



Full Year 2015 Results

24 February 2016



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



ROVI – Full Year 2015 Financial Results

ROVI reports an operating revenue growth of 3% led by the strength of pharmaceutical specialties business, where sales rose 7%

- **Operating revenue increased by 3% to 246.0 million euros in 2015, mainly driven by the strength of pharmaceutical specialties business, where sales rose 7%. Total revenue increased by 3% to 247.0 million euros in 2015, more than doubling total revenue for 2007 when ROVI held its IPO.**
- **The clinical trial of Risperidone ISM® “PRISMA-2” was successfully finished; final positive results will be presented on March 2016 at the 24th European Congress of Psychiatry. The enoxaparin biosimilar assessment process is ongoing within the pre-established timelines.**
- **ROVI expects operating revenue to grow from high single digit to low double digit for the full year 2016, 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 2015, with a 5% increase to 50.4 million euros.**
- **Sales of Vytorin®, Orvatez® and Absorcol®, the first of the five licenses of Merck Sharp & Dohme (MSD), increased by 14% to 24.3 million euros in 2015. Sales of Volutsa®, from Astellas Pharma, reached 3.2 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 3.6 times to 7.5 million euros in 2015.**

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 2015, EBITDA was impacted by (i) a 65% reduction in the Other income (subsidies) item, (ii) a 37% increase in Research and Development expenses, mainly as a result of the development of the ISM-Risperidone Phase II study and (iii) recent product launches such as Hirobriz[®], Ulunar[®], Volutsa[®] and Orvatez[®] which added selling, general and administrative expenses of 3.3 million euros in 2015 compared to 1.1 million euros added by Hirobriz[®] and Ulunar[®] launches in the fourth quarter of 2014.**
- **EBITDA decreased by 13% to 31.8 million euros in 2015, compared to the previous year, reflecting a 2.4 percentage point fall in the EBITDA margin to 12.9% in 2015 down from 15.4% in 2014. However, maintaining, in 2015, the same amount of Research and Development expenses that was registered in 2014 and excluding, in 2015 and 2014, the impact of (i) Other income and (ii) recent product launches, EBITDA would increase by 11% to 38.6 million euros, reflecting a 1.0 percentage point rise in the EBITDA margin to 15.7% in 2015 up from 14.6% in the previous year.**
- **Net profit declined to 19.8 million euros in 2015, a 18% decrease compared to the previous year. However, maintaining, in 2015, the same amount of Research and Development expenses that was registered in 2014 and excluding, in 2015 and 2014, the impact of (i) Other income and (ii) recent product launches, net profit would increase by 17% to 26.2 million euros. 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), 24th February 2016, 8:00 AM CET - ROVI released today its financial results for the fiscal year ending on 31 December 2015.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that *"in 2015, we reached 3% operating revenue growth mainly driven by the strength of our specialty pharmaceutical business, where sales rose 7% despite the difficulties that the Spanish pharmaceutical market is going through. According to IMS, Spanish innovative product market decreased by 0.9% in 2015 compared to the previous year. Nevertheless, we forecast to continue to grow thanks to, among others, our flagship product, Bemiparin, which is contributing to our growth. In particular, in 2015, Bemiparin sales increased by 5% 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 have required a



significant investment in order to gain a share in their various market segments but we expect that our effort will provide us 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. Also, 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	2015	2014	Growth	% Growth
Operating revenue	246.0	238.0	8.0	3%
Other income	1.0	2.9	-1.8	-65%
Total revenue	247.0	240.9	6.1	3%
Cost of sales	-97.1	-94.6	-2.5	3%
Gross profit	149.9	146.3	3.6	2%
<i>% margin</i>	<i>61.0%</i>	<i>61.5%</i>		-0.5pp
R&D expenses	-16.5	-12.0	-4.5	37%
Other SG&A	-101.7	-97.8	-3.9	4%
EBITDA	31.8	36.6	-4.8	-13%
<i>% margin</i>	<i>12.9%</i>	<i>15.4%</i>		-2.4pp
EBIT	21.8	27.7	-5.9	-21%
<i>% margin</i>	<i>8.9%</i>	<i>11.6%</i>		-2.8pp
Net profit	19.8	24.1	-4.3	-18%

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 2015 and the comparative information for 2014 are attached to this report (see Appendix 1).

