Full Year 2010 Results

24 February 2011

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

ROVI – Full Year 2010 Results

ROVI reports an operating revenues growth of 12% and confirms its full year guidance

- **Operating revenues increased by 12% to 158.6 million euros in 2010, driven by the strength of the specialty pharmaceutical business and the implementation of the Merck Sharp & Dohme (MSD) strategic agreement which generated a 55% growth of the toll manufacturing business area.**

- **2010 operating revenues guidance, forecast in low double digit, achieved. Forecast operating revenues growth for 2011 is 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 Bemiparin increased by 7% to 43.9 million euros, sales of Corlentor and Exxiv grew by 39% and 6% respectively in 2010. Sales of Thymanax, an innovative antidepressant from Servier that ROVI launched in March 2010, reached 3.1 million euros in 2010.**

- **EBITDA increased by 6% to 29.6 million euros in 2010, compared to the previous year, mainly as a result of the implementation of the MSD agreement. This figure includes a one-off profit of 11.8 million euros caused by the difference between the fair value and the purchase price of the Frosst Ibérica assets. Excluding the impact of this one-off profit and 1.0 million euros of Frosst Ibérica integration costs, EBITDA decreased by 33% in 2010. The impact of the measures approved to reduce the pharmaceutical expenditure represented around 40% of this 33% decrease.**

- **Net profit increased by 22% to 24.6 million euros in 2010, impacted by the same factors as EBITDA.**

- **Considering short term bank deposits of 25 million euros, free cash flow increased by 67% to 22.1 million euros in 2010, reflecting our capacity to generate cash and fund future growth.**

- **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), 24 February 2011, 8:00 AM CET - ROVI released today its financial results for the twelve months ending on 31 December 2010.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that "*in 2010, we reached an excellent 12% operating revenues growth, which matched our expectations at the beginning of the year, 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 of 3.5 million euros related to the new measures introduced by the government for the rationalisation of the pharmaceutical expenditure and the absence of sales of Pneumovax®-23, a non recurrent vaccine that helps to protect against infections caused by the bacterium pneumococcus, due to budget constraints from the Spanish government. Once again Bemiparin led the growth with a 7% increase in sales. Bemiparin sales outside Spain grew by 31%, highlighting the continued internationalisation of our flagship product as one of the Company's growth engines in the medium term. During 2010, we set an internal saving plan up, excluding the sales, marketing and R&D areas, which helped us to offset partially the negative impact of the new measures and resulted in a 4% selling general and administrative expenses decrease, excluding the impact of the global strategic agreement that we reached with Merck Sharp & Dohme (MSD) in Spain, and that was implemented on 31 March 2010, and the Frosst Ibérica integration costs. In 2011, we will continue with our strict cost control to partially offset the negative impact of 8 million euros expected as consequence of the measures of the government mentioned above. Furthermore, the agreement with MSD will allow us to strengthen our toll manufacturing area, as we have already reflected in these 2010 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. 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. The development of the research and production centre for seasonal and pandemic flu vaccines in Spain, also reflects our commitment to diversify and to reinforce our business model and, together with the MSD agreement, provide us with an excellent opportunity for growth as we maximise the potential of the infrastructure we have built and purchased. ROVI's R&D pipeline continues to hold strong potential to drive the company's growth in future years. One of the most important stages in the development of a drug is the study of how to administer it and we are conducting a leading-edge research line using drug delivery innovative technologies, giving priority to our IMS project with risperidone, with phase I already started in the second half of 2010.*"

1. Financial highlights

€ million	2010	2009	Growth	% Growth
Operating revenues	158.6	141.8	16.8	12%
Other income	1.5	4.0	-2.6	-63%
Total revenue	**160.1**	**145.9**	**14.3**	**10%**
Raw materials used and changes in inventories	-62.8	-46.4	-16.4	35%
Gross profit	**97.3**	**99.4**	**-2.1**	**-2%**
% margin	*61.3%*	*70.1%*		-8.8pp
R&D expenses	-8.5	-9.6	1.1	-12%
Other SG&A	-71.0	-61.9	-9.1	15%
Other income	11.8	-	11.8	n.a.
EBITDA	**29.6**	**27.9**	**1.7**	**6%**
% margin	*18.7%*	*19.7%*		-1.1pp
EBIT	**26.0**	**25.5**	**0.5**	**2%**
% margin	*16.4%*	*18.0%*		-1.6pp
Net profit	**24.6**	**20.1**	**4.4**	**22%**

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 2010 and the comparative information for 2009 are attached to this report (see Appendix 1).

