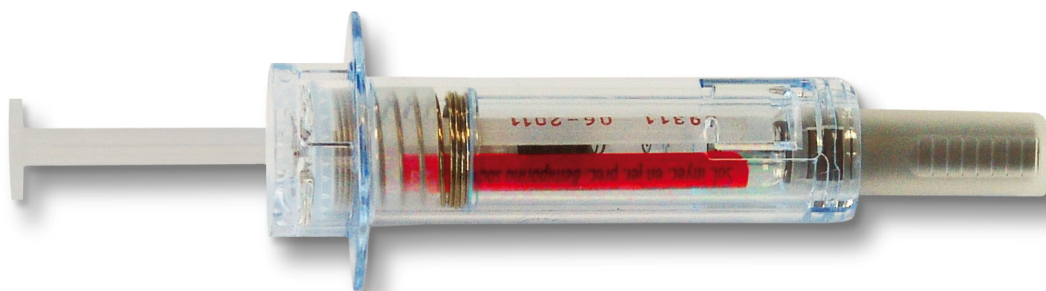




# First Quarter 2011 Results

11 May 2011



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



## **ROVI – Three-month period ended 31 March 2011**

# **ROVI reports an operating revenues growth of 40%, led by sales for pharmaceutical specialities and the MSD agreement**

- **Operating revenues increased by 40% to 46.8 million euros in the three-month period ended 31 March 2011, driven by the strength of the specialty pharmaceutical business, where sales rose 8%, and the implementation of the Merck Sharp & Dohme (MSD) strategic agreement which generated a 4,8 times growth of the toll manufacturing business area.**
- **Confirmation of guidance for the full year 2011, of operating revenues rising low double digit.**
- **In January 2011, ROVI started the marketing of Absorcol®, whose active principle is ezetimibe, and Vytorin®, which combines two active principles, ezetimibe and simvastatin, the first of the five licenses of MSD, in Spain for a period of 10 years. Sales of Absorcol® and Vytorin® reached 0.9 million euros in the first quarter of 2011.**
- **Sales of Bemiparin increased by 20% to 13.2 million euros, sales of Corlentor and Exxiv grew by 53% and 2% respectively in the three-month period ended 31 March 2011. Sales of Thymanax, an innovative antidepressant from Servier that ROVI launched in March 2010, reached 1.6 million euros in the first quarter of 2011.**
- **EBITDA decreased by 12% to 6.1 million euros in the three-month period ended 31 March 2011, compared to the same period of the previous year, as a result of the Vytorin and Absorcol launch, the increase in raw material costs for Bemiparin and the impact of the measures, introduced in the second half of 2010, to reduce the pharmaceutical expenditure. Excluding the impact of these measures, EBITDA increased by high teens in the first quarter of 2011.**
- **Net profit decreased by 3% to 4.9 million euros in the three-month period ended 31 March 2011, impacted by the same factors as EBITDA.**
- **ROVI will propose to the Shareholders General Meeting a dividend of 0.17208 euros per share on 2010 earnings. This proposed dividend would mean an increase of 22% compared to the dividend on 2009 earnings.**



**Madrid (Spain), 11 May 2011, 8:00 AM CET** - ROVI released today its financial results for the three-month period ended 31 March 2011.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that *"in the first quarter of 2011, we reached an excellent 40% operating revenues growth driven by the strength of two of our pillars of growth, our specialty pharmaceutical area and our toll manufacturing area. We continued to record sales growth in our specialty pharmaceutical business despite the negative impact related to the new measures introduced by the government for the rationalisation of the pharmaceutical expenditure, estimated at 8 million euros on 2011 sales. Once again Bemiparin led the growth with a 20% increase in sales. Bemiparin sales in Spain rose 25% mainly as a result of the 9.5% price increase, from December 2010, and outside Spain grew by 11%, highlighting the continued internationalisation of our flagship product as one of the Company's growth engines in the medium term. Furthermore, the agreement with MSD allows us to strengthen our toll manufacturing area, as we have already reflected in the 2010 results and in the first quarter 2011 results, as well as our specialty pharmaceutical area, as we have recently shown with the launch, in January 2011, of Vytorin and Absorcol, the first of the five licenses from MSD that will contribute to our growth in the coming years. This launch required a significant investment effort in human capital in order to address new prescribers, among them a selection of primary care prescribers. Our investment effort will impact 2011 net result but we expect to achieve strong sales growth and operating leverage in the coming years. In addition, the MSD agreement will allow us to launch four additional new products in the next 10 years, underpinning our belief in the sustainability of the long term outlook for the company. ROVI's R&D pipeline continues to hold strong potential to drive the company's growth in future years. We are very excited with the potential of the ISM projects, especially with the Risperidone-ISM® development, whose results are expected to be announced in the second half of this year"*.



