<b>% Growth</b>
Injectable business	9.9	17.9	-45%
Oral forms business (Frosst Ibérica)	13.1	12.9	1%
<b>Total toll manufacturing business</b>	<b>23.0</b>	<b>30.9</b>	<b>-25%</b>

**Sales outside Spain** increased by 5% to 42.6 million euros in the first half of 2018 compared to the same period the previous year mainly due to (i) the Bemiparin international sale increase; and (ii) the registration of Enoxaparin biosimilar sales. Sales outside Spain represented 29% of operating revenue in the first half of 2018 as in the first half of 2017.

**Other income** (subsidies) increased by 11% to 0.8 million euros in the first half of 2018 compared to the first half of 2017.

**Gross profit** increased by 1% to 85.1 million euros in the first half of 2018, reflecting a decrease of 2.5 percentage points in the gross margin to 58.2% from 60.7% in the first half of



2017, mainly due to the decrease of injectable business which added higher margins in the first half of 2017.

**Research and development expenses** (R&D) mainly related to ISM<sup>®</sup> technology platform rose 79% to 16.8 million euros in the first half of 2018 mainly due to the development of the Risperidone-ISM<sup>®</sup> Phase III trial and the Letrozole-ISM<sup>®</sup> Phase I trial.

**Selling, general and administrative expenses** (SG&A) increased 3% to 52.4 million euros in the first half of 2018, mainly due to international subsidiaries expenses which amounted to 2.6 million euros compared to 0.2 million euros in the first half of 2017. Excluding expenses related to international subsidiaries, SG&A would have decreased by 2% in the first half of 2018.

<i>€ million</i>	<b>1H 2018</b>	<b>1H 2017</b>	<b>% Growth</b>
Personnel expenses	35.2	31.8	10%
Other operating expenses (exc. R&D)	17.2	19.1	-10%
<b>Total SG&amp;A expenses</b>	<b>52.4</b>	<b>50.9</b>	<b>3%</b>
<i>Expenses related to intern. subsidiaries</i>	<i>2.6</i>	<i>0.2</i>	

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

**EBITDA** decreased to 13.3 million euros in the first half of 2018, a fall of 44% compared to the same period the previous year, reflecting a 7.9 percentage point decrease in the EBITDA margin, which was down to 9.1% in the first half of 2018 from 17.0% in the first half of 2017. However, EBITDA "Pre-R&D", calculated excluding R&D expenses in the first half of 2018 and 2017 and the impact of non-recurring expenses in the first half of 2018, decreased by 1%, from 33.0 million euros in the first half of 2017 to 32.7 million euros in the first half of 2018, reflecting a 1.4 percentage point fall in the EBITDA margin to 22.4% in the first half 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 half of 2018 as in the first half of 2017 and excluding the impact of non-recurring expenses in the first half of 2018, EBITDA would have decreased by 1% to 23.4 million euros, reflecting a 1.1 percentage point fall in the EBITDA margin to 16.0% in the first half of 2018, down from 17.0% in the first half of 2017 (see "Flat R&D costs and w/o one-off" columns of the table below).





<i>€ million</i>	Reported		w/o R&D costs and one-off			Flat R&D costs and w/o one-off		
	1H 2018	1H 2017	1H 2018	1H 2017	Chang	1H 2018	1H 2017	Chang
Operat. revenue	146.3	138.8	146.3	138.8	5%	146.3	138.8	5%
Other income	0.8	0.7	0.8	0.7	11%	0.8	0.7	11%
<b>Total revenue</b>	<b>147.1</b>	<b>139.4</b>	<b>147.1</b>	<b>139.4</b>	<b>5%</b>	<b>147.1</b>	<b>139.4</b>	<b>5%</b>
Cost of sales	-61.9	-55.2	-61.9	-55.2	12%	-61.9	-55.2	12%
<b>Gross profit</b>	<b>85.1</b>	<b>84.2</b>	<b>85.1</b>	<b>84.2</b>	<b>1%</b>	<b>85.1</b>	<b>84.2</b>	<b>1%</b>
<i>% margin</i>	<i>58.2%</i>	<i>60.7%</i>	<i>58.2%</i>	<i>60.7%</i>	<i>-2.5pp</i>	<i>58.2%</i>	<i>60.7%</i>	<i>-2.5pp</i>
R&D expenses	-16.8	-9.4	<b>0.0</b>	<b>0.0</b>	n.a.	<b>-9.4</b>	-9.4	n.a.
SG&A	-52.4	-50.9	-52.4	-50.9	3%	-52.4	-50.9	3%
Other expenses	-2.6	-	<b>0.0</b>	-	n.a.	<b>0.0</b>	-	n.a.
Share of P/L of a JV	0.0	-0.3	0.0	-0.3	-91%	0.0	-0.3	-91%
<b>EBITDA</b>	<b>13.3</b>	<b>23.6</b>	<b>32.7</b>	<b>33.0</b>	<b>-1%</b>	<b>23.4</b>	<b>23.6</b>	<b>-1%</b>
<i>% margin</i>	<i>9.1%</i>	<i>17.0%</i>	<i>22.4%</i>	<i>23.8%</i>	<i>-1.4pp</i>	<i>16.0%</i>	<i>17.0%</i>	<i>-1.1pp</i>

