



Nine-month period ending 30th September 2016 Results

8th November 2016



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



ROVI – Nine-month period ending 30th September 2016 Financial Results

ROVI reports an EBITDA growth of 23% and a net profit growth of 30%

- **Operating revenue increased by 8% to 191.5 million euros in the nine-month period ending 30 September 2016, mainly driven by the strength of the prescription-based pharmaceutical business, where sales rose 22%, clearly outperforming the market. Total revenue increased by 8% to 192.9 million euros in the first nine months of 2016.**
- **For 2017, ROVI expects a low-to-mid single digit growth rate for operating revenue, despite (i) a new 550 million euros reduction in pharmaceutical expenditure expected for next year, according to the Budget Plan¹ submitted by the Spanish Government to the European Commission, and (ii) growth in spending on medicine between 1% and 4% in Spain for the period 2016-2020 forecast by IMS Health².**
- **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.**
- **Sales of Bemiparin had an outstanding performance in the nine-month period ending 30 September 2016, with a 9% increase to 59.2 million euros; this growth came both from sales in Spain (+9%) and from international sales (+9%).**
- **Sales of Vytorin®, Orvatez® and Absorcol®, the first of the five licenses of Merck Sharp & Dohme (MSD), increased by 42% to 24.0 million euros in the nine-month period ending 30 September 2016. Sales of Volutsa®, from Astellas Pharma, increased by 2.5 times to 4.9 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**

¹http://www.mineco.gob.es/stfls/mineco/comun/pdf/161017_plan_presupuestario.pdf

²IMS Health, Market Prognosis October 2015



pulmonary disease known as Chronic Obstructive Pulmonary Disease (COPD), launched in Spain in the fourth quarter of 2014, increased by 88% to 8.8 million euros in the nine-month period ending 30 September 2016.

- **In the first nine months 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 6.2).**
- **EBITDA increased by 23% to 31.1 million euros in the nine-month period ending 30 September 2016, compared to the same period the previous year, reflecting a 2.0 percentage point rise in the EBITDA margin to 16.3% in the first nine months of 2016 up from 14.3% in the first nine months of 2015.**
- **Net profit rose to 21.5 million euros the nine-month period ending 30 September 2016, a 30% increase compared to the same period the previous year.**

Madrid (Spain), 8th November 2016, 8:00 AM CET - ROVI released today its financial results for the nine-month period ending 30 September 2016.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that *"in the first nine months of 2016, we reached 8% operating revenue growth mainly driven by the strength of our prescription-based pharmaceutical business, where sales rose 22%, clearly outperforming the market. According to IMS Health, Spanish innovative product market increased by 6% in the first nine months of 2016. We forecast to continue to grow thanks to, among others, our flagship product, Bemiparin, which is contributing to our growth. In particular, in the nine-month period ending 30 September 2016, Bemiparin sales increased by 9% in the domestic market and 9% in the international 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 nine-month period ending 30 September 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 third quarter this year, which is contributing 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 first quarter of 2017 as well as to develop a new phase I study for another candidate also in the first quarter next year. Likewise, we are hopeful of obtaining authorization to market a biosimilar of enoxaparin in Europe in 2016".

1. Financial highlights

€ million	9M 2016	9M 2015	Growth	% Growth
Operating revenue	191.5	177.6	13.8	8%
Other income	1.4	0.9	0.5	60%
Total revenue	192.9	178.5	14.3	8%
Cost of sales	-80.0	-68.8	-11.1	16%
Gross profit	112.9	109.7	3.2	3%
% margin	59.0%	61.7%	-	-2.8pp
R&D expenses	-13.1	-12.8	-0.3	3%
Other SG&A	-72.6	-71.5	-1.1	2%
Other income	4.0	-	4.0	n.a.
EBITDA	31.1	25.4	5.8	23%
% margin	16.3%	14.3%		2.0pp
EBIT	23.1	18.0	5.1	28%
% margin	12.1%	10.1%		1.9pp
Net profit	21.5	16.5	5.0	30%

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

The consolidated financial statements of Grupo ROVI for the first nine months of 2016 and the comparative information for 2015 (balance sheet) and for the first nine months of 2015 (consolidated income statement and cash flow statement) are attached to this report (see Appendix 1).

2. Performance of the Group

Operating revenue increased by 8% to 191.5 million euros in the nine-month period ending 30 September 2016, mainly driven by the strength of pharmaceutical specialties business, where sales rose 17%. Toll manufacturing sales decreased by 17% to 38.4 million euros in the first nine months 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 increased by 8% to 192.9 million euros in the nine-month period ending 30 September 2016.

