



First Quarter 2016 Results

27th April 2016



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



ROVI – First Quarter 2016 Financial Results

ROVI reports an EBITDA growth of 36% and a net profit growth of 46%

- **Operating revenue reached 60.7 million euros in the three-month period ending 31 March 2016, mainly driven by the strength of the prescription-based pharmaceutical business, where sales rose 15%, clearly outperforming the market.**
- **The clinical trial of Risperidone ISM® “PRISMA-2” was successfully finished; final positive results were presented on 13th March 2016 at the 24th European Congress of Psychiatry. The enoxaparin biosimilar assessment process is ongoing within the pre-established timelines.**
- **For 2016, ROVI expects a mid-to-high single digit growth rate for the operating revenue, despite (i) a 0.6% slight rise in the Spanish pharmaceutical market according to Farmaindustria¹, and (ii) stable annual growth between 1.3% and 1.6% in the Spanish pharmaceutical market for the period 2016-2019 forecast by IMS Health².**
- **Sales of Bemiparin in Spain performed well in the three-month period ending 31 March 2016, with a 4% increase to 13.1 million euros.**
- **Sales of Vytorin®, Orvatez® and Absorcol®, the first of the five licenses of Merck Sharp & Dohme (MSD), increased by 47% to 7.9 million euros in the first quarter of 2016. Sales of Volutsa®, from Astellas Pharma, increased by 3.9 times to 1.5 million euros in the same period.**
- **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 3.0 times to 2.8 million euros in the first quarter of 2016.**

¹<http://www.farmaindustria.es/web/documento/indicadores-basicos-del-sector-la-industria-farmaceutica-espanola-y-su-mercado-en-cifras/>

²IMS Health, *Market Prognosis September 2015*



- **In the first quarter of 2016, EBITDA was affected by non recurrent revenue of 4.0 million euros as a result of the creation of a joint venture between ROVI and Enervit for the distribution of nutritional products in Spain and Portugal (see section 6.1).**
- **EBITDA increased by 36% to 13.0 million euros in the three-month period ending 31 March 2016, compared to the same period the previous year, reflecting a 5.7 percentage point rise in the EBITDA margin to 21.5% in the first quarter of 2016 up from 15.8% in the first quarter of 2015.**
- **Net profit rose to 9.4 million euros in the three-month period ending 31 March 2016, a 46% increase compared to the same period the previous year. ROVI will propose to the Shareholders General Meeting a dividend of 0.1390 euros per share on 2015 earnings. This dividend represents a 35% pay out.**

Madrid (Spain), 27th April 2016, 8:00 AM CET - ROVI released today its financial results for the first quarter of 2016.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that *"in the first quarter of 2016, our operating revenue reached 60.7 million euros mainly driven by the strength of our prescription-based pharmaceutical business, where sales rose 15%, clearly outperforming the market. According to IMS Health, Spanish innovative product market increased by 2.6% in the first quarter of 2016. Nevertheless, we forecast to continue to grow thanks to, among others, our flagship product, Bemiparin, which is contributing to our growth. In particular, in the first quarter of 2016, Bemiparin sales increased by 4% in the domestic market. Furthermore, we expect (i) our entrance in the respiratory market through the launch of Hirobriz® Breezhaler® and Ulunar® Breezhaler®, from Novartis, in Spain in December 2014, (ii) our entrance in the urology field through the launch of Volutsa®, from Astellas Pharma, in Spain in February 2015, and (iii) the strengthening of the hipercolesterolaemia franchise through the launch of Orvatez®, from MSD, in Spain in June 2015, to contribute to growth in the coming years. These new 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 in the next 3 years, 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. On the other hand, our toll manufacturing business' sales decreased in the first quarter of 2016 mainly as a result of lower production levels for Merck Sharp and Dhome (MSD) since 31st March 2015, when the initial MSD contract expired. We are intensively working to acquire new clients in order to fill the spare capacity left by MSD in our Frosst Ibérica plant and that fact is evidenced by the manufacturing agreement signed with Merus Labs to produce Sintrom®, from the second half this year, which will contribute to reinforce this area.*



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 very excited with the potential of our long acting injectable technology (ISM®); we expect to start a phase III trial with our ISM® technology in the third quarter of 2016 as well as to develop a new phase I study for another candidate also this year. Likewise, we are hopeful of obtaining authorization to market a biosimilar of enoxaparin in Europe in 2016".

