



# Full Year 2016 Results

16<sup>th</sup> February 2017



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

## ROVI – Full Year 2016 Financial Results

# ROVI reports an EBITDA growth of 24% and a net profit growth of 32%

- Operating revenue increased by 8% to 265.2 million euros in 2016, mainly driven by the strength of the prescription-based pharmaceutical business, where sales rose 18%, clearly outperforming the market. Total revenue increased by 8% to 266.7 million euros in 2016, more than doubling total revenue for 2007 when ROVI held its IPO.
- 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 next year, according to the Budget Plan<sup>1</sup> submitted by the Spanish Government to the European Commission, and (ii) zero growth in spending on medicine in Spain for the period 2017-2020 forecast by QuintilesIMS<sup>2</sup>.
- The clinical trial of Risperidone ISM<sup>®</sup> “PRISMA-2” was successfully finished; final positive results were presented on 13<sup>th</sup> March 2016 at the 24<sup>th</sup> European Congress of Psychiatry. Patients’ recruitment of the “PRISMA-3” clinical trial for Risperidone ISM<sup>®</sup> approval in USA and Europe is planned to be started by the second quarter of 2017. The enoxaparin biosimilar assessment process is ongoing within the pre-established timelines.
- Sales of Bemiparin had an outstanding performance in 2016, with a 6% increase to 79.7 million euros; this growth came both from sales in Spain (+9%) and from international sales (+1%).
- 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 38% to 33.5 million euros in 2016. Sales of Volutsa<sup>®</sup>, from Astellas Pharma, increased by 2.2 times to 6.9 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>QuintilesIMS, Market Prognosis September 2016



**pulmonary disease known as Chronic Obstructive Pulmonary Disease (COPD), launched in Spain in the fourth quarter of 2014, increased by 64% to 12.2 million euros in 2016, compared to the previous year.**

- **In December 2016, ROVI started marketing Neparvis® (sacubitril/valsartan), from Novartis. The product is indicated for the treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction (see section 6.1).**
- **In 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 6.3).**
- **EBITDA increased by 24% to 39.3 million euros in 2016, compared to the previous year, reflecting a 1.9 percentage point rise in the EBITDA margin to 14.8% in 2016 up from 12.9% in 2015.**
- **Net profit rose to 26.1 million euros in 2016, a 32% increase compared to the previous year. In 2016, ROVI achieved the highest EBITDA and net profit figures in its history.**
- **ROVI will propose to the Shareholders General Meeting a dividend of 0.1830 euros per share with dividend rights on 2016 earnings. This dividend would mean an increase of 32% compared to the dividend on 2015 earnings (€0.1390/share).**

**Madrid (Spain), 16th February 2017, 8:00 AM CET** - ROVI released today its financial results for the fiscal year ending on 31 December 2016.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that *"in 2016, we reached 8% operating revenue growth mainly driven by the strength of our prescription-based pharmaceutical business, where sales rose 18%, clearly outperforming the market. According to QuintilesIMS, Spanish innovative product market increased by 4% in 2016. We forecast to continue to grow thanks to, among others, our flagship product, Bemiparin, which is contributing to our growth. In particular, in 2016, Bemiparin sales increased by 9% in the domestic market and 1% in the international market. Furthermore, we expect (i) the strengthening of the cardiovascular franchise through the launch of Neparvis®, a product of high strategic value from Novartis, in Spain in December 2016; (ii) the launch of Mysimba®, 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® Breezhaler® and Ulunar® Breezhaler®, 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 hipercolesterolaemia 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 in the next 2 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 2016 mainly as a result of lower production levels for MSD since 31<sup>st</sup> 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<sup>®</sup>, from the third quarter 2016, 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<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 first half this year. Likewise, we are hopeful of obtaining authorization to market a biosimilar of enoxaparin in Europe in the first half of 2017".