**Depreciation and amortisation expenses** decreased by 1% to 5.9 million euros in the first half of 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 7.5 million euros in the first half of 2018, reflecting a 7.7 percentage point decrease in the EBIT margin, which was down to 5.1% in the first half of 2018 from 12.8% in the first half of 2017. However, EBIT "pre-R&D", calculated excluding R&D expenses in the first half of 2018 and 2017 and the impact of non-recurring expenses in the first half of 2018, decreased by 1%, from 27.1 million euros in the first half of 2017 to 26.9 million euros in the first half of 2018, reflecting a 1.2 percentage point fall in the EBIT margin to 18.4% in the first half 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 half of 2018 as in the first half of 2017 and excluding the impact of non-recurring expenses in the first half of 2018, EBIT would have decreased by 1% to 17.5 million euros, reflecting a 0.8 percentage point fall in the EBIT margin to 12.0% in the first half of 2018, down from 12.8% in the first half 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		
	1H 2018	1H 2017	1H 2018	1H 2017	Chang	1H 2018	1H 2017	Chang
Operat. revenue	146.3	138.8	146.3	138.8	5%	146.3	138.8	5%
Other income	0.8	0.7	0.8	0.7	11%	0.8	0.7	11%
<b>Total revenue</b>	<b>147.1</b>	<b>139.4</b>	<b>147.1</b>	<b>139.4</b>	<b>5%</b>	<b>147.1</b>	<b>139.4</b>	<b>5%</b>
Cost of sales	-61.9	-55.2	-61.9	-55.2	12%	-61.9	-55.2	12%
<b>Gross profit</b>	<b>85.1</b>	<b>84.2</b>	<b>85.1</b>	<b>84.2</b>	<b>1%</b>	<b>85.1</b>	<b>84.2</b>	<b>1%</b>
% margin	58.2%	60.7%	58.2%	60.7%	-2.5pp	58.2%	60.7%	-2.5pp
R&D expenses	-16.8	-9.4	0.0	0.0	n.a.	-9.4	-9.4	n.a.
SG&A	-52.4	-50.9	-52.4	-50.9	3%	-52.4	-50.9	3%
Other expenses	-2.6	-	0.0	-	n.a.	0.0	-	n.a.
Share of P/L of a JV	0.0	-0.3	0.0	-0.3	-91%	0.0	-0.3	-91%
<b>EBITDA</b>	<b>13.3</b>	<b>23.6</b>	<b>32.7</b>	<b>33.0</b>	<b>-1%</b>	<b>23.4</b>	<b>23.6</b>	<b>-1%</b>
% margin	9.1%	17.0%	22.4%	23.8%	-1.4pp	16.0%	17.0%	-1.1pp
<b>EBIT</b>	<b>7.5</b>	<b>17.7</b>	<b>26.9</b>	<b>27.1</b>	<b>-1%</b>	<b>17.5</b>	<b>17.7</b>	<b>-1%</b>
% margin	5.1%	12.8%	18.4%	19.5%	-1.2pp	12.0%	12.8%	-0.8pp

