



# 2010 First Half Financial Results

29 July 2010



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



## **ROVI – 2010 First Half Financial Results**

# **ROVI implements the MSD agreement and reports an operating revenues growth of 20%**

- **Operating revenues increased by 20% to 72.7 million euros in the first half of 2010, driven by the strength of the specialty pharmaceutical business, where sales rose 14%, and the implementation of the Merck Sharp & Dohme (MSD) strategic agreement which generated a 39% growth of the toll manufacturing business area.**
- **Sales of Bemiparin increased by 7% to 22.5 million euros, sales of Corlentor and Exxiv grew by 43% and 15% respectively in the first half of 2010. Sales of Thymanax, an innovative antidepressant from Servier that ROVI launched in March 2010, reached 0.8 million euros in the first six months of 2010.**
- **Operating revenues and EBIT related to the MSD manufacturing and packaging agreement, implemented on 31 March 2010, amounted to 6.5 million euros and 1.6 million euros respectively in the first half of 2010.**
- **EBITDA increased by 122% to 22.0 million euros in the first half of 2010, compared to the same period of 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 0.8 million euros of Frosst Ibérica integration costs, EBITDA increased by 12% in the first half of 2010.**
- **Net profit increased by 2.7 times to 18.9 million euros in the first half of 2010, impacted by the same factors as EBITDA.**
- **Free cash flow increased by 36% to 17.8 million euros in the first half of 2010, reflecting ROVI capacity to generate cash and fund future growth.**
- **Confirmation of guidance for the full year 2010, of operating revenues rising in a range of low double digit to low teens.**



**Madrid (Spain), 29 July 2010, 8:00 AM CET** - ROVI released today its financial results for the six months ending on 30 June 2010.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that *"in the first half of 2010, we reached an impressive 20% 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 which matched our expectations at the beginning of the year. Once again Bemiparin led the way with a 7% increase in sales. Bemiparin sales outside Spain grew by 15%, highlighting the continued internationalisation of our flagship product and as one of the Company's growth engines in the medium term. The recent measures approved by the government for the rationalisation of the pharmaceutical expenditure will have an impact on the ROVI profit and loss account. The discount of 7.5% of the pharmaceutical products under patent will reduce revenues by 3.5 million euros in the second half of 2010 and by 8 million euros in 2011. We are working in an internal saving plan, excluding the sales, marketing and R&D areas, which is going to help us to offset partially this negative impact. Furthermore, the recent global strategic agreement that we have reached with Merck Sharp & Dohme (MSD) in Spain, and that was implemented on 31 March 2010, will allow us to strengthen our toll manufacturing area, as we have already shown in these 2010 first half results. In addition, the MSD agreement will allow us to launch five 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 sustained and increasingly profitable 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 and the potential involvement of Novartis Vaccines in a long term cooperation project in the vaccines area would give us also the confidence to do it. 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 starting in the second half of 2010."*

## 1. Financial highlights

€ million	H1 2010	H1 2009	Growth	% Growth
Operating revenues	72.7	60.4	12.4	20%
Other income	0.5	1.4	(0.9)	(67%)
<b>Total revenue</b>	<b>73.2</b>	<b>61.8</b>	<b>11.4</b>	<b>18%</b>
Raw materials used and changes in inventories	(26.9)	(20.1)	6.8	34%
<b>Gross profit</b>	<b>46.3</b>	<b>41.7</b>	<b>4.7</b>	<b>11%</b>
<i>% margin</i>	<i>63.7%</i>	<i>69.0%</i>		(5.3pp)
R&D expenses	(4.7)	(4.2)	0.5	12%
Other SG&A	(31.4)	(27.6)	3.8	14%
Other income	11.8	-	11.8	n.a.
<b>EBITDA</b>	<b>22.0</b>	<b>9.9</b>	<b>12.1</b>	<b>122%</b>
<i>% margin</i>	<i>30.2%</i>	<i>16.4%</i>		13.9pp
<b>EBIT</b>	<b>20.3</b>	<b>9.1</b>	<b>11.3</b>	<b>124%</b>
<i>% margin</i>	<i>27.9%</i>	<i>15.0%</i>		12.9pp
<b>Net profit</b>	<b>18.9</b>	<b>7.0</b>	<b>11.9</b>	<b>170%</b>