## 1. Financial highlights

€ million	Q1 2011	Q1 2010	Growth	% Growth
Operating revenues	46.8	33.3	13.4	40%
Other income	0.3	0.3	0.1	35%
<b>Total revenue</b>	<b>47.1</b>	<b>33.6</b>	<b>13.5</b>	<b>40%</b>
Raw materials used and changes in inventories	(18.9)	(11.2)	(7.7)	69%
<b>Gross profit</b>	<b>28.2</b>	<b>22.4</b>	<b>5.8</b>	<b>26%</b>
% margin	60.3%	67.1%		(6.8pp)
R&D expenses	(2.2)	(2.4)	0.2	(7%)
Other SG&A	(19.9)	(13.1)	(6.8)	52%
<b>EBITDA</b>	<b>6.1</b>	<b>6.9</b>	<b>(0.9)</b>	<b>(12%)</b>
% margin	13.0%	20.8%		(7.8pp)
<b>EBIT</b>	<b>5.0</b>	<b>6.1</b>	<b>(1.1)</b>	<b>(18%)</b>
% margin	10.7%	18.4%		(7.7pp)
<b>Net profit</b>	<b>4.9</b>	<b>5.0</b>	<b>(0.1)</b>	<b>(3%)</b>

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

The consolidated financial statements of Grupo ROVI for the first quarter of 2011 and the comparative information for 2010 (balance sheet) and for the first quarter of 2010 (income statement and cash flow statement) are attached to this report (see Appendix 1).

## 2. Performance of the Group

**Operating revenues** increased by 40% to 46.8 million euros in the three-month period ended 31 March 2011, driven by the strength of the specialty pharmaceutical business, where sales rose 8%, and the implementation of the Merck Sharp & Dohme (MSD) strategic agreement which generated a 4,8 times growth of the toll manufacturing business area.

Sales of prescription-based pharmaceutical products rose by 27% to 25.3 million euros in the three-month period ended 31 March 2011. Excluding the impact of the new measures to reduce the pharmaceutical expenditure, sales of prescription-based pharmaceutical products rose by around ten additional percentage points in the first quarter of 2011.

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, maintained a growth rate, with sales up 20% to 13.2 million euros. Sales of **Bemiparin** in Spain (**Hibor®**) increased by 25% at 9.3 million euros, as a result of the 9.5% price increase from December 2010, while



international sales rose by 11% from last year supported by the increased presence of Bemiparin, through strategic alliances, in countries where it was already present, and by the launch of the product in one new country, Russia, during the first quarter of 2011.

Sales of **Corlentor®**, a specialty product for stable angina from Laboratoires Servier, rose by 53% in the three-month period ended 31 March 2011, to 1.6 million euros. In August 2010, the results of the SHIFT (Systolic Heart Failure Treatment with the If Inhibitor Ivabradine Trial) study were published. SHIFT, the largest-ever morbi-mortality study of treatments for chronic heart failure showed that adding the specific heart rate lowering agent Ivabradine (Corlentor®) to standard therapy significantly reduces the risk of death and hospitalisation for heart failure. Currently, Ivabradine is immersed in the regulatory process to obtain the new indication.

Sales of **Exxiv®**, a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), increased by 2% to 2.1 million euros in the three-month period ended 31 March 2011.

Sales of **Thymanax®**, an innovative antidepressant from Laboratoires Servier, launched in March 2010 and for which ROVI has a co-marketing agreement covering Spain, reached 1.6 million euros in the first quarter of 2011.

The impact of the measures approved to reduce the pharmaceutical expenditure (section 7.4) in the first quarter of 2011 was in line with the impact expected of 8 million euros on 2011 sales, published in the earnings release for the first half of 2010.

Sales of **contrast imaging agents** and other hospital products increased by 9% in the three-month period ended 31 March 2011 to 5.8 million euros. The sales of **over-the-counter pharmaceutical products** declined by 2% to 1.6 million euros in the first quarter of 2011 compared to the same period of the previous year. This was mainly as consequence of ROVI divestiture strategy in this area. Sales of **aesthetic medical products** decreased by 86% to 0.1 million euros as a result of the termination of the distribution contract of implants for use in plastic and reconstructive surgery with Pérouse, which was effective on 31 March 2010.