Sales of **prescription-based pharmaceutical** products rose 22% to 129.8 million euros in the nine-month period ending 30 September 2016.

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, had a very positive performance in the nine-month period ending 30 September 2016, with sales up 9% to 59.2 million euros. Sales of Bemiparin in Spain (**Hibor**[®]) increased by 9% to 39.9 million euros, while international sales had a 9% rise to 19.3 million euros. ROVI expects to achieve stable international sales in 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 42% to 24.0 million euros in the nine-month period ending 30 September 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 88% to 8.8 million euros in the nine-month period ending 30 September 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 2.5 times to 4.9 million euros in the nine-month period ending 30 September 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 2% to 5.3 million euros in the nine-month period ending 30 September 2016.

Sales of **Corlontor**[®], a specialty product for stable angina and chronic heart failure from Laboratoires Servier, increased 5% to 10.4 million euros in the nine-month period ending 30 September 2016.

Sales of **Exxiv**[®], a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 9% to 4.1 million euros in the nine-month period ending 30 September 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 25% to 4.2 million euros in the nine-month period ending 30 September 2016.

According to IMS Health, Spanish innovative product market increased by 6% in the first nine months of 2016 compared to the same period the previous year. Nevertheless, ROVI prescription-based pharmaceutical product sales rose 22% in the same period, beating the market by 16 percentage points.

Also, prescription-based pharmaceutical market covering the 12-month period ending September 2016 increased by 4% compared to the same period the previous year. However, ROVI prescription-based pharmaceutical product sales rose 20% in the last year.

In addition, a new 550 million euros reduction in pharmaceutical expenditure is expected for 2017, according to the Budget Plan¹ submitted by the Spanish Government to the European Commission, and growth in spending on medicine between 1% and 4% in Spain for the period 2016-2020 is forecast by IMS Health². Despite the difficult situation the pharmaceutical industry continues to go through, ROVI forecasts to continue to grow.

Sales of **contrast imaging agents** and other hospital products increased by 3% to 20.3 million euros in the nine-month period ending 30 September 2016.

Sales of **over-the-counter pharmaceutical products** ("OTC") and **other** decreased by 48% to 2.8 million euros in the nine-month period ending 30 September 2016 compared to the same period the previous year. OTC sales exclude EnerZone product sales in the first nine months of 2016 as a result of the joint venture created by ROVI and Enervit for the distribution of nutritional products in Spain and Portugal (see section 6.2).

Toll manufacturing sales decreased by 17% to 38.4 million euros in the nine-month period ending 30 September 2016, compared to the same period the previous year, mainly because of the 6.4 million euro revenue decline in the Frost Ibérica plant to 18.0 million euros in the first nine months 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, injectable plant revenue decreased by 1.8 million euros. ROVI expects injectable business sales to slightly decrease in 2016.

¹ http://www.mineco.gob.es/stfls/mineco/comun/pdf/161017_plan_presupuestario.pdf

² IMS Health, Market Prognosis October 2015

Sales outside Spain decreased by 13% to 54.7 million euros in the nine-month period ending 30 September 2016 compared to the same period the previous year. Sales outside Spain represented 29% of operating revenue in the first nine months of 2016 compared to 35% in the first nine months 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) increased by 60% to 1.4 million euros in the first nine months of 2016 from 0.9 million euros in the first nine months of 2015.

Gross profit increased by 3% to 112.9 million euros in the nine-month period ending 30 September 2016, reflecting a decrease of 2.8 percentage points in the gross margin to 59.0% in the first nine months of 2016 from 61.7% in the first nine months of 2015. The reduction in gross margin was mainly due to the registration of low margin Sintrom product sales (9.3 million euros in the first nine months of 2016 compared to 0.4 million euros in the first nine months of 2015). The decrease in Bemiparin raw material costs impacted positively on gross margin in the first nine months of 2016.

Research and development expenses (R&D) rose 3% to 13.1 million euros in the nine-month period ending 30 September 2016. This slight increase is mainly due to a delay in the start of the Risperidone-ISM[®] phase III trial as a result of the several meetings held with the *US Food and Drug Administration* (FDA) and the *European Medicines Agency* (EMA) in order to obtain scientific advice about the design of the phase III clinical study.

Selling, general and administrative expenses (SG&A) increased by 2% to 72.6 million euros in the nine-month period ending 30 September 2016, compared to the same period the previous year, mainly due to the continued promotion of the latest products launched.