1. Financial highlights

€ million	Q1 2016	Q1 2015	Growth	% Growth
Operating revenue	60.7	60.8	-0.1	0%
Other income	0.1	0.3	-0.2	-54%
Total revenue	60.8	61.1	-0.3	0%
Cost of sales	-24.6	-25.4	0.8	-3%
Gross profit	36.2	35.7	0.5	1%
<i>% margin</i>	<i>59.7%</i>	<i>58.8%</i>		1.0pp
R&D expenses	-4.2	-3.2	-1.0	32%
Other SG&A	-23.0	-22.9	0.0	0%
Other income	4.0	-	4.0	-
EBITDA	13.0	9.6	3.5	36%
<i>% margin</i>	<i>21.5%</i>	<i>15.8%</i>		5.7pp
EBIT	10.4	7.1	3.2	45%
<i>% margin</i>	<i>17.1%</i>	<i>11.8%</i>		5.3pp
Net profit	9.4	6.5	3.0	46%

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 of 2016 and the comparative information for 2015 (balance sheet) and for the first quarter of 2015 (consolidated income statement and cash flow statement) are attached to this report (see Appendix 1).

2. Performance of the Group

Operating revenue remained stable at 60.7 million euros in the three-month period ending 31 March 2016, mainly driven by the strength of pharmaceutical specialties business, where sales rose 11%. Toll manufacturing sales decreased by 29% to 12.2 million euros in the first quarter of 2016 mainly due to lower production levels for MSD as a result of the initial MSD

contract expiration on the 31st March 2015. Total revenue decreased by 0.4% to 60.8 million euros in the first quarter of 2016.

Sales of **prescription-based pharmaceutical** products rose 15% to 40.9 million euros in the three-month period ending 31 March 2016.

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, performed well in Spain in the first quarter of 2016, with sales up 4% to 13.1 million euros. International sales decreased by 27% to 4.6 million euros. This decrease was specifically linked to the first quarter of 2016 and ROVI expects to achieve stable international sales in 2016. Bemiparin total sales decreased by 6% to 17.7 million euros in the first quarter of 2016.

Sales of **Vytorin**[®], **Orvatez**[®] and **Absorcol**[®], the first of the five licenses of MSD, indicated as adjunctive therapy to diet in patients with hypercholesterolemia, increased by 47% to 7.9 million euros in the three-month period ending 31 March 2016.

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 3.0 times to 2.8 million euros in the first quarter of 2016.

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 3.9 times to 1.5 million euros in the three-month period ending 31 March 2016.

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, increased by 3% to 2.1 million euros in the first quarter of 2016.

Sales of **Corlontor**[®], a specialty product for stable angina and chronic heart failure from Laboratoires Servier, remained flat at 3.4 million euros in the three-month period ending 31 March 2016.

Sales of **Exxiv**[®], a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 11% to 1.4 million euros in the first quarter of 2016, mainly due to a continued deceleration of the COX-2 market.

Sales of **Thymanax**[®], an innovative antidepressant from Laboratoires Servier and for which ROVI has a co-marketing agreement covering Spain, decreased by 27% to 1.4 million euros in the three-month period ending 31 March 2016.



According to IMS, Spanish innovative product market increased by 2.6% in the first quarter of 2016 compared to the same period the previous year. Nevertheless, ROVI prescription-based pharmaceutical product sales rose 15% in the same period, beating the market by 12.4 percentage points.

Also, prescription-based pharmaceutical market covering the 12-month period ending March 2016 increased by 0.1% compared to the same period the previous year. However, ROVI prescription-based pharmaceutical product sales rose 10% in the last year.

In addition, a slight 0.6% annual increase of the Spanish pharmaceutical expenditure is expected for 2016, according to Farmaindustria¹, and stable annual growth between 1.3% and 1.6% in the pharmaceutical market for the period 2016-2019 is forecast by IMS Health². Despite the difficult situation the pharmaceutical industry continues to go through, ROVI forecasts to grow above the growth estimates of the pharmaceutical expenditure.