**Toll manufacturing** sales increased by 4.8 times in the first quarter of 2011, to 13.7 million euros, compared with same period of the previous year, as a result of the implementation of the MSD manufacturing and packaging agreement, which was effective on 31 March 2010 (see section 7.5). Revenues from the MSD manufacturing and packaging agreement amounted to 11.5 million euros in the three-month period ended 31 March 2011 due to the advance of some production to this first quarter, as a result of the final integration of Frosst Iberica into the ROVI Group. ROVI does not expect to repeat this manufacturing volume for MSD in the next quarters of this year. This agreement contributes to strength in this business area and ROVI expects this contribution increases in 2011. The Frosst Ibérica plant has current manufacturing capabilities of 3 billion of capsules and 100 million of boxes. ROVI counts on a spare capacity of 50% in this plant which will allow it to acquire new customers in



order to maximise the potential of the acquired infrastructure. In January 2011, ROVI signed an agreement with Farmalíder, a pharmaceutical company specialised in the development of branded, OTC, value-added, and traditional generic products, for the manufacturing, research and conditioning of pharmaceutical specialties based on Ibuprofen and Paracetamol. Farmalíder has undertaken to work towards providing ROVI with annual manufacturing that will represent an increase in the production of the plant of Frosst Ibérica by 10% to 15% (see section 7.1).

**Gross profit** increased by 26% in the three-month period ended 31 March 2011 to 28.2 million euros, as a result of the MSD agreement implementation, reflecting a fall in the gross margin to 60.3% in the first quarter of 2011 from 67.1% in the first quarter of 2010 mainly due to:

- the increase in the Bemiparin raw material prices, despite the 9.5% Bemiparin price increase in Spain, from December 2010, which partially offset the fall. In the first quarter of 2011 the raw material costs for Bemiparin were running at more than 2 times 2010 first quarter costs. The increase in the Bemiparin raw material prices represented around 2.6 percentage points of the 6.8 percentage points gross margin fall in the first quarter of 2011 compared to the same period of the previous year. In the first quarter of 2011, ROVI continued to buy Bemiparin raw material under the raw material peak price achieved in 2010 and expects that this positive trend continues during 2011. ROVI expects that this factor, as well as the Bemiparin price increase, impact positively on the second half 2011 gross margin.
- the new measures to reduce the pharmaceutical expenditure (see section 7.4), which represented around 1.7 percentage points of the 6.8 percentage points gross margin fall in the first quarter of 2011 compared to the same period of the previous year.

**Research and development expenses** decreased by 7% to 2.2 million euros, reflecting ROVI investments in products that are under development, and the search for greater cost efficiency.

**Selling, general and administrative expenses** increased by 52% in 2010 compared with the same period of the previous year, as a result of the MSD manufacturing and packaging agreement implementation and the launch of Vytorin and Absorcol, the first of the five licenses of MSD. Excluding the impact of the MSD agreement, selling, general and administrative expenses increased by 22%. This 22% increase reflected ROVI investment effort in human capital to address primary care, main target of Vytorin and Absorcol products.

**EBITDA** decreased by 12% to 6.1 million euros in the three-month period ended 31 March 2011, compared to the same period of the previous year, as a result of the Vytorin and Absorcol launch, the increase in raw material costs for Bemiparin and the impact of the new measures to reduce the pharmaceutical expenditure. Excluding the impact of these measures, EBITDA increased by high teens in the first quarter of 2011.



**Depreciation and amortisation expenses** increased by 34% in the three-month period ended 31 March 2011, compared with the same period of previous year, mainly as a result of the implementation of the MSD agreement and the new property plant and equipment purchases made during 2010 and 2011.

**EBIT** decreased by 18% to 5.0 million euros in the three-month period ended 31 March 2011 compared with the same period of the previous year, impacted by the same factors as EBITDA.

The **financial expense** line increased by 53% in the three-month period ended 31 March 2011, compared with the same period in the 2010 financial year, as a result of the implied interests increase related to the new reimbursable loans collected from 1 April 2010 to 31 March 2011 and to the debt from purchase of Frosst Ibérica shares, registered as of 1 April 2010.

**Financial income** increased by 2.2 times in the three-month period ended 31 March 2011 compared with the same period of the previous year as a result of higher returns on financial investments.

The **effective tax rate** was 0% in the first quarter of 2011 compared with 15.9% in the first quarter of 2010. ROVI has not paid taxes on Frosst Ibérica 2011 first quarter profits as this company has negative tax bases, which amounted to 56.3 million euros as of 31 December 2009. This figure would be significantly increased by the negative tax bases generated in 2010. ROVI expects not to pay taxes on Frosst Ibérica profits in the coming years.