EBITDA increased by 23% to 31.1 million euros in the nine-month period ending 30 September 2016, compared to the same period the previous year, reflecting a 2.0 percentage point rise in the EBITDA margin to 16.3% in the first nine months of 2016 up from 14.3% in the first nine months of 2015, mainly due to the positive 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 6.2). However, excluding the impact of the non recurrent revenue mentioned above, EBITDA would increase by 7% to 27.1 million euros, reflecting a stable EBITDA margin of 14.2% in the first nine months of 2016.

Depreciation and amortisation expenses increased by 9% to 8.1 million euros in the nine-month period ending 30 September 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 28% to 23.1 million euros in the nine-month period ending 30 September 2016, compared to the same period the previous year, reflecting a 1.9 percentage point rise in the EBIT margin to 12.1% in the first nine months of 2016 up from 10.1% in the first nine months of 2015, mainly due to the positive impact of non recurrent revenue of 4.0 million euros as a result of the joint venture created by ROVI and Enervit (see section 6.2). However, excluding the impact of the non recurrent revenue mentioned above, EBIT would increase by 6% to 19.1 million euros, reflecting a stable EBIT margin of 10.0% in the first nine months of 2016.

Financial expense decreased by 34% in the nine-month period ending 30 September 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 46% in the first nine months of 2016, compared to the first nine months of 2015, mainly because of higher returns on financial investments as a result of foreign exchange operations in the first nine months of 2015.

The **effective tax rate** was 5.6% in the nine-month period ending 30 September 2016 compared to 5.4% in the nine-month period ending 30 September 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 were used in the 2015 income tax and 2.8 million euros in the first nine months 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 21.5 million euros in the nine-month period ending 30 September 2016, a 30% increase compared to the same period the previous year, positively impacted by non recurrent revenue of 4.0 million euros related to the ROVI and Enervit joint venture creation (see section 6.2). However, excluding the impact of the non recurrent revenue mentioned above, net profit would increase by 7% to 17.7 million euros.

The ROVI General Shareholders Meeting, on 31 May 2016, approved the payment of a **gross dividend** of 0.1390 euros per share on 2015 earnings. This dividend was paid on 5 July 2016 and it represented a 35% pay-out.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that *"we are satisfied with the results for the first nine months of 2016. Total revenue increased by 8% thanks to the strength of our leading products, which continue to enjoy good sales prospects. We also expect the spare capacity in the Alcalá de Henares and San Sebastián de los Reyes manufacturing facilities, that will shortly start being used, will allow us to increase our profit margins. EBITDA margin increased in the nine-month period ending 30 September 2016, mainly as a result of the operating leverage contributed by our last product launches. 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[®], 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 6.8 million euros in the first nine months of 2016, compared to 12.2 million euros in the first nine months of 2015. Of this amount:

- 1.3 million euros corresponds to investment capex related to the injectable facility, versus 2.1 million euros in the first nine months of 2015;
- 0.4 million euros corresponds to investment capex related to the Granada facility, versus 1.1 million euros in the first nine months of 2015;
- 1.1 million euros corresponds to investment capex related to the Alcalá de Henares (Frosst Ibérica) facility, versus 2.4 million euros in the first nine months of 2015;
- 2.1 million euros corresponds to investment capex related to the San Sebastián de los Reyes plant in the first half of 2016, versus 4.4 million euros invested in the acquisition of this plant's assets in the first nine months of 2015; and
- 1.9 million euros corresponds to expenditure on maintenance and other, versus 2.2 million euros in the first nine months of 2015.

3.2 Debt

As of 30 September 2016, ROVI had total debt of 37.6 million euros. Debt with public administration, which is 0% interest rate debt, represented 37% of total debt as of 30 September 2016.



<i>In thousand euros</i>	30 September 16	31 December 15
Bank borrowings	23,738	28,179
Debt with public administration	13,889	14,599
Total	37,627	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 23.8 million euros in the nine-month period ending 30 September 2016 from 3.9 million euros in the nine-month period ending 30 September 2015 mainly due to (i) the decrease of 5.4 million euros in Capex; (ii) the increase of 1.8 million euros in the "inventories" item, compared to an increase of 5.5 million euros in the first nine months of 2015 and (iii) the decrease of 1.7 million euros in the "trade and other payables" item in the first nine months of 2016, compared to a decrease of 10.4 million euros in the first nine months of 2015. These positive impacts were partially offset by the decrease of 5.2 million euros in the "trade and other receivables" item in the first nine months of 2016, compared to a decrease of 6.8 million euros in the first nine months of 2015.

