Full Year 2011 Results

21 February 2012

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

ROVI – Full Year 2011 Results

ROVI reports an operating revenues growth of 16% and confirms its full year guidance

- **Operating revenues increased by 16% to 184.7 million euros in 2011, driven by the strength of the specialty pharmaceutical business, where sales rose 13%, and of the toll manufacturing business which grew by 28% in 2011.**

- **2011 operating revenues guidance, upgraded from low double digit to mid teens on November 8, 2011, achieved. Forecast operating revenues growth for 2012 is from high single digit to low double digit.**

- **Sales of Bemiparin increased by 15% to 50.5 million euros and sales of Corlentor and Osseor, from Servier, grew by 40% and 7% respectively in 2011. Sales of Thymanax, an innovative antidepressant from Servier that ROVI launched in March 2010, increased by 2.7 times to 8.6 million euros in 2011.**

- **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 Merck Sharp & Dohme (MSD), in Spain. Sales of Absorcol® and Vytorin® reached 5.7 million euros in 2011.**

- **In the second quarter of 2011, Fitoladius® product was sold to a third part. This sale contributed with revenues of 5.6 million euros in 2011.**

- **Excluding the impact of the one-off profit of 11.8 million euros, registered in the second quarter of 2010, caused by the difference between the fair value and the purchase price of the Frosst Ibérica assets, EBITDA increased by 33% in 2011. EBITDA decreased by 20% to 23.7 million euros in 2011, compared to the previous year, as a result of the impact of the one-off profit of 11.8 million euros registered in the second quarter of 2010.**
  - **Excluding the impact of the Fitoladius sale and the impact of the measures to reduce the pharmaceutical expenditure, EBITDA increased by around 22% in 2011.**

- **Net profit decreased by 26% to 18.1 million euros in 2011, impacted by the same factors as EBITDA. Recurrent net profit rose 42% in 2011, above the single digit growth guidance provided for 2011.**

- **ROVI will propose to the Shareholders General Meeting a dividend of 0.1269 euros per share on 2011 earnings. This proposed dividend would imply the pay-out of 35% of consolidated net profit for 2011.**

Madrid (Spain), 21 February 2012, 8:00 AM CET - ROVI released today its financial results for the twelve months ending on 31 December 2011.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that "*in 2011, we reached an excellent 16% 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 measures introduced by the government in the second half of 2010 for the rationalisation of the pharmaceutical expenditure, estimated at 8 million euros on 2011 sales. Our young portfolio has protected us from the latest governmental measures, which were effective from November 2011, and we expect to have an impact of less than 1 million euros on 2012 sales. Once again Bemiparin led the growth with a 15% increase in sales. Bemiparin sales in Spain rose 14% and outside Spain grew by 18%, 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 and 2011 results, as well as our specialty pharmaceutical area, as we have 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 had an impact on 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. 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. We are committed to the flu vaccines business as one of the future growth drivers 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 technology, especially with the Risperidone-ISM® project development, whose phase I positive results were announced in July. This gives us the confidence and security to continue, not only with our development of Risperidone ISM, but*

also with the development of other candidates with which we are already in an advanced pre-clinical phase".

1. Financial highlights

€ million	2011	2010	Growth	% Growth
Operating revenues	184.7	158.6	26.1	16%
Other income	3.5	1.5	2.0	131%
Total revenue	**188.2**	**160.1**	**28.0**	**17%**
Raw materials used and changes in inventories	-69.4	-62.8	-6.6	11%
Gross profit	**118.7**	**97.3**	**21.4**	**22%**
% margin	*64.3%*	*61.3%*		2.9pp
R&D expenses	-8.4	-8.5	0.1	-1%
Other SG&A	-86.6	-71.0	-15.6	22%
Other income		11.8	-11.8	n.a.
EBITDA	**23.7**	**29.6**	**-5.9**	**-20%**
% margin	*12.8%*	*18.7%*		-5.8pp
EBIT	**19.0**	**26.0**	**-7.0**	**-27%**
% margin	*10.3%*	*16.4%*		-6.1pp
Net profit	**18.1**	**24.6**	**-6.5**	**-26%**

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 2011 and the comparative information for 2010 are attached to this report (see Appendix 1).