2. Performance of the Group

Operating revenues increased by 12% to 158.6 million euros in 2010, driven by the strength of the specialty pharmaceutical business and the implementation of the MSD strategic agreement which generated a 55% growth of the toll manufacturing area in 2010.

Sales of prescription-based pharmaceutical products rose by 4% to 87.7 million euros in 2010. Excluding the impact of the new measures to reduce the pharmaceutical expenditure and the absence of sales of Pneumovax®-23, a non recurrent vaccine that helps to protect against infections caused by the bacterium pneumococcus, in 2010, sales of prescription-based pharmaceutical products rose by 12% in 2010.

ROVI's low molecular weight heparin (LMWH), **Bemiparin,** maintained a growth rate, with sales up 7% to 43.9 million euros. Sales of **Bemiparin** in Spain **(Hibor®)** remained flat at 31.1 million euros, while international sales rose by 31% 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 5 new countries: Chile, Romania, Georgia, Moldova and Morocco, during 2010.

Sales of **Corlentor®**, a specialty product for stable angina from Laboratoires Servier, rose by 39% in 2010, to 5.1 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 Corlentor®/Procolaran® (Ivabradine) to standard therapy significantly reduces the risk of death and hospitalisation for heart failure. Currently, Corlentor®/Procolaran® is immerse in the regulatory process to obtain the new indication.

Sales of **Exxiv®**, a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), increased by 6% to 8.3 million euros in 2010.

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 3.1 million euros in 2010.

In 2010, ROVI did not register sales of Pneumovax®-23, a non recurrent vaccine that helps to protect against serious infections caused by the bacterium pneumococcus, licensed by Sanofi Pasteur MSD in July 2008 for marketing by ROVI, due to budget constraints from the Spanish government. Sales of Pneumovax®-23 reached 2.8 million euros in 2009.

The impact of the measures approved to reduce the pharmaceutical expenditure (section 7.6) in 2010 was in line with the impact of 3.5 million euros on 2010 sales, published in the earnings release for the first half of 2010.

Sales of **contrast imaging agents** and other hospital products increased by 11% in 2010 to 21.0 million euros. The sales of **over-the-counter pharmaceutical products** declined by 4% to 7.2 million euros in 2010 compared to the same period of the previous year. This was mainly as consequence of the sale of Glycilax product, in the fourth quarter of 2009, which was stopped to be marketed. Excluding the impact of the sale of Glycilax, OTC sales increased by 2%. Sales of **aesthetic medical products** decreased by 57% to 1.4 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 55% in 2010, to 36.7 million euros, compared with 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 7.9). Revenues from the MSD manufacturing and packaging agreement amounted to 22.1 million euros in 2010. 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). It is worth mentioning that the flu vaccine campaign performed weaker in 2010 compared with the previous year. Turnover related to the flu vaccine campaign amounted to 6.2 million euros in 2010 compared to 8.6 million euros in 2009.

Gross profit decreased by 2% in 2010 to 97.3 million euros, reflecting a fall in the gross margin to 61.3% in 2010 from 70.1% in the previous year. Excluding the impact of other income (subsidies), which decreased by 63% in 2010, gross profit increased by 0.5%, reflecting a fall in the gross margin to 60.4% in 2010 from 67.3% in 2009, mainly as a result of:

- the increase in the Bemiparin raw material prices, despite the 4.9% Bemiparin price increase in Spain which partially offset the fall. In 2010 the raw material costs for Bemiparin were running at more than 2 times 2009 costs. The increase in the Bemiparin raw material prices represented around 5.1 percentage points of the 6.9 percentage points gross margin fall (excluding other income) in 2010 compared to the previous year. Spanish health authorities were conscious of the significant increase of the raw material prices and increased Bemiparin price by 9.5% from December 2010. In addition, in the fourth quarter of 2010, ROVI started to buy Bemiparin raw material under the raw material peak price and expects that this positive trend continues during 2011. ROVI expects that both factors impact positively on the second half 2011 gross margin.

