



# First Quarter 2017 Results

21<sup>st</sup> April 2017



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



## **ROVI – First Quarter 2017 Financial Results**

# **ROVI reports total revenue growth of 11% and recurrent EBITDA growth of 13%**

- **Operating revenue increased by 11% to 67.5 million euros in the first quarter of 2017, driven by the strength of the toll manufacturing business, where sales rose 28%, and by the specialty pharmaceutical business, which grew by 7%, outperforming the market. Total revenue increased by 11% to 67.8 million euros in the first quarter of 2017.**
- **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 (biosimilar of enoxaparin) was completed with positive outcome. It has been initiated, therefore, 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.**
- **For 2017, ROVI expects a low-to-mid single digit growth rate for operating revenue, despite (i) a new 550 million euro reduction in pharmaceutical expenditure expected for 2017, according to the Budget Plan<sup>1</sup> submitted by the Spanish Government to the European Commission; and (ii) 1-4% growth rate in spending on medicine in Spain to 2021 forecast by QuintilesIMS<sup>2</sup>.**
- **Sales of Bemiparin had an outstanding performance in the first quarter of 2017, with a 14% increase to 20.1 million euros; this growth came both from sales in Spain (+7%) and from international sales (+31%).**
- **Sales of Vytorin<sup>®</sup>, Orvatez<sup>®</sup> and Absorcol<sup>®</sup>, the first of the five licenses of Merck Sharp & Dohme (MSD), increased by 11% to 8.8 million euros in the first quarter of 2017. Sales of Volutsa<sup>®</sup>, from Astellas Pharma, increased by 37% to 2.0 million euros in the same period.**
- **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**

<sup>1</sup> [http://www.mineco.gob.es/stfls/mineco/comun/pdf/161017\\_plan\\_presupuestario.pdf](http://www.mineco.gob.es/stfls/mineco/comun/pdf/161017_plan_presupuestario.pdf)

<sup>2</sup> *Outlook for Global Medicines through 2021. Report by the QuintilesIMS Institute.*



**pulmonary disease known as Chronic Obstructive Pulmonary Disease (COPD), launched in Spain in the fourth quarter of 2014, increased by 22% to 3.5 million euros in the first quarter of 2017, compared to the first quarter of 2016.**

- **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 0.4 million euros in the first quarter of 2017.**
- **In the first quarter of 2016, EBITDA was affected by non-recurrent revenue of 4.0 million euros as a result of the joint venture created by ROVI and Enervit for the distribution of nutritional products in Spain and Portugal.**
- **EBITDA declined by 21% to 10.2 million euros in the three-month period ending 31 March 2017, compared to the same period of 2016, reflecting a 6.3 percentage point fall in the EBITDA margin down to 15.2% in the first quarter of 2017 from 21.5% in the same period of 2016. Excluding the impact of the non-recurrent revenue in the first quarter of 2016, EBITDA would have increased by 13% in the first quarter of 2017, reflecting a 0.3 percentage point rise in the EBITDA margin.**
- **Net profit decreased to 6.4 million euros in the three-month period ending 31 March 2017, a 32% fall compared to the same period of the previous year. Excluding the non-recurrent revenue of 4.0 million euros, net profit would have increased 12%.**
- **ROVI will propose to the Shareholders General Meeting a dividend of 0.1830 euros per share on 2016 earnings. This dividend represents a 35% pay out.**

**Madrid (Spain), 21<sup>st</sup> April 2017, 8:00 AM CET** - ROVI released today its financial results for the first quarter of 2017.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that *"in the first quarter 2017, we reached 11% operating revenue growth mainly driven by the strength of the toll manufacturing business, where sales rose 28%, and by the specialty pharmaceutical business, which grew by 7%. According to QuintilesIMS, Spanish innovative product market increased by 3% in the first quarter of 2017. We forecast to continue to grow thanks to, among others, our flagship product, Bemiparin, which is contributing to our growth, with a sales increase of 7% in the domestic market and 31% in the international market. Furthermore, we expect (i) the strengthening of the cardiovascular franchise through the launch of Neparvis<sup>®</sup>, a product of high strategic value from Novartis, in Spain in December 2016; (ii) the launch of Mysimba<sup>®</sup>, a*