## 1. Financial highlights

€ million	2016	2015	Growth	% Growth
Operating revenue	265.2	246.0	19.2	8%
Other income	1.6	1.0	0.6	54%
<b>Total revenue</b>	<b>266.7</b>	<b>247.0</b>	<b>19.7</b>	<b>8%</b>
Cost of sales	-112.0	-97.1	-14.9	15%
<b>Gross profit</b>	<b>154.7</b>	<b>149.9</b>	<b>4.8</b>	<b>3%</b>
<i>% margin</i>	<i>58.3%</i>	<i>61.0%</i>		-2.6pp
R&D expenses	-17.5	-16.5	-1.0	6%
Other SG&A	-101.9	-101.7	-0.2	0%
Other income	4.0	-	4.0	n.a.
<b>EBITDA</b>	<b>39.3</b>	<b>31.8</b>	<b>7.5</b>	<b>24%</b>
<i>% margin</i>	<i>14.8%</i>	<i>12.9%</i>		1,9pp
<b>EBIT</b>	<b>28.3</b>	<b>21.8</b>	<b>6.5</b>	<b>30%</b>
<i>% margin</i>	<i>10.7%</i>	<i>8.9%</i>		1,8pp
<b>Net profit</b>	<b>26.1</b>	<b>19.8</b>	<b>6.3</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 2016 and the comparative information for 2015 are attached to this report (see Appendix 1).

## 2. Performance of the Group

**Operating revenue** increased by 8% to 265.2 million euros in 2016, mainly driven by the strength of pharmaceutical specialties business, where sales rose 14%. Toll manufacturing sales decreased by 9% to 56.6 million euros in 2016 mainly due to lower production levels for MSD as a result of the initial MSD contract expiration on the 31<sup>st</sup> March 2015. Total revenue increased by 8% to 266.7 million euros in 2016, more than doubling total revenue for 2007 when ROVI held its IPO.

Sales of **prescription-based pharmaceutical** products rose 18% to 177.3 million euros in 2016.

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, had a very positive performance in 2016, with sales up 6% to 79.7 million euros. Sales of Bemiparin in Spain (**Hibor**<sup>®</sup>) increased by 9% to 54.7 million euros, while international sales had a 1% rise to 24.9 million euros, supported by the launch of the product in two new countries in 2016: Argentina and the Philippines.

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 38% to 33.5 million euros in 2016.

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 64% to 12.2 million euros in 2016, compared to 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 2.2 times to 6.9 million euros in 2016.

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, increased by 2% to 7.6 million euros in 2016.

Sales of **Corlontor**<sup>®</sup>, a specialty product for stable angina and chronic heart failure from Laboratoires Servier, increased 3% to 13.8 million euros in 2016.

Sales of **Exxiv**<sup>®</sup>, a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 9% to 5.4 million euros in 2016, 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 26% to 5.4 million euros in 2016.

According to QuintilesIMS, Spanish innovative product market increased by 4% in 2016 compared to the previous year. Nevertheless, ROVI prescription-based pharmaceutical product sales rose 18% in the same period, beating the market by 14 percentage points.

In addition, a new 550 million euro reduction in pharmaceutical expenditure is expected for 2017, according to the Budget Plan<sup>1</sup> submitted by the Spanish Government to the European Commission, and zero growth in spending on medicine for the period 2017-2020 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 6% to 27.9 million euros in 2016.

Sales of **over-the-counter pharmaceutical products** ("OTC") and **other** decreased by 52% to 3.2 million euros in 2016 compared to the previous year. In 2016, OTC sales only include first quarter EnerZone product sales as a result of the joint venture created by ROVI and Enervit for the distribution of nutritional products in Spain and Portugal (see section 6.3).

**Toll manufacturing** sales decreased by 9% to 56.6 million euros in 2016, compared to the previous year, mainly because of the 5.1 million euro revenue decline in the Frosst Ibérica plant to 25.8 million euros in 2016, due to lower production levels for MSD as a result of the initial MSD contract expiration on the 31<sup>st</sup> March 2015. In addition, injectable plant revenue decreased by 0.6 million euros.

