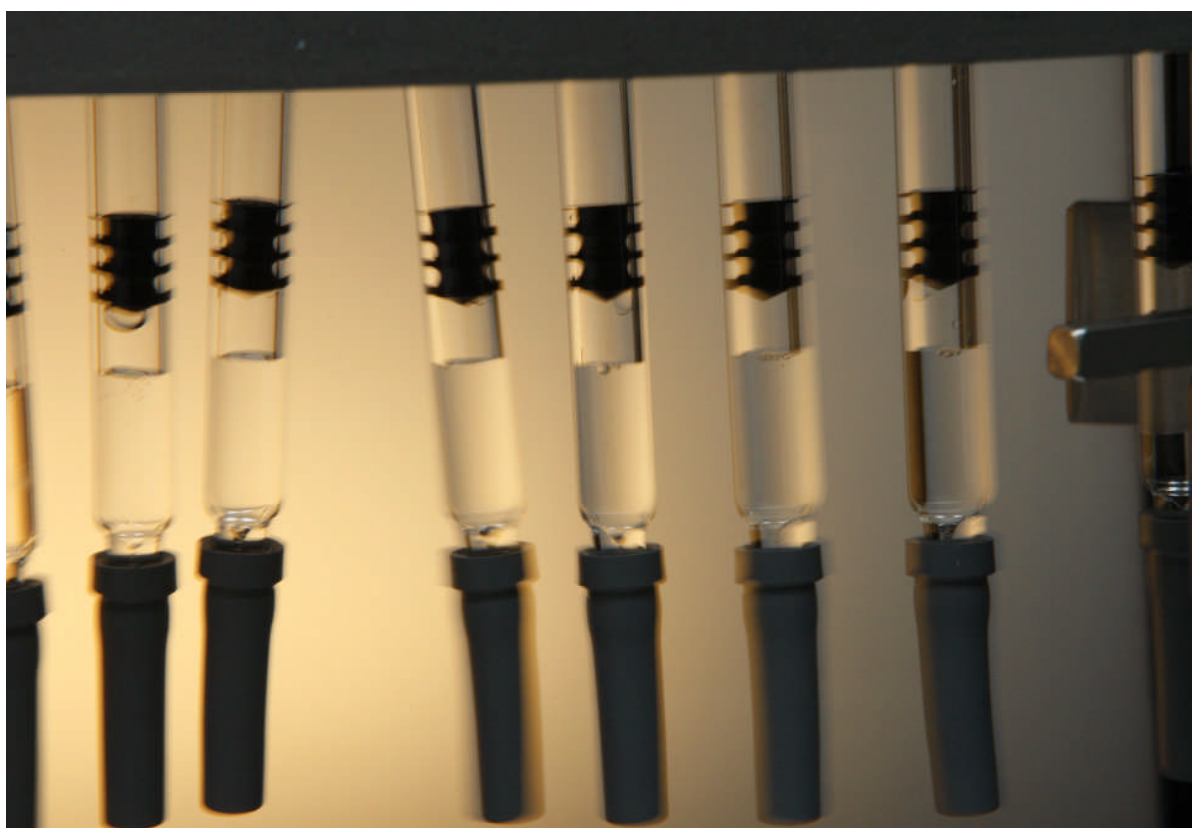




# Nine-month period ended 30 September 2012 Results

8 November 2012



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

Investor Relations



## **ROVI – Nine-month period ended 30 September 2012**

# **ROVI reports an operating revenues growth of 10%, led by the strength of the toll manufacturing business and by sales for pharmaceutical specialities, and a net income growth of 6%**

- **Operating revenues increased by 10% to 153.6 million euros in the nine-month period ended 30 September 2012, driven by the strength of the toll manufacturing business, where sales rose 37%, and by the specialty pharmaceutical business, which grew by 1%. In the second quarter of 2011, Fitoladius was sold to a third party. This sale contributed with revenues of 5.6 million euros. Excluding the impact of Fitoladius in the nine-month period ended 30 September 2011, operating revenues increased by 15% and sales of the specialty pharmaceutical business grew by 7% in the nine-month period ended 30 September 2012.**
- **Confirmation of the guidance for the full year 2012, of operating revenues rising from high single digit to low double digit. However, because of the impact of the last measures package, which was effective on the 1<sup>st</sup> of July and meant a pharmaceutical expenditure decrease of above 20% monthly from July to September 2012 and a reduction of the prescriptions number of 21% in September, ROVI forecasts 2012 operating revenue growth to reach the low range of the guidance.**
- **Despite the impact of the last measures package and the Spanish pharmaceutical market decrease of 13% expected for 2013 according to Farmaindustria<sup>1</sup>, the Spanish Pharmaceutical Association, ROVI forecasts to continue growing but it expects these factors could slow down its growth. Therefore, ROVI expects to grow operating revenues from mid to high single digit for the full year 2013.**