- the weakness of the 2010 flu vaccine campaign, which represented around 0.6 percentage points of the 6.9 percentage points gross margin fall (excluding other income) in 2010 compared to the previous year.

- the new measures to reduce the pharmaceutical expenditure (see section 7.6), which represented 0.9 percentage points of the 6.9 percentage points gross margin fall (excluding other income) in 2010 compared to the previous year.

Research and development expenses decreased by 12% to 8.5 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 15% in 2010 compared with the previous year, as a result of the MSD manufacturing and packaging agreement implementation. Excluding the impact of the MSD agreement, selling, general and

administrative expenses decreased by 2%. This decrease of 2% includes 1.0 million euros of integration costs related to Frosst Ibérica. Excluding the Frosst Ibérica integration costs, the selling, general and administrative expenses decreased by 4% in 2010, compared with 2009, reflecting ROVI continued cost control.

In 2010, ROVI registered a **one-off income** of 11.8 million euros caused by the acquisition of 100% of Frosst Ibérica, S.A. shares. The effective date of the acquisition and from which ROVI takes control over Frosst Ibérica is the 1st April 2010. According to the International Financial Reporting Standards 3, "Business Combinations" (IFRS 3), ROVI has performed a valuation of the acquired assets and the assumed liabilities considering their fair value on the acquisition date. This valuation resulted in a net amount of 28.2 million euros. The one-off income of 11.8 million euros registered in this item is due to the difference between the figure of 28.2 million euros and the fair value of the purchase price, 16.4 million euros, which includes the payment of 3.5 million euros for the Frosst Ibérica shares acquisition and the payment of 12.9 million euros for the Frosst Ibérica working capital.

EBITDA increased by 6% to 29.6 million euros in 2010, compared to the same period of the previous year, as a result of the implementation of the MSD manufacturing and packaging agreement. This figure includes the one-off profit of 11.8 million euros caused by the difference between the fair value and the purchase price of the Frosst Ibérica assets. Excluding the impact of this one-off profit, EBITDA decreased by 36% in 2010, to 17.8 million euros, mainly as a result of the increase in raw material costs for Bemiparin, the addition of 1.0 million euros of Frosst Ibérica integration costs, the weakness of the 2010 flu vaccine campaign and the impact of the new measures to reduce the pharmaceutical expenditure. Excluding the Frosst Ibérica integration costs, EBITDA decreased by 33% in 2010. The impact of the measures approved to reduce the pharmaceutical expenditure represents around 40% of this 33% decrease. The contribution of the Frosst Ibérica plant to the EBITDA of the group amounted to 5.5 million euros in 2010.

Depreciation and amortisation expenses increased by 49% in 2010 compared with the previous year mainly as a result of the amortisation of assets related to the facility in Granada which started to work in the second half of 2009.

EBIT increased by 2% to 26.0 million euros in 2010 compared with 2009, impacted by the same factors as EBITDA. The contribution of the Frosst Ibérica plant to the EBIT of the group amounted to 5.3 million euros in 2010.

The **financial expense** line remained stable at 1.6 million euros in 2010 compared with the previous year.

Financial income increased by 3.2 times in 2010 compared with 2009 as a result of higher returns on financial investments.

The **effective tax rate** was 5.2% in 2010 compared with 17.6% in 2009. This difference is mainly due to the one-off income, mentioned above, which is only registered in the consolidated profit and loss account of the group and therefore it has not tax impact on the tax base of the tax group. Excluding the impact of this one-off profit, the effective tax rate was 9.5% in 2010. ROVI has not paid taxes on Frosst Ibérica 2010 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 grew by 22% to 24.6 million euros in 2010 compared with 2009.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that, "*we are satisfied with the results for 2010. Operating revenues increased by 12% 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 2010, mainly because of the rise in the price of heparin related raw materials, which is outside our control, and of the impact of the measures introduced by the government to reduce pharmaceutical expenditure as well as the reduction of public aids to develop R&D projects due to budget constraints from the Spanish government. It is difficult to be definitive on raw material pricing for our heparin products but we started to buy Bemiparin raw material under peak price at the end of 2010 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 recently acquired MSD manufacturing facility, that has been already started to be used, will allow us to reverse over time the erosion of profit margins seen over the last 12 months. 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 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.*"