**Sales outside Spain** decreased by 8% to 76.4 million euros in 2016 compared to the previous year. Sales outside Spain represented 29% of operating revenue in 2016 compared to 34% in 2015, mainly as a result of the deceleration of the toll manufacturing business, where most of the sales are linked to international markets.

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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> QuintilesIMS, Market Prognosis September 2016

**Other income** (subsidies) increased by 54% to 1.6 million euros in 2016 from 1.0 million euros in 2015.

**Gross profit** increased by 3% to 154.7 million euros in 2016, reflecting a decrease of 2.6 percentage points in the gross margin to 58.3% in 2016 from 61.0% in 2015. The reduction in gross margin was mainly due to the registration of low margin Sintrom product sales (12.4 million euros in 2016 compared to 3.3 million euros in 2015). The decrease in Bemiparin raw material costs impacted positively on gross margin in 2016.

**Research and development expenses** (R&D) rose 6% to 17.5 million euros in 2016 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. This slight increase is mainly due to a delay in the start of the Risperidone-ISM<sup>®</sup> 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) stood flat at 101.9 million euros in 2016, compared to the previous year, despite the increase in sales, mainly due to (i) the product launches such as Hirobriz<sup>®</sup>, Ulunar<sup>®</sup>, Volutsa<sup>®</sup> and Orvatez<sup>®</sup> in 2015, which added expenses of 3.3 million euros that year, and (ii) ROVI's strict cost control policy.

**EBITDA** increased by 24% to 39.3 million euros in 2016, compared to the previous year, reflecting a 1.9 percentage point rise in the EBITDA margin to 14.8% in 2016 up from 12.9% in 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 6.3). However, excluding the impact of the non recurrent revenue mentioned above, EBITDA would increase by 11% to 35.3 million euros, reflecting a 0.4 percentage point rise in the EBITDA margin to 13.3% in 2016.

**Depreciation and amortisation expenses** increased by 11% to 11.0 million euros in 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 30% to 28.3 million euros in 2016, compared to the previous year, reflecting a 1.8 percentage point rise in the EBIT margin to 10.7% in 2016 up from 8.9% in 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 6.3). However, excluding the impact of the non recurrent revenue mentioned above, EBIT would increase by 11% to 24.3 million euros, reflecting a 0.3 percentage point rise in the EBIT margin to 9.2% in 2016.

**Financial expense** decreased by 49% in 2016, compared to 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 49% in 2016, compared to 2015 when positive returns on specific financial investments related to exchange rate were obtained.

The **effective tax rate** was 6.4% in 2016 compared to 5.2% in 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 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.

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 mid to high single digits 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** rose to 26.1 million euros in 2016, a 32% increase compared to 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 6.3). However, excluding the impact of the non recurrent revenue mentioned above, net profit would increase by 13% to 22.3 million euros.

In 2016, ROVI achieved the highest EBITDA and net profit figures in its history.

ROVI will pay a **dividend** of 0.1830 euros per share with dividend rights 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 would mean 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 satisfied with the results for 2016. Total revenue increased by 8% thanks to the strength of our leading products, which continue to enjoy good sales prospects. EBITDA margin increased in 2016, mainly as a result of the operating leverage contributed by our last product launches. We also expect 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<sup>®</sup>, Volutsa<sup>®</sup>, Ulunar<sup>®</sup>, Orvatez<sup>®</sup> or Mysimba<sup>®</sup>, 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 18.1 million euros in 2016, compared to 19.9 million euros in 2015. Of this amount:

- 2.6 million euros relates to investment capex regarding the injectable facility, versus 4.3 million euros in 2015;
- 0.6 million euros relates to investment capex regarding the Granada facility, versus 1.5 million euros in 2015;
- 2.6 million euros relates to investment capex regarding the Alcalá de Henares (Frosst Ibérica) facility, versus 3.7 million euros in 2015;
- 3.2 million euros relates to investment capex regarding the San Sebastián de los Reyes plant in 2016, versus 6.1 million euros invested in the acquisition of this plant’s assets in 2015; and
- 9.1 million euros relates to expenditure on maintenance and other capex (including capex invested for the new distribution agreements (see sections 6.1 and 6.2), versus 4.3 million euros in 2015.