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

The consolidated financial statements of Grupo ROVI for the first half of 2010 and the comparative information for 2009 (the balance sheet) and for the first half of 2009 (the profit and loss account and cash flow statement) are attached to this report (see Appendix 1).

## 2. Key operating and financial events

### 2.1 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.

## **2.2 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 plans to launch 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.

## **2.3 ROVI signs a letter of intent with Novartis 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.

## **2.4 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 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.

## **2.5 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 our 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."*

## **2.6 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 the coming months, 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.

## 2.7 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.

## 3 Performance of the Group

**Operating revenues** increased by 20% to 72.7 million euros in the first half of 2010, driven by the strength of the specialty pharmaceutical business, where sales rose 14%, and the implementation of the MSD strategic agreement with MSD which generated a 39% growth of the toll manufacturing area in the six-month period ended 30 June 2010.

Sales of prescription-based pharmaceutical products rose by 14% to 41.6 million euros in the first half of 2010. ROVI's low molecular weight heparin (LMWH), **Bemiparin**, maintained a growth rate, with sales up 7% to 22.5 million euros. Sales of **Bemiparin** in Spain (**Hibor®**) increased by 4% to 15.5 million euros, while international sales rose by 15% from last year supported by our increased presence, through strategic alliances, in countries such as Italy, Greece and the Czech Republic, among other, and by the launch of the product in 4 new countries during the first half of 2010.

Sales of **Corlontor®**, ROVI's specialty product for stable angina, rose by 43% in the six-month period ended 30 June 2010, to 2.3 million euros.

**Osseor®** sales decreased by 8% to 3.3 million euros in the six-month period ended 30 June 2010. The product appears to have lost some sales momentum in the first half of 2010 from the same period of the previous year but ROVI continues to have confidence in the potential of the product.

Sales of **Exxiv®** increased by 15% to 4.2 million euros in the six-month period ended 30 June 2010. According to IMS, Exxiv® had a market share in Spain of 13% at the end of June 2010.

Sales of **Thymanax®**, an innovative antidepressant from Servier, launched in March 2010 and for which ROVI has a co-marketing agreement covering Spain, reached 0.8 million euros in the first six months of 2010.

Sales of **contrast imaging agents** and other hospital products increased by 12% in the six-month period ended 30 June 2010 to 10.6 million euros. The sales of over-the-counter pharmaceutical products declined by 4% to 4.0 million euros in the first half of 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 28% to 1.2 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 39% in the six-month period ended 30 June 2010, to 11.9 million euros, compared with the same period in 2009, as a result of the implementation of the MSD manufacturing and packaging agreement, which was effective on 31 March 2010 (see section 2.4). Revenues from the MSD manufacturing and packaging agreement amounted to 6.5 million euros in the second quarter of 2010. This agreement contributes to strength in this business area and ROVI expects this contribution increases as the year progresses. 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.

**Gross profit** increased by 11% in the six-month period ended 30 June 2010 to 46.3 million euros, reflecting a fall in the gross margin to 63.7% in the six-month period ended 30 June 2010 from 69.0% in the same period of the previous year. The main cause is the increase in the Bemiparin raw material prices, despite the 4.9% Bemiparin price increase in Spain which partially offset the fall. In the first half of 2010 the raw material costs for Bemiparin were running at 2 times first half of 2009 costs. The contribution of the Frosst Ibérica plant to the gross profit of the group amounted to 5.0 million euros in the first half of 2010, reflecting a gross margin of 76.6%, which is 12.9 percentage points above the gross margin of the group. ROVI believes that raw material prices will be maintained in 2010 at least on the same level than in 2009. In addition, the new measures to reduce the pharmaceutical expenditure (see section 2.1) will have an impact on 2010 gross margin.