2. Performance of the Group

Operating revenue increased by 3% to 246.0 million euros in 2015, mainly driven by the strength of pharmaceutical specialties business, where sales rose 7%. Total revenue increased

by 3% to 247.0 million euros in 2015, more than doubling total revenue for 2007 when ROVI held its IPO.

Sales of **prescription-based pharmaceutical** products rose 7% to 150.5 million euros in 2015.

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, performed well in Spain in 2015, with sales up 5% to 50.4 million euros. International sales remained stable at 24.7 million euros supported by the launch of the product in China and Brasil in the fourth quarter, where sales reached 0.9 million euros, thus making up for the sales deceleration in the first nine months of 2015. Bemiparin total sales increased by 3% to 75.1 million euros in 2015.

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 14% to 24.3 million euros in 2015.

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 3.6 times to 7.5 million euros in 2015.

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, reached 3.2 million euros in 2015 (see section 6.5).

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, decreased by 1% to 7.4 million euros in 2015.

Sales of **Corlantor**[®], a specialty product for stable angina and chronic heart failure from Laboratoires Servier, decreased by 3% to 13.4 million euros in 2015.

Sales of **Exxiv**[®], a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 14% to 5.9 million euros in 2015, 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 28% to 7.4 million euros in 2015.



According to IMS, Spanish innovative product market decreased by 0.9% in 2015 compared to the previous year. Nevertheless, ROVI prescription-based pharmaceutical product sales rose 7% in the same period, beating the market by 7.9 percentage points.

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 increased by 7% to 26.3 million euros in 2015.

Sales of **over-the-counter pharmaceutical products** ("OTC") and **other** decreased by 5% to 6.7 million euros in 2015 compared to 2014.

Toll manufacturing sales decreased by 5% to 62.3 million euros in 2015 compared to the previous year. The positive evolution of the injectables plant, whose revenue increased by 10% to 31.4 million euros in 2015 partially offset the 6.1 million euros revenue decline in the Frosst Ibérica plant to 30.9 million euros in 2015, as a consequence of a lower production for Merck Sharp and Dohme (MSD).

Sales outside Spain decreased by 3% to 82.8 million euros in 2015 compared to the previous year. Sales outside Spain represented 34% of operating revenue in 2015 compared to 36% in 2014.

Other income (subsidies) decreased by 65% to 1.0 million euros in 2015 from 2.9 million euros in 2014.

Gross profit increased by 2% to 149.9 million euros in 2015, reflecting a decrease of 0.5 percentage points in the gross margin to 61.0% in 2015 from 61.5% in 2014. However, excluding the impact of the Other income (subsidies) item, gross margin would increase by 0.3 percentage points to 60.5% in 2015 from 60.3% in 2014. The decrease of the Bemiparin raw material cost impacted positively in 2015 gross margin.

Research and development expenses increased by 37% to 16.5 million euros in 2015 mainly due to (i) the development of the PRISMA-2 study, a phase II trial carried out in several USA centres for evaluating the safety and pharmacokinetics of Risperidone-ISM[®] and

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*

(ii) the performing of development activities of the formulation for the Risperidone-ISM[®] phase III trial and the Letrozole-ISM[®] phase I trial.

Selling, general and administrative expenses (SG&A) increased by 4% to 101.7 million euros in 2015, compared to the previous year, mainly due to recent product launches such as Hirobriz[®], Ulunar[®], Volutsa[®] and Orvatez[®]. However, excluding the impact (i), in 2015, of the launches mentioned above, which added expenses of 3.3 million euros, and (ii), in 2014, of Hirobriz[®] and Ulunar[®] launches, which added expenses of 1.1 million euros in the fourth quarter, selling, general and administrative expenses would increase by 2% to 98.4 million euros in 2015. Also, the SG&A rise in 2015 reflected ROVI investment effort in human capital to address pneumologists and primary care, main targets of Hirobriz[®] and Ulunar[®] products.