As a result of the factors noted above, the **net profit** of ROVI decreased by 3% to 4.9 million euros in the three-month period ended 31 March 2011 compared with the same period of the previous year.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that, *"we are satisfied with the results for the first quarter of 2011. Operating revenues increased by 40% despite the difficulties in the economic and regulatory environments. We attribute this out-performance to the strength of our leading products, which continue to gain share in their various market segments, and to the contribution of the MSD manufacturing and packaging agreement. Margins have continued to be affected in the first quarter of 2011, mainly because of the rise in the heparin raw material costs and of the impact of the measures introduced by the government to reduce pharmaceutical expenditure. It is difficult to be definitive on raw material pricing for our heparin products but we continued to buy Bemiparin raw material under peak price in the first quarter of 2011 and we expect that this positive trend continues and, together with Bemiparin sale price increase, has a positive impact on 2011 gross margin. In addition, we are working to increase efficiencies in the manufacturing process and this should off-set some of the gross margin erosion caused by higher raw material cost. We also expect that the spare capacity in the MSD manufacturing facility, that has been already*



*started to be used, will allow us to reverse over time the erosion of profit margins. It is very gratifying to witness the growth in the strength of our balance sheet and our excellent capacity to generate cash, which allow us to finance organic growth through the launch of new products, such as Vytorin and Absorcol, 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 better the utilisation of our asset base. In addition, I would like also to highlight the 22% increase of the dividend to be paid on 2010 earnings, once it is approved by the General Shareholders Meeting, which shows our financial strength in a difficult environment and our commitment with investors."*

### 3. Balance Sheet items

#### 3.1 Capital expenditure

ROVI invested 1.1 million euros in the first quarter of 2011, compared to 0.5 million euros in the first quarter of 2010. Of this amount, 0.5 million euros correspond to investment capex related to Granada facility and the rest to expenditure on maintenance versus 0.5 million euros of maintenance capex in the first quarter of 2010.

#### 3.2 Debt

As of 31 March 2011, ROVI had total debt of 54.2 million euros. Debt with public administration represented, as of 31 March 2011, 65% of total debt and 87% of total debt is 0% interest rate debt.

*In thousand euros*

	<b>31 March 11</b>	<b>31 December 10</b>
Loans from banks	6,416	6,891
Debt with public administration	35,511	28,441
Liabilities from financial leases	510	676
Debt from purchase of shares	11,736	15,896
<b>Total</b>	<b>54,173</b>	<b>51,904</b>

The debt from purchase of shares registered as of 31 March 2011 corresponds to the outstanding payment related to the Frosst Ibérica acquisition, which includes the payment of 2.1 million euros for the Frosst Ibérica shares acquisition (the first two payments of 0.7 million euros each one were executed on 31 March 2010 and on 31 March 2011) and the payment of 9.7 million euros for the Frosst Ibérica working capital (the first payment of 3.2 million euros was executed on 31 March 2011). The payments of this debt of 11.7 million euros will be executed annually, starting on 31 March 2012 and ending on 31 March 2014.





### **3.3 Free cash flow**

Free cash flow decreased by 0.2 million euros in the first quarter of 2011 compared to the same period of the previous year, mainly due to 1.1 million euros of capex invested in the first quarter of 2011 compared to 0.5 million euros of capex invested in the first quarter of 2010.

### **3.4 Net and gross cash position**

As of 31 March 2011, ROVI had a gross cash position of 64.8 million euros and a net cash position of 10.6 million euros (financial assets and cash minus short term and long term debt), providing it with a high level of financial flexibility.

### **3.5 Working capital**

The positive trend in working capital in the first quarter of 2011 is mainly due to an increase in cash of 5.0 million euros, a decrease in "trade and other receivables" item of 1.2 million euros and a decrease in the "inventories" line of 0.1 million euros. The "trade and other payable" item decreased by 3.8 million euros.

### **3.6 Tax credit**

Because of the impairment registered in the Frosst Ibérica accounts as of 31 December 2009 and the losses registered by the company in the last years, on the acquisition date, Frosst Ibérica had negative tax bases (tax credit) of 56.3 million euros.

From the acquisition of Frosst Ibérica, S.A., which was effective on 1 April 2010, to 31 December 2010, the company registered a net income of 5.6 million euros. Nevertheless, from 1 January to 31 December 2010, Frosst Ibérica, S.A. generated losses which would significantly increase the tax credit registered as of 31 December 2009.

As of 31 March 2011, ROVI had 3.6 million euros of tax savings generated by the Frosst Ibérica acquisition, considering a tax rate of 30% over negative tax bases of 12.1 million euros.