**Research and development expenses** increased by 12% to 4.7 million euros, reflecting ROVI investments in products that are under development, and the search for greater cost efficiency. This increase is mainly the result of the progress that have been made in various projects, including the Phase III trials for diabetic foot ulcers and the Phase II "ABEL" trial of Bemiparin in small cell lung cancer.

**Selling, general and administrative expenses** rose by 14% in the six-month period ended 30 June 2010 compared with the same period of 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 increased by 2%, below the growth of this item in 2009. This increase of 2% includes 0.8 million euros of integration costs related to Frosst Ibérica. Excluding the Frosst Ibérica integration costs, the selling, general and administrative expenses decreased by 1% in the first half of 2010, compared with the same period of the previous year, reflecting ROVI continued cost control.

In the first half of 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 1<sup>st</sup> 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, of which 31.9 million euros corresponded to the assets of the company. 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 122% to 22.0 million euros in the first half of 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 increased by 3%, in the first half of 2010, to 10.2 million euros, mainly as a result of the increase in raw material costs for Bemiparin and the addition of 0.8 million euros of Frosst Ibérica integration costs. Excluding these integration costs, EBITDA increased by 12%, in the first half of 2010. The contribution of the Frosst Ibérica plant to the EBITDA of the group amounted to 1.6 million euros in the first half of 2010.

**Depreciation and amortisation expenses** increased by 103% in the six-month period ended 30 June 2010 compared with the same period of 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 124% to 20.3 million euros in the six-month period ended 30 June 2010 compared with the same period of the previous year, impacted by the same factors as EBITDA. The contribution of the Frosst Ibérica plant to the EBIT of the group amounted to 1.6 million euros in the first half of 2010. ROVI expects that the Frosst Ibérica plant contributes with lower EBIT margin in 2010 than EBIT margin achieved in the first half of the year.

The **financial expense** line decreased by 30% for the six-month period ended 30 June 2010 compared with the same period in the 2009 financial year. This was as a result of a one-time loss on sale of a portfolio investment in the first half of 2009, resulting in higher financial expenses in H1 2009.

**Financial income** increased by 42% in the six-month period ended 30 June 2010 compared with the same period of 2009 as a result of higher returns on financial investments.

The **effective tax rate** was 6.3% in the first half of 2010 compared with 17.2% in the same period of the previous year. 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.

As a result of the factors noted above, the **net profit** of ROVI grew by 170% to 18.9 million euros in the six-month period ended 30 June 2010 compared with the same period of 2009.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that, *"we are very satisfied with the results for the first half of 2010. Operating revenues increased by 20% despite the difficulties in the economic and regulatory environments. We attribute this out-performance to the strength of our leading products, which continue to gain share in their various market segments, and to the contribution of the MSD manufacturing and packaging agreement. Margins have continued to be affected in the first half of 2010, mainly because of the rise in the price of heparin related raw materials which is outside our control. It is difficult to be definitive on raw material pricing for our heparin products. However 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 prices. We also expect that the spare capacity in the recently acquired MSD manufacturing facility 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. The free cash flow generated in the first half of 2010 allows us to be in a strong position to benefit in the current operating environment as we review various options to expand our sales base and better the utilisation of our asset base."*

## **4 Balance Sheet items**

### **4.1 Capital expenditure**

ROVI invested 1.0 million euros in the first half of 2010, compared to 2.3 million euros in the same period of the previous year. The amount invested in the first six months of 2010 corresponds to maintenance capex versus 1.4 million in the first six months of 2009. The rest of the amount invested in the first half of 2009 is related to the construction of the centre in Granada, which was inaugurated in May 2009.