Sales of **contrast imaging agents** and other hospital products decreased by 1% to 6.4 million euros in the three-month period ending 31 March 2016.

Sales of **over-the-counter pharmaceutical products** ("OTC") and **other** decreased by 24% to 1.2 million euros in the three-month period ending 31 March 2016 compared to the same period the previous year.

Toll manufacturing sales decreased by 29% to 12.2 million euros in the three-month period ending 31 March 2016, compared to the same period the previous year, mainly because of the 3.6 million euro revenue decline in the Frosst Ibérica plant to 6.2 million euros in the first quarter of 2016, due to lower production levels for MSD as a result of the initial MSD contract expiration on the 31st March 2015. In addition, the injectable plant revenue decreased by 1.3 million euros. This reduction in the injectable plant was specifically linked to the first quarter of 2016 and ROVI expects injectable business sales to grow in 2016.

Sales outside Spain decreased by 27% to 16.3 million euros in the three-month period ending 31 March 2016 compared to the same period the previous year. Sales outside Spain represented 27% of operating revenue in the first quarter of 2016 compared to 37% in the first quarter of 2015, mainly as a result of the deceleration of the toll manufacturing business, where most of the sales are linked to international markets.

Other income (subsidies) decreased by 54% to 0.1 million euros in the first quarter of 2016 from 0.3 million euros in the first quarter of 2015.

¹ <http://www.farmaindustria.es/web/documento/indicadores-basicos-del-sector-la-industria-farmaceutica-espanola-y-su-mercado-en-cifras/>

² IMS Health, Market Prognosis September 2015

Gross profit increased by 1.5% to 36.2 million euros in the three-month period ending 31 March 2016, reflecting an increase of 1.0 percentage points in the gross margin to 59.7% in the first quarter of 2016 from 58.8% in the first quarter of 2015. However, excluding the impact of the Other income (subsidiaries) item, gross margin would increase by 1.2 percentage points to 59.5% in the first quarter of 2016 from 58.3% in the first quarter of 2015. The decrease in Bemiparin raw material costs impacted positively on gross margin in the first quarter of 2016.

Research and development expenses (R&D) increased by 32% to 4.2 million euros in the three-month period ending 31 March 2016 mainly due to (i) the end of the PRISMA-2 study; (ii) the preparation of the Risperidone-ISM[®] phase III trial; and (iii) the performing of development activities for the formulation of the Risperidone-ISM[®] phase III trial and the Letrozole-ISM[®] phase I trial.

Selling, general and administrative expenses (SG&A) remained flat at 23.0 million euros in the three-month period ending 31 March 2016, compared to the same period the previous year, mainly due to lower production levels in the injectable and Frosst Ibérica plants.

EBITDA increased by 36% to 13.0 million euros in the three-month period ending 31 March 2016, compared to the same period the previous year, reflecting a 5.7 percentage point rise in the EBITDA margin to 21.5% in the first quarter of 2016 up from 15.8% in the first quarter of 2015, mainly due to the impact of 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 (see section 6.1). However;

- ✓ excluding the impact of the non recurrent revenue mentioned above, EBITDA would decrease by 6% to 9.0 million euros, reflecting a 0.9 percentage point fall in the EBITDA margin to 14.9% in the first quarter of 2016 down from 15.8% in the first quarter of 2015 mainly due to R&D expense increase; then
- ✓ maintaining, in the first quarter of 2016, the same amount of R&D expenses that was registered in the first quarter of 2015, EBITDA would increase by 5% to 10.1 million euros, reflecting a 0.8 percentage point rise in the EBITDA margin to 16.6% in the first quarter of 2016 up from 15.8% in the first quarter of 2015.

Depreciation and amortisation expenses increased by 10% to 2.7 million euros in the three-month period ending 31 March 2016, mainly as a result of the new property, plant and equipment and intangible assets purchases made over the last twelve months.

