



Full Year 2012 Results

21 February 2013



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



ROVI – Full Year 2012 Results

ROVI reports an operating revenue growth of 9% and an EBITDA growth of 14%

- **Operating revenue increased by 9% to 201.9 million euros in 2012, driven by the strength of the toll manufacturing business, where sales rose 34%, 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 revenue of 5.6 million euros. Excluding the impact of Fitoladius in 2011, operating revenue increased by 13% and sales of the specialty pharmaceutical business grew by 6% in 2012.**
- **The 2012 guidance, for operating revenue rising from high single digit to low double digit growth and later on July 26, 2012 forecast to reach the low range of the guidance, was achieved. This was despite a monthly pharmaceutical expenditure decrease of more than 20% on average from July to December 2012 and a monthly reduction of the number of prescriptions by 15% on average in the same period, mainly as a result of the latest package of measures which was effective on July 1, 2012.**
- **ROVI expects to grow operating revenue from mid to high single digit for 2013, despite the impact of the latest package of measures and the Spanish pharmaceutical market decrease of 13% expected for 2013 according to Farmaindustria¹, the Spanish Pharmaceutical Association.**
- **Sales of Bemiparin increased by 10% to 55.7 million euros and sales of Corlontor, from Servier, grew by 29% in 2012. Sales of Thymanax, an innovative antidepressant from Servier that ROVI launched in March 2010, increased by 35% to 11.6 million euros in 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 2.2 times to 12.4 million euros in 2012.**



- **EBITDA increased by 14% to 27.0 million euros in 2012, compared to the same period of the previous year, impacted by (i) the sale of Fitoladius to a third party in the second quarter of 2011, which contributed revenue of 5.6 million euros in 2011, and (ii) other income registered in 2012 as a result of Frosst Ibérica tax inspection. Excluding the impact of Fitoladius in 2011 and the impact of Frosst Ibérica tax inspection in 2012, EBITDA increased by 46% in 2012, reflecting a stable gross margin of 63.2% in 2012.**
- **Net profit increased by 8% to 19.5 million euros in 2012, compared to the previous year, impacted by the sale of Fitoladius in 2011. Excluding the impact of Fitoladius in 2011, net profit increased by 59% in 2012.**
- **ROVI will propose to the Shareholders General Meeting a dividend of 0.1366 euros per share on 2012 earnings. This proposed dividend would mean an increase of 8% compared to the dividend on 2011 earnings.**

Madrid (Spain), 21 February 2013, 8:00 AM CET - ROVI released today its financial results for the twelve months ending on 31 December 2012.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that *"in 2012, we reached an excellent 9% operating revenue growth driven by the strength of two of our pillars of growth, our specialty pharmaceutical area and our toll manufacturing area. Our young portfolio protected us from the governmental measures which were effective from November 2011, and these measures had an impact of less than 1 million euros on 2012 sales. On 20 April 2012, the Spanish Government announced a new package of measures 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 was affected by the list of drugs excluded from reimbursement, which was published on the 29th of June. The introduction of the latest package of measures, especially the pharmaceutical copayment, which was effective on the 1st of July, meant a monthly pharmaceutical expenditure decrease of above 20% on average from July to December 2012 and the number of prescriptions was reduced monthly by 15% on average in the same period. According to Farmaindustria¹, the Spanish Pharmaceutical Association, the Spanish pharmaceutical market will decrease by 13% in 2013, in line with 2012. 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 10% increase in sales. Bemiparin sales in Spain rose 3% and outside Spain grew by 26%, highlighting the continued internationalisation of

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



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 2012 results, as well as our specialty pharmaceutical area, as we showed with the launch, in January 2011, of Vytorin and Absorcol, the first of the five licenses from MSD that will contribute to our growth in the coming years. This launch required a significant investment effort in human capital in 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".

1. Financial highlights

€ million	2012	2011	Growth	% Growth
Operating revenue	201.9	184.7	17.2	9%
Other income	1.2	3.5	-2.2	-64%
Total revenue	203.2	188.2	15.0	8%
Raw materials used and changes in inventories	-75.5	-69.4	-6.1	9%
Gross profit	127.6	118.7	8.9	8%
<i>% margin</i>	<i>63.2%</i>	<i>64.3%</i>		-1.1pp
R&D expenses	-9.2	-8.4	-0.8	10%
Other SG&A	-92.7	-86.6	-6.1	7%
Other income	1.3	-	-	n.a.
EBITDA	27.0	23.7	3.3	14%
<i>% margin</i>	<i>13.4%</i>	<i>12.8%</i>		0.5pp
EBIT	21.7	19.0	2.7	14%
<i>% margin</i>	<i>10.7%</i>	<i>10.3%</i>		0.5pp
Net profit	19.5	18.1	1.4	8%

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 2012 and the comparative information for 2011 are attached to this report (see Appendix 1).