EBITDA decreased by 13% to 31.8 million euros in 2015, compared to the previous year, reflecting a 2.4 percentage point fall in the EBITDA margin to 12.9% in 2015 down from 15.4% in 2014. However, maintaining, in 2015, the same amount of Research and Development expenses that was registered in 2014 and excluding, in 2015 and 2014, the impact of (i) Other income and (ii) recent product launches, EBITDA would increase by 11% to 38.6 million euros, reflecting a 1.0 percentage point rise in the EBITDA margin to 15.7% in 2015 up from 14.6% in 2014 (see "w/o impacts" columns of the table below).

€ million	Reported		w/o impacts			
	2015	2014	2015	2014	Growth	% Growth
Operating revenue	246.0	238.0	246.0	238.0	8.0	3%
Other income	1.0	2.9	-	-	-	-
Total revenue	247.0	240.9	246.0	238.0	8.0	3%
Cost of sales	-97.1	-94.6	-97.1	-94.6	-2.5	3%
Gross profit	149.9	146.3	148.9	143.5	5.5	4%
<i>% margin</i>	<i>61.0%</i>	<i>61.5%</i>	<i>60.5%</i>	<i>60.3%</i>		0.3pp
R&D expenses	-16.5	-12.0	-12.0	-12.0	-	-
Other SG&A	-101.7	-97.8	-98.4	-96.7	-1.7	2%
EBITDA	31.8	36.6	38.6	34.8	3.7	11%
<i>% margin</i>	<i>12.9%</i>	<i>15.4%</i>	<i>15.7%</i>	<i>14.6%</i>		1.0pp

Depreciation and amortisation expenses increased by 12% to 10.0 million euros in 2015, mainly as a result of the new property, plant and equipment and intangible assets purchases made during the last twelve months.

EBIT decreased by 21% to 21.8 million euros in 2015, compared to 2014, reflecting a 2.8 percentage point decline in the EBIT margin to 8.9% down from 11.6% in 2014. However, maintaining, in 2015, the same amount of Research and Development expenses that was

registered in 2014 and excluding, in 2015 and 2014, the impact of (i) Other income and (ii) recent product launches, EBIT would increase by 10% to 28.6 million euros, reflecting a 0.7 percentage point rise in the EBIT margin to 11.6% in 2015 up from 10.9% in 2014.

Financial expense decreased by 32% in 2015, compared to the previous year, mainly due to the registration, in 2014, of the interests related to the return of the loan granted by the Ministry of Health, Social Services and Equality for the development of the vaccine project in 2009. 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 increased by 54% in 2015, compared to 2014, mainly because of higher returns on financial investments as a result of foreign exchange operations.

The **effective tax rate** was 5.2% in 2015 compared to 5.9% in 2014. 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. (Frosst Ibérica). 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.

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 declined to 19.8 million euros in 2015, a 18% decrease compared to the previous year. However, maintaining, in 2015, the same amount of Research and Development expenses that was registered in 2014 and excluding, in 2015 and 2014, the impact of (i) Other income and (ii) recent product launches, net profit would increase by 17% to 26.2 million euros.



€ million	Reported		w/o impacts			
	2015	2014	2015	2014	Growth	% Growth
Operating revenue	246.0	238.0	246.0	238.0	8.0	3%
Other income	1.0	2.9	-	-	-	-
Total revenue	247.0	240.9	246.0	238.0	8.0	3%
Cost of sales	-97.1	-94.6	-97.1	-94.6	-2.5	3%
Gross profit	149.9	146.3	148.9	143.5	5.5	4%
% margin	61.0%	61.5%	60.5%	60.3%		0.3pp
R&D expenses	-16.5	-12.0	-12.0	-12.0	-	-
Other SG&A	-101.7	-97.8	-98.4	-96.7	-1.7	2%
EBITDA	31.8	36.6	38.6	34.8	3.7	11%
% margin	12.9%	15.4%	15.7%	14.6%		1.0pp
EBIT	21.8	27.7	28.6	25.9	2.7	10%
% margin	8.9%	11.6%	11.6%	10.9%		0.7pp
Net profit	19.8	24.1	26.2	22.5	3.7	17%