## **4. Guidance for 2011**

Despite the impact estimated at 8 million euros on 2011 sales, published in ROVI 2010 first half results, and the double digit decrease expected for the Spanish pharmaceutical market in 2011, as a result of the new measures for the rationalisation of the pharmaceutical expenditure, ROVI expects to grow operating revenues in low double digit. ROVI expects its growth drivers to be Bemiparin, its existing portfolio of specialty pharmaceuticals, recent launches such as Vytorin, Absorcol, Thymanax and Bertanel and the MSD agreement which was implemented at the end of the first quarter of 2010. The strength of these areas could be



offset by lower growth or declines in sales in injectable toll manufacturing and in the OTC line. Regarding injectable toll manufacturing, ROVI does not expect to fill syringes for Sanofi Aventis in 2011. In addition, the OTC franchise is impacted by consumers' discretionary spending and ROVI divestiture strategy in this business line. ROVI forecasts that the combination of all of these factors should result in a low double digit growth of operating revenues for the full year 2011.

## 5. Research and Development update

After the latest results of the clinical trials that were published during the past months and the progress of the pre-clinical developments, ROVI R&D strategy has been redeployed and these are the highlights:

- ISM® platform ("in situ microparticles") for antipsychotics: in September 2010, the clinical testing stage began for the first Phase I trial of Risperidone-ISM® on healthy volunteers and has just finished by the end of 1Q 2011. This first trial aims mainly to evaluate the pharmacokinetics and the tolerability of a single intramuscular administration of Risperidone in an ISM formulation; the results will be announced by the second quarter of this year. This trial will serve not only to confirm the pharmacokinetic profile of this innovative depot formulation for the monthly administration of a recognised anti-psychotic, but it will also serve as proof of concept for validating ISM technology as a base platform for other developments. ROVI is currently on animal testing phase with another widely used antipsychotic, olanzapine, using the ISM® technology for a safe and effective monthly administration in schizophrenic patients.
- Letrozole-ISM®: the company is also dedicating its efforts for the development of a novel formulation for a quarterly injection of a well-recognised aromatase inhibitor, letrozole. Letrozole is currently considered as a key therapy for the treatment of the hormone-dependent breast cancer and the ISM technology may provide better compliance and additional benefits to those patients who are suffering from this type of cancer. The project is already in pre-clinical phase under animal testing.
- In December 2010, ROVI announced to refocus the wound healing research line on the development of glycosaminoglycan compounds for topical application. In vivo studies in animal models are progressing as planned and hopefully these will lead ROVI to start phase I in human beings by first half 2012.



## 6. New product launches

In January 2011, ROVI launched Absorcol® and Vytorin®, the first of the five marketing licenses for its products that Merck Sharp & Dohme (MSD) awarded to ROVI as part of the strategic marketing and manufacturing agreement of 23 July 2009. Absorcol®, whose active principle is ezetimibe, and Vytorin®, which combines two active principles, ezetimibe and simvastatin, are marketed in Spain in a co-marketing regime with Ezetrol® and Inegy® respectively, for a period of 10 years. Although they are two different products, ROVI and MSD have agreed to consider them as one product in terms of the marketing rights granted to ROVI by MSD, as Vytorin® is a combination of ezetimibe, the selected active principle, and simvastatin (see section 7.2). In addition, the strategic agreement reached with MSD, implemented on the 31 March 2010, will allow ROVI the launch of four additional new products during the next 10 years.

Iván López-Belmonte Encina, Deputy CEO and Head of Corporate Development of ROVI, said that, *"we are very excited with the potential of Absorcol® and Vytorin®. These drugs provide coronary and diabetic patients with the best and simplest therapeutic option for reaching LDL-c targets and lowering cardiovascular risks, and they reflect ROVI's commitment to improving the quality of life of patients. Winning licenses for new products will continue to be one of the cornerstones of our plans for future growth, and this will be complemented by our own internal R&D efforts. We are currently analysing various opportunities to obtain licenses, and our aim continues to be to market one or two new products per year. In addition, the launch of four new products from MSD during the next 10 years will contribute to a sustained growth of the company for the long term."*

## 7. Key operating and financial events

### 7.1 ROVI signs a contract with Farmalíder for the manufacturing of oral forms

ROVI signed a contract with Farmalíder, a pharmaceutical company that specialises in the development of branded products, OTC pharmaceutical products that are available without prescription, products with added value, and generic products, for the manufacturing, research and conditioning of pharmaceutical specialties based on Ibuprofen and Paracetamol.

ROVI has been authorised by the Spanish Agency for Medicines and Medical Devices (AEMPS) for the manufacturing of these products.