### **4.2 Debt**

As of 30 June 2010, ROVI had total debt of 55.8 million euros. Debt with public administration represented, as of 30 June 2010, 51% of total debt.

<i>In thousand euros</i>	<b>30 June 10</b>	<b>31 December 09</b>
Loans from banks	10,494	10,567
Debt with public administration	28,576	19,897
Liabilities from financial leases	1,008	1,334
Debt from purchase of shares	15,730	-
<b>Total</b>	<b>55,808</b>	<b>31,798</b>

The debt from purchase of shares registered as of 30 June 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 12.9 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 15.7 million euros will be executed annually, starting on 31 March 2011 and ending on 31 March 2014.

#### **4.3 Free cash flow**

Free cash flow increased by 36% to 17.8 million euros in the first half of 2010 from 13.0 million in the same period of the previous year, reflecting ROVI excellent capacity to generate cash.

#### **4.4 Net and gross cash position**

As of 30 June 2010, ROVI had a gross cash position of 66.7 million euros and a net cash position of 10.9 million euros (financial assets and cash minus short term and long term debt), providing it with a high level of financial flexibility.

#### **4.5 Working capital**

The positive trend in working capital in the first half of 2010 is mainly due to an increase in cash of 29.6 million euros and an increase in "trade and other payables" item of 7.8 million euros, mainly due, in both cases, to the incorporation of Frosst Ibérica to the group. The "trade and other receivables" item decreased by 3.7 million. In addition, the "inventories" line increased by 6.7 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).

#### **4.6 Tax credit**

As of 30 June 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.

On 1 April 2010, ROVI performed a new impairment on Frosst Ibérica assets which generated a loss of 26.7 million euros, therefore existing tax credit would increase significantly as of 31 December 2010.

### **5 Guidance for 2010**

Despite the impact on sales caused by the new measures for the rationalisation of the pharmaceutical expenditure, ROVI is confirming once again the guidance for 2010 that it published in its earnings release for the first nine months of 2009, when it forecast operating revenue growth in a range of low double digit to low teens, and that it already confirmed in its earnings release for the full year 2009 and for the first quarter of 2010. The starting point for the 2010 guidance calculation is 141.8 million euros operating revenues recognised in 2009. ROVI expects its growth drivers to be Bemiparin, its existing portfolio of specialty pharmaceuticals, new launches such as Thymanax, Cimzia and Bertanel, new product distribution licenses 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 and aesthetic medicine lines. Regarding injectable toll manufacturing, ROVI is unsure on how the vaccine campaign may develop this year after the vaccination coverage on the pandemic outbreak of 2009. As well, the contract with Sanofi Aventis has expired and though ROVI will continue working for them, it expects to fill lower quantities. The OTC franchise is impacted by consumers' discretionary spending and the divestiture of Glycilax product. The aesthetic medical line is impacted by the termination of the distribution contract with Pérouse. 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 2010.

### **6 Research and Development update**

ROVI is maintaining its commitment to R&D, investing in the development of new projects in its two principal lines: heparin derivatives, and systems for drug delivery.

In the first half of 2010, at the Fifth International Conference on Thrombosis and Hemostasis Issues in Cancer at Stresa (Italy), the company presented the results of an intermediate "ABEL" analysis (Adjuvant Bemiparin Evaluation study in small cell Lung cancer), which was

designed to evaluate the effectiveness and safety of Bemiparin (3,500 IU/day for 26 weeks) in patients with limited small cell lung cancer receiving standard anti-tumour treatment. The intermediate results (based on a small number of patients) showed that Bemiparin could have a beneficial impact on the progression of the tumour and on the survival of patients suffering from the disease. The trial is currently continuing, after the inclusion of new patients was interrupted due to a very slow pace of recruitment. The study is expected to be concluded in the last quarter of 2010, when the final analysis of all the data from the 39 patients included in the trial will be made. At the end of the year, when Rovi has the new results, it will update and announce its clinical development strategy for this new indication for Bemiparin.