<sup>1</sup> <http://www.coib.org/uploadsBO/Generica/Documents/24-10.PDF>



- **Sales of Bemiparin increased by 14% to 42.9 million euros and sales of Corlantor, from Servier, grew by 30% in the nine-month period ended 30 September 2012. Sales of Thymanax, an innovative antidepressant from Servier that ROVI launched in March 2010, increased by 46% to 8.7 million euros in the nine-month period ended 30 September 2012.**
- **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® increased by 2.5 times to 8.9 million euros in the nine-month period ended 30 September 2012.**
- **EBITDA increased by 4% to 21.4 million euros in the nine-month period ended 30 September 2012, compared to the same period of the previous year, impacted by the sale of Fitoladius to a third party in the second quarter of 2011. Excluding the impact of Fitoladius in the nine-month period ended 30 September 2011, EBITDA increased by 48% in the nine-month period ended 30 September 2012, reflecting a rise in the gross margin to 63.0% in the nine-month period ended 30 September 2012 up from 62.5% in the same period of the previous year.**
- **Net profit increased by 6% to 16.6 million euros in the nine-month period ended 30 September 2012, compared to the same period of the previous year, impacted by the same factors as EBITDA.**

**Madrid (Spain), 8 November 2012, 8:00 AM CET** - ROVI released today its financial results for the nine-month period ended 30 September 2012.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that *"in the nine-month period ended 30 September 2012, we reached an excellent 10% operating revenues growth driven by the strength of two of our pillars of growth, our specialty pharmaceutical area and our toll manufacturing area. Our young portfolio has protected us from the governmental measures which were effective from November 2011, and we expect these measures to have an impact of less than 1 million euros on 2012 sales. On 20 April 2012, the Spanish Government announced a new measures package in order to achieve savings of more than 7 billion euros in healthcare expenditure. Among these new measures, the exclusion of some drugs from reimbursement and the copayment became more relevant. I would like to highlight that no significant ROVI product has been affected by the list of drugs excluded from reimbursement, which was published on the 29<sup>th</sup> of June. The introduction of the last measures package, specially of the pharmaceutical copayment, which was effective on the 1<sup>st</sup>*



*of July, meant a pharmaceutical expenditure decrease of above 20% monthly from July to September 2012 and the number of prescriptions was reduced by 21% in September. According to Farmaindustria<sup>1</sup>, the Spanish Pharmaceutical Association, the Spanish pharmaceutical market will also decrease by 15% and 13% in 2012 and 2013 respectively. Despite the difficult situation that the pharmaceutical industry is going through, we forecast to continue growing but we expect these factors could slow down our growth.*

*Once again Bemiparin led the growth with a 14% increase in sales. Bemiparin sales in Spain rose 4% and outside Spain grew by 34%, 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, 2011 and the nine-month period ended 30 September 2012 results, as well as our specialty pharmaceutical area, as we have shown with the launch, in January 2011, of Vytarin 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 2011 in order to address new prescribers. We expect this effort to result in a significant 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 7 years, underpinning our belief in the sustainability of the long term outlook for the company. ROVI's R&D pipeline continues to hold strong potential to drive the company's growth in future years. We are very excited with the potential of the ISM technology, especially with the Risperidone-ISM® project development, whose phase I/II studies are planned to start by the first half of 2013. 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".*

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<sup>1</sup> <http://www.coib.org/uploadsBO/Generica/Documents/24-10.PDF>



## 1. Financial highlights

€ million	9M 2012	9M 2011	Growth	% Growth
Operating revenues	153.6	140.2	13.4	10%
Other income	1.0	2.3	-1.3	-57%
<b>Total revenue</b>	<b>154.6</b>	<b>142.5</b>	<b>12.1</b>	<b>8%</b>
Raw materials used and changes in inventories	-57.8	-52.7	-5.1	10%
<b>Gross profit</b>	<b>96.8</b>	<b>89.8</b>	<b>7.0</b>	<b>8%</b>
% margin	63.0%	64.1%		-1.1pp
R&D expenses	-6.9	-6.6	-0.4	6%
Other SG&A	-68.4	-62.7	-5.7	9%
<b>EBITDA</b>	<b>21.4</b>	<b>20.5</b>	<b>0.9</b>	<b>4%</b>
% margin	13.9%	14.6%		-0.7pp
<b>EBIT</b>	<b>17.6</b>	<b>17.1</b>	<b>0.6</b>	<b>3%</b>
% margin	11.5%	12.2%		-0.7pp
<b>Net profit</b>	<b>16.6</b>	<b>15.7</b>	<b>0.9</b>	<b>6%</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 nine-month period ended 30 September 2012 and the comparative information for 2011 (balance sheet) and for the nine-month period ended 30 September 2011 (income statement and cash flow statement) are attached to this report (see Appendix 1).