3. Balance Sheet items

3.1 Capital expenditure

ROVI invested 5.6 million euros in 2010, compared to 5.4 million euros in 2009. Of this amount, 1.1 million euros correspond to the Frosst Ibérica integration and the rest to expenditure on maintenance versus 4.3 million euros of maintenance capex in 2009. The rest of the amount invested in 2009 is related to the construction of the centre in Granada, which was inaugurated in May 2009.

3.2 Debt

As of 31 December 2010, ROVI had total debt of 51.9 million euros. Debt with public administration represented, as of 31 December 2010, 55% of total debt and 85% of total debt is 0% interest rate debt.

In thousand euros	**31 December 10**	**31 December 09**
Loans from banks	6,891	10,567
Debt with public administration	28,441	19,897
Liabilities from financial leases	676	1,334
Debt from purchase of shares	15,896	-
Total	**51,904**	**31,798**

The debt from purchase of shares registered as of 31 December 2010 corresponds to the outstanding payment related to the Frosst Ibérica acquisition, which includes the payment of 2.8 million euros for the Frosst Ibérica shares acquisition (the first payment of 0.7 million euros was executed on 31 March 2010) and the payment of 13.1 million euros for the Frosst Ibérica working capital. The Frosst Ibérica working capital is composed of 96% of trade and other receivables, 27% of cash, 12% of inventories and -35% of trade and other payables. The payments of this debt of 15.9 million euros will be executed annually, starting on 31 March 2011 and ending on 31 March 2014.

3.3 Free cash flow

Considering short term bank deposits of 25 million euros, free cash flow increased by 67% to 22.1 million euros in 2010 from 13.2 million in 2009, reflecting our excellent capacity to generate cash.

3.4 Net and gross cash position

As of 31 December 2010, ROVI had a gross cash position of 59.8 million euros and a net cash position of 7.9 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 2010 is mainly due to an increase in cash of 22.7 million euros, considering short term bank deposits of 25 million euros, and an increase in "trade and other payables" item of 5.9 million euros, mainly due, in both cases, to the incorporation of Frosst Ibérica to the group. The "trade and other receivables" item remained stable. In addition, the "inventories" line increased by 11.4 million euros, mainly as a result of the incorporation of Frosst Ibérica as well as of the stock of the three MSD products added to the ROVI portfolio (Ameride, Tryptizol and Prinivil) and the stock of the MSD products recently launched, Vytorin and Absorcol.

3.6 Tax credit

As of 31 December 2010, 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.

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.

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. 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 results of the clinical trials that were published during the year and the progress of the pre-clinical developments, the most important milestones related to ROVI R&D strategy are the following:

- Phase I clinical trial for the oral administration of Bemiparin using the OCAP platform: the trial was completed in 2010 and in January 2011 ROVI informed about the termination of the OCAP program for Bemiparin due to the lack of enough gastrointestinal absorption, following tests of various formulations and dosages (see section 7.3).

- Nautiol clinical programme: as it was made known in the second quarter, Phase III trial did not demonstrate that Bemiparin was more effective than the placebo in the treatment of diabetic foot ulcers. Although the results for the effectiveness of the Nautiol group were similar to the starting scenario of the trial, unexpectedly the results from the placebo group were much better. In December, ROVI announced to suspend the development of Nautiol for the treatment of diabetic foot ulcers, and to refocus this research line on the development of glycosaminoglycan compounds for topical application (see section 7.4).

- ISM® platform (in situ microparticles): in September 2010, the experimental stage began for the first Phase I trial of Risperidone-ISM® on healthy volunteers. This first trial aims mainly to evaluate the pharmacokinetics and the tolerability of a single intramuscular administration of Risperidone in an ISM formulation; 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. Consequently, ROVI is currently concentrating its efforts and resources on the ISM® drug delivery platform. In this regard, olanzapine-ISM®, for the monthly administration of another widely used anti-psychotic, and letrozole-ISM®, for the quarterly administration of a recognised aromatase inhibitor that is currently used extensively in the treatment of hormone-dependent breast cancer, are already in a pre-clinical phase

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.