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 increased by 3%, compared to 2014, despite the difficulties in the economic and regulatory environments. We attribute this out-performance to the strength of our injectable toll manufacturing business as well as of our leading products, which continue to enjoy good sales prospects. Our commitment to reach new agreements with other laboratories to market its drugs in Spain as well as our focus on R&D to commercialise our own products led us to significantly invest in 2015, impacting the 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[®], Vytorin[®] 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 19.9 million euros in 2015, compared to 25.1 million euros in 2014. Of this amount:

- 4.3 million euros corresponds to investment capex related to the injectables facility mainly due to the preparation of the plant for the development of the ISM® project, versus 12.7 million euros in 2014;
- 1.5 million euros corresponds to investment capex related to the Granada facility, versus 4.6 million euros in 2014;
- 3.7 million euros corresponds to investment capex related to the Alcalá (Frosst Ibérica) facility, versus 2.3 million euros in 2014; and
- 4.3 million euros corresponds to expenditure on maintenance and other, vs. 5.5 million euros in 2014.
- The rest of the capex invested in 2015 corresponds mainly to the acquisition of assets of a manufacturing plant in San Sebastián de los Reyes (see section 6.4).

3.2 Debt

As of 31 December 2015, ROVI had total debt of 42.8 million euros. Debt with public administration, which is 0% interest rate debt, represented 34% of total debt as of 31 December 2015.

<i>In thousand euros</i>	31 December 15	31 December 14
Bank borrowings	28,179	20,560
Debt with public administration	14,599	15,746
Total	42,778	36,306

As of 31 December 2015, bank borrowings increased by 7.6 million euros. In 2015, ROVI refinanced its banking debt with more advantageous financing conditions; banking debt was increased by 10 million euros with interest rates for the outstanding debt ranging from 0.70% to 1%.

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 10.3 million euros in 2015 from -1.6 million euros in 2014 mainly due to (i) the decrease of 5.2 million euros in Capex, (ii) the decrease of 6.7 million euros in the "trade and other receivables" item in 2015, compared to an increase of 7.8 million euros in 2014; and (iii) the decrease of 3.7 million euros in the "inventories" item, compared to an increase of 8.8 million

euros in 2014. These positive impacts were partially offset by the decrease of 9.3 million euros in the “trade and other payables” item in 2015, compared to an increase of 11.5 million euros in 2014.

3.4 Gross cash position and net debt

As of 31 December 2015, ROVI had gross cash position of 30.7 million euros, compared to 28.0 million euros as of 31 December 2014, and net debt (available-for-sale financial assets plus deposits plus cash and cash equivalents minus short term and long term financial debt) of 12.1 million euros, compared to 8.3 million euros as of 31 December 2014. As of 30 September 2015, ROVI had gross cash position of 27.0 million euros and net debt of 17.1 million euros.

3.5 Working capital

The increase in working capital in 2015 was due to a decrease in the “trade and other payables” line of 9.3 million euros. Inventories decreased by 3.7 million euros mainly because of a larger Bemiparin production in 2014. Cash and cash equivalents increased by 2.6 million euros and the “trade and other receivables” line decreased by 6.7 million euros in 2015.

As of 31 December 2015, Social Security and Public Administrations’ total debt with ROVI amounted to 1.2 million euros. In the fourth quarter of 2015, ROVI signed a non-recourse factoring agreement for the amount of 6.1 million euros, whereby ROVI received the monetary value of the invoices issued to the Spanish and Portuguese public authorities before 18 December 2015.

4. Guidance for 2016

ROVI expects **operating revenue to grow from high single digit to low double digit for the full year 2016**, 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 expects its growth drivers to be Bemiparin, the new license agreements (Volutsa[®], Orvatez[®], Ulunar[®] and Hirobriz[®]), contribution from Vytarin[®] and Absorcol[®], its existing

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

portfolio of specialty pharmaceuticals, new product distribution licenses and new contracts in the toll manufacturing area.

5. Research and Development update

ISM®

ROVI informed that the clinical trial of Risperidone ISM® "PRISMA-2" was successfully finished; final positive results will be presented on March 2016 at the 24th European Congress of Psychiatry (see section 6.1).