EBIT increased by 45% to 10.4 million euros in the three-month period ending 31 March 2016, compared to the same period the previous year, reflecting a 5.3 percentage point rise in the EBIT margin to 17.1% in the first quarter of 2016 up from 11.8% in the first quarter of 2015, mainly due to the impact of non recurrent revenue of 4.0 million euros as a result of the joint venture created by ROVI and Enervit (see section 6.1). However;

- ✓ excluding the impact of the non recurrent revenue mentioned above, EBIT would decrease by 11% to 6.4 million euros, reflecting a 1.2 percentage point fall in the EBIT margin to 10.5% in the first quarter of 2016 down from 11.8% in the first quarter of 2015. Nevertheless;
- ✓ maintaining, in the first quarter of 2016, the same amount of R&D expenses that was registered in the first quarter of 2015, EBIT would increase by 4% to 7.4 million euros, reflecting a 0.5 percentage point rise in the EBIT margin to 12.2% in the first quarter of 2016 up from 11.8% in the first quarter of 2015.

Financial expense decreased by 1% in the first quarter of 2016, compared to the same period 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 13% in the first quarter of 2016, compared to the first quarter of 2015.

The **effective tax rate** was 7.0% in the first quarter of 2016 compared to 6.5% in the first quarter of 2015. 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 2015, Frosst Ibérica negative tax bases amounted to 42.5 million euros, of which 5.7 million euros will be used in the 2015 income tax and 1.3 million euros in the first quarter of 2016.

On 27 November 2014, a deep tax reform was approved by law (see <http://www.boe.es/boe/dias/2014/11/28/pdfs/BOE-A-2014-12328.pdf>) in order to simplify taxes, reduce withholding taxes and improve Spanish companies' competitiveness. These tax measures, that have been in force since January 2015, have positively affected (and will positively affect) ROVI income statement and income tax payable rate. Then, ROVI expects to maintain an effective tax rate from mid to high single digit for the following years.

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

- ✓ the tax rate is reduced from 30% to 28% in 2015 and to 25% from 2016;
- ✓ tax losses may offset positive taxable income faster and without time limit; and
- ✓ R&D tax credit schedule is maintained.

Net profit rose to 9.4 million euros in the three-month period ending 31 March 2016, a 46% increase compared to the same period the previous year, impacted by non recurrent revenue of 4.0 million euros related to the ROVI and Enervit joint venture creation (see section 6.1). However;

- ✓ excluding the impact of the non recurrent revenue mentioned above, net profit would decrease by 12% to 5.7 million euros. Nevertheless;

- ✓ maintaining, in the first quarter of 2016, the same amount of R&D expenses that was registered in the first quarter of 2015, net profit would increase by 3% to 6.6 million euros.

ROVI will pay a **dividend** of 0.1390 euros per share on 2015 earnings if the Shareholders General Meeting approves the application of the 2015 profit, under proposal of ROVI's Board of Directors. This proposed dividend represents a 35% pay-out.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that *"operating revenue remained stable in the first quarter of 2016, thanks to the strength of our leading products, which continue to enjoy good sales prospects. We also expect that the spare capacity in the Alcalá and San Sebastián de los Reyes manufacturing facilities, that will shortly start being used, will allow us to increase our profit margins. Our focus on R&D to commercialise our own products led us to significantly invest in the first half of 2016, impacting the recurrent EBITDA figure. Nevertheless, we expect EBITDA to recover the path of sustained growth shortly. 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 Volutsa[®], Ulunar[®], Hirobriz[®], Orvatez[®], Vytarin[®] or Medikinet[®], 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 1.3 million euros in the first quarter of 2016, compared to 1.4 million euros in the first quarter of 2015. Of this amount:

- 0.2 million euros corresponds to investment capex related to the injectables facility, versus 0.6 million euros in the first quarter of 2015;
- 0.1 million euros corresponds to investment capex related to the Granada facility, versus 0.4 million euros in the first quarter of 2015;
- 0.1 million euros corresponds to investment capex related to the Alcalá (Frosst Ibérica) facility, in line with the first quarter of 2015;
- 0.5 million euros corresponds to expenditure on maintenance and other, vs. 0.3 million euros in the first quarter of 2015; and
- 0.4 million euros were invested in the San Sebastián de los Reyes plant in the first quarter of 2016.