In addition, in the first half of 2010, ROVI disclosed the final results of the Phase III clinical trials for Nautiol® (Bemiparin) for the treatment of diabetic foot ulcers. Unfortunately, these results did not confirm the positive data that had been obtained in an earlier trial. The effectiveness of the placebo in the group was unexpectedly much higher than had been estimated at the start of the trial (50% healing or improvement in the ulcer), although the results for the Bemiparin group were similar to the starting scenario (with a 70% level of healing or improvement in the ulcer). However, the results have reinforced the good safety profile of Bemiparin. 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 the coming months, 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.

In the third quarter of 2010, ROVI expects to have news on its products based on advanced technologies for drug delivery: the final results of the Phase I study of OCAP for the oral administration of Bemiparin will be announced, and the first Phase I study of ISM ("in situ" micro-particle technology) will begin, for a formulation of the anti-psychotic Risperidone to be injected every four weeks.

ROVI is currently working on new projects, some of which are already in advanced pre-clinical phases, which will enable it to progress with the development of its technology platforms for drug delivery, and also to achieve synergies with its industrial plants.

## **7 New product launches**

In December 2009, ROVI entered into a partnership with UCB for the co-promotion of Cimzia®, indicated for the treatment of rheumatoid arthritis disease, in Spain, and in January 2010, ROVI obtained the license to market Thymanax® from Laboratoires Servier, an innovative antidepressant indicated for adults with major depressive episodes. In addition, the strategic agreement reached with MSD, implemented on the 31 March 2010, will allow ROVI the launch of five new products during the next 10 years. ROVI expects to launch the first one of these five products during the second half of 2010. In addition, ROVI has obtained the



license to market Bertanel®, from EBEWE, the new parenteral methotrexate indicated for rheumatoid arthritis, juvenile idiopathic arthritis, and psoriatic arthritis, in Spain. ROVI expects to launch Bertanel® in September 2010.

Iván López-Belmonte Encina, Deputy CEO and Head of Corporate Development of ROVI, said that, *"we are very excited with the potential of Bertanel®. The rheumatoid arthritis market has been developed very strongly from the introduction of the biological therapies, emphasizing higher efficacy rates in its association with methotrexate, which is considered the cornerstone in the rheumatoid arthritis treatment. 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 the five new products from MSD during the next 10 years will contribute to a sustained growth of the company for the long term."*

## **About ROVI**

ROVI is a fully-integrated, profitable 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 product and product candidates and the 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.

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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 30 JUNE 2010 AND 31 DECEMBER 2009

(Thousand Euros)

	30 June 2010	31 December 2009
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, Plant and Equipment	40,975	32,539
Intangible assets	1,275	974
Deferred income tax assets	3,792	263
Available for sale financial assets	70	2,090
Trade and other receivables	2,324	2,608
	<b>48,436</b>	<b>38,474</b>
<b>Current assets</b>		
Inventories	37,137	30,390
Trade and other receivables	55,383	59,095
Current income tax assets	1,776	889
Cash and cash equivalents	65,527	35,939
	<b>159,823</b>	<b>126,313</b>
<b>Total assets</b>	<b>208,259</b>	<b>164,787</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS AS OF 30 JUNE 2010 AND 31 DECEMBER 2009**

(Thousand Euros)

	<b>30 June 2010</b>	<b>31 December 2009</b>
<b>EQUITY</b>		
<b>Capital and reserves attributable to Company shareholders</b>		
Share capital	3,000	3,000
Legal reserves	600	600
Treasury stock	(1,825)	(1,198)
Retained earnings	77,876	64,741
Profit attributable to parent company	18,929	20,141
Available for sale assets reserve	(2)	(79)
<b>Total equity</b>	<b>98,578</b>	<b>87,205</b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>		
Borrowings	45,193	25,989
Deferred income tax liabilities	1,743	1,519
Non-current deferred revenues	7,710	11,355
	<b>54,646</b>	<b>38,863</b>
<b>Current liabilities</b>		
Trade and other payables	39,133	31,307
Borrowings	10,615	5,809
Current deferred revenues	4,278	575
Provisions for other liabilities and charges	1,009	1,028
	<b>55,035</b>	<b>38,719</b>
<b>Total liabilities</b>	<b>109,681</b>	<b>77,582</b>
<b>Total equity and liabilities</b>	<b>208,259</b>	<b>164,787</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED INCOME STATEMENTS FOR THE SIX-MONTH PERIODS ENDED 30 JUNE**  
**2010 AND 30 JUNE 2009**