#### 3.2 Debt

As of 31 December 2016, ROVI had total debt of 33.8 million euros. Debt with public administration, which is 0% interest rate debt, represented 38% of total debt as of 31 December 2016.

<i>In thousand euros</i>	<b>31 December 16</b>	<b>31 December 15</b>
Bank borrowings	20,931	28,179
Debt with public administration	12,863	14,599
<b>Total</b>	<b>33,794</b>	<b>42,778</b>

#### 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 28.2 million euros in 2016 from 10.3 million euros in 2015 mainly due to (i) the increase of

14.1 million euros in the “trade and other payables” item in 2016, compared to a decrease of 9.3 million euros in 2015 and (ii) the decrease of 1.8 million euros in Capex. These positive impacts were partially offset by (i) the decrease of 3.2 million euros in the “trade and other receivables” item in 2016, compared to a decrease of 6.7 million euros in 2015, and (ii) the increase of 3.5 million euros in the “inventories” item, compared to a decrease of 3.7 million euros in 2015.

### 3.4 Gross cash position and net debt

As of 31 December 2016, ROVI had gross cash position of 42.8 million euros, compared to 30.7 million euros as of 31 December 2015, and net cash position of 9.0 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 debt of 12.1 million euros as of 31 December 2015.

### 3.5 Working capital

The decrease in working capital in 2016 was mainly due to (i) an increase in the “trade and other payables” line of 14.1 million euros and (ii) a decrease in the “trade and other receivables” line of 3.2 million euros. “Inventories” increased by 3.5 million euros mainly due to higher sodium heparin stock levels in 2016, and “cash and cash equivalents” increased by 12.1 million euros in 2016, compared to the previous year.

As of 31 December 2016, Social Security and Public Administrations total debt with ROVI amounted to 6.0 million euros, of which 4.9 million euros in Spain and the other 1.1 million euros in Portugal.

## 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 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) zero growth in spending on medicine in Spain for the period 2017-2020 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.

<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> QuintilesIMS, Market Prognosis September 2016

## 5. Research and Development update

### ISM®

In 2016 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 November 2016 the results of the phase I trial PRISMA-1 has been published in the medical journal *International Clinical Psychopharmacology*, which showed that Risperidone ISM was safe and well tolerated and provided a sustained release of risperidone, suitable for a 4-weekly administration without oral supplementation, and achieved therapeutic plasma levels within the first day.<sup>1</sup>

Likewise, the phase II clinical trial of Risperidone ISM® "PRISMA-2" was successfully finished and the final positive results were presented on 13<sup>th</sup> March 2016 at the 24<sup>th</sup> European Congress of Psychiatry<sup>2</sup>. The PRISMA-2 is an open-label, parallel phase II clinical trial that was carried out in four USA sites, for evaluating the safety and pharmacokinetics of multiple intramuscular doses of Risperidone ISM® in 67 patients with stable schizophrenia. The PRISMA-2 study also 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).

These results, along with data from previous studies and the proposed phase III program, were 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. Additionally, the study protocol for the phase III trial "PRISMA-3" has been further evaluated by the FDA through a *Special Protocol Assessment*. Subsequently, clinical trial submissions have been initiated in December 2016. Patients' recruitment of the "PRISMA-3" clinical trial for Risperidone ISM® approval in USA and Europe is planned to be started by the second quarter of 2017.

On the other hand, in October ROVI has requested to the FDA a *pre-Investigational New Drug Application (pre-IND) meeting* for obtaining advice on the clinical development of Letrozol

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

ISM®. Afterwards 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 Neparvis® in Spain**

On 22<sup>nd</sup> November 2016, the market was informed by publication of a relevant fact that ROVI signed an agreement with Novartis Farmacéutica, S.A. to market Neparvis® (sacubitril/valsartan) in Spain, that corresponds to Entresto® of Novartis.

