



## First Half 2012 Results

26 July 2012



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



## **ROVI – First Half 2012 Results**

# **ROVI reports an operating revenues growth of 9%, led by the strength of the toll manufacturing business and by sales for pharmaceutical specialities, and a net income growth of 1%**

- **Operating revenues increased by 9% to 104.9 million euros in the six-month period ended 30 June 2012, driven by the strength of the toll manufacturing business, where sales rose 36%, and by the specialty pharmaceutical business, which grew by 2% in the first half of 2012. In the first half 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 first half of 2011, operating revenues increased by 17% in the first half of 2012.**
- **Confirmation of the guidance for the full year 2012, of operating revenues rising from high single digit to low double digit. As the last measures package, approved by the Spanish Government in order to achieve savings of more than 7 billion euros in healthcare expenditure, has recently been effective (on the 1<sup>st</sup> of July) and its impact on the ROVI Group accounts is still pending to be known, ROVI forecasts 2012 operating revenue growth to reach the low range of the guidance.**
- **Sales of Bemiparin increased by 16% to 31.6 million euros and sales of Corlentor, from Servier, grew by 33% in the six-month period ended 30 June 2012. Sales of Thymanax, an innovative antidepressant from Servier that ROVI launched in March 2010, increased by 59% to 6.0 million euros in the first half of 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 2.8 times to 5.9 million euros in the first half of 2012.**
- **EBITDA decreased by 1% to 16.0 million euros in the six-month period ended 30 June 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 first half of 2011, EBITDA increased by 59% in the first half of 2012, reflecting a rise in the gross margin to 62.4% in the first half of 2012 up from 61.3% in the same period of the previous year.**

- **Net profit increased by 1% to 13.0 million euros in the six-month period ended 30 June 2012, compared to the same period of the previous year, impacted by the same factors as EBITDA.**

**Madrid (Spain), 26 July 2012, 8:00 AM CET** - ROVI released today its financial results for the six-month period ended 30 June 2012.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that *"in the first half of 2012, we reached an excellent 9% 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. In addition, the pharmaceutical copayment was introduced from the 1<sup>st</sup> of July and the potential impact of this measure as well as of other measures related to this last package, such as the creation of a joint purchasing centre, on the ROVI Group accounts is pending to be known. Once again Bemiparin led the growth with a 16% increase in sales. Bemiparin sales in Spain rose 4% and outside Spain grew by 40%, 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 first half 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 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 9 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 second half of 2012. 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	H1 2012	H1 2011	Growth	% Growth
Operating revenues	104.9	95.9	9.0	9%
Other income	0.8	1.2	-0.5	-39%
<b>Total revenue</b>	<b>105.6</b>	<b>97.1</b>	<b>8.5</b>	<b>9%</b>
Raw materials used and changes in inventories	-40.1	-36.1	-4.0	11%
<b>Gross profit</b>	<b>65.5</b>	<b>61.0</b>	<b>4.5</b>	<b>7%</b>
<i>% margin</i>	<i>62.4%</i>	<i>63.6%</i>		-1.2pp
R&D expenses	-4.6	-4.4	-0.2	5%
Other SG&A	-44.8	-40.4	-4.4	11%
<b>EBITDA</b>	<b>16.0</b>	<b>16.2</b>	<b>-0.2</b>	<b>-1%</b>
<i>% margin</i>	<i>15.3%</i>	<i>16.9%</i>		-1.6pp
<b>EBIT</b>	<b>13.6</b>	<b>13.9</b>	<b>-0.4</b>	<b>-3%</b>
<i>% margin</i>	<i>13.0%</i>	<i>14.5%</i>		-1.6pp
<b>Net profit</b>	<b>13.0</b>	<b>12.9</b>	<b>0.1</b>	<b>1%</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 2012 and the comparative information for 2011 (balance sheet) and for the first half of 2011 (consolidated income statement and cash flow statement) are attached to this report (see Appendix 1).

## 2. Performance of the Group

**Operating revenues** increased by 9% to 104.9 million euros in the six-month period ended 30 June 2012, driven by the strength of the toll manufacturing business, where sales rose 36%, and by the specialty pharmaceutical business, which grew by 2% in the first half of 2012. In the first half 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 first half of 2011, operating revenues increased by 17% in the first half of 2012, compared to the same period of the previous year, and sales of specialty pharmaceutical business increased by 11% in the same period.