2. Performance of the Group

Operating revenues increased by 16% to 184.7 million euros in 2011, driven by the strength of the specialty pharmaceutical business, where sales rose 13%, and of the toll manufacturing business which grew by 28% in 2011.

Sales of prescription-based pharmaceutical products rose 15% to 100.5 million euros in 2011. Excluding the impact of the measures to reduce the pharmaceutical expenditure, sales of prescription-based pharmaceutical products rose around 19% in 2011.

ROVI's low molecular weight heparin (LMWH), **Bemiparin,** maintained a growth rate, with sales up 15% to 50.5 million euros. Sales of **Bemiparin** in Spain **(Hibor®)** increased by 14% to 35.4 million euros, while international sales rose by 18% 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 four new countries, Bolivia, Byelorussia Russia and Bahrain, during 2011.

Sales of **Corlentor®**, a specialty product for stable angina and chronic heart failure[1] from Laboratoires Servier, rose 40% in 2011, to 7.1 million euros. In February 2012, Corlentor® has been approved by the European Commission for the treatment of patients with chronic heart failure[1]. The European Commission's decision to authorise this new indication for Corlentor® followed the review of data from the SH*I*fT trial, the largest-ever morbi-mortality study of treatments for chronic heart failure involving more than 6000 patients. It demonstrated that the treatment significantly reduced the risk of death and hospitalisation from heart failure, and improved the quality of life of people living with the disease.[2,3] This reduction in mortality was highly significant in patients with a heart rate of 75 beats per minute (bpm), or above, for whom Corlentor® is now indicated.[1]

Sales of **Osseor®,** a specialty product for the treatment of postmenopausal osteoporosis from Laboratoires Servier, increased by 7% in 2011, to 7.1 million euros.

Sales of **Exxiv®**, a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 3% to 8.0 million euros in 2011 mainly due to a slight deceleration of the COX-2 market.

Sales of **Thymanax®**, an innovative antidepressant from Laboratoires Servier, launched in March 2010 and for which ROVI has a co-marketing agreement covering Spain, increased by 2.7 times to 8.6 million euros in 2011.

Sales of **Vytorin®** and **Absorcol®**, the first of the five licenses of MSD, launched in January 2011, reached 5.7 million euros in 2011.

The impact of the measures approved to reduce the pharmaceutical expenditure (section 7.7) in 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.

1. EMA announcement
2. Swedberg K, Komajda M, Böhm M et al. Ivabradine and outcomes in chronic heart failure (SHIFT): a randomised placebo-controlled study. *Lance*t 2010; 376:875-85
3. Ekman I, Chassany O, Komajda M et al. Heart rate reduction with ivabradine and health related quality of life in patients with chronic heart failure: results from the SHIFT study. *Eur Heart J.* 2011; DOI:10.1093/eurheartj/ehr343. Available at: http://eurheartj.oxfordjournals.org

On 21st of July of 2011, the Spanish government announced a new measures package to reduce the pharmaceutical expenditure.
(see http://www.msps.es/gabinetePrensa/notaPrensa/desarrolloNotaPrensa.jsp?id=2165).
The impact of these new measures, which were effective from November 2011, will not be significant for the accounts of the company in 2012. ROVI expects that this impact could be less than 1 million euros in 2012.

In the second quarter of 2011, Fitoladius product was sold to a third part. This sale contributed with revenues of 5.6 million euros in the 2011. This profit was already included in the 2011 operating revenues guidance, published in the earnings release for the nine-month period ended 30 September 2010.

In the third quarter of 2011, no sales from **Levrison®** vaccine were registered, foreseeing the signature of the agreement between Alentia Biotech, joint venture of ROVI and Grupo Ferrer, and Novartis Vaccines & Diagnostics (see section 7.2). Through this agreement, Alentia Biotech will be entitled to market seasonal flu vaccines under a co-marketing regime with Novartis Vaccines & Diagnostics for an estimated five-year period. Sales of Levrison® amounted to 4.3 million euros in 2010.

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, reached 1.2 million euros in 2011. In 2010, no sales of Pneumovax-23 were registered.