2. Performance of the Group

Operating revenue increased by 9% to 201.9 million euros in 2012, driven by the strength of the toll manufacturing business, where sales rose 34%, and by the specialty pharmaceutical business, which grew by 1% in 2012. In the second quarter of 2011, Fitoladius was sold to a third party. This sale contributed revenue of 5.6 million euros in 2011. Excluding the impact of Fitoladius, operating revenue increased by 13% in 2012, compared to the same period of the previous year, and sales of the specialty pharmaceutical business increased by 6% in the same period.

Sales of **prescription-based pharmaceutical products** rose 10% to 110.8 million euros in 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 2011, sales of prescription-based pharmaceutical products increased by 14% in 2012.

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, maintained a growth rate, with sales up 10% to 55.7 million euros. Sales of Bemiparin in Spain (**Hibor®**) increased by 3% to 36.6 million euros, while international sales rose 26% to 19.1 million euros in 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 2012.

Sales of **Vytorin®** and **Absorcol®**, the first of the five licenses of MSD, launched in January 2011, increased by 2.2 times to 12.4 million euros in 2012.

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 35% to 11.6 million euros in 2012.

Sales of **Corlantor®**, a specialty product for stable angina and chronic heart failure from Laboratoires Servier, rose 29% to 9.2 million euros in 2012. In February 2012, Corlantor® was approved by the European Commission for the treatment of patients with chronic heart failure¹. The European Commission's decision to authorise this new indication for Corlantor® 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.^{2,3} This reduction in mortality was highly significant in patients with a heart rate of 75 beats per minute (bpm), or above, for whom Corlentor® is now indicated (see section 6.3).

Sales of **Osseor®**, a specialty product for the treatment of postmenopausal osteoporosis from Laboratoires Servier, decreased by 14% to 6.1 million euros in 2012.

Sales of **Exxiv®**, a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 11% to 7.2 million euros in 2012, mainly due to a slight deceleration of the COX-2 market.

On 21st of July of 2011, the Spanish government announced a package of measures to reduce the pharmaceutical expenditure (see <http://www.msps.es/gabinetePrensa/notaPrensa/desarrolloNotaPrensa.jsp?id=2165>). The impact for ROVI of these measures, which were effective from November 2011, on 2012 sales was less than 1 million euros.

On 20th of April of 2012, the Spanish government announced a new package of measures 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 24th 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 29th 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 1st of July. The introduction of the latest package of measures, especially of the pharmaceutical copayment, meant a monthly pharmaceutical expenditure decrease of above 20% on average from July to December 2012 and the number of prescriptions was reduced monthly by 15% on average in the same period. In addition, according to Farmaindustria⁴, the Spanish Pharmaceutical Association, the Spanish pharmaceutical market will decrease by 13% in 2013, in line with 2012. Despite the difficult situation that the pharmaceutical industry is going

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>

4. <http://www.coib.org/uploads/BO/Generica/Documents/24-10.PDF>



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 revenue of 5.6 million euros in 2011. Revenue related to Fitoladius distribution amounted to 0.7 million euros in 2011.

In 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. Revenue related to EMLA® promotion amounted to 1.3 million euros in 2012. Revenue related to EMLA® distribution (in the first half of 2011) and promotion (in the second half of 2011) amounted to 3.7 million euros in 2011.

Sales of **Pneumovax®-23**, a non recurrent vaccine that helps to protect against serious infections caused by the bacterium pneumococcus, licensed by Sanofi Pasteur MSD in July 2008 for marketing by ROVI, reached 0.4 million euros in 2012 compared to 1.2 million euros in 2011 due to budget constraints from the Spanish government.

Sales of **over-the-counter pharmaceutical products** declined by 14% to 5.9 million euros in 2012 compared to the previous year. This was mainly as consequence of the reduction of consumption in the current Spanish economic environment.

Sales of **contrast imaging agents** and other hospital products decreased by 6% to 20.7 million euros in 2012.