Additionally, as previously communicated, ROVI is currently constructing a new plant that will allow manufacturing new ISM products for high potency active principles, e.g. letrozole. After completing the regulatory non-clinical studies for Letrozole ISM®, this new product will be progressing into clinical development. The new manufacturing facility will produce the medication for the first study in humans with Letrozole ISM®, planned to be started by first half 2016.

Enoxaparin biosimilar

Regarding Glycomics, on February 9th, 2015, after the end of the validation phase, the assessment process started in order for ROVI to be granted the Marketing Authorisation in Europe of a low-molecular-weight heparin, a biosimilar of enoxaparin. This assessment process is ongoing within the pre-established timelines.

6. Key operating and financial events

6.1 ROVI announces that the clinical trial of Risperidone ISM® "PRISMA-2" has successfully finished

As part of the clinical development of the novel long-acting injectable Risperidone ISM®, the company has successfully concluded the PRISMA-2 study.

The PRISMA-2 is an open-label, parallel phase II clinical trial that has been 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 schizophrenia¹. Sixty-seven schizophrenic subjects randomly received four

¹ *Pharmacokinetics and Tolerability Study of Risperidone ISM® in Schizophrenia (PRISMA-2)*. [<http://clinicaltrials.gov/show/NCT02086786>].

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

These final positive results will be presented at 24th *European Congress of Psychiatry* on March 13, 2016¹.

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

6.2 ROVI signs an agreement with Merus Labs to manufacture Sintrom[®]

ROVI announces that it has signed an agreement with the company Merus Labs Netherland B.V. ("Merus"), pharmaceutical company specialized in acquisition and licensing to third parties of pharmaceutical products, through which ROVI will manufacture for Merus the pharmaceutical product Sintrom[®] (acenocoumarol), indicated for the treatment and prophylaxis of thromboembolic disorders.

Under the terms of the contract signed, ROVI will provide Merus manufacturing and packaging services, on an exclusive basis, of the product Sintrom[®] to supply Spain and Portugal, during a period of five years. In this sense, it is expected that annual production of this product will lead to an increase of, approximately, 25% of the production of the plant of Frosst Ibérica. Within the same agreement, it is established that ROVI provides logistics and distribution services of Sintrom[®] in Spain, on exclusivity basis, for a period of a year, renewable yearly.

¹ *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://www.epa-congress.org/scientific-information/scientific-programme-2#.VrMTASKDMyY>]

ROVI started providing logistics and distribution services of Sintrom® in the third quarter of 2015, once authorization was obtained from the Spanish Agency of Medicines and Health Products (AEMPS). Likewise, ROVI expects to obtain authorization from the mentioned agency to manufacture this product in the second half of 2016.

6.3 ROVI announces the upcoming marketing of Orvatez® in Spain

ROVI announces it has signed an agreement with Merck Sharp & Dohme S.A. (MSD) to market in Spain Orvatez®, a drug that combines two active principle ingredients, ezetimibe and atorvastatin, which act by inhibiting the two sources of origin of cholesterol. It is indicated for adults patients with primary hypercholesterolemia (increased levels of cholesterol in blood) or mixed (high levels in blood of cholesterol and triglycerides) when the use of product combination is considered adequate. Orvatez® can be used in patients not controlled adequately with a single statine or in patients already treated with statine and ezetimibe. Orvatez® is marketed in Spain, under a co-marketing regimen with Atozet® which is being marketed by MSD.

Orvatez® is part of the first of the five marketing agreements that MSD granted ROVI on their products, under the strategic pharmaceutical agreement to market and to manufacture reached on the 23rd of July, 2009, and notified on the next day, on July the 24th 2009, to the National Stock Market Commission as Relevant Fact, with number 111,707.

With Orvatez®, ROVI expands its product's portfolio and strengthen its commitment to the area of hypercholesterolemia in which is currently offering two products of MSD, Absorcol® and Vytorin®, as alternative therapies for cholesterol problems.