In the second half of 2011, ROVI did not register sales from the **EMLA®** distribution, a topical anaesthetic licensed by AstraZeneca that has been marketed by ROVI since 1998. In June 2011, the **EMLA®** distribution agreement with AstraZeneca was replaced by a promotion agreement. Revenues related to **EMLA®** promotion amounted to 0.6 million euros in the second half of 2011. Revenues related to EMLA® distribution amounted to 2.6 million euros in the second half of 2010.

Sales of **over-the-counter pharmaceutical products** declined by 5% to 6.9 million euros in 2011 compared to the previous year. This was mainly as consequence of ROVI divestiture strategy in this area.

Sales of **contrast imaging agents** and other hospital products increased by 5% in 2011 to 21.9 million euros.

Toll manufacturing sales increased by 28% in 2011, to 47.1 million euros, compared with the previous year, mainly as a result of the implementation of the MSD manufacturing and packaging agreement, which was effective on 31 March 2010 (see section 7.8). Revenues from the MSD manufacturing and packaging agreement amounted to 32.2 million euros 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 40% 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 7.4).

Gross profit increased by 22% in 2011 to 118.7 million euros, reflecting an increase in the gross margin to 64.3% in 2011 from 61.3% in 2010.

- Excluding the impact of the Fitoladius sale, gross margin increased to 63.2% in 2011 from 61.3% in 2010.
- Excluding the impact of other income (subsidies), which increased by 2.3 times in 2011, gross margin increased to 61.2% in 2011 from 60.4% in 2010 mainly due to the contribution of the Frosst Iberica plant for twelve months in 2011 compared to its contribution for nine months in 2010.

In 2011, ROVI continued to buy Bemiparin raw material at around 40 euros per million of international units and it expects that this stable trend continues during 2012.

Research and development expenses decreased by 1% to 8.4 million euros, reflecting ROVI investments in products that are under development.

Selling, general and administrative expenses increased by 22% to 86.6 million euros in 2011 compared to the previous year, as a result of the MSD manufacturing and packaging agreement implementation, which was effective on 31 March 2010, and the launch of Vytorin and Absorcol, the first of the five licenses of MSD. Excluding the impact of the MSD toll manufacturing agreement in the first quarter of 2011, selling, general and administrative expenses increased by 16%. This 16% increase reflected ROVI investment effort in human capital to address primary care, main target of Vytorin and Absorcol products.

EBITDA decreased by 20% to 23.7 million euros in 2011, compared to the previous year, as a result of the impact of a one-off profit of 11.8 million euros, registered in the second quarter of 2010, 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 increased by 33% in 2011.
- This 33% increase includes a profit of 5.6 million euros related to Fitoladius product sale to a third part, registered in the second quarter of 2011.
- Excluding the impact of the Fitoladius sale, EBITDA increased by 2% in 2011, considering no Fitoladius sales registered from its sale to a third part in 2011.

Considering that ROVI maintained the product in 2011, EBITDA increased by 8% in 2011.

- Excluding the impact of the Fitoladius sale and the impact of the measures to reduce the pharmaceutical expenditure, EBITDA increased by around 22% in 2011.

Depreciation and amortisation expenses increased by 31% in 2011, compared to the previous year, mainly as a result of the implementation of the MSD agreement and the new property plant and equipment and intangible assets purchases made during 2011.

EBIT decreased by 27% to 19.0 million euros in 2011, compared to the previous year, impacted by the same factors as EBITDA.

The **financial expense** line increased by 51% in 2011, compared to the 2010 financial year, mainly as a result of the implied interests increase related to the new reimbursable loans collected from 1 January 2011 to 31 December 2011 and of the implied interests increase related to the debt from purchase of Frosst Ibérica shares, registered as of 1 April 2010.

Financial income increased by 56% in 2011, compared to the previous year, as a result of higher returns on financial investments.

The **effective tax rate** was 4.2% in 2011 compared with 5.2% in 2010 despite the new tax measures package, approved by law on August 19, 2011 (http://www.boe.es/boe/dias/2011/08/20/pdfs/BOE-A-2011-14021.pdf), which affects tax bases. Previously, ROVI did not pay taxes on Frosst Ibérica profits as this company has negative tax bases and profits could be offset without limit. According to the new law, ROVI has to pay taxes on Frosst Ibérica profits as this company can only offset its profits by 50% of the tax bases of the group during the period 2011-2013. Frosst Ibérica negative tax bases amounted to 56.3 million euros as of 31 December 2009 and increased significantly by the negative tax bases generated in 2010, which amounted to 20.2 million euros. In 2011, 6.4 million euros of these 76.5 million euros of negative tax bases were used.