*new pharmacological alternative for treating obesity, from Orexigen, in Spain in January 2017; (iii) our entrance in the respiratory market through the launch of Hirobriz<sup>®</sup> Breezhaler<sup>®</sup> and Ulunar<sup>®</sup> Breezhaler<sup>®</sup>, from Novartis, in Spain in December 2014; (iv) our entrance in the urology field through the launch of Volutsa<sup>®</sup>, from Astellas Pharma, in Spain in February 2015; and (v) the strengthening of the hypercholesterolaemia franchise through the launch of Orvatez<sup>®</sup>, from Merck Sharp and Dohme (MSD), in Spain in June 2015, to contribute to growth in the coming years. These recent launches cover growing demand needs and we expect they will provide us with a sustainable and profitable growth opportunity in the future. In addition, the MSD agreement will allow us to launch four additional new products until July 2019, underpinning our belief in the sustainability of our long term outlook. All these new product launches will lead us to extend the average life of our product portfolio by several years.*

*Our toll manufacturing business' sales increased 28% in the first quarter of 2017 mainly because of the good performance of the injectable business, where revenue increased 56% as a result of higher volumes manufactured for some customers.*

*Furthermore, we are confident of the potential of our current pipeline of R&D projects, making important investment efforts as we trust they will be the company's growth engine in the future. We are excited with the potential of our long acting injectable technology (ISM<sup>®</sup>); we expect to start a phase III trial with our ISM<sup>®</sup> technology in the second quarter of 2017 as well as to develop a new phase I study for another candidate in the second half this year. Likewise, our biosimilar of enoxaparin, which is currently facing the national phase of the registration process in Europe, represents an excellent growth opportunity for us considering the size of the European enoxaparin market, which amounts to more than 1 billion euros".*



## 1. Financial highlights

<i>€ million</i>	<b>1Q 2017</b>	<b>1Q 2016</b>	<b>Growth</b>	<b>% Growth</b>
Operating revenue	67.5	60.7	6.8	11%
Other income	0.3	0.1	0.2	115%
<b>Total revenue</b>	<b>67.8</b>	<b>60.8</b>	<b>7.0</b>	<b>11%</b>
Cost of sales	-26.3	-24.6	-1.7	7%
<b>Gross profit</b>	<b>41.5</b>	<b>36.2</b>	<b>5.3</b>	<b>15%</b>
<i>% margin</i>	<i>61.5%</i>	<i>59.7%</i>	-	<i>1.8pp</i>
R&D expenses	-6.2	-4.2	-1.9	46%
Other SG&A	-25.1	-23.0	-2.1	9%
Other income	-	4.0	-4.0	n.a.
<b>EBITDA</b>	<b>10.2</b>	<b>13.0</b>	<b>-2.8</b>	<b>-21%</b>
<i>% margin</i>	<i>15.2%</i>	<i>21.5%</i>	-	<i>-6.3pp</i>
<b>EBIT</b>	<b>7.3</b>	<b>10.4</b>	<b>-3.1</b>	<b>-30%</b>
<i>% margin</i>	<i>10.8%</i>	<i>17.1%</i>	-	<i>-6.3pp</i>
<b>Net profit</b>	<b>6.4</b>	<b>9.4</b>	<b>-3.0</b>	<b>-32%</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 quarter 2017 and the comparative information for 2016 (balance sheet) and for the first quarter of 2016 (consolidated income statement and cash flow statement) are attached to this report (see Appendix 1).

## 2. Performance of the Group

**Operating revenue** increased by 11% to 67.5 million euros in the first quarter of 2017, driven by the strength of the toll manufacturing business, where sales rose 28%, and by the specialty pharmaceutical business, which grew by 7%, outperforming the market. Total revenue increased by 11% to 67.8 million euros in the first quarter of 2017.

Sales of **prescription-based pharmaceutical** products rose 7% to 43.9 million euros in the first quarter of 2017.

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, had a very positive performance in the first quarter of 2017, with sales up 14% to 20.1 million euros. Sales of Bemiparin in Spain (**Hibor**<sup>®</sup>) increased by 7% to 14.0 million euros, while international sales grew by 31% to 6.1 million euros. This significant increase in international sales was specifically linked to the first quarter of 2017 and ROVI expects to maintain stable international sales in 2017.