Toll manufacturing sales increased by 34% to 63.2 million euros in 2012 compared with the previous year, mainly as a result of the contribution of the Frosst Ibérica plant whose revenue amounted to 44.1 million euros in 2012. The Frosst Ibérica plant has current manufacturing capabilities of 3 billion of tablets 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 30% since the plant acquisition. For the time being, the spare capacity is less than 20% 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 36% to 81.3 million euros in 2012 compared with the previous year. Sales outside Spain represented 40% of operating revenue in 2012 compared to 32% in 2011.

Gross profit increased by 8% to 127.6 million euros in 2012, reflecting a decrease in the gross margin to 63.2% in 2012, from 64.3% in 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 (subsidiaries) in 2012.

- Excluding the impact of Fitoladius, gross margin remained stable at 63.2% in 2012.
- Excluding the impact of Fitoladius and the impact of other income, which decreased by 64% in 2012, gross margin increased by 1.4 percentage points to 62.6% in 2012 from 61.2% in 2011.

The decrease of the Bemiparin raw material cost impacted positively in the 2012 gross margin. In 2012, ROVI continued to buy Bemiparin raw material for less than 40 euros per million of international units and it expects this stable trend to continue in 2013.

Research and development expenses increased by 10% to 9.2 million euros in 2012, reflecting ROVI investments in products that are under development.

Selling, general and administrative expenses increased by 7% to 92.7 million euros in 2012, compared to the same period of the previous year, mainly as a result of (i) the increase in the toll manufacturing volumes and (ii) the preparation of the injectables facility for a FDA (*US Food and Drug Administration*) inspection.

As a result of Frosst Ibérica tax inspection for the period 2006-2008, ROVI registered a compensation of 1.3 million euros in the **other income** item in 2012 from the owner of Frosst Ibérica during the period reviewed, which assumed this payment. As a counterpart for this 1.3 million euros income, an expense was mainly registered in the "income tax" line.

EBITDA increased by 14% to 27.0 million euros in 2012, compared to the previous year, impacted by (i) the Fitoladius sale to a third party in the second quarter of 2011, which contributed revenue of 5.6 million euros in 2011, and (ii) other income registered in 2012 as a result of Frosst Ibérica tax inspection.

- Excluding the impact of Fitoladius in 2011 and the impact of Frosst Ibérica tax inspection in 2012, EBITDA increased by 46% in 2012, compared to the previous year.

Depreciation and amortisation expenses increased by 13% in 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 (see section 3.1).



EBIT increased by 14% to 21.7 million euros in 2012, compared to the previous year, impacted by (i) the Fitoladius sale to a third party in the second quarter of 2011 and (ii) other income registered in 2012 as a result of Frosst Ibérica tax inspection.

- Excluding the impact of Fitoladius in 2011 and the impact of Frosst Ibérica tax inspection in 2012, EBIT increased by 58% in 2012, compared to the previous year.

Financial expense decreased by 8% in 2012, compared to the previous year.

The **financial income** line decreased by 42% in 2012, compared to the previous year, mainly as a result of: (i) the reduction in the average amount of deposits in 2012 and (ii) the reduction of delay interests from Court decisions related to pending invoices due for collection from Public Administration in 2012.

The **effective tax rate** was 6.4% in 2012 compared with 4.2% in 2011. This favourable effective tax rate is due to the deduction of existing research and development expenses and the capitalisation of existing negative tax bases resulting from the Frosst Ibérica integration. As of today, Frosst Ibérica negative tax bases amount to 62.8 million euros, of which 5.3 million euros will be used in the 2012 income tax.

On 19th August 2011, a package of tax measures 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

On 30th March 2012, a package of tax measures (<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 and the reduction of the deductions limits affected 2012 ROVI Group income statement. In addition, these measures will affect ROVI income tax payable rate.

On 13th July 2012, a new package of tax measures (<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 forecast the tax payable rate could represent a percentage in the high single to low double digit range over the 2012 profit before income tax.



The **net profit** of ROVI increased by 8% to 19.5 million euros in 2012, compared to the previous year, impacted by the Fitoladius sale in 2011.

- Excluding the impact of Fitoladius in 2011, net profit increased by 59% in 2012, compared to the previous year.

ROVI will pay a **dividend** of 0.1366 euros per share on 2012 earnings if the Shareholders General Meeting approves the application of the 2012 profit, under proposal of ROVI Board of Directors. This proposed dividend would mean an increase of 8% compared to the dividend on 2011 earnings. In addition, this dividend would imply the pay-out of 35% of consolidated net profit for 2012.