The **net profit** of ROVI decreased by 26% to 18.1 million euros in 2011 compared to the previous year, impacted by the same factors as EBITDA. Recurrent net profit, which excludes the impact of the one-off profit of 11.8 million euros, rose 42% in 2011, above the single digit growth guidance provided for 2011.

- Excluding the impact of the Fitoladius sale, recurrent net profit remained stable in 2011, considering no Fitoladius sales registered from its sale to a third part in 2011. Considering that ROVI maintained the product in 2011, recurrent net profit increased by 8% in 2011.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that, "*we are satisfied with the results for the full year 2011. Operating revenues increased by 16% from the previous*

year. This was in line with expectations 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 increased in 2011 mainly as a result of the contribution of the Frosst Iberica plant. We expect margins to be stable in 2012. 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".

3. Balance Sheet items

3.1 Capital expenditure

ROVI invested 8.4 million euros in 2011, compared to 5.6 million euros in 2010. Of this amount, 2.4 million euros correspond to investment capex related to the Alcalá facility (Frosst Ibérica), versus 1.1 million euros in 2010, 1.3 million euros correspond to investment capex related to the injectables facility in order to prepare the plant for a FDA (*US Food and Drug Administration*) inspection and for the development of the ISM project (see section 5), and the rest to expenditure on maintenance versus 4.5 million euros of maintenance capex in 2010.

3.2 Debt

As of 31 December 2011, ROVI had total debt of 50.7 million euros. Debt with public administration represented, as of 31 December 2011, 67% of total debt and 91% of total debt is 0% interest rate debt.

In thousand euros	**31 December 11**	**31 December 10**
Loans from banks	4,695	6,891
Debt with public administration	34,000	28,441
Liabilities from financial leases	-	676
Debt from purchase of shares	11,985	15,896
Total	**50,680**	**51,904**

The debt from purchase of shares registered as of 31 December 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 9.9 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 12.0 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 amounted to 21.0 million euros in 2011 mainly due to the contracting of 25 million euros of short term bank deposits in 2010 which were sold in 2011.

3.4 Net and gross cash position

As of 31 December 2011, ROVI had a gross cash position of 61.7 million euros, compared to 59.8 million euros as of 31 December 2010, and a net cash position (financial assets and cash minus short term and long term debt) of 11.0 million euros, compared to 7.9 million euros as of 31 December 2010, providing it with a high level of financial flexibility.

3.5 Working capital

The increase in working capital in 2011 is mainly due to an increase in cash of 15.9 million euros and a decrease in the "inventories" line of 0.5 million euros. The "trade and other receivables" item increased by 9.6 million euros and the "trade and other payable" item increased by 4.5 million euros.

4. Guidance for 2012

Despite the impact of the new additional measures, approved in August 2011, for the rationalization of the pharmaceutical expenditure and the subsequent significant decrease expected for the Spanish pharmaceutical market also in 2012, ROVI expects to grow operating revenues from high single digit to low double digit for the full year 2012. ROVI expects its growth drivers to be Bemiparin, its existing portfolio of specialty pharmaceuticals, last launches such as Vytorin, Absorcol, Thymanax and Bertanel, new product distribution licenses and new customers in the toll manufacturing area.

5. Research and Development update

ROVI firmly believes that R&D should be one of the pillars of the company, and, as it has been previously informed, in 2011 the strategy in this key area was revised. The most important aspects of the R&D projects are summarized below:

- ISM® platform for antipsychotics: in September 2010, the clinical testing stage began for the first Phase I trial of Risperidone-ISM® on healthy volunteers and finished by the

end of 1Q 2011. This first trial aimed mainly to evaluate the pharmacokinetics and the tolerability of a single intramuscular administration of Risperidone in an ISM formulation. The results were announced in July 2011, and were confirming the expected pharmacokinetic profile of this innovative long-acting intramuscular formulation for the monthly administration of risperidone, a widely used antipsychotic (see section 7.3). Further Phase I/II studies are planned to start patient recruitment by the first half of 2012, which should allow to progress into Phase III trials by second half of 2013. On the other hand, this study has also served as "proof of concept" for validating ISM technology for the development of other candidates, such as other atypical antipsychotics or antiestrogens drugs.