3.2 Debt

As of 31 March 2016, ROVI had total debt of 41.4 million euros. Debt with public administration, which is 0% interest rate debt, represented 35% of total debt as of 31 March 2016.

<i>In thousand euros</i>	31 March 16	31 December 15
Bank borrowings	26,877	28,179
Debt with public administration	14,565	14,599
Total	41,442	42,778

3.3 Free cash flow

Free cash flow (net cash generated (used) from operating activities minus (plus) property, plant and equipment and intangible assets purchases (sales) plus interest received) increased to 12.0 million euros in the first quarter of 2016 from 1.0 million euros in the first quarter of 2015 mainly due to (i) the decrease of 5.7 million euros in the "trade and other receivables" item in the first quarter of 2016, compared to an increase of 1.2 million euros in the first quarter of 2015; and (ii) the decrease of 2.1 million euros in the "inventories" item, compared to an increase of 1.7 million euros in the first quarter of 2015. These positive impacts were partially offset by the decrease of 6.7 million euros in the "trade and other payables" item in the first quarter of 2016, compared to a decrease of 5.7 million euros in the first quarter of 2015.

3.4 Gross cash position and net debt

As of 31 March 2016, ROVI had gross cash position of 41.4 million euros, compared to 30.7 million euros as of 31 December 2015, and zero net debt (available-for-sale financial assets plus deposits plus cash and cash equivalents minus short term and long term financial debt), compared to 12.1 million euros as of 31 December 2015.

3.5 Working capital

The increase in working capital in the first quarter of 2016 was mainly due to (i) a decrease in the "trade and other payables" line of 6.7 million euros; (ii) an increase in the "cash and cash equivalents" item of 10.7 million euros; (iii) a decrease in the "trade and other receivables" line of 5.7 million euros in the first quarter of 2016; and (iv) a decrease in "inventories" of 2.1 million euros mainly because of lower Bemiparin stock levels in the first quarter of 2016.

As of 31 March 2016, Social Security and Public Administrations total debt with ROVI amounted to 4.8 million euros, of which 4.4 million euros in Spain and the other 0.4 million euros in Portugal. Almost all this debt is expected to be collected through the usual channels.

4. Guidance for 2016

For 2016, ROVI expects **a mid-to-high single digit growth rate for the operating revenue**, despite (i) a 0.6% slight rise in the Spanish pharmaceutical market according to Farmaindustria¹, and (ii) stable annual growth between 1.3% and 1.6% in the Spanish pharmaceutical market for the period 2016-2019 forecast by IMS Health².

ROVI is revising the 2016 guidance for operating revenue that it published in its earnings release for the first nine months of 2015 and for the full year 2015, when it forecast operating revenue growth within a range of high single digit to low double digit growth. This is mainly due to the exclusion of (i) Enerzona product sales from the operating revenue line, from 1st April 2016, and (ii) the potential growth expected for the nutritional product business, as a result of the creation of a joint venture between ROVI and Enervit for the distribution of nutritional products in Spain and Portugal. Enerzona product sales amounted to 3.8 million euros in 2015.

ROVI expects its growth drivers to be Bemiparin, the new license agreements (Volutsa[®], Orvatez[®], Ulunar[®] and Hirobriz[®]), contribution from Vytorin[®] and Absorcol[®], its existing portfolio of specialty pharmaceuticals, new product distribution licenses and new contracts in the toll manufacturing area.

5. Research and Development update

ISM[®]

As ROVI previously informed, the clinical trial of Risperidone ISM[®] "PRISMA-2" was successfully finished and the final positive results were presented on 13th March 2016 at the 24th European Congress of Psychiatry³.