Sales of **prescription-based pharmaceutical products** rose 15% to 60.1 million euros in the six-month period ended 30 June 2012. In the first quarter of 2011, ROVI marketed Fitoladius, which was sold to a third party in the second quarter of 2011, and EMLA, which was stopped to be marketed and started to be only promoted in June 2011. Excluding the impact of Fitoladius and EMLA distribution in the first half of 2011, sales of prescription-based pharmaceutical products increased by 22% in the first half of 2012.

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, maintained a growth rate, with sales up 16% to 31.6 million euros. Sales of Bemiparin in Spain (**Hibor®**) increased by 4% to 19.2 million euros, while international sales rose 40% to 12.4 million euros in the first half of 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 first half of 2012. This accelerated growth of the international sales was specific to the first half of 2012 and a more moderate growth is expected for 2012.

Sales of **Corlentor®**, a specialty product for stable angina and chronic heart failure from Laboratoires Servier, rose 33% to 4.5 million euros in the six-month period ended 30 June 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>1</sup> (see section 6.1).

Sales of **Osseor®**, a specialty product for the treatment of postmenopausal osteoporosis from Laboratoires Servier, decreased by 4% to 3.4 million euros in the six-month period ended 30 June 2012.

Sales of **Exxiv®**, a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 8% to 3.9 million euros in the six-month period ended 30 June 2012, mainly due to a slight deceleration of the COX-2 market.

---

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 59% to 6.0 million euros in the six-month period ended 30 June 2012.

Sales of **Vytorin**® and **Absorcol**®, the first of the five licenses of MSD, launched in January 2011, increased by 2.8 times to 5.9 million euros in the six-month period ended 30 June 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>). According to the Spanish government comments, this new measures package would contribute to reduce drugs demand.

Among these new measures, (i) the exclusion of some drugs from reimbursement and (ii) the pharmaceutical copayment have recently been introduced. 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 potential impact of the copayment measure as well as of other measures related to this last package, such as the creation of a joint purchasing centre, on the ROVI Group accounts is pending to be known as these measures are difficult to be evaluated.

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 six-month period ended 30 June 2011. Revenues related to Fitoladius distribution amounted to 0.7 million euros in the first half of 2011.

In the first half of 2012, 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 0.8 million euros in the first half of 2012. Revenues related to EMLA® distribution amounted to 3.1 million euros in the first half of 2011.



Sales of **over-the-counter pharmaceutical products** declined by 9% to 3.6 million euros in the six-month period ended 30 June 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 5% to 11.0 million euros in the six-month period ended 30 June 2012.

**Toll manufacturing** sales increased by 36% to 29.6 million euros in the six-month period ended 30 June 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 24.0 million euros in the six-month period ended 30 June 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 43% to 43.3 million euros in the first half of 2012 compared with the same period of the previous year. Sales outside Spain represented 41% of operating revenues in the first half of 2012 compared to 32% in the first half of 2011.

**Gross profit** increased by 7% to 65.5 million euros in the six-month period ended 30 June 2012, reflecting a decrease in the gross margin to 62.4% in the first half of 2012, from 63.6% in the first half of 2011, as a result of the Fitoladius sale to a third party in the second quarter of 2011.

- Excluding the impact of Fitoladius, gross margin increased to 62.4% in the first half of 2012 from 61.3% in the first half of 2011.
- Excluding the impact of other income (subsidies), which decreased by 39% in the six-month period ended 30 June 2012, gross margin increased to 61.7% in the first half of 2012 from 59.9% in the first half of 2011.

The decrease of the Bemiparin raw material cost impacted positively in the first half 2012 gross margin. In the first half of 2012, 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** increased by 5% to 4.6 million euros in the six-month period ended 30 June 2012, reflecting ROVI investments in products that are under development.

**Selling, general and administrative expenses** increased by 11% to 44.8 million euros in the six-month period ended 30 June 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** decreased by 1% to 16.0 million euros in the six-month period ended 30 June 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 first half of 2011.

- Excluding the impact of Fitoladius in the first half of 2011, EBITDA increased by 59% in the first half of 2012, compared to the same period of the previous year.