Hypercholesterolemia is the presence of increased levels of cholesterol in the blood. It is one of main cardiovascular risk factors. The cardiovascular diseases such as angina pectoris, myocardial infarction, cerebrovascular diseases, and the peripheral vascular disease are one of the main causes of death in our country. In Spain, the CODIMET study evidenced that just 12% of the patients with coronary heart disease or equivalent risk have their LDL cholesterol levels controlled¹.

6.4 ROVI agrees to acquire assets of a manufacturing plant in San Sebastián de los Reyes

As it was communicated to the market on 3 June 2015 through Relevant Fact number 223905, ROVI has reached an agreement with Crucell Spain, S.A. ("Crucell") by which it has acquired

¹ Pérez de Isla L, Saltijeral Cerezo A, Vitale G, Gonzalez Timón B, Torres Do Rego A, Álvarez-Sala LA. Prevalencia del colesterol LDL inadecuado en pacientes con enfermedad coronaria y/o diabetes mellitus tipo 2. *Rev Clin Esp* 2012; 212:475-81

assets of the manufacturing plant at San Sebastián de los Reyes, owned by Crucell, with the main objective to expand in the future the injectables production lines of ROVI's group (others than the ones being manufactured by Crucell). These production assets will remain inoperative for some time while ROVI carries out investments for necessary and significant adaptation and refurbishment. Through this operation, ROVI intends to strengthen its contract manufacturing business and ensure the production capacity required to carry out its future strategic plans of international expansion of Bemiparin and, predictably, marketing and development of its potential new low molecular weight heparin, biosimilar of enoxaparin. Until the to be acquired assets begin to operate and ROVI obtains relevant approvals, ROVI will perform the technical analysis required in order to adapt mentioned assets to ROVI's methodology and procedures.

The assets purchased by ROVI consist in three parcels in San Sebastián de los Reyes and a list of property assets, including: two production lines (one of them high speed) for the filling of syringes, one production line for the filling of vials, a high speed line for the inspection of syringes and other for syringe's packaging.

By this agreement, ROVI will strengthen for the future its capacity to perform contract manufacturing operations as well as its international expansion strategy of Bemiparin and its potential new low molecular weight heparin, thus favouring company's sustained growth in the long term. This agreement is in line with ROVI's global strategy with its current manufacturing model to achieve greater effectiveness and allow its long term growth, while continue with its constant commitment of economic growth in Spain.

The agreement implied an investment by ROVI of approximately 4 million euros. The operation was financed by available funds from the Company; therefore it was not required seeking external financing.

6.5 ROVI announces the agreement to market Volutsa® in Spain

ROVI announces it has signed an agreement with Astellas Pharma, S.A. ("Astellas") to market Volutsa® (solifenacin succinate and tamsulosin hydrochloride) in Spain, which corresponds to Astellas' Vesomni® product.

Under the terms of this marketing agreement, ROVI undertakes the promotion and distribution in Spain of Volutsa®, a modified release tablet containing two active substances, solifenacin and tamsulosin. Solifenacin is an anticholinergic drug and tamsulosin belongs to a drugs group called alpha-antagonists. Volutsa® is indicated for the treatment of moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia (BPH) in men who are not adequately responding to treatment with monotherapy.



When the prostate becomes enlarged, urinary problems (voiding symptoms) such as urinary hesitancy (difficulty to initiate urination), reduction of the flow of urine (weak stream), urine leakage and sensation of incomplete emptying of the bladder, may occur. At the same time, the bladder may also be affected and it contracts spontaneously at times when urination is delayed. This causes bladder (storage) symptoms such as changes in the sensation of the bladder, urgency (having an uncontrollable urge to urinate) and a high urinary frequency to occur. Solifenacin reduces involuntary contractions of the bladder and increases the amount of urine that the bladder can hold. Tamsulosin allows the urine to pass more easily through the urethra, thereby facilitating urination.

ROVI started to market Volutsa® in the first quarter of 2015, at the same time Astellas started commercialising Vesomni®.