**Financial expense** decreased by 19% in the first half of 2018, compared to the same period the previous year.

**Financial income** decreased by 88% in the first half of 2018, compared to the first half of 2017.

The **effective tax rate** was -7.4% in the first half of 2018, generating a positive income tax of 0.5 million euros, compared to 8.6% in the first half of 2017 (negative income tax of 1.5 million euros). This improvement in the effective tax rate is due to the increase in the capitalisation of (i) research and development deductions and (ii) negative tax bases from Frosst Ibérica, S.A. As of 30 June 2018, Frosst Ibérica negative tax bases amounted to 35.1 million euros, of which 1.5 million euros will be used in the 2017 income tax and 0.7 million euros in the first half 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, 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** decreased by 52%, from 15.8 million euros in the first half of 2017 to 7.6 million euros in the first half of 2018. However, net profit "pre-R&D", calculated excluding R&D



expenses in the first half of 2018 and 2017 and the impact of non-recurring expenses in the first half of 2018, increased by 17%, from 24.3 million euros in the first half of 2017 to 28.4 million euros in the first half 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 half of 2018 as in the first half of 2017 and excluding the impact of non-recurring expenses in the first half of 2018, net profit would have increased by 16% to 18.3 million euros (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		
	1H 2018	1H 2017	1H 2018	1H 2017	Chang	1H 2018	1H 2017	Chang
Operat. revenue	146.3	138.8	146.3	138.8	5%	146.3	138.8	5%
Other income	0.8	0.7	0.8	0.7	11%	0.8	0.7	11%
<b>Total revenue</b>	<b>147.1</b>	<b>139.4</b>	<b>147.1</b>	<b>139.4</b>	<b>5%</b>	<b>147.1</b>	<b>139.4</b>	<b>5%</b>
Cost of sales	-61.9	-55.2	-61.9	-55.2	12%	-61.9	-55.2	12%
<b>Gross profit</b>	<b>85.1</b>	<b>84.2</b>	<b>85.1</b>	<b>84.2</b>	<b>1%</b>	<b>85.1</b>	<b>84.2</b>	<b>1%</b>
<i>% margin</i>	<i>58.2%</i>	<i>60.7%</i>	<i>58.2%</i>	<i>60.7%</i>	<i>-2.5pp</i>	<i>58.2%</i>	<i>60.7%</i>	<i>-2.5pp</i>
R&D expenses	-16.8	-9.4	<b>0.0</b>	<b>0.0</b>	n.a.	<b>-9.4</b>	-9.4	n.a.
SG&A	-52.4	-50.9	-52.4	-50.9	3%	-52.4	-50.9	3%
Other expenses	-2.6	-	<b>0.0</b>	-	n.a.	<b>0.0</b>	-	n.a.
Share of P/L of a JV	0.0	-0.3	0.0	-0.3	-91%	0.0	-0.3	-91%
<b>EBITDA</b>	<b>13.3</b>	<b>23.6</b>	<b>32.7</b>	<b>33.0</b>	<b>-1%</b>	<b>23.4</b>	<b>23.6</b>	<b>-1%</b>
<i>% margin</i>	<i>9.1%</i>	<i>17.0%</i>	<i>22.4%</i>	<i>23.8%</i>	<i>-1.4pp</i>	<i>16.0%</i>	<i>17.0%</i>	<i>-1.1pp</i>
<b>EBIT</b>	<b>7.5</b>	<b>17.7</b>	<b>26.9</b>	<b>27.1</b>	<b>-1%</b>	<b>17.5</b>	<b>17.7</b>	<b>-1%</b>
<i>% margin</i>	<i>5.1%</i>	<i>12.8%</i>	<i>18.4%</i>	<i>19.5%</i>	<i>-1.2pp</i>	<i>12.0%</i>	<i>12.8%</i>	<i>-0.8pp</i>
<b>Net profit</b>	<b>7.6</b>	<b>15.8</b>	<b>28.4</b>	<b>24.3</b>	<b>17%</b>	<b>18.3</b>	<b>15.8</b>	<b>16%</b>
<i>% margin</i>	<i>5.2%</i>	<i>11.4%</i>	<i>19.4%</i>	<i>17.5%</i>	<i>1.9pp</i>	<i>12.5%</i>	<i>11.4%</i>	<i>1.2pp</i>

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 5<sup>th</sup> July 2018 and it represented a 35% pay-out.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that "we are happy with the results of the first half of 2018. Total revenue increased by 5% thanks to the strength of our leading products, which continue to enjoy good sales prospects. The development of the Risperidone ISM<sup>®</sup> 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 half 2018 EBITDA figure. We continue to have a strong balance sheet and an excellent cash-generating capacity, which allow us to finance organic growth through the launch of new products, such as Neparvis<sup>®</sup>, Volutsa<sup>®</sup>, Ulunar<sup>®</sup> and Orvatez<sup>®</sup>,