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.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that, *"we are satisfied with the results for 2012. Operating revenue increased by 9% from the previous year. This was in line with expectations despite the difficulties in the economic and regulatory environments. We attribute this out-performance to the strength of our leading products, which continue to gain share in their various market segments, and to the contribution of the toll manufacturing business. Margins increased in 2012, excluding the impacts of the Fitoladius sale in 2011 and the decrease of other income in 2012, mainly as a result of the reduction of the Bemiparin raw material costs and of a higher contribution of the toll manufacturing business. We expect to keep margin expansion in 2013. 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 13.7 million euros in 2012, compared to 8.4 million euros in 2011. Of this amount:

- 3.7 million euros corresponds to investment capex related to the Alcalá facility (Frosst Ibérica) mainly for a new manufacturing module, versus 2.4 million euros in 2011;
- 2.5 million euros corresponds to investment capex related to the Granada facility for the future implementation of a second production line, versus 1.1 million euros in 2011;



- 3.9 million euros corresponds 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, versus 1.3 million euros in 2011; and
- 3.6 million euros corresponds to expenditure on maintenance, in line with 2011.

3.2 Debt

As of 31 December 2012, ROVI had total debt of 38.4 million euros. Debt with public administration represented, as of 31 December 2012, 72% of total debt and 93% of total debt is 0% interest rate debt.

<i>In thousand euros</i>	31 December 12	31 December 11
Loans from banks	2,813	4,799
Debt with public administration	27,505	33,897
Debt from purchase of shares	8,072	11,984
Total	38,390	50,680

The debt from purchase of shares registered as of 31 December 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 6.7 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 8.1 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 plus/minus property, plant and equipment and intangible assets purchases/sales plus interest received) increased by 9% to 7.3 million euros in 2012, 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 31 December 2012, ROVI had a gross cash position of 45.9 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 7.5 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 2012 was mainly due to a cash reduction of 32.9 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 2012, 31.9 million euros of cash were used to contract other financial assets and deposits and 14.8 million euros were collected from the sale of part of these other financial assets and deposits. The "trade and other receivables" item decreased by 14.3 million euros in 2012, impacting positively the cash item, mainly due to the collection, in 2012, of 13.5 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 14.9 million euros mainly as a result of a larger Bemiparin production in 2012. The "trade and other payable" item decreased by 1.9 million euros in 2012.

4. Guidance for 2013

ROVI expects **to grow operating revenue from mid to high single digit for the full year 2013**, in spite of (i) the impact of the latest package of measures, approved by the Spanish Government on 20 April 2012, which was effective on the 1st of July in order to obtain savings of more than 7 billion euros in healthcare expenditure, and (ii) the decrease of the Spanish pharmaceutical market of 13% expected for 2013, according to Farmaindustria¹, the Spanish Pharmaceutical Association.

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 ISM technology has already been validated after obtaining positive results from a "proof of concept" phase I study on healthy subjects. In 2012, ROVI held a pre-IND meeting with the Food and Drug Administration (FDA) in order to get scientific advice on the drug development program of Risperidone-ISM®. As planned, patients' enrolment for additional Phase I and II studies are being started by the first half of 2013.



Besides, the ISM® program has also been advancing with two additional compounds. Accordingly, the first clinical trial with another second-generation antipsychotic drug, paliperidone, is planned to start by second half of 2013, and preclinical testing is progressing as well with a novel quarterly injection formulation of letrozole; letrozol (an aromatase inhibitor) is a well-established therapy for hormone-dependent breast cancer and at present it is only available as a once daily oral formulation.

ROVI is also researching in glycomics. The degree of specialization achieved in this area allows consideration of the expansion of applications, indications and alternative mechanisms of action for the heparin-derived products and other glycosaminoglycans, based on both anticoagulant and non-anticoagulant activities.

6. Key operating and financial events

6.1 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.

6.2 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.

6.3 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®.

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.^{2,3} This reduction in mortality was highly significant in patients with a heart rate of 75 beats per minute (bpm), or above, for whom 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_fT 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*".