Under this marketing agreement, ROVI will take care of the promotion and distribution in the Spanish territory of Neparvis®, a medicine indicated for the treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction (the proportion of blood leaving the heart). It is a tablet that is taken twice a day with a unique mechanism of action that reduces the workload of the failed heart.

The two active ingredients of Neparvis®, sacubitril and valsartan, act in different ways. The sacubitril blocks the degradation of the natriuretic peptides that are produced by the body. The natriuretic peptides make that sodium and water pass to the urine, thus reducing heart's workload. The natriuretic peptides also reduce blood pressure and protect the heart from the development of fibrosis (scar tissues) that are produced in the heart failure. The valsartan is an «antagonist of the angiotensin II receptors», what means that blocks the action of a hormone called angiotensin II. The effects of the angiotensin II can be harmful in patients with heart failure. By blocking the receptors that angiotensin II usually binds to, the valsartan interrupts the adverse effects of this hormone on the heart, and also reduces the blood pressure, allowing blood vessels to widen.

The heart failure is a debilitating and potentially fatal clinical syndrome, in which the heart can't pump enough blood to the rest of the body because the muscles of the heart become too weak or too rigid to work properly. As a result, patients face a high risk of death, repeated hospitalisations, and symptoms such as difficulty breathing, tiredness, and retention of liquids that affect significantly their quality of life. Despite that millions of people live with heart

failure, most people don't recognise symptoms, which means that they have been misdiagnosed, or that the symptoms are attributed wrongly to aging.

ROVI has started to market Neparvis® in December 2016, under the co-marketing agreement terms with Entresto®, for a period of ten years.

According to data from IMS Health, during the last twelve months up to September of 2016 (TAM September of 2016), the market of heart failure of reduced ejection fraction (where is included Neparvis®) means in Spain a consumption of approximately 2 million units of ACE (angiotensin converting enzyme) inhibitors and approximately 280,000 patients suffer from this disease annually.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, commented: *"We are very excited about the potential of Neparvis® that has shown to reduce the rate of deaths due to cardiovascular disease and hospital admissions related to heart failure, a disease that presents a higher risk of death and worst quality of life than any other chronic disease. This new agreement of ROVI follows its permanent objective to improve patients' quality of life. Additionally, this is a product of high strategic value and it will contribute to give us projection in the coming years"*.

## **6.2 Marketing agreement of Mysimba® in Spain**

On 1<sup>st</sup> 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 ( $\geq 18$  years) with an initial Body Mass Index (BMI) of  $\geq 30$  kg/m<sup>2</sup> (obese), or  $\geq 27$  kg/m<sup>2</sup> to  $< 30$  kg/m<sup>2</sup> (overweight) in the presence of one or more weight-related co-morbidities (e.g., type 2 diabetes, dyslipidaemia, or controlled hypertension).

ROVI has started to market Mysimba® in the first quarter of 2017, 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."*

### **6.3 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<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 DECEMBER 2016 AND 31 DECEMBER 2015

(Thousands of euros)

	31 December 2016	31 December 2015
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, Plant and Equipment	82,822	81,803
Intangible assets	24,872	18,881
Investment in a joint venture	2,571	-
Deferred income tax assets	10,252	8,871
Available-for-sale financial assets	70	70
Financial receivables	189	139
	<b>120,776</b>	<b>109,764</b>
<b>Current assets</b>		
Inventories	67,386	63,859
Trade and other receivables	53,842	57,028
Current income tax assets	4,466	3,945
Cash and cash equivalents	41,378	29,251
	<b>167,072</b>	<b>154,083</b>
<b>Total assets</b>	<b>287,848</b>	<b>263,847</b>



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

(Thousands of euros)