3.4 Gross cash position and net debt

As of 30 September 2016, ROVI had gross cash position of 42.2 million euros, compared to 30.7 million euros as of 31 December 2015, and negative net debt of 4.6 million euros (available-for-sale financial assets plus deposits plus cash and cash equivalents minus short term and long term financial debt), compared to positive net debt of 12.1 million euros as of 31 December 2015.

3.5 Working capital

The increase in working capital in the first nine months of 2016 was mainly due to (i) an increase in the "cash and cash equivalents" item of 11.5 million euros; (ii) a decrease in the "trade and other receivables" line of 5.2 million euros; (iii) a decrease in the "trade and other payables" line of 1.7 million euros; and (iv) an increase in "inventories" of 1.8 million euros mainly due to higher sodium heparin stock levels, in the first nine months of 2016, in order to be prepared for the potential approval of our enoxaparin biosimilar.

As of 30 September 2016, Social Security and Public Administrations total debt with ROVI amounted to 6.7 million euros, of which 5.7 million euros in Spain and the other 1.0 million euros in Portugal. Almost all this debt is expected to be collected through the usual channels.

4. Guidance for 2017

For 2017, ROVI expects **a low-to-mid single digit growth rate for the operating revenue**, despite (i) a new 550 million euros reduction in pharmaceutical expenditure expected for next year, according to the Budget Plan¹ submitted by the Spanish Government to the European Commission, and (ii) growth in spending on medicine between 1% and 4% in Spain for the period 2016-2020 forecast by IMS Health².

ROVI expects its growth drivers to be Bemiparin, the latest license agreements (Volutsa[®], Orvatez[®], Ulunar[®] and Mysimba[®]), 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 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

¹ http://www.mineco.gob.es/stfls/mineco/comun/pdf/161017_plan_presupuestario.pdf

² IMS Health, Market Prognosis October 2015

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

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

period over multiple intramuscular injections, regardless the injection site (gluteus or deltoid muscle).

The PRISMA-2 results, along with data from previous studies and the proposed phase III program, have been reviewed by the *US Food and Drug Administration* (FDA) and the *European Medicines Agency* (EMA) and thereafter discussed during an *End of Phase II meeting* and a *Scientific Advice meeting*, respectively. Besides, the study protocol for the phase III trial has been further evaluated by the FDA through a *Special Protocol Assessment*. The aforementioned protocol has been refined and resubmitted to FDA. Clinical trial submissions are planned to take place by the fourth quarter of 2016.

On the other hand, ROVI is planning by the fourth quarter of 2016 to request the FDA a *pre-Investigational New Drug Application (pre-IND) meeting* for obtaining advice on the clinical development of Letrozol ISM[®]. Subsequently the company will submit an IND in order to initiate the first phase I clinical trial. 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 Marketing agreement of Mysimba[®] in Spain

On 1st August 2016, the market was informed by publication of a relevant fact that ROVI signed an agreement with Orexigen Therapeutics Ireland Ltd. (Orexigen), a biopharmaceutical company focused on the treatment of obesity, for rights to market Mysimba[®] (naltrexone HCl / bupropion HCl prolonged release) in Spain.

Under this marketing agreement, ROVI will have exclusive rights in the Spanish territory to distribute Mysimba[®], a medicine approved by the European Medicines Agency for the management of weight in adult patients (≥ 18 years) with an initial Body Mass Index (BMI) of ≥ 30 kg/m² (obese), or ≥ 27 kg/m² to < 30 kg/m² (overweight) in the presence of one or more weight-related co-morbidities (e.g., type 2 diabetes, dyslipidaemia, or controlled hypertension).

ROVI expects to begin marketing Mysimba[®] by year-end 2016 for an initial period of five years, renewable for an additional five year period, according to the terms of the Agreement.

Obesity and related comorbidities are a significant health problem in Spain, where approximately 53% of adults are overweight or obese, according to recent statistics from the National Health Institute.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, commented: *"We are very excited to offer specialist physicians this new pharmacological alternative for treating obesity. Obesity is a modern disease which is becoming increasingly prevalent among the adult population. This new partnership advances our long-term objective to improve patients' quality of life. In addition, we expect Mysimba to contribute to the Group's revenue in the next few years, strengthening our specialty pharmaceutical product portfolio."*

"We are excited to work with ROVI to bring Mysimba to the Spanish market as a differentiated new treatment option to address the significant and growing problem of obesity in Spain," said Michael Narachi, CEO of Orexigen. *"With this agreement, Orexigen's first in Western Europe, we are continuing to execute on the company's ex-U.S. commercial strategy to expand the availability of Contrave® and Mysimba for patients and physicians by establishing agreements that support the drug's commercialization in additional territories worldwide."*

6.2 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 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