## 2. Performance of the Group

**Operating revenues** increased by 10% to 153.6 million euros in the nine-month period ended 30 September 2012, driven by the strength of the toll manufacturing business, where sales rose 37%, and by the specialty pharmaceutical business, which grew by 1% in the nine-month period ended 30 September 2012. In the second quarter of 2011, Fitoladius was sold to a third party. This sale contributed with revenues of 5.6 million euros. Excluding the impact of Fitoladius in the nine-month period ended 30 September 2011, operating revenues increased by 15% in the nine-month period ended 30 September 2012, compared to the same period of the previous year, and sales of the specialty pharmaceutical business increased by 7% in the same period.

Sales of **prescription-based pharmaceutical products** rose 12% to 83.7 million euros in the nine-month period ended 30 September 2012. In the second quarter of 2011, Fitoladius was sold to a third party and, in June 2011, EMLA was stopped to be marketed and started to be only promoted. Excluding the impact of Fitoladius and EMLA distribution in the nine-month period ended 30 September 2011, sales of prescription-based pharmaceutical products increased by 17% in the nine-month period ended 30 September 2012.

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, maintained a growth rate, with sales up 14% to 42.9 million euros. Sales of Bemiparin in Spain (**Hibor®**) increased by 4% to 27.0 million euros, while international sales rose 34% to 15.8 million euros in the nine-month period ended 30 September 2012 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 six new countries, Mexico, Venezuela, Saudi Arabia, Iraq, Syria and Oman, during the nine-month period ended 30 September 2012.

Sales of **Corlentor®**, a specialty product for stable angina and chronic heart failure from Laboratoires Servier, rose 30% to 6.7 million euros in the nine-month period ended 30 September 2012. In February 2012, Corlentor® was approved by the European Commission for the treatment of patients with chronic heart failure<sup>1</sup>. The European Commission's decision to authorise this new indication for Corlentor® followed the review of data from the SHIFt 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.<sup>2,3</sup> 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<sup>3</sup> (see section 7.3).

Sales of **Osseor®**, a specialty product for the treatment of postmenopausal osteoporosis from Laboratoires Servier, decreased by 10% to 4.7 million euros in the nine-month period ended 30 September 2012.

Sales of **Exxiv®**, a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 10% to 5.5 million euros in the nine-month period ended 30 September 2012, mainly due to a slight deceleration of the COX-2 market.

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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. *Lancet* 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>



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 46% to 8.7 million euros in the nine-month period ended 30 September 2012.

Sales of **Vytorin®** and **Absorcol®**, the first of the five licenses of MSD, launched in January 2011, increased by 2.5 times to 8.9 million euros in the nine-month period ended 30 September 2012.

On 21<sup>st</sup> of July of 2011, the Spanish government announced a measures package to reduce the pharmaceutical expenditure

(see <http://www.msps.es/gabinetePrensa/notaPrensa/desarrolloNotaPrensa.jsp?id=2165>).

The impact of these 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.

On 20<sup>th</sup> of April of 2012, the Spanish government announced a new measures package in order to achieve savings of more than 7 billion euros in healthcare expenditure. These new measures were published on the official state gazette on the 24<sup>th</sup> of April (see <http://www.boe.es/boe/dias/2012/04/24/pdfs/BOE-A-2012-5403.pdf>).

Among these new measures, (i) the exclusion of some drugs from reimbursement and (ii) the pharmaceutical copayment, became more relevant. The list of drugs excluded from reimbursement was published on the 29<sup>th</sup> of June (see <http://www.msssi.gob.es/profesionales/farmacia/pdf/ProyectoResolucionExclusion.pdf>), without any material impact for the ROVI product portfolio, and the pharmaceutical copayment was effective from the 1<sup>st</sup> of July. The introduction of the last measures package, specially of the pharmaceutical copayment, meant a pharmaceutical expenditure decrease of above 20% monthly from July to September 2012 and the number of prescriptions was reduced by 21% in September. In addition, according to Farmaindustria<sup>1</sup>, the Spanish Pharmaceutical Association, the Spanish pharmaceutical market will decrease by 15% and 13% in 2012 and 2013 respectively. Despite the difficult situation that the pharmaceutical industry is going through, ROVI forecasts to continue growing but it expects these factors could slow down its growth.

In the second quarter of 2011, **Fitoladius®** product was sold to a third party. This sale contributed with revenues of 5.6 million euros in the nine-month period ended 30 September 2011. Revenues related to Fitoladius distribution amounted to 0.7 million euros in nine-month period ended 30 September 2011.

In the nine-month period ended 30 September 2012, ROVI did not register sales from the **EMLA®** distribution, a topical anaesthetic licensed by AstraZeneca that has been marketed by

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<sup>1</sup> <http://www.coib.org/uploadsBO/Generica/Documents/24-10.PDF>





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 1.0 million euros in the nine-month period ended 30 September 2012. Revenues related to EMLA® distribution (in the first half of 2011) and promotion (in the third quarter of 2011) amounted to 3.4 million euros in the nine-month period ended 30 September 2011.