	<b>31 December 2016</b>	<b>31 December 2015</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	(8,701)	(8,112)
Retained earnings and voluntary reserves	162,421	149,490
Profit for the period	26,089	19,809
Reserve for available-for-sale assets	(3)	(2)
<b>Total equity</b>	<b>183,406</b>	<b>164,785</b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>		
Financial debt	20,828	32,631
Deferred income tax liabilities	1,640	1,344
Deferred revenues	5,532	5,861
	<b>28,000</b>	<b>39,836</b>
<b>Current liabilities</b>		
Trade and other payables	59,852	45,742
Financial debt	12,966	10,147
Deferred revenues	746	840
Provisions for other liabilities and charges	2,878	2,497
	<b>76,442</b>	<b>59,226</b>
<b>Total liabilities</b>	<b>104,442</b>	<b>99,062</b>
<b>Total equity and liabilities</b>	<b>287,848</b>	<b>263,847</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED INCOME STATEMENTS FOR THE FULL YEARS 2016 AND 2015**

(Thousands of euros)

	Full Year	
	2016	2015
Revenue	265,166	246,009
Cost of sales	(112,024)	(97,075)
Employee benefit expenses	(60,465)	(61,769)
Other operating expenses	(58,916)	(56,361)
Amortisation	(11,023)	(9,975)
Recognition of government grants on non financial non-current assets and other	1,565	1,013
Other income	3,997	-
<b>OPERATING PROFIT</b>	<b>28,300</b>	<b>21,842</b>
Finance income	426	837
Finance costs	(915)	(1,781)
<b>FINANCE COSTS - NET</b>	<b>(489)</b>	<b>(944)</b>
Share of profit of a joint venture	71	-
<b>PROFIT BEFORE INCOME TAX</b>	<b>27,882</b>	<b>20,898</b>
Income tax	(1,793)	(1,089)
<b>PROFIT FOR THE PERIOD</b>	<b>26,089</b>	<b>19,809</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED CASH FLOW STATEMENTS FOR THE FULL YEARS 2016 AND 2015**

(Thousands of euros)

	Full Year	
	2016	2015
<b>Cash flows from operating activities</b>		
Profit before income tax	27,882	20,898
<b>Adjustments for non-monetary transactions:</b>		
Amortisation	11,023	9,975
Interest income	(426)	(837)
Impairment	1,864	(2,013)
Interest expense	915	1,781
Net changes in provisions	381	470
Grant for non-financial fixed assets and income from distribution licences	(1,847)	(638)
Profit from creation of joint venture	(4,068)	-
<b>Changes in working capital</b>		
Trade and other receivables	4,131	6,508
Inventories	(4,940)	5,041
Trade and other payables	13,505	(9,276)
<b>Other collections and payments</b>		
Proceeds from distribution licenses	505	110
Interest paid	-	(645)
Income tax cash flow	(3,399)	(1,982)
<b>Net cash generated (used) from operating activities</b>	<b>45,526</b>	<b>29,392</b>
<b>Cash flows from investing activities</b>		
Purchases of intangible assets	(8,396)	(3,657)
Purchases of property, plant and equipment	(9,680)	(16,244)
Proceeds from sale of property, plant and equipment	43	41
Contracting current bank deposits	-	(170)
Investment in a joint venture	(3)	-
Proceeds from sale of shares in joint venture	1,000	-
Interest received	738	776
<b>Net cash generated (used) in investing activities</b>	<b>(16,298)</b>	<b>(19,254)</b>
<b>Cash flows from financing activities</b>		
Repayments of financial debt	(10,274)	(5,671)
Proceeds from financial debt	797	11,607
Interest paid	(230)	-
Purchase of treasury shares	(987)	(6,546)
Reissue of treasury shares	446	1,398
Dividends paid	(6,853)	(8,346)
<b>Net cash generated (used) in financing activities</b>	<b>(17,101)</b>	<b>(7,558)</b>
<b>Net (decrease)/increase in cash and cash equivalents</b>	<b>12,127</b>	<b>2,580</b>
<b>Cash and cash equivalents at beginning of the period</b>	<b>29,251</b>	<b>26,671</b>
<b>Cash and cash equivalents at end of the period</b>	<b>41,378</b>	<b>29,251</b>