The PRISMA-2 is an open-label, parallel phase II clinical trial that was carried out in four USA centres. The main objective of this trial was to evaluate the safety and pharmacokinetics, as well as to explore the efficacy, of multiple intramuscular doses of Risperidone ISM[®] in patients with stable schizophrenia⁴. Sixty-seven schizophrenic subjects randomly received four monthly

¹<http://www.farmaindustria.es/web/documento/indicadores-basicos-del-sector-la-industria-farmaceutica-espanola-y-su-mercado-en-cifras/>

²IMS Health, *Market Prognosis September 2015*

³Pharmacokinetics, 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). 24th European Congress of Psychiatry, March 13, 2016, Madrid (Spain) [<http://epa-abstracts-2016.elsevier.cc/#289/z>]

⁴Pharmacokinetics and Tolerability Study of Risperidone ISM[®] in Schizophrenia (PRISMA-2). [<http://clinicaltrials.gov/show/NCT02086786>].

doses of Risperidone ISM[®] 75mg, injected either in the gluteus or the deltoid muscle, without any supplementation of oral risperidone. All subjects achieved therapeutic levels (>7.5 ng/mL for the active moiety) between 2-8 hours after drug administration. The mean concentrations were maintained above therapeutic levels throughout the 4-weeks dosing period. No significance changes across the study were observed, either on *Positive and Negative Syndrome Scale* or *Extrapyramidal Symptoms Scale*. Risperidone ISM[®] was also found to be safe and well tolerated. Therefore, it was concluded that Risperidone ISM[®] achieved 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).

The PRISMA-2 results, along with data from previous studies, have already been submitted to the *US Food and Drug Administration* (FDA) and *European Medicines Agency* (EMA) in order to request scientific advice about the design of the phase III clinical study. Accordingly, an *End of Phase II meeting* has been held with the FDA on February 25th, 2016. Besides a meeting with the EMA for *Pre-submission of Scientific Advice* was held on January 15th, 2016, and final adoption of the scientific advice at CHMP (*Committee for Medicinal Products for Human Use*) is expected by late April or early May 2016. After that, the study protocol for phase III trial will be refined, if needed, and patients' recruitment will be starting by third quarter 2016.

On the other hand, activities are already underway in order to start the first phase I clinical trial with Letrozol ISM[®] by second half 2016. Letrozol ISM[®] is a long-acting injectable aromatase inhibitor intended for the treatment of hormone-dependent breast cancer.

Enoxaparin biosimilar

With regards to the assessment process started in order for ROVI to be granted the Marketing Authorisation in Europe of a biosimilar of enoxaparin, still is ongoing within the pre-established timelines.

6. Key operating and financial events

6.1 Enervit Nutrition, joint venture of ROVI and Enervit, will distribute nutritional products and other non-pharmacological products in Spain and Portugal

Enervit Nutrition, S.L., joint venture participated by Laboratorios Farmacéuticos Rovi, S.A. ("ROVI") and the Italian company Enervit, S.p.A., aims the joint distribution and co-marketing,



by ROVI and Enervit, S.p.A., of dietary, food and nutrition products, as well as other non pharmacological products in the territories of Spain and Portugal.

Enervit, S.p.A is listed on the Milan Stock Exchange and leads the special nutrition market in Italy for those who do sports and have an interest in keeping fit.

Among the products owned by Enervit, S.p.A. that Enervit Nutrition, S.L. will market, ROVI had already been distributing some of them, in particular EnerZone, a range of products based in the principles of The Zone diet, under a previously signed agreement with Enervit, S.p.A.

Through this operation, ROVI intends to develop its business of nutritional products thanks to a lasting partnership that allows to both members of the joint venture to benefit from the synergies derived from their respective contributions to the same. Accordingly, ROVI will contribute with its knowledge, presence and portfolio of customers in the Spanish market as well as with its current licence rights over the EnerZone products. In turn, Enervit, S.p.A. will bring the extension of its licensing rights of EnerZone products, with regard to its duration, and the incorporation of new nutritional products, in order to ensure the innovative and extensive offering that this market demands.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, and Alberto Sorbini, Chairman of Enervit, S.p.A., commented: *"this strategic alliance implies joining efforts to achieve our common objective: satisfying the needs of a society increasingly concerned for keeping a healthy and balanced diet that allows not only improving the physical appearance, but also helps to prevent diseases such as obesity, quite common in Spain during the last years. We are very enthusiastic with our presence in a sector that is at one of their highpoints and faces a promising future"*.