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 31 DECEMBER 2015 AND 31 DECEMBER 2014

(Thousands of euros)

	31 December 2015	31 December 2014
ASSETS		
Non-current assets		
Property, Plant and Equipment	81,803	73,593
Intangible assets	18,881	17,206
Deferred tax assets	8,871	8,280
Available-for-sale financial assets	70	71
Financial receivables	139	137
	109,764	99,287
Current assets		
Inventories	63,859	67,567
Trade and other receivables	57,028	63,678
Current income tax assets	3,945	4,117
Cash and cash equivalents	29,251	26,671
	154,083	162,033
Total assets	263,847	261,320



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS AS OF 31 DECEMBER 2015 AND 31 DECEMBER 2014

(Thousands of euros)

	31 December 2015	31 December 2014
EQUITY		
Capital and reserves attributable to shareholders of the company		
Share capital	3,000	3,000
Legal reserve	600	600
Treasury shares	(8,112)	(2,813)
Retained earnings and voluntary reserves	149,490	133,569
Profit for the period	19,809	24,116
Reserve for available-for-sale assets	(2)	(2)
Total equity	164,785	158,470
LIABILITIES		
Non-current liabilities		
Financial debt	32,631	32,032
Deferred income tax liabilities	1,344	1,818
Non-current deferred revenues	5,861	6,883
	39,836	40,733
Current liabilities		
Trade and other payables	45,742	55,018
Financial debt	10,147	4,274
Current deferred revenues	840	798
Provisions for other liabilities and charges	2,497	2,027
	59,226	62,117
Total liabilities	99,062	102,850
Total equity and liabilities	263,847	261,320



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED INCOME STATEMENTS FOR THE FULL YEARS 2015 AND 2014

(Thousands of euros)

	Full Year	
	2015	2014
Revenue	246,009	238,047
Cost of sales	(97,075)	(94,578)
Employee benefit expenses	(61,769)	(58,085)
Other operating expenses	(56,361)	(51,663)
Depreciation, amortisation and impairment charges	(9,975)	(8,884)
Recognition of government grants on non financial non-current assets and other	1,013	2,855
OPERATING PROFIT	21,842	27,692
Finance income	837	545
Finance costs	(1,781)	(2,603)
FINANCE COSTS - NET	(944)	(2,058)
PROFIT BEFORE INCOME TAX	20,898	25,634
Income tax	(1,089)	(1,518)
PROFIT FOR THE PERIOD	19,809	24,116



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED CASH FLOW STATEMENTS FOR THE FULL YEARS 2015 AND 2014

(Thousands of euros)

	Full Year	
	2015	2014
Cash flows from operating activities		
Profit before income tax	20,898	25,634
Adjustments for non-monetary transactions:		
Amortisation	9,975	8,884
Interest income	(837)	(545)
Impairment	(2,013)	2,865
Interest expense	1,781	2,603
Net changes in provisions	470	(344)
Grant for non-financial fixed assets and income from distribution licenses	(638)	(2,268)
Changes in working capital		
Trade and other receivables	6,508	(7,746)
Inventories	5,041	(11,229)
Trade and other payables	(9,276)	11,533
Other collections and payments		
Proceeds from distribution licenses	110	210
Interest paid	(645)	(2,658)
Income tax cash flow	(1,982)	(3,937)
Net cash generated (used) from operating activities	29,392	23,002
Cash flows from investing activities		
Purchases of intangible assets	(3,657)	(4,201)
Purchases of property, plant and equipment	(16,244)	(20,853)
Proceeds from sale of property, plant and equipment	41	38
Proceeds from sale of available-for-sale financial assets	-	16,201
Contracting current bank deposits	(170)	-
Interest received	776	365
Net cash generated (used) in investing activities	(19,254)	(8,450)
Cash flows from financing activities		
Repayments of financial debt	(5,671)	(18,907)
Proceeds from financial debt	11,607	21,636
Purchase of treasury shares	(6,546)	(3,345)
Dividends paid	(8,346)	(8,042)
Reissue of treasury shares	1,398	1,376
Net cash generated in financing activities	(7,558)	(7,282)
Net (decrease)/increase in cash and cash equivalents	2,580	7,270
Cash and cash equivalents at beginning of the period	26,671	19,401
Cash and cash equivalents at end of the period	29,251	26,671