- Letrozole-ISM®: ROVI is also dedicating its efforts for the development of a novel formulation for a quarterly injection of a well-recognised aromatase inhibitor, letrozole. The project is already in pre-clinical phase under animal testing. 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.

6. New product launches

In January 2011, ROVI launched Absorcol® and Vytorin®, the first of the five marketing licenses for its products that 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, 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 (see section 7.5). 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 The results of the ABEL clinical trial suggest that Bemiparin could be beneficial against small cell lung cancer

In October 2011, ROVI announced that the results of the final analysis of the "ABEL" clinical trial (*Adjuvant Bemiparin Evaluation study in small cell Lung cancer*) were presented during the XIII National Congress of the Spanish Society of Medical Oncology[2]; the study was aimed to assess the effectiveness and safety of Bemiparin (3,500 IU/day for 26 weeks) in patients with limited small cell lung cancer who are receiving standard anti-tumour treatment (platinum-based chemotherapy and radiotherapy).

These final results confirm the positive results that had been seen in an interim analysis[3]. The disease progression-free survival time, the primary outcome of the trial, increased by 1.5-fold, and the overall survival time increased by 3.3-fold, in the group of patients who received Bemiparin, compared to the control group without Bemiparin, with no rise in the incidence of haemorrhage.

The "ABEL" trial is a Phase II multi-centre clinical trial, sponsored by the *Instituto Científico y Tecnológico de Navarra, S.A.*, with the cooperation of ROVI, and designed as a proof of concept. Ten Spanish hospitals participated in the trial, with a total of 39 patients with limited stage disease of small cell lung cancer (after being stopped the inclusion of new patients because of a slow recruitment rate). The trial was directed, as principal investigator, by Prof. Eduardo Rocha, Ordinary Professor of Haematology at the Faculty of Medicine of the University of Navarra.

In the light of these results, and taking into consideration the fact that the time and resources needed to continue with the development of Bemiparin for this new therapeutic area are significant, ROVI has decided to look for a partner that specialises in oncology, with the appropriate experience and resources for undertaking the clinical development with sufficient guarantees.

[2] B. Massuti, et al. Phase II randomized CT of bemiparin in association with chemotherapy in small cell lung cancer. Final results of the ABEL study. Oral communication O-21. XIII SEOM National Congress (Málaga, 19th-21st October, 2011).
[3] R. Lecumberri, et al. Adjuvant bemiparin in small cell lung cancer: results from the ABEL study. Thromb Res. 2010. 125 (Suppl 2): S163.

7.2 Alentia Biotech, a future joint venture of Ferrer and ROVI, plans to construct a national production centre to supply the Spanish population with flu vaccines

Alentia Biotech, a future joint venture in which Grupo Ferrer Internacional, S.A. and Laboratorios Farmacéuticos Rovi, S.A. will participate, plans to construct a manufacturing plant in Granada to produce flu vaccines in the Spanish market.
On 21 December 2011, the Spain's National Competition Commission approved this transaction. Once the approval was obtained, the procedure has been started in order to integrate Grupo Ferrer in the Alentia government bodies during the next year and to launch the Alentia business which is currently in an incipient phase.

On the 26th of September, Alentia Biotech announced that it has signed an agreement with Novartis Vaccines & Diagnostics for the transfer and granting of a licence of use for technology, belonging to the latter, for the production of vaccines against seasonal and pandemic flu mainly for Spain and Portugal.

The signature of the agreement was presided by the President of the Andalucian Government and the Minister of Health, Social Policy and Equality

Through these agreements, Alentia Biotech will commence the construction of a production plant in Granada (Spain) that will require an estimated investment of approximately 92 million euros to complete the operation.

The production plant will have an annual manufacturing capacity of 10 million doses of seasonal flu vaccine and 30 million doses of pandemic flu vaccine.

Likewise, during the construction of the production plant, Alentia Biotech will be entitled to market seasonal flu vaccines under a co-marketing regime with Novartis Vaccines & Diagnostics for an estimated five-year period.

One the production plant comes into operation, Alentia Biotech and Novartis Vaccines and Diagnostics will market the vaccines manufactured at the plant through a commercial joint venture.