In the nine-month period ended 30 September 2012, ROVI did not almost register sales of **Pneumovax®-23**, a non recurrent vaccine that helps to protect against serious infections caused by the bacterium pneumococcus, licensed by Sanofi Pasteur MSD in July 2008 for marketing by ROVI. Sales of Pneumovax®-23 reached 1.2 million euros in the nine-month period ended 30 September 2011. ROVI expects to register additional sales of this vaccine in the fourth quarter of 2012.

Sales of **over-the-counter pharmaceutical products** declined by 12% to 4.9 million euros in the nine-month period ended 30 September 2012 compared to the same period of the previous year. This was mainly as consequence of the reduction of consumption in the current economic environment.

Sales of **contrast imaging agents** and other hospital products decreased by 6% to 15.5 million euros in the nine-month period ended 30 September 2012.

**Toll manufacturing** sales increased by 37% to 48.2 million euros in the nine-month period ended 30 September 2012 compared with the same period of the previous year, mainly as a result of the contribution of the Frosst Ibérica plant whose revenues amounted to 35.2 million euros in the nine-month period ended 30 September 2012. The Frosst Ibérica plant has current manufacturing capabilities of 3 billion of capsules and 100 million of boxes. ROVI counted on a spare capacity of 50% in this plant when it was acquired in the second quarter of 2010. The company is using this spare capacity and it has been reduced by more than 20% since the plant acquisition. For the time being, the spare capacity is less than 30% in this plant which will allow ROVI to continue acquiring 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%.

**Sales outside Spain** increased by 51% to 63.8 million euros in the nine-month period ended 30 September 2012 compared with the same period of the previous year. Sales outside Spain represented 42% of operating revenues in the nine-month period ended 30 September 2012 compared to 30% in the nine-month period ended 30 September 2011.





**Gross profit** increased by 8% to 96.8 million euros in the nine-month period ended 30 September 2012, reflecting a decrease in the gross margin to 63.0% in the nine-month period ended 30 September 2012, from 64.1% in the nine-month period ended 30 September 2011, mainly as a result of the Fitoladius sale to a third party in the second quarter of 2011 and of the reduction of other income (subsidies) in the nine-month period ended 30 September 2012.

- Excluding the impact of Fitoladius, gross margin increased to 63.0% in the nine-month period ended 30 September 2012 from 62.5% in the nine-month period ended 30 September 2011.
- Excluding the impact of Fitoladius and the impact of other income, which decreased by 57% in the nine-month period ended 30 September 2012, gross margin increased by 1.6 percentage points to 62.4% in the nine-month period ended 30 September 2012 from 60.8% in the nine-month period ended 30 September 2011.

The decrease of the Bemiparin raw material cost impacted positively in the nine-month period ended 30 September 2012 gross margin. In the nine-month period ended 30 September 2012, ROVI continued to buy Bemiparin raw material for less than 40 euros per million of international units and it expects that this stable trend continues during 2012.

**Research and development expenses** increased by 6% to 6.9 million euros in the nine-month period ended 30 September 2012, reflecting ROVI investments in products that are under development.

**Selling, general and administrative expenses** increased by 9% to 68.4 million euros in the nine-month period ended 30 September 2012, compared to the same period of the previous year, mainly as a result of the increase in the toll manufacturing volumes and of the preparation of the injectables facility for a FDA (*US Food and Drug Administration*) inspection.

**EBITDA** increased by 4% to 21.4 million euros in the nine-month period ended 30 September 2012, compared to the same period of the previous year, impacted by the Fitoladius sale to a third party in the second quarter of 2011, which contributed with revenues of 5.6 million euros in the nine-month period ended 30 September 2011.

- Excluding the impact of Fitoladius in the nine-month period ended 30 September 2011, EBITDA increased by 48% in the nine-month period ended 30 September 2012, compared to the same period of the previous year.

**Depreciation and amortisation expenses** increased by 10% in the nine-month period ended 30 September 2012, compared to the same period of the previous year, mainly as a result of the new property plant and equipment and intangible assets purchases made during the last twelve months.



**EBIT** increased by 3% to 17.6 million euros in the nine-month period ended 30 September 2012, compared to the same period of the previous year, impacted by the Fitoladius sale to a third party in the second quarter of 2011.

- Excluding the impact of Fitoladius in the nine-month period ended 30 September 2011, EBIT increased by 60% in the nine-month period ended 30 September 2012, compared to the same period of the previous year.

**Financial expense** decreased by 21% in the nine-month period ended 30 September 2012, compared to the same period of the previous year.

The **financial income** line decreased by 10% in the nine-month period ended 30 September 2012, compared to the same period of the previous year, mainly as a result of the reduction in the average amount of deposits in the nine-month period ended 30 September 2012.