In September 2010, ROVI launched Bertanel®, from EBEWE, the new parenteral methotrexate indicated for rheumatoid arthritis, juvenile idiopathic arthritis, and psoriatic arthritis, in Spain. In addition, in January 2010, ROVI obtained the license to market Thymanax® from Laboratoires Servier, an innovative antidepressant indicated for adults with major depressive episodes.

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 that it will soon be marketing 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® will be 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

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 sufficent 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 prophlyactic 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 Update of the research strategy for diabetic foot ulcers

ROVI stated that after a careful evaluation of the results of the clinical trial on the effectiveness and safety of subcutaneous Bemiparin in the treatment of diabetic foot ulcers, it has decided not to continue with the clinical development of Nautiol®. In addition, ROVI announced that this research line has been refocused onto the development of various compounds (including Bemiparin) for the topical treatment of a range of different types of torpid ulcers, including both skin ulcers and corneal ulcers.

On 10 May, the company informed the market that the results of the Phase III clinical trial of Bemiparin for patients with diabetic foot ulcers did not confirm the positive results that had previously been obtained in another clinical trial, as the placebo group had unexpectedly performed much better than had been forecast when the trial was designed. Although the group of patients with deeper ulcers (Wagner grade II) had a higher incidence of healing (not statistically significant) when treated with Bemiparin (22.9%) than the placebo group (18.8%), the percentage of patients who attained the primary efficacy endpoint, complete healing or improvement of the ulcer (reduction >50% of the ulcer area and/or a decline of one Wagner grade), was not different between the two groups (66.1% and 65.8%, for the Bemiparin and placebo group respectively).

However, although these results were not positive, ROVI remains committed to the development of glycosaminoglycan derivatives and formulations for the topical treatment of torpid ulcers, both skin ulcers and corneal ulcers. This type of ulcers can be associated with systemic problems, above all diabetes, but also autoimmune diseases such as rheumatoid arthritis, lupus, Behçet's syndrome or sarcoidosis. In addition, it is estimated that between 5 and 30% of the population suffers from dry eye syndrome, which in serious cases can result in corneal ulcers. ROVI has already begun the animal testing phase with some of these glycosaminoglycan candidates, using the topic route of administration as it is considered that this route can present more advantages than the subcutaneous one, especially in terms of the acceptance and adherence to the treatment by the patient. ROVI expects to start the clinical phase in the first quarter of 2012.

7.5 Results from the SHIFT (Systolic Heart Failure Treatment with the If Inhibitor Ivabradine Trial) study

The largest-ever morbi-mortality study of treatments for chronic heart failure has shown that adding the specific heart rate lowering agent Corlentor ®/Procolaran ® (Ivabradine) to standard therapy significantly reduces the risk of death and hospitalisation for heart failure. Results from this new study, SHIFT (Systolic Heart Failure Treatment with the If Inhibitor Ivabradine Trial), were presented on the 29th August 2010 at the European Congress of Cardiology in Stockholm and published in The Lancet.

SHIFT involved over 6,500 patients from 37 countries with moderate to severe heart failure and heart rate above 70 bpm who were followed up for an average of 23 months. The results showed that Ivabradine reduces the primary endpoint, a composite of cardiovascular death or hospitalisation for worsening heart failure, by 18% ($p<0.0001$). Ivabradine also reduced the likelihood of death from heart failure by over a quarter (26%, $p=0.014$) and the risk of hospitalisation due to worsening heart failure by the same amount (26%, $p<0.0001$). These benefits were evident in just three months of treatment with Ivabradine and despite the fact that patients were already receiving guideline recommended therapy (beta-blockers, angiotensin converting enzyme (ACE) inhibitors, diuretics or aldosterone antagonists). The study also confirmed that Ivabradine has a good tolerability profile in these fragile patients.

"*Twenty years after Angiostensin Converting Enzyme Inhibitors and ten years after beta-blockers, we now have a new life-saving drug available for our patients*", pointed out SHIFT executive committee co-chairman Professor Michel Komajda, Professor of Cardiology, University Pierre et Marie Curie Paris 6, France.