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® 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

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 MARCH 2016 AND 31 DECEMBER 2015

(Thousands of euros)

	31 March 2016	31 December 2015
ASSETS		
Non-current assets		
Property, Plant and Equipment	80,725	81,803
Intangible assets	18,551	18,881
Investment in a joint venture	2,550	-
Deferred tax assets	9,482	8,871
Available-for-sale financial assets	70	70
Financial receivables	139	139
	111,517	109,764
Current assets		
Inventories	61,718	63,859
Trade and other receivables	51,301	57,028
Current income tax assets	935	3,945
Cash and cash equivalents	39,930	29,251
	153,884	154,083
Total assets	265,401	263,847



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS AS OF 31 MARCH 2016 AND 31 DECEMBER 2015

(Thousands of euros)

	31 March 2016	31 December 2015
EQUITY		
Capital and reserves attributable to shareholders of the company		
Share capital	3,000	3,000
Legal reserve	600	600
Treasury shares	(8,336)	(8,112)
Retained earnings and voluntary reserves	169,315	149,490
Profit for the period	9,406	19,809
Reserve for available-for-sale assets	(3)	(2)
Total equity	173,982	164,785
LIABILITIES		
Non-current liabilities		
Financial debt	29,963	32,631
Deferred income tax liabilities	1,877	1,344
Non-current deferred revenues	5,723	5,861
	37,563	39,836
Current liabilities		
Trade and other payables	39,080	45,742
Financial debt	11,479	10,147
Current deferred revenues	782	840
Provisions for other liabilities and charges	2,515	2,497
	53,856	59,226
Total liabilities	91,419	99,062
Total equity and liabilities	265,401	263,847



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED INCOME STATEMENTS FOR THE THREE-MONTH PERIODS ENDING 31
MARCH 2016 AND 31 MARCH 2015

(Thousands of euros)

	Three-month periods ending 31 March	
	2016	2015
Revenue	60,667	60,766
Cost of sales	(24,575)	(25,369)
Employee benefit expenses	(15,765)	(15,602)
Other operating expenses	(11,430)	(10,533)
Depreciation, amortisation and impairment charges	(2,666)	(2,432)
Recognition of government grants on non financial non-current assets and other	144	312
Other income	3,997	-
OPERATING PROFIT	10,372	7,142
Finance income	86	99
Finance costs	(342)	(344)
FINANCE COSTS - NET	(256)	(245)
PROFIT BEFORE INCOME TAX	10,116	6,897
Income tax	(710)	(446)
PROFIT FOR THE PERIOD	9,406	6,451



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED CASH FLOW STATEMENTS FOR THE THREE-MONTH PERIODS ENDING 31
MARCH 2016 AND 31 MARCH 2015

(Thousands of euros)

	Three-month periods ending 31 March	
	2016	2015
Cash flows from operating activities		
Profit before income tax	10,116	6,897
Adjustments for non-monetary transactions:		
Amortisation	2,666	2,432
Interest income	(86)	(99)
Impairment losses	617	91
Interest expense	254	344
Net changes in provisions	18	273
Grant for non-financial fixed assets and distribution licence income	(185)	106
Profit from joint venture creation	(3,997)	-
Changes in working capital		
Trade and other receivables	6,456	(1,404)
Inventories	1,535	(1,809)
Trade and other payables	(6,662)	(6,293)
Other collections and payments		
Interest paid	-	(85)
Income tax cash flow	2,222	1,900
Net cash generated (used) from operating activities	12,954	2,353
Cash flows from investing activities		
Purchases of intangible assets	(227)	(567)
Purchases of property, plant and equipment	(1,033)	(855)
Proceeds of property, plant and equipment	2	6
Investment in a joint venture	(3)	-
Cash increase due to sale of joint venture shares	500	-
Interest received	284	48
Net cash generated (used) in investing activities	(477)	(1,368)
Cash flows from financing activities		
Repayments of financial debt	(1,533)	(322)
Proceeds from financial debt	-	305
Interest paid	(57)	-
Purchase of treasury shares	(318)	(330)
Reissue of treasury shares	110	546
Net cash generated in financing activities	(1,798)	199
Net (decrease)/increase in cash and cash equivalents	10,679	1,184
Cash and cash equivalents at beginning of the period	29,251	26,671
Cash and cash equivalents at end of the period	39,930	27,855