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 11% to 8.8 million euros in the first quarter of 2017.

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 22% to 3.5 million euros in the first quarter of 2017, compared to the same period of 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 37% to 2.0 million euros in the first quarter of 2017.

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 1% to 2.0 million euros in the first three months of 2017.

Sales of **Corlontor**<sup>®</sup>, a specialty product for stable angina and chronic heart failure from Laboratoires Servier, decreased 43% to 1.9 million euros in the first three months of 2017, due to a price reduction of the product as units sold grew by 4% in this period.

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 0.4 million euros in the first quarter of 2017.

Sales of **Exxiv**<sup>®</sup>, a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 14% to 1.2 million euros in the first quarter of 2017, mainly due to a continued deceleration of the COX-2 market.

Sales of **Thymanax**<sup>®</sup>, an innovative antidepressant from Laboratoires Servier and for which ROVI has a co-marketing agreement covering Spain, decreased by 22% to 1.1 million euros in the first quarter of 2017.

According to QuintilesIMS, Spanish innovative product market increased by 3% in the first quarter of 2017 compared to the same period the previous year. Nevertheless, ROVI prescription-based pharmaceutical product sales rose 7% in the same period, beating the market by 4 percentage points.



Also, prescription-based pharmaceutical market covering the 12-month period ending March 2017 increased by 5% compared to the same period the previous year. However, ROVI prescription-based pharmaceutical product sales rose 16% in the last year.

In addition, a new 550 million euro reduction in pharmaceutical expenditure is expected for 2017, according to the Budget Plan submitted by the Spanish Government to the European Commission<sup>1</sup>, and a 1-4% growth rate in spending on medicine in Spain to 2021, is forecast by QuintilesIMS<sup>2</sup>. Despite the difficult situation the Spanish pharmaceutical industry continues to go through, ROVI forecasts to continue to grow.

Sales of **contrast imaging agents** and other hospital products increased by 16% to 7.4 million euros in the first quarter of 2017.

Sales of **over-the-counter pharmaceutical products** ("OTC") **and other** decreased by 45% to 0.6 million euros in the first quarter of 2017 compared to the same period of the previous year. In the first quarter of 2017, OTC sales did not include Enerzone product sales, while 0.6 million euro sales were included in the first quarter of 2016, before the creation of the joint venture of ROVI and Enervit for the distribution of nutritional products in Spain and Portugal.

**Toll manufacturing** sales increased by 28% to 15.5 million euros in the first three months of 2017, compared to the same period the previous year, mainly because of the good performance of the injectable business, where revenue increased 56% as a result of higher volumes manufactured for some customers. This significant increase in the injectable business was specifically linked to the first quarter of 2017 and ROVI expects to achieve a mid-to-high single digit growth rate for the business in 2017. Likewise, ROVI expects to achieve a slight growth for the toll manufacturing area in 2017 compared to a fall of 9% in 2016.

**Sales outside Spain** increased by 22% to 19.9 million euros in the first quarter of 2017 compared to the same period the previous year mainly due to the Bemiparin international sale increase. Sales outside Spain represented 29% of operating revenue in the first quarter of 2017 compared to 27% in the first quarter of 2016.

**Other income** (subsidies) increased by 2.2 times to 0.3 million euros in the first quarter of 2017 from 0.1 million euros in the same period in 2016, due to new subsidies granted for R&D projects.

**Gross profit** increased by 15% to 41.5 million euros in the three-month period ending 31 March 2017, reflecting an increase of 1.8 percentage points in the gross margin to 61.5% from

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<sup>1</sup> [http://www.mineco.gob.es/stfls/mineco/comun/pdf/161017\\_plan\\_presupuestario.pdf](http://www.mineco.gob.es/stfls/mineco/comun/pdf/161017_plan_presupuestario.pdf)

<sup>2</sup> *Outlook for Global Medicines through 2021. Report by the QuintilesIMS Institute.*



59.7% in the same period of 2016, mainly due to the increase of injectable business' sales, which contributed with higher margins.

**Research and development expenses** (R&D) rose 46% to 6.2 million euros in the first quarter of 2017 mainly due to (i) the preparation of the Risperidone-ISM<sup>®</sup> phase III trial and (ii) the performing of development activities for the formulation 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) rose 9% to 25.1 million euros in the three-month period ending 31 March 2017, compared to the same period of 2016, mainly due to Neparvis<sup>®</sup> and Mysimba<sup>®</sup> product launches which added expenses of 0.8 million euros.