According to the terms of the contract, ROVI will provide manufacturing, research and conditioning services to Farmalíder for a period of eight years. In addition, Farmalíder has undertaken to work towards providing ROVI with annual manufacturing that could represent an increase in the production of the plant of Frosst Ibérica, S.A. by 10% to 15%.



## **7.2 Marketing of Absorcol and Vytorin, the first of the five licenses from MSD**

ROVI announced the marketing of Vytorin® and Absorcol® in Spain, the first of the five marketing licenses for its products that Merck Sharp & Dohme (MSD) awarded to ROVI as part of the strategic marketing and manufacturing agreement of 23 July 2009, stated to the Comisión Nacional del Mercado de Valores on 24 July 2009 as Relevant Fact number 111.707.

Absorcol®, whose active principle is ezetimibe, is indicated, combined with another statin, for the treatment of primary hypercholesterolemia and homozygous familial hypercholesterolemia in patients who are not adequately controlled with one single statin. Absorcol®, as a monotherapy, is indicated for patients with primary hypercholesterolemia for whom one statin is considered to be inadequate or which is not tolerated, and for patients with homozygous familial sitosterolemia. Absorcol® is a drug of choice for diabetic and coronary patients, who following their treatment with a statin have not reached indicated LDL-c levels, thanks to its single and unique action mechanism, which is able to inhibit, simultaneously with the statin, intestinal absorption and hepatic synthesis.

Vytorin® is an innovative drug which combines two active principles, ezetimibe and simvastatin, recently marketed by MSD under the brand of Inegy®. It is indicated for the treatment of patients with primary hypercholesterolemia or mixed hyperlipidemia, in those cases in which the prescription of a statin together with ezetimibe is necessary.

Vytorin® and Absorcol® are marketed in Spain from January 2011 in a co-marketing regime with Ezetrol® and Inegy® respectively, for a period of 10 years. Although they are two different products, ROVI and MSD have agreed to consider them as one product in terms of the marketing rights granted to ROVI by MSD, as Vytorin® is a combination of ezetimibe, the selected active principle, and simvastatin.

## **7.3 Results of the Phase I trial of oral Bemiparin based on the OCAP technology**

In January 2011, ROVI announced the results of the Phase I trial of oral Bemiparin in which healthy volunteers were treated with six oral formulations of Bemiparin using Oral Carbohydrate And Protein (OCAP®) technology.

The levels of anticoagulant (anti-factor Xa) of the various formulations and doses of sodic Bemiparin administered orally were below the detection limit (0.1 IU/mL) or slightly above it, and hence it was concluded that there had not been sufficient gastrointestinal absorption. Nevertheless, the formulations were tolerated well by the volunteers, with maximum doses of up to 50,000-80,000 IU of Bemiparin.

The clinical trial consisted of a parallel open-label test of increasing single doses in a course of two doses separated by 24 hours and administered orally, and the administration of a single



prophylactic dose of Bemiparin administered subcutaneously, on a total of 102 healthy volunteers of both sexes. The main aim of the trial was to assess the anti-factor Xa activity profile of Bemiparin when administered orally in six different formulations (pills and capsules). In addition, the secondary aims of the trial included the gaining of an understanding of the safety and tolerability of these formulations of Bemiparin, and also the comparison of the bioavailability obtained from the doses administered orally with the information from the subcutaneous administration of Bemiparin in prophylactic doses for venous thromboembolism (2,500 IU).

OCAP® technology is based on the incorporation of active substances, with low levels of bioavailability when administered orally, into polymeric vehicles that enable their systemic absorption in the intestinal lumen. OCAP® formulations that are administered orally enable the active substance to be protected from the luminal environment, and provide a vehicle for it to reach the area where absorption takes place. Preclinical results on various animal models (rabbits, dogs and monkeys) were positive and led to approval for this first test on humans.

In light of these Phase I results of oral Bemiparin, ROVI has decided to discontinue the development of OCAP® technology for the oral administration of Bemiparin, and to concentrate its efforts and resources on the ISM® drug delivery platform. As ROVI recently announced, in September 2010 it began the experimental stage of the first Phase I trial on healthy volunteers of the anti-psychotic drug Risperidone-ISM®. This clinical trial will also serve as a proof of concept for validating ISM® technology as a base platform for other developments, some of which are already in advanced pre-clinical phases.