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™ 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

For further enquiries, please contact:

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

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

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

Forward-looking statements

This news release contains forward-looking statements. Such forward looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition, performance, or achievements of ROVI or industry results,



to be materially different from any future results, performance, or achievements expressed or implied by such forward looking statements. The statements in this press release represent ROVI's expectations and beliefs as of the date of this press release. ROVI anticipates that subsequent events and developments may cause these expectations and beliefs to change. However, while ROVI may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, 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 31 DECEMBER 2012 AND 31 DECEMBER 2011

(Thousand of euros)

	31 December 2012	31 December 2011
ASSETS		
Non-current assets		
Property, Plant and Equipment	53,791	45,857
Intangible assets	3,176	2,736
Deferred tax assets	6,073	4,856
Available-for-sale financial assets	28,148	5,117
Financial receivables	133	325
	91,321	58,891
Current assets		
Inventories	56,225	41,306
Trade and other receivables	54,377	68,698
Current income tax assets	3,855	3,682
Bank deposits	-	6,000
Cash and cash equivalents	16,585	49,491
	131,042	169,177
Total assets	222,363	228,068



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

(Thousand of euros)

	31 December 2012	31 December 2011
EQUITY		
Capital and reserves attributable to shareholders of the company		
Share capital	3,000	3,000
Legal reserve	600	600
Treasury shares	(2,060)	(1,922)
Retained earnings and voluntary reserves	105,692	93,920
Profit for the year	19,514	18,127
Reserve for available-for-sale assets	(299)	256
Total equity	126,447	113,981
LIABILITIES		
Non-current liabilities		
Financial debt	29,135	41,246
Deferred income tax liabilities	3,256	3,635
Non-current deferred revenue	8,393	12,450
	40,784	57,331
Current liabilities		
Trade and other payables	39,878	41,775
Financial debt	9,255	9,434
Current deferred revenue	4,348	4,298
Provisions for other liabilities and charges	1,651	1,249
	55,132	56,756
Total liabilities	95,916	114,087
Total equity and liabilities	222,363	228,068



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED INCOME STATEMENTS FOR THE FULL YEARS 2012 AND 2011

(Thousand of euros)

	Full Year	
	2012	2011
Revenue	201,923	184,706
Changes in inventories	14,919	(518)
Raw materials and consumables used	(90,432)	(68,921)
Employee benefit expenses	(53,546)	(51,133)
Other operating expenses	(48,359)	(43,893)
Depreciation, amortisation and impairment charges	(5,320)	(4,709)
Recognition of government grants on non financial non-current assets and other	1,236	3,453
Other income	1,256	-
OPERATING PROFIT	21,677	18,985
Finance income	1,341	2,319
Finance costs	(2,180)	(2,376)
FINANCE COSTS - NET	(839)	(57)
PROFIT BEFORE INCOME TAX	20,838	18,928
Income tax	(1,324)	(801)
PROFIT FOR THE YEAR	19,514	18,127



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED CASH FLOW STATEMENTS FOR THE FULL YEARS 2012 AND 2011

(Thousand of euros)

	Full year	
	2012	2011
Cash flows from operating activities		
Profit before income tax	20,838	18,928
Adjustments for non-monetary transactions:		
Amortisation	5,320	4,709
Interest income	(1,341)	(2,319)
Gains or losses on sales of available-for-sale financial assets	-	(88)
Gains or losses on derecognition of financial assets and liabilities	21	109
Interest expense	2,180	2,376
Net changes in provisions	402	9
Grant for non-financial fixed assets and distribution licence income	(999)	(2,435)
Changes in working capital		
Trade and other receivables	12,359	(12,598)
Inventories	(14,919)	518
Trade and other payables	(2,074)	4,139
Other collections and payments		
Collection for distribution licenses	-	700
Interest paid	(105)	(155)
Income tax cash flow	(2,068)	(1,209)
Net cash generated (used) from operating activities	19,614	12,684
Cash flows from investing activities		
Purchases of intangible assets	(915)	(800)
Purchases of property, plant and equipment	(12,805)	(7,553)
Proceeds of property, plant and equipment	26	-
Purchases of available-for-sale financial assets	(30,859)	(6,400)
Proceeds from sale of available-for-sale financial assets	7,737	1,810
Contracting short term bank deposits	(1,055)	(6,000)
Liquidating current deposits	7,014	25,000
Purchases of other financial assets	-	(65)
Cash decrease due to sale of Alentia Biotech	(10,278)	-
Interest received	1,341	2,319
Net cash generated (used) in investing activities	(39,794)	8,311
Cash flows from financing activities		
Repayments of financial debt	(8,833)	(8,613)
Proceeds from financial debt	2,757	12,012
Purchase of treasury shares	(1,838)	(147)
Reissue of treasury shares	1,488	156
Dividends paid	(6,300)	(8,547)
Net cash generated in financing activities	(12,726)	(5,139)
Net (decrease)/increase in cash and cash equivalents	(32,906)	15,856
Cash and cash equivalents at beginning of the year	49,491	33,635
Cash and cash equivalents at end of the year	16,585	49,491