In the first quarter of 2016, EBITDA was affected by non-recurrent revenue of 4.0 million euros as a result of the joint venture created by ROVI and Enervit for the distribution of nutritional products in Spain and Portugal.

**EBITDA** decreased by 21% to 10.2 million euros in the three-month period ending 31 March 2017, compared to the same period of 2016, reflecting a 6.3 percentage point fall in the EBITDA margin down to 15.2% in the first quarter of 2017 from 21.5% in the same period of 2016. Excluding the impact of the non-recurrent revenue in the first quarter of 2016, EBITDA would have increased by 13%, from 9.0 million euros in the first quarter of 2016 to 10.2 million euros in the first quarter of 2017, reflecting a 0.3 percentage point rise in the EBITDA margin.

**Depreciation and amortisation expenses** increased by 10% to 2.9 million euros in the first quarter of 2017, mainly due to the new property, plant and equipment and intangible assets purchases made during the last twelve months.

**EBIT** declined by 30% to 7.3 million euros in the first quarter of 2017, compared to the same period of 2016, reflecting a 6.3 percentage point drop in the EBIT margin to 10.8% in the first quarter of 2017, from 17.1% in the first quarter of 2016. Excluding the impact of the non-recurrent revenue in first quarter of 2016, EBIT would have increased by 15%, reflecting a 0.3 percentage point rise in the EBIT margin.

**Financial expense** decreased by 26% in the first quarter of 2017, compared to the same period of the previous year. The financial expense line also includes the implicit interests registered as a result of the recognition at fair value of reimbursable loans, at zero interest rate, granted by Public Administrations.

**Financial income** decreased by 87% in the first quarter of 2017, compared to first quarter of 2016, due to the reduction of delay interests from Court decisions related to pending invoices due for collection from Public Administration in the first quarter of 2017.





The **effective tax rate** was 8.5% in the first quarter of 2017 compared to 7.0% in the same period of 2016. This favourable effective tax rate is due to the deduction of existing research and development expenses and the capitalisation of negative tax bases from Frosst Ibérica, S.A. As of 31 December 2016, Frosst Ibérica negative tax bases amounted to 36.7 million euros, of which 1.6 million euros will be used in the 2016 income tax and 0.3 million euros in the first quarter of 2017.

On 3 December 2016, the Official State Gazette published the Royal Decree-Law 3/2016, taking tax measures regarding the consolidation of public finance and other urgent social measures. These tax measures, that came into force on that date, will negatively affect ROVI's income statement and income tax payable rate. Nevertheless, ROVI expects to maintain an effective tax rate from high single digit to low double digit for the foreseeable future.

Among the tax measures that will affect corporate income tax, it should be noted that:

- ✓ the compensation of negative tax bases from previous years is limited to 25%; and
- ✓ R&D tax credit schedule is maintained.

**Net profit** decreased to 6.4 million euros in the first quarter of 2017, a 32% fall compared to the same period of the previous year. Excluding the impact of the non-recurrent revenue in the first quarter of 2016, net profit would have increased by 12% in the first quarter of 2017.

ROVI will pay a **dividend** of 0.1830 euros per share on 2016 earnings if the Shareholders General Meeting approves the application of the 2016 profit, under proposal of ROVI's Board of Directors. This proposed dividend means an increase of 32% compared to the dividend on 2015 earnings (0.1390 euros per share) and implies approximately a 35% pay-out.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that *"we are very happy with the results of the first quarter of 2017. Total revenue increased by 11% thanks to the strength of our leading products, which continue to enjoy good sales prospects, as well as of our injectable toll manufacturing business. Recurrent EBITDA margin increased 0.3 percentage points in this period mainly as a result of the operating leverage contributed by our last product launches. We also expect the potential commercialisation of our biosimilar of enoxaparin and the expansion of our injectable toll manufacturing business will allow us to increase our profit margins in the future. It is very gratifying to witness the strength of our balance sheet and our excellent capacity to generate cash, which allows us to finance organic growth through the launch of new products, such as Neparvis®, Volutsa®, Ulunar®, Orvatez® or Mysimba®, and to be in a strong position to benefit in the current operating environment as we will pay 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 3.1 million euros in the first quarter of 2017, compared to 1.3 million euros in the first quarter of 2016. Of this amount:

- 0.5 million euros corresponds to investment capex related to the injectable facility, versus 0.2 million euros in the first quarter of 2016;
- 0.1 million euros relates to investment capex regarding the San Sebastián de los Reyes plant, versus 0.4 million euros invested in the first quarter of 2016;
- 0.1 million euros were invested in the Granada and the Alcalá de Henares (Frosst Ibérica) facilities, versus 0.2 million euros in the first quarter of 2016; and
- 2.4 million euros relates to expenditure on maintenance and other capex (including capex related to the biosimilar of enoxaparin), versus 0.5 million euros in the first quarter of 2016.

ROVI expects capital expenditure for 2017 to be below the 2016 figure (18.1 million euros).

#### 3.2 Debt

As of 31 March 2017, ROVI had total debt of 51.3 million euros. Debt with public administration, which is 0% interest rate debt, represented 25% of total debt as of 31 March 2017.

<i>In thousand euros</i>	<b>31 March 17</b>	<b>31 December 16</b>
Bank borrowings	38,442	20,931
Debt with public administration	12,858	12,863
<b>Total</b>	<b>51,300</b>	<b>33,794</b>

As of 31 March 2017, bank borrowings increased by 17.5 million euros. In the first quarter of 2017, ROVI increased its banking debt through a 20-million-euro new loan, with a fixed interest rate of 0.65% and a 3-year amortization period with a grace period of 17 months.

#### 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 -11.3 million euros in the first quarter of 2017 from 12.0 million euros in the first quarter of 2016 mainly due to (i) the decrease of 9.9 million euros in the "trade and other payables" item in the first quarter of 2017, compared to a decrease of 6.7 million euros in the first quarter of 2016; (ii) the increase of 4.6 million euros in the "inventories" line in the first quarter of 2017, compared to a decrease of 2.1 million euros in the first quarter of 2016; (iii) the increase in the

“trade and other receivables” line of 5.6 million euros in the first quarter of 2017, compared to a decrease of 5.7 million euros in the first quarter of 2016; and (iv) the increase of 1.8 million euros in Capex.

### 3.4 Gross cash position and net debt

As of 31 March 2017, ROVI had gross cash position of 49.1 million euros, compared to 42.8 million euros as of 31 December 2016, and net debt of 2.2 million euros (available-for-sale financial assets plus deposits plus cash and cash equivalents minus short term and long term financial debt), compared to net cash of 9.0 million euros as of 31 December 2016.

### 3.5 Working capital

The increase in working capital in the first quarter of 2017 was mainly due to (i) a decrease in the “trade and other payables” line of 9.9 million euros; (ii) an increase in the “trade and other receivables” line of 5.6 million euros; (iii) an increase in the “inventories” line of 4.6 million euros mainly due to higher heparin stock levels in the first quarter of 2017; and (iv) an increase in the “cash and cash equivalents” item of 6.3 million euros.

As of 31 March 2017, Social Security and Public Administrations total debt with ROVI amounted to 6.2 million euros, of which 4.9 million euros in Spain and the other 1.3 million euros in Portugal.

## 4. Guidance for 2017

In 2017, ROVI expects **a low-to-mid single digit growth rate for the operating revenue**, despite (i) a new 500 million euro reduction in pharmaceutical expenditure expected for next year, according to the Budget Plan<sup>1</sup> submitted by the Spanish Government to the European Commission, and (ii) 1-4% growth rate in spending on medicine in Spain to 2021 forecast by QuintilesIMS<sup>2</sup>.

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

Potential sales of the biosimilar of enoxaparin are not included in this guidance for 2017.

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<sup>1</sup>[http://www.mineco.gob.es/stfls/mineco/comun/pdf/161017\\_plan\\_presupuestario.pdf](http://www.mineco.gob.es/stfls/mineco/comun/pdf/161017_plan_presupuestario.pdf)

<sup>2</sup>Outlook for Global Medicines through 2021. Report by the QuintilesIMS Institute.