**Depreciation and amortisation expenses** increased by 10% in the six-month period ended 30 June 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** decreased by 3% to 13.6 million euros in the six-month period ended 30 June 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 first half of 2011, EBIT increased by 73% in the first half of 2012, compared to the same period of the previous year.

**Financial expense** decreased by 19% in the six-month period ended 30 June 2012, compared to the same period of the previous year.

The **financial income** line increased by 12% in the six-month period ended 30 June 2012, compared to the same period of the previous year, as a result of higher returns on financial investments.

The **effective tax rate** was 2.7% in the six-month period ended 30 June 2012 compared with 3.1% in the first half of 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 69.4 million euros, of which 6.4 million euros and 3.1 million euros were used in 2011 and in the first half of 2012 respectively.

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 1% to 13.0 million euros in the six-month period ended 30 June 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 first half of 2012. Operating revenues increased by 9% 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 first half of 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 Vytarin 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 4.2 million euros in the six-month period ended 30 June 2012, compared to 2.8 million euros in the six-month period ended 30 June 2011. Of this amount:

- 0.7 million euros correspond to investment capex related to the Alcalá facility (Frosst Ibérica), versus 0.5 million euros in the first half of 2011;
- 1.1 million euros correspond to investment capex related to Granada facility, versus 0.7 million euros in the first half of 2011;
- 0.8 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
- 1.6 million euros correspond to expenditure on maintenance, in line with the first half of 2011.

ROVI expects capital expenditure for 2012 to be in line with the first half 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 June 2012, ROVI had total debt of 39.0 million euros. Debt with public administration represented, as of 30 June 2012, 70% of total debt and 90% of total debt is 0% interest rate debt.

*In thousand euros*

	<b>30 June 12</b>	<b>31 December 11</b>
Loans from banks	3,762	4,799
Debt with public administration	27,294	33,897
Debt from purchase of shares	7,907	11,984
<b>Total</b>	<b>38,963</b>	<b>50,680</b>

The debt from purchase of shares registered as of 30 June 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 6.5 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 7.9 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 9.6 million euros in the six-month period ended 30 June 2012, from 3.3 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 June 2012, ROVI had a gross cash position of 55.8 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 16.8 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 six-month period ended 30 June 2012 was mainly due to a cash reduction of 13.0 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 first half of 2012, 17.8 million euros of cash were used to contract other financial assets and deposits and 10.7 million euros were collected from the sale of part of these other financial assets and deposits. The "trade and other receivables" item decreased by 10.7 million euros in the first half of 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 7.9 million euros mainly as a result of a larger Bemiparin production in the first half of 2012. The "trade and other payable" item increased by 0.5 million euros in the first half of 2012.

## **4. Guidance for 2012**

Despite the impact of (i) the additional measures approved by the Government in August 2011 for the rationalization of the pharmaceutical expenditure, (i) 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, 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.

Although the last measures package has been recently introduced and its impact on the ROVI Group accounts is still pending to be known, ROVI expects to achieve 2012 guidance but it 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, new product distribution licenses and new customers in the toll manufacturing area.

## 5. 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 second half of 2012.

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.

## 6. Key operating and financial events

### 6.1 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 *Les 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 SHIF<sup>T</sup> 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 SHIF<sup>T</sup> 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 SHIF<sup>T</sup> 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".

## 6.2 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)

**For further enquiries, please contact:**

Juan López-Belmonte Encina  
Chief Executive Officer  
913756235  
[jlopez-belmonte@rovi.es](mailto:jlopez-belmonte@rovi.es)  
[www.rovi.es](http://www.rovi.es)

Javier López-Belmonte Encina  
Chief Financial Officer  
913756266  
[javierbelmonte@rovi.es](mailto:javierbelmonte@rovi.es)  
[www.rovi.es](http://www.rovi.es)

Marta Campos Martínez  
Investor Relations  
912444422  
[mcampos@rovi.es](mailto:mcampos@rovi.es)  
[www.rovi.es](http://www.rovi.es)

**Forward-looking statements**

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



## APPENDIX 1

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

(Thousand of euros)