The **effective tax rate** was 3.4% in the nine-month period ended 30 September 2012 compared with 3.9% in the nine-month period ended 30 September 2011.

On 19<sup>th</sup> August 2011, a tax measures package was approved by law (<http://www.boe.es/boe/dias/2011/08/20/pdfs/BOE-A-2011-14021.pdf>) affecting 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 this 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. As of today, Frosst Ibérica negative tax bases amount to 62.8 million euros, of which 4.2 million euros were used in the nine month period ended 30 September 2012.

On 30<sup>th</sup> March 2012, a tax measures package (<http://www.boe.es/boe/dias/2012/03/31/pdfs/BOE-A-2012-4441.pdf>) was approved by law in order to reduce Spanish public deficit. Among these tax measures, the elimination of the freedom of depreciation incentive, the reduction of the deductions limits and the consideration of the reinvestment deduction in the calculation of the deductions limit could affect ROVI Group income statement.

On 14<sup>th</sup> July 2012, a new tax measures package (<http://www.boe.es/boe/dias/2012/07/14/pdfs/BOE-A-2012-9364.pdf>) was approved by law in order to guarantee budgetary stability and to promote competitiveness. Among these new tax measures, the limitation of the negative tax bases to be offset, which was reduced to 25% from 50%, and the tax rate increase for the payment on account, from 27% to 29% for ROVI, as well as the minimum disbursement for this payment, from 8% to 12%, will affect ROVI income tax payable rate.

ROVI expects to achieve an effective income tax expense rate of mid single digit for 2012 as the company has negative tax bases pending to be capitalised and research and development



expenses to be deducted. Nevertheless, the March and July 2012 measures will affect ROVI income tax payable rate. The tax payable rate would represent a percentage in the high single to low double digit range over the profit before income tax.

The **net profit** of ROVI increased by 6% to 16.6 million euros in the nine-month period ended 30 September 2012, compared to the same period of the previous year, impacted by the same factors as EBITDA.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that, *"we are satisfied with the results for the nine-month period ended 30 September 2012. Operating revenues increased by 10% from the same period of 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 toll manufacturing business. Margins increased in the nine-month period ended 30 September 2012, excluding the impact of the Fitoladius sale to a third party in the second quarter of 2011, mainly as a result of the reduction in the Bemiparin raw material costs and of a higher contribution of the toll manufacturing business. 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 7.5 million euros in the nine-month period ended 30 September 2012, compared to 4.2 million euros in the nine-month period ended 30 September 2011. Of this amount:

- 1.9 million euros correspond to investment capex related to the Alcalá facility (Frosst Ibérica), versus 0.6 million euros in the nine-month period ended 30 September 2011;
- 1.7 million euros correspond to investment capex related to Granada facility, versus 0.9 million euros in the nine-month period ended 30 September 2011;
- 1.8 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; and
- 2.1 million euros correspond to expenditure on maintenance, versus 2.7 million euros in the nine-month period ended 30 September 2011.



ROVI expects capital expenditure for 2012 to be in line with the nine-month period ended 30 September 2012 figure mainly as a result of (i) the preparation of the injectables facility for a FDA (*US Food and Drug Administration*) inspection and for the development of the ISM project, and (ii) the future implementation of a second production line in the Granada facility.

### 3.2 Debt

As of 30 September 2012, ROVI had total debt of 38.5 million euros. Debt with public administration represented, as of 30 September 2012, 71% of total debt and 91% of total debt is 0% interest rate debt.

<i>In thousand euros</i>	<b>30 September 12</b>	<b>31 December 11</b>
Loans from banks	3,309	4,799
Debt with public administration	27,216	33,897
Debt from purchase of shares	7,990	11,984
<b>Total</b>	<b>38,515</b>	<b>50,680</b>

The debt from purchase of shares registered as of 30 September 2012 corresponds to the outstanding payment related to the Frosst Ibérica acquisition, which includes the payment of 1.4 million euros for the Frosst Ibérica shares acquisition (the first three payments of 0.7 million euros each one were executed on 31 March 2010, 31 March 2011 and 20 April 2012) and the payment of 6.6 million euros for the Frosst Ibérica working capital (the first two payments of 3.2 million euros each one were executed on 31 March 2011 and on 12 April 2012). The outstanding debt of 8.0 million euros will be paid annually starting on 31 March 2013 and ending on 31 March 2014.

### 3.3 Free cash flow

Free cash flow (net cash generated (used) from operating activities minus property, plant and equipment and intangible assets purchases plus interest received) amounted to 10.8 million euros in the nine-month period ended 30 September 2012, from 7.6 million euros in the same period of the previous year, mainly as a result of the positive impact on the working capital of collections related to pending invoices from Spanish Public Administrations (see section 3.5).