## 5. Research and Development update

### ISM®

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

In 2016 the results of the phase I trial PRISMA-1 were published in the medical journal *International Clinical Psychopharmacology*<sup>1</sup>, as well as the results of the phase II study "PRISMA-2" were presented on the 24<sup>th</sup> *European Congress of Psychiatry*<sup>2</sup>. Both studies have demonstrated that Risperidone ISM® achieves therapeutic levels from the first hours after drug administration, without needing oral risperidone supplementation, and provided a sustained release throughout the 4-weeks dosing period over multiple intramuscular injections, regardless the injection site (gluteus or deltoid muscle).

During December 2016 and first quarter 2017, the study protocol for the phase III trial "PRISMA-3" has already been submitted in the participant countries and patients' recruitment is planned to be started by the second quarter of 2017.

On the other hand, Rovi is planning to initiate the first phase I clinical trial of Letrozol ISM® by second semester 2017. Letrozol ISM® is a long-acting injectable aromatase inhibitor intended for the treatment of hormone-dependent breast cancer.

### Enoxaparin biosimilar

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 (biosimilar of enoxaparin) was completed with positive outcome (see section 6.1).

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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>Pharmacokinetics, Safety, and Tolerability of Four 28 Days Cycle Intramuscular Injections for Risperidone-ISM 75 Mg in Patients with Schizophrenia: A Phase-2 Randomized Study (PRISMA-2). 24<sup>th</sup> European Congress of Psychiatry, March 13, 2016, Madrid (Spain) [<http://epa-abstracts-2016.elsevier.cc/#289/z>]



## 6. Key operating and financial events

### 6.1 The Decentralised procedure used for the registration of ROVI's biosimilar of enoxaparin has been completed with positive outcome

On 7<sup>th</sup> of March 2017, the market was informed by publication of a relevant fact (number 249265) that the Decentralised procedure used for the Company to submit, in twenty-six countries of the European Union, the marketing authorization application of a low molecular weight heparin (biosimilar of enoxaparin) was completed with positive outcome.

In the mentioned Decentralised procedure, Germany has acted as Reference Member State (RMS). It has been initiated, therefore, 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. This national phase could last from three to ten months.

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

### About ROVI

ROVI is a fully integrated Spanish specialty pharmaceutical company engaged in the research, development, in-licensing, manufacturing and marketing of small molecule and specialty biologic drugs. The Company has a diversified portfolio of products that it markets in Spain through its specialized sales force, calling on specialist physicians, hospitals and pharmacies. ROVI's portfolio of 30 principal marketed products is currently anchored by the internally-developed, second generation low molecular weight heparin, Bemiparin. ROVI's research and development pipeline is focused primarily on the expansion of applications, indications and alternative mechanisms of action for the heparin-derived products and other glycosaminoglycans and on the development of new controlled release mechanisms based on ISM<sup>®</sup> technology, with the aim of obtaining new pharmaceutical products that enable the regular administration of formulations which are administered daily in chronic and prolonged treatments. ROVI manufactures the active biological ingredient (Bemiparin) for its principal proprietary products and for injectable pharmaceutical products developed by its in-house research team, and utilizes its state-of-the-art filling and packaging capabilities to provide a broad array of toll manufacturing services to leading international pharmaceutical companies, primarily in the area of pre-filled syringes. In addition, ROVI provides contract manufacturing and packaging services of solid oral pharmaceutical dosage forms, using the most enhanced technology, Roller Compaction. Additional information about ROVI is available on the company's website: [www.rovi.es](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 31 MARCH 2017 AND 31 DECEMBER 2016

(Thousands of euros)

	31 March 2017	31 December 2016
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, Plant and Equipment	81,370	82,822
Intangible assets	26,459	24,872
Investment in a joint venture	2,475	2,571
Deferred income tax assets	10,338	10,252
Available-for-sale financial assets	69	70
Financial receivables	115	189
	<b>120,826</b>	<b>120,776</b>
<b>Current assets</b>		
Inventories	72,032	67,386
Trade and other receivables	59,488	53,842
Current income tax assets	1,934	4,466
Cash and cash equivalents	47,662	41,378
	<b>181,116</b>	<b>167,072</b>
<b>Total assets</b>	<b>301,942</b>	<b>287,848</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS AS OF 31 MARCH 2017 AND 31 DECEMBER 2016**

(Thousands of euros)