*and to be in a strong position to benefit in the current operating environment, as we will pay special attention to potential opportunities to expand our sales base and improve the utilisation of our asset base”.*

### 3. Balance Sheet items

#### 3.1 Capital expenditure

ROVI invested 5.1 million euros in the first half of 2018, the same amount as in the first half of 2017. Of this amount:

- 0.9 million euros corresponds to investment capex related to the injectable facility, the same amount as in the first half of 2017;
- 0.9 million euros relates to investment capex regarding the San Sebastián de los Reyes plant, versus 1.1 million euros in the first half of 2017;
- 1.2 million euros were invested in the Granada facility, versus 0.1 million euros in the first half of 2017;
- 1.2 million euros were invested in the Alcalá de Henares (Frosst Ibérica) facility, versus 0.2 million euros in the first half of 2017; and
- 0.8 million euros relates to expenditure on maintenance and other capex, versus 2.7 million euros in the first half of 2017 (including capex related to the biosimilar of enoxaparin).

	<b>1H 2018</b>	<b>1H 2017</b>	<b>% Growth</b>
Injectable plant	0.9	0.9	3%
San Sebastián de los Reyes plant	0.9	1.1	-16%
Granada plant	1.2	0.1	n.a.
Alcalá de Henares plant (Frosst Ibérica)	1.2	0.2	n.a.
Expenditure on maintenance and other capex	0.8	2.7	-70%
<b>Total Capex</b>	<b>5.1</b>	<b>5.1</b>	<b>-2%</b>

#### 3.2 Debt

As of 30 June 2018, ROVI had total debt of 38.5 million euros. Debt with public administration, which is 0% interest rate debt, represented 33% of total debt as of 30 June 2018.

<i>In thousand euros</i>	<b>30 June 18</b>	<b>31 December 17</b>
Bank borrowings	25,906	30,938
Debt with public administration	12,552	12,299
<b>Total</b>	<b>38,458</b>	<b>43,237</b>

As of 30 June 2018, bank borrowings decreased by 5.0 million euros due to debt amortization.

In December 2017, ROVI announced the European Investment Bank (EIB) granted it a loan to support its investments in Research, Development and Innovation. The loan is for 45 million euros. ROVI may draw down this amount during a period of 24 months as from signature of the contract and the loan will mature in 2029. The loan provides for a three-year grace period and financial conditions (i.e. applicable interest rates, repayment periods, etc.) favorable to ROVI. As of 30 June 2018, ROVI has not yet made use of 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 -5.8 million euros in the first half of 2018 compared to -3.4 million euros in the first half of 2017 mainly due to (i) the increase of 15.9 million euros in the "inventories" line in the first half of 2018, compared to an increase of 6.0 million euros in the first half of 2017; (ii) the increase in the "trade and other receivables" line of 7.4 million euros in the first half of 2018, compared to a decrease of 0.8 million euros in the first half of 2017; (iii) the increase of 18.4 million euros in the "trade and other payables" item in the first half of 2018, compared to a decrease of 6.8 million euros in the first half of 2017 and (iv) the decrease of 10.2 million euros in profit before income tax.

### **3.4 Gross cash position and net debt**

As of 30 June 2018, ROVI had gross cash position of 31.4 million euros, compared to 42.1 million euros as of 31 December 2017, and net debt of 7.0 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 decrease in working capital in the first half of 2018 was mainly due to (i) an increase of 15.9 million euros in the "inventories" line, mainly due to higher heparin stock levels in the first half of 2018; (ii) an increase of 7.4 million euros in the "trade and other receivables" line; (iii) an increase of 18.4 million euros in the "trade and other payables" line, partly due to (a) the inclusion of 3.8 million euros, previously recognised as "provisions for other liabilities and charges", in this line in the first half of 2018, in accordance with the rules of the new standard IFRS 15, and (b) the recognition of a 6.0 million euros dividend in the first half of 2018, which had not yet been paid at the end of the period; and (iv) a decrease of 10.7 million euros in the "cash and cash equivalents" item.

As of 30 June 2018, Social Security and Public Administrations total debt with ROVI amounted to 5.2 million euros, of which 3.7 million euros in Spain and the other 1.5 million euros in Portugal.