### 3.4 Net and gross cash position

As of 30 September 2012, ROVI had a gross cash position of 49.7 million euros, compared to 61.7 million euros as of 31 December 2011, and a net cash position (financial assets and cash minus short term and long term debt) of 11.2 million euros, compared to 11.0 million euros as of 31 December 2011, providing it with a high level of financial flexibility.



### 3.5 Working capital

The decrease in working capital in the nine-month period ended 30 September 2012 was mainly due to a cash reduction of 27.9 million euros, of which 10.3 million euros correspond to Alentia Biotech cash and cash equivalents, retired from ROVI Group balance sheet as a result of the sale of 50% of the Alentia Biotech share capital to Grupo Ferrer Internacional. In addition, in the nine-month period ended 30 September 2012, 28.8 million euros of cash were used to contract other financial assets and deposits and 13.0 million euros were collected from the sale of part of these other financial assets and deposits. The "trade and other receivables" item decreased by 11.2 million euros in the nine-month period ended 30 September 2012, impacting positively the cash item, mainly due to the collection, in June 2012, of 12.4 million euros from Spanish Public Administrations which correspond to pending invoices due for collection from the Autonomous Regions by 31st December 2011. These collections fall within the "Suppliers Plan" put in place by the Spanish Government in February 2012. Inventories increased by 10.5 million euros mainly as a result of a larger Bemiparin production in the nine-month period ended 30 September 2012. The "trade and other payable" item decreased by 4.4 million euros in the nine-month period ended 30 September 2012.

### 4. Guidance for 2012

ROVI confirms the guidance for 2012 that it published in its earnings release for the first nine months of 2011, when it forecast operating revenue growth in a range of high single digit to low double digit, and in its earnings release for the full year 2011, despite the impact of (i) the additional measures approved by the Government in August 2011 for the rationalization of the pharmaceutical expenditure, (ii) the new measures package, approved by the Spanish Government on 20 April 2012, which was effective on the 1<sup>st</sup> of July in order to obtain savings of more than 7 billion euros in healthcare expenditure and (iii) the subsequent significant decrease expected for the Spanish pharmaceutical market also in 2012.

Nevertheless, because of the last measures package introduced, which meant a pharmaceutical expenditure decrease of above 20% monthly from July to September 2012 and a reduction of the prescriptions number of 21% in September, ROVI forecasts 2012 operating revenue growth to reach the low range of the guidance.

ROVI expects its growth drivers to be Bemiparin, its existing portfolio of specialty pharmaceuticals, last launches such as Vytorin, Absorcol and Thymanax, and new customers in the toll manufacturing area.



## 5. Guidance for 2013

In spite of (i) the impact of the last measures package of the Government, mentioned in the previous section, and (ii) the decrease of the Spanish pharmaceutical market of 13% expected for 2013, according to Farmaindustria<sup>1</sup>, the Spanish Pharmaceutical Association, ROVI forecasts to continue growing but it expects these factors could slow down its growth. Therefore, ROVI expects to grow operating revenues from mid to high single digit for the full year 2013.

ROVI expects its growth drivers to be Bemiparin, its existing portfolio of specialty pharmaceuticals, last launches such as Vytorin, Absorcol and Thymanax, new product distribution licenses and new customers in the toll manufacturing area.

## 6. Research and Development update

ROVI's R&D projects are mainly focused on the ISM® platform, which is an own proprietary drug delivery system aimed to improve patients' therapeutic compliance. The most advanced candidate is Risperidone-ISM®, a second-generation antipsychotic drug. The results of a phase I study on healthy subjects were announced in 2011 and were confirming the expected pharmacokinetic profile of this innovative long-acting intramuscular formulation for the monthly administration of risperidone. As a consequence of the positive outcome of this "proof of concept" for validating ISM technology, further clinical development on Risperidone-ISM® is progressing. Accordingly, ROVI has recently held a pre-IND meeting in order to get scientific advice from the FDA on the drug development program of Risperidone-ISM®. Patients' enrolment for additional Phase I and II studies is expected to be started by the first half of 2013.

In addition, the antipsychotic ISM program is continuing its preclinical development on a new candidate, paliperidone, in order to start human testing by next year.

Likewise, ROVI is also developing another novel formulation for a quarterly injection of letrozole, a well-recognised aromatase inhibitor which is currently considered as a key therapy for the treatment of the hormone-dependent breast cancer.

<sup>1</sup> <http://www.coib.org/uploadsBO/Generica/Documents/24-10.PDF>





## 7. Key operating and financial events

### 7.1 ROVI obtains FDA approval of its injectables plant

In September 2012, ROVI announced that the Food and Drug Administration in the United States had approved the company's contract manufacturing injectables plant in Madrid, for filling syringes that are prefilled with Water for Injection using the terminal sterilization process. Syringes prefilled with Water for Injection by ROVI at its contract manufacturing plant will be able to be commercialized in the United States in the coming months.