This strategic agreement falls within the spirit of the Protocol of Intent signed by ROVI on 30 June, 2009 with the Ministry of Health and Social Policy and the Andalusian Regional Government's Departments of Innovation, Science and Enterprises and of Health for research into new technologies and the production of seasonal and pandemic flu vaccines, which envisaged the construction of a national production centre for seasonal and pandemic flu vaccines to supply the entire Spanish population.

The project would be implemented with the collaboration of the Department of Economy, Innovation and Science of the Regional Government of Andalusia and the Ministry of Health, Social Policy and Equality of the Spanish Government and likewise has the backing of the Ministry of Science and Innovation.

7.3 Positive results of the Risperidone-ISM Phase I study

In July 2011, ROVI disclosed the positive results obtained from a Phase I clinical trial for the once-monthly injectable formulation of Risperidone-ISM. The trial has been developed with a long-acting formulation of this antipsychotic and the analysis of the data shows that ISM technology enables the sustained delivery of Risperidone from the first day, which will allow for once-monthly administration without the need for supplementary oral Risperidone in the first weeks. These characteristics will facilitate the adherence with treatment of schizophrenic patients, and represent an improvement on the Risperidone formulations that are currently available.

The clinical trial was carried out on 17 healthy volunteers and was designed to evaluate the pharmacokinetics, safety and tolerability of the intramuscular administration of Risperidone in escalating single doses (25 mg and 37.5 mg) using the ISM drug delivery system. The plasma concentrations of Risperidone and its active metabolite that were obtained up to 59 days confirm the expected pharmacokinetic profile, which had previously been demonstrated in studies carried out with animals. In general, Risperidone-ISM was well tolerated by the volunteers, and the adverse reactions that were recorded were expected and understood for this antipsychotic.

The full results were presented on 30 September 2011 in Berlin, in an oral communication at the 3rd European Conference on Schizophrenia Research[4.]

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

In January 2011, 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.

[1] *3rd European Conference on Schizophrenia Research. Berlin (Germany) 29 Sept.-1 Oct. 2011.* http://www.schizophrenianet.eu/

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 by 10% to 15%.

7.5 Marketing of Absorcol and Vytorin, the first of the five licenses from MSD

In January 2011, 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.

7.6 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 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.

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

The Spanish government 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 continued 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 continued 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 the impact on 2011 sales amounted to around 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.

7.8 ROVI implements the Strategic Pharmaceutical Manufacturing and Marketing Agreement in Spain reached with MSD

ROVI implemented the strategic agreement for the marketing and manufacturing of pharmaceuticals reached by ROVI and 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 has started the marketing in Spain of Vytorin® and Absorcol®, the first of the five marketing licenses for its products that MSD awarded to ROVI as part of the Strategic Agreement (see section 7.5).

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.

7.9 Dividend payment

The ROVI General Shareholders Meeting, on 14 June 2011, approved the payment of a gross dividend of 0.17208 euros per share on 2010 earnings. This dividend was paid on 6 July 2011 and meant an increase of 22% compared to the dividend on 2009 earnings. In addition, this dividend implied the pay-out of 35% of consolidated net profit for 2010.

ROVI will pay a dividend of 0.1269 euros per share on 2011 earnings if the Shareholders General Meeting approves the application of the 2011 profit, under proposal of ROVI Board of Directors. This proposed dividend would imply the pay-out of 35% of consolidated net profit for 2011.

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

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Forward-looking statements

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

APPENDIX 1

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

(Thousand of euros)

	31 December 2011	31 December 2010
ASSETS		
Non-current assets		
Property, Plant and Equipment	45,857	42,659
Intangible assets	2,736	2,290
Deferred tax assets	4,856	3,851
Available-for-sale financial assets	5,117	70
Financial receivables	325	2,086
	58,891	**50,956**
Current assets		
Inventories	41,306	41,824
Trade and other receivables	68,698	59,084
Current income tax assets	3,682	2,388
Bank deposits	6,000	25,000
Cash and cash equivalents	49,491	33,635
	169,177	**161,931**
Total assets	**228,068**	**212,887**

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

(Thousand of euros)