#### **7.4 Impact of the measures for the reduction of the pharmaceutical expenditure**

The Spanish government has approved a reduction of the pharmaceutical expenditure of 2.8 billion euros through the introduction of two pieces of pricing legislation. The first one was approved in March 2010 and was focused on the generic products. With regards to these products, which are those out of patent, the reduction was 25% on average applied to the sale price to laboratories. The second package, which was approved in May 2010 and applied from June 2010, was addressed to the pharmaceutical products under patent. A discount of 7.5% has been applied to the sale price to the public for these products. The impact of the measures approved in March was minimal in 2010 and continue to be insignificant in 2011 for ROVI because the majority of its products are under patent. Nevertheless, the impact of the measures approved in May was significant in 2010 and will continue to impact strongly ROVI sales during 2011, mainly affecting the specialty pharmaceutical area. The impact on 2010 sales was around 3.5 million euros and we estimate that the impact on 2011 sales will probably amount to 8 million euros. In order to offset the impact of the sales reduction, ROVI is working on an internal saving plan to try to improve the efficiency of its internal and external operating processes, without affecting the marketing, sales and R&D areas.



## **7.5 ROVI implements the Strategic Pharmaceutical Manufacturing and Marketing Agreement in Spain reached with MSD**

ROVI has implemented the strategic agreement for the marketing and manufacturing of pharmaceuticals reached by ROVI and Merck Sharp & Dohme (MSD) in Spain on 23 July 2009, which was communicated the following day 24 July 2009 as a Relevant Fact, with number 111.707, to the Comisión Nacional del Mercado de Valores.

The implementation of this strategic agreement resulted in the transfer of the manufacturing and packaging plant at Alcalá de Henares, Frosst Ibérica, to ROVI Imaging, S.L., a subsidiary of Laboratorios Farmacéuticos Rovi, S.A. (ROVI), and the implementation, with effect from 31 March 2010, of the main agreements reached on 23 July 2009. These agreements include: (i) the manufacturing by ROVI of the pharmaceutical products of MSD that are currently produced at the plant, and their packaging for worldwide supply for a period of five years, and packaging for Spain for a period of seven years, and (ii) the granting of distribution rights in Spain, in a co-marketing regime, for five products of MSD, which can be selected by ROVI over the course of the next 10 years.

In addition, as of 23 July 2009, ROVI transferred into its marketed portfolio two MSD products for sale in Spain, Tryptizol™ (amitriptyline) and Ameride™ (amiloride & hydrochlorothiazide), and from 1 January 2010, Prinivil® and Prinivil® Plus were transferred thereby completing the MSD product transfers to ROVI.

On the other hand, ROVI announced the marketing in Spain of Vytarin® and Absorcol®, the first of the five marketing licenses for its products that Merck Sharp & Dohme (MSD) awarded to ROVI as part of the Strategic Agreement (see section 7.2).

All these actions have been implemented in accordance with the terms of the agreement reached on 23 July 2009, with no major deviation in terms of timing and cost which is a testament to the strength of the working relationship between the two companies.

## **7.6 Dividend payment**

The ROVI General Shareholders Meeting, on 16 June 2010, approved the payment of a gross dividend of 0.1410 euros per share on 2009 earnings. This dividend was paid on 6 July 2010 and implied the pay-out of 35% of consolidated net profit for 2009.

ROVI will pay a dividend of 0.17208 euros per share on 2010 earnings if the Shareholders General Meeting approves the application of the 2010 profit, under proposal of ROVI Board of Directors. This proposed dividend would mean an increase of 22% compared to the dividend on 2009 earnings and would imply the pay-out of 35% of consolidated net profit for 2010.



## 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 27 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 addressing currently unmet medical needs by developing new LMWH-based products and expanding applications for its existing LMWH-based products. 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. Additional information about ROVI is available on the company's website: [www.rovi.es](http://www.rovi.es)

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## Forward-looking statements

This news release contains forward-looking statements. Such forward looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition, performance, or achievements of ROVI or industry results,



to be materially different from any future results, performance, or achievements expressed or implied by such forward looking statements. The statements in this press release represent ROVI's expectations and beliefs as of the date of this press release. ROVI anticipates that subsequent events and developments may cause these expectations and beliefs to change. However, while ROVI may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing ROVI's expectations or beliefs as of any date subsequent to the date of this press release.