#### 4. Guidance for 2018

In 2018, ROVI expects a **mid-single-digit growth rate for the operating revenue, with sales of its Enoxaparin biosimilar within a range of between 20 and 30 million euros**. The Company forecasts that it will continue to grow at a higher rate than Spanish pharmaceutical market expenditure in the first five months of 2018, which, according to the Ministry of Health, Consumption and Social Welfare, showed a growth rate of 3.5%.

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

In the second quarter of 2018, the active principle ezetimibe went out of patent and the price of Absorcol<sup>®</sup> was reduced. Likewise, generics formulated with ezetimibe and simvastatin have recently been marketed, so the price of Vytorin<sup>®</sup> has been reduced to be competitive. However, Vytorin<sup>®</sup> is patent protected until April 2019, then ROVI is evaluating the most convenient way to protect its licensing rights.

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

#### 5. Research and Development update

##### ISM<sup>®</sup> technology platform

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

After successfully finishing the phase I & II program<sup>1,2</sup> of DORIA<sup>®</sup>, ROVI started the pivotal phase III trial "PRISMA-3"<sup>3</sup> with the recruitment of the first patient in May 2017. An update of the project with details of the design and cost of Phase III was released, together with a presentation to analysts on 24<sup>th</sup> October 2017. The company plans to file an NDA (New Drug

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<sup>1</sup> 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.

<sup>2</sup> Anta L, Llaudó J, Ayani I, Martínez J, Litman RE, Gutierrez 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.

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





Application) US Registration Dossier for the FDA (Food and Drug Administration), the second half 2019 (see section 6.2).

On the other hand, in November 2017 ROVI started the clinical development of Letrozole ISM<sup>®</sup>, 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<sup>1</sup>, is an open-label, dose escalation study to evaluate the pharmacokinetics, safety and tolerability of single intramuscular injections of Letrozole ISM<sup>®</sup> at different strengths in healthy post-menopausal women. The clinical trial is currently ongoing as scheduled.

## 6. Key operating and financial events

### **6.1 ROVI has commenced the marketing of the Enoxaparin biosimilar in Germany, UK and Italy and has reached distribution and marketing agreements with Hikma and Sandoz**

ROVI informed (by publication of the relevant fact number 249265 dated 7<sup>th</sup> 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 half 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 half of 2018, ROVI commenced the marketing of Enoxaparin biosimilar in UK and Italy.

As of 30<sup>th</sup> June 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 and Denmark.

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



In April 2018, ROVI has signed a licensing agreement with Hikma Pharmaceuticals PLC, the quoted multinational pharmaceutical group (LSE: HIK), for the exclusive distribution and marketing of its Enoxaparin biosimilar in 17 MENA<sup>1</sup> (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.

Besides Europe, by July 2018, ROVI has distribution and marketing agreements for the Enoxaparin biosimilar in 45 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.

## **6.2 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.

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<sup>2</sup>, having initiated patients' recruitment in May 2017, as previously informed the 25th of October 2017 on a relevant fact (number 257753).

As expected, ROVI has 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 DMC has received unblinded results from this interim analysis and has communicated to ROVI the blinded outcome, concluding that the clinical trial can continue and an increase of the study sample size is not needed.

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<sup>1</sup> *The agreement does not include Morocco and Lebanon has a semi-exclusive agreement.*

<sup>2</sup> <https://clinicaltrials.gov/ct2/show/NCT03160521>



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<sup>®</sup> 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](http://www.rovi.es)

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## **Forward-looking statements**

This news release contains forward-looking statements. Such forward looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition, performance, or achievements of ROVI or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward looking statements. The statements in this press release represent ROVI's expectations and beliefs as of the date of this press release. ROVI anticipates that subsequent events and developments may cause these expectations and beliefs to change. However, while ROVI may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing ROVI's expectations or beliefs as of any date subsequent to the date of this press release.