Ivabradine is an innovative treatment that is currently used in angina patients as it relieves symptoms, myocardial ischemia and reduces the risk of coronary events. The SHIFT study has now also demonstrated the prognostic benefits of Ivabradine chronic heart failure patients.

The SHIFT study is also the first study to specifically confirm that, due to Ivabradine, isolated heart rate reduction reduces the risk of death or hospitalisation for heart failure. This finding confirms that heart rate plays a key role in the progression of disease.

SHIFT co-chairman, Professor Karl Swedberg from the Head of the Department of Emergency and Cardiovascular Medicine at University of Gothenburg, Sweden, said: "*The SHIFT study has important implications for our clinical practice. It tells us that having a high heart rate is bad for heart failure patients. So we should routinely measure heart rate in all heart failure patients and, if it is above 70 beats per minute, heart rate lowering with Ivabradine should be considered, irrespective of their background treatment*".

7.6 Impact of the measures for the reduction of the pharmaceutical expenditure

The Spanish government has approved a reduction of the pharmaceutical expenditure of 2,800 million 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 will be minimal for ROVI because the majority of its products are under patent. Nevertheless, the impact of the measures approved in May will be significant and will mainly affect the specialty pharmaceutical area. We estimate that the impact on 2010 and 2011 sales will probably amount to 3.5 million euros and 8 million euros respectively. 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.

7.7 ROVI reaches an agreement with EBEWE to market Bertanel® in Spain

ROVI and EBEWE, an Austrian pharmaceutical company, have reached an agreement under which EBEWE has awarded ROVI the marketing of Bertanel® in Spain. ROVI launched Bertanel® in September 2010.

Bertanel®, whose active principle is methotrexate, is indicated for rheumatoid arthritis, juvenile idiopathic arthritis, and psoriatic arthritis. Bertanel® stands out for having the highest number of doses loaded in a pre-filled syringe, which results in a better compliance with the treatment and in an excellent cost-effectiveness ratio. In addition, Bertanel® is effective without individual inter-variability.

According to data from IMS Health, the rheumatoid arthritis market for DMARDs (Disease-Modifying Antirheumatic Drugs) totalled 39.1 million euros in the twelve months to January 2010 (TAM January 2010), a rise of 11.3% for the period.

7.8 ROVI signs a letter of intent with Novartis Vaccines for the production of vaccines for seasonal and pandemic influenza

ROVI has signed a letter of intent with Novartis Vaccines, with the aim of exploring a definitive agreement for the transfer to ROVI of the patented technology of Novartis Vaccines used in the production of vaccines against seasonal and pandemic influenza.

Novartis produces vaccines for seasonal and pandemic flu using two of the most advanced technologies that are currently available for the production influenza vaccines: 1) traditional technology based on incubation in eggs and 2) technology based on cell culture. Both

technologies are approved for use with their patented adjuvant technology. The technology to be transferred to ROVI would be selected after a profound analysis of reliability and costs in order to achieve the main aims of minimizing the risk of the project and complying with the established schedule.

According to the letter of intent, ROVI and Novartis Vaccines would establish a joint venture that would market influenza vaccines in Spain.

This letter of intent is consistent with the protocol signed on 10 June 2009 by the Ministry of Health and Social Policy and by the Regional Ministries of Innovation, Science and Enterprise, and Health of the Government of Andalusia for the research of new technologies and the production of flu vaccines.

7.9 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.

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.

7.10 Positive results from the ABEL trial of Bemiparin in small cell lung cancer

ROVI released the results of an intermediate analysis of the ABEL clinical trials (Adjuvant Bemiparin Evaluation study in small cell Lung cancer) which aims to assess the effectiveness and safety of bemiparin (3,500 IU/day for 26 weeks) in patients with limited small cell lung cancer (SLC) who are receiving standard anti-tumour treatment (platinum-based chemotherapy and radiotherapy).

The ABEL trial is a Phase II multi-centre clinical trial, designed as a proof of concept, in which 10 Spanish hospitals are participating. In accordance with the protocol approved for the trial, an interim analysis has been carried out after 30 randomized patients had completed 18 months of follow-up. The analysis of the main variable of the study has shown that the median progression-free survival was 410 days in the group of patients who received bemiparin, and 249 days in the control group who did not receive bemiparin (p=0.01). In addition, after 18 months of follow-up, 77% of the bemiparin group of patients had survived, compared to 20% of the control group who did not receive bemiparin (p<0.01)., with no increase observed in the incidence of hemorrhage.