	31 December 2011	31 December 2010
EQUITY		
Capital and reserves attributable to shareholders of the company		
Share capital	3,000	3,000
Legal reserve	600	600
Treasury shares	(1,922)	(1,960)
Retained earnings and voluntary reserves	93,920	77,914
Profit for the year	18,127	24,582
Reserve for available-for-sale assets	256	(2)
Total equity	**113,981**	**104,134**
LIABILITIES		
Non-current liabilities		
Financial debt	41,246	43,089
Deferred income tax liabilities	3,635	1,633
Non-current deferred revenues	12,450	12,404
	57,331	**57,126**
Current liabilities		
Trade and other payables	41,775	37,238
Financial debt	9,434	8,815
Current deferred revenues	4,298	4,334
Provisions for other liabilities and charges	1,249	1,240
	56,756	**51,627**
Total liabilities	**114,087**	**108,753**
Total equity and liabilities	**228,068**	**212,887**

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED INCOME STATEMENTS FOR THE FULL YEARS 2011 AND 2010

(Thousand of euros)

	Full Year	
	2011	**2010**
Revenue	184,706	158,645
Changes in inventories	(518)	11,434
Raw materials and consumables used	(68,921)	(74,255)
Employee benefit expenses	(51,133)	(42,207)
Other operating expenses	(43,893)	(37,306)
Depreciation, amortisation and impairment charges	(4,709)	(3,586)
Recognition of government grants on non financial non-current assets and other	3,453	1,493
Others gains and losses - net	-	11,785
OPERATING PROFIT	**18,985**	**26,003**
Finance income	2,319	1,488
Finance costs	(2,376)	(1,570)
FINANCE COSTS - NET	**(57)**	**(82)**
PROFIT BEFORE INCOME TAX	**18,928**	**25,921**
Income tax	(801)	(1,339)
PROFIT FOR THE YEAR	**18,127**	**24,582**

LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED CASH FLOW STATEMENTS FOR THE FULL YEARS 2011 AND 2010

(Thousand of euros)

	Full year	
	2011	**2010**
Cash flows from operating activities		
Profit before income tax	18,928	25,921
Adjustments for non-monetary transactions:		
Amortisation	4,709	3,586
Interest income	(2,319)	(1,488)
Gains or losses on sales of available-for-sale financial assets	(88)	18
Gains or losses on derecognition of financial assets and liabilities	109	(45)
Interest expense	2,376	1,552
Net changes in provisions	9	212
Income from acquisition of Frosst Ibérica, S.A.	-	(11,785)
Grant for non-financial fixed assets and distribution licence income	(2,435)	(1,380)
Changes in working capital		
Trade and other receivables	(12,598)	15,183
Inventories	518	(9,802)
Trade and other payables	4,139	1,885
Other collections and payments		
Proceeds from distribution licenses	700	-
Interest paid	(155)	(179)
Income tax cash flow	(1,209)	(2,488)
Net cash generated (used) from operating activities	**12,684**	**21,190**
Cash flows from investing activities		
Purchases of intangible assets	(800)	(1,143)
Purchases of property, plant and equipment	(7,553)	(4,433)
Purchases of available-for-sale financial assets	(6,400)	-
Proceeds from sale of available-for-sale financial assets	1,810	2,112
Liquidating current bank deposits (*)	25,000	-
Contracting current bank deposits (*)	(6,000)	(25,000)
Purchases of other financial assets	(65)	(182)
Increase in cash from acquisition of Frosst Ibérica, S.A.	-	3,034
Interest received	2,319	1,488
Net cash generated (used) in investing activities	**8,311**	**(24,124)**
Cash flows from financing activities		
Repayments of financial debt	(8,613)	(5,902)
Proceeds from financial debt	12,012	14,262
Purchase of treasury shares	(147)	(1,402)
Reissue of treasury shares	156	683
Dividends paid	(8,547)	(7,011)
Net cash generated in financing activities	**(5,139)**	**630**
Net (decrease)/increase in cash and cash equivalents	**15,856**	**(2,304)**
Cash and cash equivalents at beginning of the year	**33,635**	**35,939**
Cash and cash equivalents at end of the year (*)	**49,491**	**33,635**

(*) As of 31 December 2011, the Group held current bank deposits maturing at over three months of 6 million euros (25 million euros at 31 December, 2010). These current bank deposits are fully available.