## APPENDIX 1

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

(Thousands of euros)

	30 June 2018	31 December 2017
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, Plant and Equipment	89,095	89,056
Intangible assets	26,233	27,078
Investment in a joint venture	2,029	2,054
Deferred income tax assets	13,183	11,893
Equity securities	69	69
Financial receivables	65	65
	<b>130,674</b>	<b>130,215</b>
<b>Current assets</b>		
Inventories	91,422	75,492
Trade and other receivables	57,152	49,747
Current income tax assets	3,033	2,228
Cash and cash equivalents	29,966	40,700
	<b>181,573</b>	<b>168,167</b>
<b>Total assets</b>	<b>312,247</b>	<b>298,382</b>



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

(Thousands of euros)

	<b>30 June 2018</b>	<b>31 December 2017</b>
<b>EQUITY</b>		
<b>Capital and reserves attributable to shareholders of the company</b>		
Share capital	3,000	3,000
Legal reserve	600	600
Treasury shares	(8,600)	(8,407)
Retained earnings and voluntary reserves	190,567	179,255
Profit for the period	7,550	17,241
Other reserves	(3)	(2)
<b>Total equity</b>	<b>193,114</b>	<b>191,687</b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>		
Financial debt	19,389	27,029
Deferred income tax liabilities	937	1,438
Contract liabilities	3,710	-
Deferred income	3,906	5,005
	<b>27,942</b>	<b>33,472</b>
<b>Current liabilities</b>		
Financial debt	19,069	16,208
Trade and other payables	71,333	52,942
Contract liabilities	76	-
Deferred income	713	565
Provisions for other liabilities and charges	-	3,508
	<b>91,191</b>	<b>73,223</b>
<b>Total liabilities</b>	<b>119,133</b>	<b>106,695</b>
<b>Total equity and liabilities</b>	<b>312,247</b>	<b>298,382</b>





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

(Thousands of euros)

	Six-month periods ending 30 June	
	2018	2017
Revenue	146,309	138,759
Changes in inventories of finished goods and work in progress	8,719	9,435
Raw materials and consumables used	(70,662)	(64,675)
Employee benefit expenses	(36,266)	(31,846)
Other operating expenses	(35,513)	(28,426)
Amortisation	(5,858)	(5,918)
Recognition of government grants on non-financial non-current assets and other	754	681
<b>OPERATING PROFIT</b>	<b>7,483</b>	<b>18,010</b>
Finance income	7	57
Finance costs	(438)	(544)
<b>FINANCE COSTS - NET</b>	<b>(431)</b>	<b>(487)</b>
Share of profit of joint venture	(25)	(289)
<b>PROFIT BEFORE INCOME TAX</b>	<b>7,027</b>	<b>17,234</b>
Income tax	523	(1,477)
<b>PROFIT FOR THE PERIOD</b>	<b>7,550</b>	<b>15,757</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED CASH FLOW STATEMENTS FOR THE SIX-MONTH PERIODS ENDING 30**  
**JUNE 2018 AND 30 JUNE 2017**

(Thousands of euros)

	Six-month periods ending 30 June	
	2018	2017
<b>Cash flows from operating activities</b>		
Profit before income tax	7,027	17,234
<b>Adjustments for non-monetary transactions:</b>		
Amortisation	5,858	5,918
Finance income	(7)	(57)
Valuation allowance	2,226	499
Finance expense	438	544
Net changes in provisions	-	178
Grant on non-financial assets and income from distribution licences	(792)	(763)
Share of profit of joint venture	25	289
<b>Changes in working capital:</b>		
Trade and other receivables	(7,068)	276
Inventories	(18,234)	(6,628)
Trade and other payables	8,854	(16,013)
<b>Other collections and payments:</b>		
Proceeds from distribution licenses	2,910	87
Income tax cash flow	(2,074)	87
<b>Net cash generated from (used in) operating activities</b>	<b>(837)</b>	<b>1,651</b>
<b>Cash flows from investing activities</b>		
Purchases of intangible assets	(369)	(2,448)
Purchases of property, plant and equipment	(4,695)	(2,694)
Proceeds from sale of property, plant and equipment	12	-
Proceeds from sale of shares in joint venture	-	450
Interest received	95	48
<b>Net cash generated from (used in) investing activities</b>	<b>(4,957)</b>	<b>(4,644)</b>
<b>Cash flows from financing activities</b>		
Repayments of financial debt	(6,677)	(6,522)
Proceeds from financial debt	1,933	21,882
Interest paid	(103)	(127)
Purchase of treasury shares	(490)	(264)
Reissue of treasury shares	397	768
<b>Net cash generated from (used in) financing activities</b>	<b>(4,940)</b>	<b>15,737</b>
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(10,734)</b>	<b>12,744</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>40,700</b>	<b>41,378</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>29,966</b>	<b>54,122</b>