These results are highly encouraging and confirm the Company belief that Bemiparin has potential in a number of as yet untapped indications. Dr. Eduardo Rocha, the Coordinator Investigator of the ABEL study and the Ordinary Professor of the Faculty of Medicine of the Navarra University (Spain) said that "*the results of this interim analysis are promising, as they are not only positive in terms of the progression-free survival, but also because they show that the addition of bemiparin in standard anti-tumour therapy could increase the overall survival of patients with limited small cell lung cancer. This is encouraging, as unfortunately with this sort of treatment this patient type continues to have a poor short term prognosis*." However, Dr. Rocha noted that these results "*refer to an interim analysis with a small sample of patients and therefore we must be cautious in interpreting them*."

7.11 Results from the phase III clinical trials for Bemiparin on diabetic foot ulcers

ROVI announced that the analysis of the final results of the clinical trial of the efficacy and safety of Bemiparin in the treatment of diabetic foot ulcers does not show that Bemiparin is better treatment than a placebo.

The clinical trial is a phase III multicentric and international study designed to confirm the efficacy and safety of Bemiparin compared to a placebo in the treatment of neuropathic diabetic foot ulcers with Wagner grade I or II. Three hundred and twenty nine patients from 6 countries (Croatia, Poland, Romania, Russia, Serbia and Spain) randomly received daily subcutaneous injection of 3,500 IU of Bemiparin or a placebo, for 3 months or until the complete healing of the ulcer. All patients received the standard care of the ulcers as the base treatment. The percentage of patients in which the primary efficacy endpoint, the complete healing or improvement of the ulcer (a reduction of >50% in the area of the ulcer and/or a

decrease in the Wagner grade of the ulcer), was not statistically different in the Bemiparin group (66.1%) to the placebo group (65.8%). In addition, no significant differences were seen between the two groups in terms of the proportion of patients whose ulcer was completely healed (25.2% for Bemiparin and 25.6% for the placebo group). In the subpopulation of patients with deeper ulcers (Wagner grade II), a higher number of healed ulcers was recorded in the Bemiparin group (22.9%) than in the placebo group (18.8%), but the difference was not statistically significant. No significant differences were observed in the proportion of patients with at least one serious adverse event, with a very low rate of major bleeding events (1 in each group).

ROVI is currently working with the Management Committee for the trial and with other experts to review and interpret the results not only of the main data but also of the other sub-analyses and exploratory analyses included in the protocol. In November, ROVI will announce its strategic decision for this therapeutic area, where it believes that there is still a need to develop new, more effective treatments to prevent diabetic foot ulcers from being the main cause of non-traumatic amputations.

7.12 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

For further enquiries, please contact:

Juan López-Belmonte Encina
Chief Executive Officer
913756235
jlopez-belmonte@rovi.es
www.rovi.es

Javier López-Belmonte Encina
Chief Financial Officer
913756266
javierlbelmonte@rovi.es
www.rovi.es

Marta Campos Martínez
Investor Relations
912444422
mcampos@rovi.es
www.rovi.es

Forward-looking statements

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

APPENDIX 1

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS AS OF 31 DECEMBER 2010 AND 2009

(Thousand of euros)

	31 December 2010	31 December 2009
ASSETS		
Non-current assets		
Property, Plant and Equipment	42,659	32,539
Intangible assets	2,290	974
Deferred tax assets	3,851	263
Available-for-sale financial assets	70	2,090
Financial receivables	2,086	2,608
	50,956	**38,474**
Current assets		
Inventories	41,824	30,390
Trade and other receivables	59,084	59,095
Current income tax assets	2,388	889
Bank deposits	25,000	-
Cash and cash equivalents	33,635	35,939
	161,931	**126,313**
Total assets	**212,887**	**164,787**

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS AS OF 31 DECEMBER 2010 AND 2009

(Thousand of euros)