	<b>31 March 2017</b>	<b>31 December 2016</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	(8,511)	(8,701)
Retained earnings and voluntary reserves	188,560	162,421
Profit for the period	6,374	26,089
Reserve for available-for-sale assets	(2)	(3)
<b>Total equity</b>	<b>190,021</b>	<b>183,406</b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>		
Financial debt	38,299	20,828
Deferred income tax liabilities	1,524	1,640
Deferred revenues	5,412	5,532
	<b>45,235</b>	<b>28,000</b>
<b>Current liabilities</b>		
Trade and other payables	49,926	59,852
Financial debt	13,001	12,966
Deferred revenues	845	746
Provisions for other liabilities and charges	2,914	2,878
	<b>66,686</b>	<b>76,442</b>
<b>Total liabilities</b>	<b>111,921</b>	<b>104,442</b>
<b>Total equity and liabilities</b>	<b>301,942</b>	<b>287,848</b>





**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED INCOME STATEMENTS FOR THE THREE-MONTH PERIODS ENDING 31**  
**MARCH 2017 AND 31 MARCH 2016**

(Thousands of euros)

	Three-month periods ending 31 March	
	2017	2016
Revenue	67,460	60,667
Cost of sales	(26,269)	(24,575)
Employee benefit expenses	(16,083)	(15,765)
Other operating expenses	(15,169)	(11,430)
Amortisation	(2,941)	(2,666)
Recognition of government grants on non financial non-current assets and other	310	144
Other income	-	3,997
<b>OPERATING PROFIT</b>	<b>7,308</b>	<b>10,372</b>
Finance income	11	86
Finance costs	(254)	(342)
<b>FINANCE COSTS - NET</b>	<b>(243)</b>	<b>(256)</b>
Share of profit of a joint venture	(96)	-
<b>PROFIT BEFORE INCOME TAX</b>	<b>6,969</b>	<b>10,116</b>
Income tax	(595)	(710)
<b>PROFIT FOR THE PERIOD</b>	<b>6,374</b>	<b>9,406</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED CASH FLOW STATEMENTS FOR THE THREE-MONTH PERIODS ENDING 31**  
**MARCH 2017 AND 31 MARCH 2016**

(Thousands of euros)

	Three-month periods ending 31 March	
	2017	2016
<b>Cash flows from operating activities</b>		
Profit before income tax	6,969	10,116
<b>Adjustments for non-monetary transactions:</b>		
Amortisation	2,941	2,666
Interest income	(11)	(86)
Impairment	261	617
Interest expense	254	254
Net changes in provisions	36	18
Grant for non-financial fixed assets and income from distribution	(353)	(185)
Profit from creation of joint venture	-	(3,997)
Share of profit of a joint venture	96	-
<b>Changes in working capital</b>		
Trade and other receivables	(5,198)	6,456
Inventories	(5,024)	1,535
Trade and other payables	(9,938)	(6,662)
<b>Other collections and payments</b>		
Proceeds from distribution licenses	(30)	-
Income tax cash flow	1,746	2,222
<b>Net cash generated (used) from operating activities</b>	<b>(8,251)</b>	<b>12,954</b>
<b>Cash flows from investing activities</b>		
Purchases of intangible assets	(2,319)	(227)
Purchases of property, plant and equipment	(757)	(1,033)
Proceeds from sale of property, plant and equipment	-	2
Investment in a joint venture	-	(3)
Proceeds from sale of shares in joint venture	-	500
Interest received	6	284
<b>Net cash generated (used) in investing activities</b>	<b>(3,070)</b>	<b>(477)</b>
<b>Cash flows from financing activities</b>		
Repayments of financial debt	(2,803)	(1,533)
Proceeds from financial debt	20,224	-
Interest paid	(56)	(57)
Purchase of treasury shares	(167)	(318)
Reissue of treasury shares	407	110
<b>Net cash generated (used) in financing activities</b>	<b>17,605</b>	<b>(1,798)</b>
<b>Net (decrease)/increase in cash and cash equivalents</b>	<b>6,284</b>	<b>10,679</b>
<b>Cash and cash equivalents at beginning of the period</b>	<b>41,378</b>	<b>29,251</b>
<b>Cash and cash equivalents at end of the period</b>	<b>47,662</b>	<b>39,930</b>