*"FDA approval represents a significant milestone in our manufacturing capacity and an excellent opportunity to penetrate the US market and maximize the plant's potential. In addition, it reflects our continuous interest in serving the globalized pharmaceutical market,"* said Juan López-Belmonte Encina, the Chief Executive Officer of ROVI.

### 7.2 ROVI and UCB end their commercial relationship with regards to Cimzia®

In September 2012, ROVI and UCB reached an agreement under which they ended their commercial relationship with regards to Cimzia® (certolizumab pegol), PEGylated anti-TNF alpha drug for the treatment of rheumatoid arthritis disease.

Since 15th of June 2010, Cimzia® had been jointly co-promoted in Spain by ROVI and UCB. In this period and as a result of the activities carried out by ROVI, Cimzia® is available in more than 80% of the key public hospitals, which means that more than 85% of the Spanish population already has access to the drug and can benefit from its clinical efficiency, shown by a significant improvement in the quality of life of the patients treated.

Under this agreement, Cimzia® is being promoted and commercialised exclusively by UCB in Spain from 1st of September 2012. Most of the ROVI sales team that promoted Cimzia® among the healthcare professionals joined UCB staff.

ROVI continues to commercialise and promote its Rheumatology product portfolio in osteoarticular pathology, as well as continuing to develop its business within the hospital sector.

### 7.3 Corlentor® receives approval for use in heart failure

In February 2012, ROVI announced that the company's heart rate lowering agent, **Corlentor®** (ivabradine), the first selective  $I_f$  channel inhibitor, was approved by the European Commission for the treatment of patients with chronic heart failure. Corlentor®



(ivabradine) is a product that has been developed by Laboratoires Servier and is marketed by them as Procolaran<sup>®</sup>.

The European Commission's decision to authorise this new indication for ivabradine followed the review of data from the SHIFT 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.<sup>2,3</sup> This reduction in mortality was highly significant in patients with a heart rate of 75 beats per minute (bpm), or above, for whom ivabradine is now indicated.

Professor Michel Komajda, Co-Chairman of the SHIFT Executive Committee commented: "*The decision to authorise this new indication for ivabradine is good news for doctors and patients, and is a significant step forward in the treatment of heart failure. While ACE inhibitors and beta-blockers remain the main stay in the treatment of heart failure, the results of the SHI<sub>f</sub>T trial demonstrate that a reduction in heart rate when elevated with ivabradine improves clinical outcomes and symptoms, prevents disease progression, and has beneficial effect on daily activities and the quality of life of heart failure patients*".

#### **7.4 Dividend payment**

The ROVI General Shareholders Meeting, on 13 June 2012, approved the payment of a gross dividend of 0.1269 euros per share on 2011 earnings. This dividend was paid on 4 July 2012 and it implied 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 30 principal marketed products is currently anchored by the internally-developed, second generation low molecular weight heparin, Bemiparin. ROVI's research and development pipeline is focused primarily on the expansion of applications, indications and alternative mechanisms of action for the heparin-derived products and other glycosaminoglycans and on the development of new controlled release mechanisms based on ISM<sup>TM</sup> technology, with the aim of obtaining new pharmaceutical products that enable the regular administration of formulations which are administered daily in chronic and prolonged treatments. ROVI manufactures the active biological ingredient (Bemiparin) for its principal proprietary products and for injectable pharmaceutical products developed by its in-house



research team, and utilizes its state-of-the-art filling and packaging capabilities to provide a broad array of toll manufacturing services to leading international pharmaceutical companies, primarily in the area of pre-filled syringes. In addition, ROVI provides contract manufacturing and packaging services of solid oral pharmaceutical dosage forms, using the most enhanced technology, Roller Compaction. Additional information about ROVI is available on the company's website: [www.rovi.es](http://www.rovi.es)

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**Forward-looking statements**

This news release contains forward-looking statements. Such forward looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition, performance, or achievements of ROVI or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward looking statements. The statements in this press release represent ROVI's expectations and beliefs as of the date of this press release. ROVI anticipates that subsequent events and developments may cause these expectations and beliefs to change. However, while ROVI may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, except in case of substantive



changes. 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 SEPTEMBER 2012 AND 31 DECEMBER 2011

(Thousand of euros)

	30 September 2012	31 December 2011
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, Plant and Equipment	49,394	45,857
Intangible assets	2,937	2,736
Deferred tax assets	5,947	4,856
Available-for-sale financial assets	26,398	5,117
Trade and other receivables	133	325
	<b>84,809</b>	<b>58,891</b>
<b>Current assets</b>		
Inventories	51,855	41,306
Trade and other receivables	57,472	68,698
Current income tax assets	1,161	3,682
Bank deposits	-	6,000
Cash and cash equivalents	21,623	49,491
	<b>132,111</b>	<b>169,177</b>
<b>Total assets</b>	<b>216,920</b>	<b>228,068</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS AS OF 30 SEPTEMBER 2012 AND 31 DECEMBER**  
**2011**