	30 June 2012	31 December 2011
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, Plant and Equipment	47,411	45,857
Intangible assets	2,892	2,736
Deferred tax assets	5,828	4,856
Available-for-sale financial assets	17,654	5,117
Trade and other receivables	132	325
	<b>73,917</b>	<b>58,891</b>
<b>Current assets</b>		
Inventories	49,199	41,306
Trade and other receivables	58,033	68,698
Current income tax assets	1,629	3,682
Bank deposits	-	6,000
Cash and cash equivalents	36,489	49,491
	<b>145,350</b>	<b>169,177</b>
<b>Total assets</b>	<b>219,267</b>	<b>228,068</b>



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

(Thousand of euros)

	<b>30 June 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	(2,077)	(1,922)
Retained earnings and voluntary reserves	105,754	93,920
Profit for the period	12,959	18,127
Reserve for available-for-sale assets	10	256
<b>Total equity</b>	<b>120,246</b>	<b>113,981</b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>		
Financial debt	30,260	41,246
Deferred income tax liabilities	3,775	3,635
Non-current deferred revenues	8,124	12,450
	<b>42,159</b>	<b>57,331</b>
<b>Current liabilities</b>		
Trade and other payables	42,312	41,775
Financial debt	8,703	9,434
Current deferred revenues	4,348	4,298
Provisions for other liabilities and charges	1,499	1,249
	<b>56,862</b>	<b>56,756</b>
<b>Total liabilities</b>	<b>99,021</b>	<b>114,087</b>
<b>Total equity and liabilities</b>	<b>219,267</b>	<b>228,068</b>





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

(Thousand of euros)

	Six-month periods ended 30 June	
	2012	2011
Revenue	104,876	95,887
Changes in inventories	7,893	(3,803)
Raw materials and consumables used	(48,035)	(32,328)
Employee benefit expenses	(25,977)	(24,501)
Other operating expenses	(23,483)	(20,326)
Depreciation, amortisation and impairment charges	(2,444)	(2,221)
Recognition of government grants on non financial non-current assets and other	752	1,230
<b>OPERATING PROFIT</b>	<b>13,582</b>	<b>13,938</b>
Finance income	904	805
Finance costs	(1,173)	(1,452)
<b>FINANCE COSTS - NET</b>	<b>(269)</b>	<b>(647)</b>
<b>PROFIT BEFORE INCOME TAX</b>	<b>13,313</b>	<b>13,291</b>
Income tax	(354)	(417)
<b>PROFIT FOR THE PERIOD</b>	<b>12,959</b>	<b>12,874</b>



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

**(Thousand of euros)**

	<b>Six-month periods ended</b>	
	<b>30 June</b>	
	<b>2012</b>	<b>2011</b>
<b>Cash flows from operating activities</b>		
Profit before income tax	13,313	13,291
<b>Adjustments for non-monetary transactions:</b>		
Amortisation	2,444	2,221
Interest income	(904)	(805)
Gains or losses on derecognition of financial assets and liabilities	21	109
Interest expense	1,173	1,452
Net changes in provisions	250	(1)
Grant for non-financial fixed assets and distribution licence income	(390)	(1,235)
<b>Changes in working capital</b>		
Trade and other receivables	9,668	(5,869)
Inventories	(7,893)	3,923
Trade and other payables	(5,737)	(8,966)
<b>Other collections and payments</b>		
Collection for distribution licenses	-	200
Interest paid	(63)	(80)
Income tax cash flow	972	1,026
<b>Net cash generated (used) from operating activities</b>	<b>12,854</b>	<b>5,266</b>
<b>Cash flows from investing activities</b>		
Purchases of intangible assets	(374)	(562)
Purchases of property, plant and equipment	(3,780)	(2,238)
Purchases of available-for-sale financial assets	(16,708)	(3,400)
Proceeds from sale of available-for-sale financial assets	4,240	152
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	904	805
<b>Net cash generated (used) in investing activities</b>	<b>(20,564)</b>	<b>8,692</b>
<b>Cash flows from financing activities</b>		
Repayments of financial debt	(6,668)	(6,182)
Proceeds from financial debt	1,636	11,286
Purchase of treasury shares	(685)	(104)
Reissue of treasury shares	425	-
<b>Net cash generated in financing activities</b>	<b>(5,292)</b>	<b>5,000</b>
<b>Net (decrease)/increase in cash and cash equivalents</b>	<b>(13,002)</b>	<b>18,958</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>36,489</b>	<b>52,593</b>