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Forward-looking statements

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



APPENDIX 1

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS AS OF 30 SEPTEMBER 2016 AND 31 DECEMBER 2015

(Thousands of euros)

	30 September 2016	31 December 2015
ASSETS		
Non-current assets		
Property, Plant and Equipment	80,813	81,803
Intangible assets	18,603	18,881
Investment in a joint venture	2,657	-
Deferred income tax assets	10,103	8,871
Available-for-sale financial assets	71	70
Financial receivables	189	139
	112,436	109,764
Current assets		
Inventories	65,610	63,859
Trade and other receivables	51,825	57,028
Current income tax assets	732	3,945
Cash and cash equivalents	40,721	29,251
	158,888	154,083
Total assets	271,324	263,847



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS AS OF 30 SEPTEMBER 2016 AND 31 DECEMBER 2015

(Thousands of euros)

	30 September 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	(8,589)	(8,112)
Retained earnings and voluntary reserves	162,490	149,490
Profit for the period	21,515	19,809
Reserve for available-for-sale assets	(3)	(2)
Total equity	179,013	164,785
LIABILITIES		
Non-current liabilities		
Financial debt	24,274	32,631
Deferred income tax liabilities	1,688	1,344
Non-current deferred revenues	5,902	5,861
	31,864	39,836
Current liabilities		
Trade and other payables	44,011	45,742
Financial debt	13,353	10,147
Current deferred revenues	751	840
Provisions for other liabilities and charges	2,332	2,497
	60,447	59,226
Total liabilities	92,311	99,062
Total equity and liabilities	271,324	263,847



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED INCOME STATEMENTS FOR THE NINE-MONTH PERIODS ENDING 30
SEPTEMBER 2016 AND 30 SEPTEMBER 2015

(Thousands of euros)

	Nine-month periods ending 30 September	
	2016	2015
Revenue	191,453	177,643
Cost of sales	(79,969)	(68,846)
Employee benefit expenses	(45,319)	(45,716)
Other operating expenses	(40,435)	(38,592)
Depreciation, amortisation and impairment charges	(8,061)	(7,364)
Recognition of government grants on non financial non-current assets and other	1,409	879
Other income	3,997	-
OPERATING PROFIT	23,075	18,004
Finance income	296	545
Finance costs	(732)	(1,105)
FINANCE COSTS - NET	(436)	(560)
Share of profit of a joint venture	157	-
PROFIT BEFORE INCOME TAX	22,796	17,444
Income tax	(1,281)	(934)
PROFIT FOR THE PERIOD	21,515	16,510



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED CASH FLOW STATEMENTS FOR THE NINE-MONTH PERIODS ENDING 30
SEPTEMBER 2016 AND 30 SEPTEMBER 2015

(Thousands of euros)

	Nine-month periods ending 30 September	
	2016	2015
Cash flows from operating activities		
Profit before income tax	22,796	17,444
Adjustments for non-monetary transactions:		
Amortisation	8,061	7,364
Interest income	(296)	(545)
Impairment	(221)	(964)
Interest expense	732	1,105
Net changes in provisions	(165)	319
Grant for non-financial fixed assets and income from distribution licences	(1,536)	(239)
Profit from creation of joint venture	(4,154)	-
Changes in working capital		
Trade and other receivables	5,916	6,907
Inventories	(1,279)	(5,073)
Trade and other payables	(1,431)	(10,967)
Other collections and payments		
Proceeds from distribution licenses	505	100
Interest paid	-	(281)
Income tax cash flow	1,044	438
Net cash generated (used) from operating activities	29,972	15,608
Cash flows from investing activities		
Purchases of intangible assets	(1,381)	(2,049)
Purchases of property, plant and equipment	(5,436)	(10,198)
Proceeds of property, plant and equipment	24	6
Contracting current bank deposits	-	(170)
Investment in a joint venture	(3)	-
Proceeds from sale of shares in joint venture	1,000	-
Interest received	575	493
Net cash generated (used) in investing activities	(5,221)	(11,918)
Cash flows from financing activities		
Repayments of financial debt	(6,604)	(2,779)
Proceeds from financial debt	797	10,749
Interest paid	(188)	-
Purchase of treasury shares	(741)	(5,694)
Dividends paid	(6,853)	(8,346)
Reissue of treasury shares	308	1,285
Net cash generated (used) in financing activities	(13,281)	(4,785)
Net (decrease)/increase in cash and cash equivalents	11,470	(1,095)
Cash and cash equivalents at beginning of the period	29,251	26,671
Cash and cash equivalents at end of the period	40,721	25,576