## APPENDIX 1

### LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS AS OF 31 MARCH 2011 AND 31 DECEMBER 2010

(Thousand of euros)

	31 March 2011	31 December 2010
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, Plant and Equipment	42,644	42,659
Intangible assets	2,320	2,290
Deferred tax assets	3,860	3,851
Available-for-sale financial assets	71	70
Financial receivables	2,100	2,086
	<b>50,995</b>	<b>50,956</b>
<b>Current assets</b>		
Inventories	41,731	41,824
Trade and other receivables	57,899	59,084
Current income tax assets	2,214	2,388
Bank deposits	25,000	25,000
Cash and cash equivalents	38,673	33,635
	<b>165,517</b>	<b>161,931</b>
<b>Total assets</b>	<b>216,512</b>	<b>212,887</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS AS OF 31 MARCH 2011 AND 31 DECEMBER 2010**

(Thousand of euros)

	<b>31 March 2011</b>	<b>31 December 2010</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	(2,003)	(1,960)
Retained earnings and voluntary reserves	102,496	77,914
Profit for the year	4,852	24,582
Reserve for available-for-sale assets	(2)	(2)
<b>Total equity</b>	<b>108,943</b>	<b>104,134</b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>		
Financial debt	45,427	43,089
Deferred income tax liabilities	1,641	1,633
Non-current deferred revenues	12,198	12,404
	<b>59,266</b>	<b>57,126</b>
<b>Current liabilities</b>		
Trade and other payables	33,458	37,238
Financial debt	8,746	8,815
Current deferred revenues	4,794	4,334
Provisions for other liabilities and charges	1,305	1,240
	<b>48,303</b>	<b>51,627</b>
<b>Total liabilities</b>	<b>107,569</b>	<b>108,753</b>
<b>Total equity and liabilities</b>	<b>216,512</b>	<b>212,887</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED INCOME STATEMENTS FOR THE THREE-MONTH PERIODS ENDED 31**  
**MARCH 2011 AND 31 MARCH 2010**

(Thousand of euros)

	Three-month periods ended 31 March	
	2011	2010
Revenue	46,776	33,349
Changes in inventories	(93)	1,799
Raw materials and consumables used	(18,947)	(13,016)
Employee benefit expenses	(12,814)	(8,808)
Other operating expenses	(9,187)	(6,645)
Depreciation, amortisation and impairment charges	(1,073)	(800)
Recognition of government grants on non financial non-current assets and other	346	257
<b>OPERATING PROFIT</b>	<b>5,008</b>	<b>6,136</b>
Finance income	451	201
Finance costs	(607)	(398)
<b>FINANCE COSTS - NET</b>	<b>(156)</b>	<b>(197)</b>
<b>PROFIT BEFORE INCOME TAX</b>	<b>4,852</b>	<b>5,939</b>
Income tax	-	(945)
<b>PROFIT FOR THE YEAR</b>	<b>4,852</b>	<b>4,994</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED CASH FLOW STATEMENTS FOR THE THREE-MONTH PERIODS ENDED 31**  
**MARCH 2011 AND 31 MARCH 2010**

**(Thousand of euros)**

	<b>Three-month periods ended 31 March</b>	
	<b>2011</b>	<b>2010</b>
<b>Cash flows from operating activities</b>		
Profit before income tax	4,852	5,939
<b>Adjustments for non-monetary transactions:</b>		
Amortisation	1,073	800
Interest income	(451)	(201)
Available-for-sale financial asset impairment charge	-	102
Interest expense	607	296
Net changes on provisions	65	(32)
Grant for non-financial fixed assets and distribution licence income	(253)	(302)
<b>Changes in working capital</b>		
Trade and other receivables	(2,145)	(215)
Inventories	93	(1,894)
Trade and other payables	(3,770)	(5,289)
<b>Other collections and payments</b>		
Interest paid	(40)	(48)
Income tax cash flow	174	(15)
<b>Net cash generated (used) from operating activities</b>	<b>205</b>	<b>(859)</b>
<b>Cash flows from investing activities</b>		
Purchases of intangible assets	(101)	(19)
Purchases of property, plant and equipment	(987)	(453)
Proceeds from sale of available-for-sale financial assets	-	1,064
Purchases of other financial assets	-	(182)
Interest received	451	201
<b>Net cash generated (used) in investing activities</b>	<b>(637)</b>	<b>611</b>
<b>Cash flows from financing activities</b>		
Repayments of financial debt	(4,993)	(2,550)
Proceeds from financial debt	10,506	14,782
Purchase of treasury shares	(43)	(1,226)
Reissue of treasury shares	-	372
<b>Net cash generated in financing activities</b>	<b>5,470</b>	<b>11,378</b>
<b>Net (decrease)/increase in cash and cash equivalents</b>	<b>5,038</b>	<b>11,130</b>
<b>Cash and cash equivalents at beginning of the year</b>	<b>33,635</b>	<b>35,939</b>
<b>Cash and cash equivalents at end of the year</b>	<b>38,673</b>	<b>47,069</b>