(Thousand of euros)

	<b>30 September 2012</b>	<b>31 December 2011</b>
<b>EQUITY</b>		
<b>Capital and reserves attributable to shareholders of the company</b>		
Share capital	3,000	3,000
Legal reserve	600	600
Treasury shares	(2,148)	(1,922)
Retained earnings and voluntary reserves	105,700	93,920
Profit for the period	16,632	18,127
Reserve for available-for-sale assets	(210)	256
<b>Total equity</b>	<b>123,574</b>	<b>113,981</b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>		
Financial debt	29,735	41,246
Deferred income tax liabilities	3,528	3,635
Non-current deferred revenues	7,939	12,450
	<b>41,202</b>	<b>57,331</b>
<b>Current liabilities</b>		
Trade and other payables	37,352	41,775
Financial debt	8,780	9,434
Current deferred revenues	4,348	4,298
Provisions for other liabilities and charges	1,664	1,249
	<b>52,144</b>	<b>56,756</b>
<b>Total liabilities</b>	<b>93,346</b>	<b>114,087</b>
<b>Total equity and liabilities</b>	<b>216,920</b>	<b>228,068</b>





**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED INCOME STATEMENTS FOR THE NINE-MONTH PERIODS ENDED 30**  
**SEPTEMBER 2012 AND 30 SEPTEMBER 2011**

(Thousand of euros)

	Nine-month periods ended 30 September	
	2012	2011
Revenue	153,585	140,168
Changes in inventories	10,549	(1,488)
Raw materials and consumables used	(68,371)	(51,228)
Employee benefit expenses	(39,637)	(37,401)
Other operating expenses	(35,722)	(31,879)
Depreciation, amortisation and impairment charges	(3,776)	(3,431)
Recognition of government grants on non financial non-current assets and other	1,019	2,349
<b>OPERATING PROFIT</b>	<b>17,647</b>	<b>17,090</b>
Finance income	1,154	1,286
Finance costs	(1,578)	(1,987)
<b>FINANCE COSTS - NET</b>	<b>(424)</b>	<b>(701)</b>
<b>PROFIT BEFORE INCOME TAX</b>	<b>17,223</b>	<b>16,389</b>
Income tax	(591)	(640)
<b>PROFIT FOR THE PERIOD</b>	<b>16,632</b>	<b>15,749</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED CASH FLOW STATEMENTS FOR THE NINE-MONTH PERIODS ENDED 30**  
**SEPTEMBER 2012 AND 30 SEPTEMBER 2011**

(Thousand of euros)

	Nine-month periods ended 30 September	
	2012	2011
<b>Cash flows from operating activities</b>		
Profit before income tax	17,223	16,389
<b>Adjustments for non-monetary transactions:</b>		
Amortisation	3,776	3,431
Interest income	(1,154)	(1,286)
Gains or losses on derecognition of financial assets and liabilities	21	109
Interest expense	1,578	1,987
Net changes in provisions	415	19
Grant for non-financial fixed assets and distribution licence income	(792)	(1,820)
<b>Changes in working capital</b>		
Trade and other receivables	10,129	(8,038)
Inventories	(10,549)	1,608
Trade and other payables	(4,352)	(3,080)
<b>Other collections and payments</b>		
Collection for distribution licenses	-	200
Interest paid	(86)	(117)
Income tax cash flow	931	1,090
<b>Net cash generated (used) from operating activities</b>	<b>17,140</b>	<b>10,492</b>
<b>Cash flows from investing activities</b>		
Purchases of intangible assets	(537)	(637)
Purchases of property, plant and equipment	(6,977)	(3,590)
Purchases of available-for-sale financial assets	(27,708)	(3,400)
Proceeds from sale of available-for-sale financial assets	6,473	369
Proceeds from short term bank deposits	6,487	20,000
Contracting short term bank deposits	(1,055)	(6,000)
Purchases of other financial assets	-	(65)
Reduction in cash from sale of Alentia Biotech	(10,278)	-
Interest received	1,154	1,286
<b>Net cash generated (used) in investing activities</b>	<b>(32,441)</b>	<b>7,963</b>
<b>Cash flows from financing activities</b>		
Repayments of financial debt	(7,549)	(7,215)
Proceeds from financial debt	1,712	11,608
Purchase of treasury shares	(1,837)	(140)
Dividends paid	(6,300)	(8,548)
Reissue of treasury shares	1,407	139
<b>Net cash generated in financing activities</b>	<b>(12,567)</b>	<b>(4,156)</b>
<b>Net (decrease)/increase in cash and cash equivalents</b>	<b>(27,868)</b>	<b>14,299</b>
<b>Cash and cash equivalents at beginning of the period</b>	<b>49,491</b>	<b>33,635</b>
<b>Cash and cash equivalents at end of the period</b>	<b>21,623</b>	<b>47,934</b>