**(Thousand Euros)**

	<b>Six-month periods ended</b>	
	<b>30 June</b>	
	<b>2010</b>	<b>2009</b>
Revenues	72,719	60,357
Changes in inventories of finished goods and work in progress	6,186	3,486
Raw materials and consumables used	(33,059)	(23,596)
Personnel expenses	(19,120)	(15,904)
Other operating expenses	(16,996)	(15,849)
Depreciation, amortisation and impairment charges	(1,673)	(826)
Recognition of government grants on non-financial assets and others	476	1,424
Others gains and losses - net	11,785	(32)
<b>OPERATING PROFIT</b>	<b>20,318</b>	<b>9,060</b>
Financial income	579	407
Financial expenses	(701)	(998)
<b>FINANCIAL RESULT</b>	<b>(122)</b>	<b>(591)</b>
<b>PROFIT BEFORE TAX</b>	<b>20,196</b>	<b>8,469</b>
Income tax expense	(1,267)	(1,459)
<b>PROFIT FOR THE YEAR</b>	<b>18,929</b>	<b>7,010</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED CASH FLOW STATEMENTS FOR THE SIX-MONTH PERIODS ENDED 30**  
**JUNE 2010 AND 30 JUNE 2009**

**(Thousand euros)**

	<b>Six-month periods ended</b>	
	<b>30 June</b>	
	<b>2010</b>	<b>2009</b>
Profit before income tax	20,196	8,469
<b>Adjustments of items not involving cash movements:</b>		
Amortization	1,673	826
Interest income	(579)	(407)
Available-for-sale financial asset impairment charge	18	-
Gains on disposal of financial assets and liabilities	(45)	-
Interest expenses	683	839
Net changes on provisions	(19)	(44)
Share-based payment expense	-	50
Gains on Frosst Ibérica acquisition	(11,785)	-
Grant for non-financial fixed assets and distribution license income	(538)	(742)
<b>Changes in working capital:</b>		
Trade and other receivables	13,314	9,868
Inventories	(5,115)	(3,474)
Trade and other payables	(2,972)	(2,735)
Interest paid	(89)	(262)
Income tax cash flow	(1,551)	(770)
<b>Net cash flows generated (used) in operating activities</b>	<b>13,191</b>	<b>11,618</b>
Purchases of property, plant and equipment	(936)	(2,285)
Purchases of intangible assets	(28)	(12)
Purchases of available-for-sale financial assets	-	(153)
Proceeds from available-for-sale financial assets	2,112	4,871
Purchases of other financial assets	(182)	(1,407)
Proceeds from the Frosst Ibérica acquisition	3,034	-
Interest received	579	407
<b>Net cash flows generated (used) in investing activities</b>	<b>4,579</b>	<b>1,421</b>
Repayment of borrowings	(3,630)	(3,271)
Proceeds of borrowings	16,031	6,561
Purchase of treasury shares	(1,267)	(2,043)
Reissue of treasury shares	684	440
<b>Net cash flows generated in financing activities</b>	<b>11,818</b>	<b>1,687</b>
<b>Net variation in cash and cash equivalents</b>	<b>29,588</b>	<b>14,726</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>35,939</b>	<b>19,640</b>
<b>Cash and cash equivalents at end of period</b>	<b>65,527</b>	<b>34,366</b>