	31 December 2010	31 December 2009
EQUITY		
Capital and reserves attributable to shareholders of the company		
Share capital	3,000	3,000
Legal reserve	600	600
Treasury shares	(1,960)	(1,198)
Retained earnings and voluntary reserves	77,914	64,741
Profit for the year	24,582	20,141
Reserve for available-for-sale assets	(2)	(79)
Total equity	**104,134**	**87,205**
LIABILITIES		
Non-current liabilities		
Financial debt	43,089	25,989
Deferred income tax liabilities	1,633	1,519
Non-current deferred revenues	12,404	11,355
	57,126	**38,863**
Current liabilities		
Trade and other payables	37,238	31,307
Financial debt	8,815	5,809
Current deferred revenues	4,334	575
Provisions for other liabilities and charges	1,240	1,028
	51,627	**38,719**
Total liabilities	**108,753**	**77,582**
Total equity and liabilities	**212,887**	**164,787**

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED INCOME STATEMENTS FOR THE FULL YEARS 2010 AND 2009

(Thousand of euros)

	Full Year	
	2010	**2009**
Revenue	158,645	141,809
Changes in inventories	11,434	4,848
Raw materials and consumables used	(74,255)	(51,274)
Employee benefit expenses	(42,207)	(33,964)
Other operating expenses	(37,306)	(37,688)
Depreciation, amortisation and impairment charges	(3,586)	(2,414)
Recognition of government grants on non financial non-current assets and other	1,493	4,045
Other (losses)/gains – net	11,785	162
OPERATING PROFIT	**26,003**	**25,524**
Finance income	1,488	466
Finance costs	(1,570)	(1,560)
FINANCE COSTS - NET	**(82)**	**(1,094)**
PROFIT BEFORE INCOME TAX	**25,921**	**24,430**
Income tax	(1,339)	(4,289)
PROFIT FOR THE YEAR	**24,582**	**20,141**

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED CASH FLOW STATEMENTS FOR THE FULL YEARS 2010 AND 2009

(Thousand of euros)

	Full year	
	2010	**2009**
Cash flows from operating activities		
Profit before income tax	25,921	24,430
Adjustments for non-monetary transactions:		
Amortisation	3,586	2,414
Interest income	(1,488)	(466)
Available-for-sale financial asset impairment charge	18	280
Gains on disposal of financial assets and liabilities	(45)	-
Interest expense	1,552	1,280
Net changes on provisions	212	126
Income from acquisition of Frosst Ibérica, S.A.	(11,785)	-
Grant for non-financial fixed assets and distribution licence income	(1,380)	(2,159)
Changes in working capital		
Trade and other receivables	15,183	(6,442)
Inventories	(9,802)	(4,574)
Trade and other payables	1,885	1,929
Other collections and payments		
Interest paid	(179)	(423)
Income tax cash flow	(2,488)	(2,990)
Net cash generated (used) from operating activities	**21,190**	**13,405**
Cash flows from investing activities		
Sale of a subsidiary	-	3.453
Purchases of intangible assets	(1,143)	(261)
Purchases of property, plant and equipment	(4,433)	(5,104)
Purchases of available-for-sale financial assets	-	(2,176)
Proceeds from sale of available-for-sale financial assets	2,112	4,839
Contracting short term bank deposits (*)	(25,000)	-
Purchases of other financial assets	(182)	(1,407)
Increase in cash from acquisition of Frosst Ibérica, S.A.	3,034	-
Interest received	1,488	466
Net cash generated (used) in investing activities	**(24,124)**	**(190)**
Cash flows from financing activities		
Repayments of financial debt	(5,902)	(5,367)
Proceeds from financial debt	14,262	10,184
Purchase of treasury shares	(1,402)	(3,285)
Reissue of treasury shares	683	5,833
Dividends paid	(7,011)	(4,281)
Net cash generated in financing activities	**630**	**3,084**
Net (decrease)/increase in cash and cash equivalents	**(2,304)**	**16,299**
Cash and cash equivalents at beginning of the year	**35,939**	**19,640**
Cash and cash equivalents at end of the year (*)	**33,635**	**35,939**

(*) As of 31 December 2010, the Group had short term bank deposits, with maturity over three months, of 25 million euros. These short term bank deposits are fully available.