



# First Quarter 2014 Financial Results

29 April 2014



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

Investor Relations

## **ROVI – First Quarter 2014 Results**

# **ROVI reports an EBITDA growth of 18% and a net profit growth of 11%, led by the strength of pharmaceutical specialities business**

- **Operating revenue increased by 7% to 57.6 million euros in the three-month period ended 31 March 2014, mainly driven by the strength of the prescription-based pharmaceutical business, where sales rose 13%.**
- **For 2014, ROVI expects a mid-to-high single digit growth rate for the operating revenue despite (i) a new contraction in the Spanish pharmaceutical market as forecast by Farmaindustria<sup>1</sup>, and (ii) the continued decreases in the pharmacy retail market at least until 2016 forecast by IMS Health<sup>2</sup>.**
- **Sales of Bemiparin had an outstanding performance in the first quarter of 2014, with a 12% increase to 18.6 million euros; this growth came both from sales in Spain (+10%) and from international sales (+13%).**
- **Sales of Corlantor<sup>®</sup>, from Servier, grew by 22% to 3.2 million euros in the first quarter of 2014. Sales of Absorcol<sup>®</sup> and Vytorin<sup>®</sup>, the first of the five licenses of Merck Sharp & Dohme (MSD), increased by 25% to 4.8 million euros in the three-month period ended 31 March 2014.**
- **EBITDA increased by 18% to 9.0 million euros in the three-month period ended 31 March 2014, compared to the same period of the previous year, reflecting a 1.5 percentage points rise in the EBITDA margin to 15.6% in the first quarter of 2014 up from 14.1% in the first quarter of 2013.**
- **Net profit increased by 11% to 5.9 million euros in the first quarter of 2014, compared to the same period of the previous year.**
- **ROVI will propose to the Shareholders General Meeting a dividend of 0.1612 euros per share on 2013 earnings. This dividend would mean an increase of 18% compared to the dividend on 2012 earnings (€0.1366).**

<sup>1</sup> [http://www.farmaindustria.es/Farma\\_Public/Imprimir\\_Public/FARMA\\_124496?idDoc=FARMA\\_124496](http://www.farmaindustria.es/Farma_Public/Imprimir_Public/FARMA_124496?idDoc=FARMA_124496)

<sup>2</sup> *IMS Market Prognosis March 2013*



**Madrid (Spain), 29 April 2014, 8:00 AM CET** - ROVI released today its financial results for the first quarter of 2014.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that *“in the first quarter of 2014, we reached an excellent 7% operating revenue growth mainly driven by the strength of our specialty pharmaceutical area. Sales of prescription-based pharmaceutical products rose 13% in this period despite the difficulties that the Spanish pharmaceutical market is going through and the estimate of an additional 2% contraction for 2014, according to Farmaindustria<sup>1</sup>. Nevertheless, we forecast to continue growing. Our flagship product, Bemiparin, is contributing significantly to this growth. In the first quarter of 2014, Bemiparin sales increased by double digit growth both in the domestic and in the international markets. In this line, we expect the continued internationalisation of our main product to be one of the Company’s growth engines in the medium term.*

*Furthermore, we expect the reinforcement of our Central Nervous System franchise through the agreement we signed in the last quarter of 2013 with Medice to market, on exclusivity basis, Medicebran® and Medikinet® in Spain and the entrance in the respiratory field through the agreement achieved with Novartis at the end of last year to commercialise Hirobriz® Breezhaler® and Ulunar® Breezhaler® in Spain to contribute to our growth in the coming years. In addition, the MSD agreement will allow us to launch four additional new products in the next 6 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 our long acting injectables technology (ISM®), especially with the Risperidone-ISM® project development, whose phase II trial is starting in the first half of 2014. 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”.*

---

<sup>1</sup>[http://www.farmaindustria.es/Farma\\_Public/Imprimir\\_Public/FARMA\\_124496?idDoc=FARMA\\_124496](http://www.farmaindustria.es/Farma_Public/Imprimir_Public/FARMA_124496?idDoc=FARMA_124496)



## 1. Financial highlights

€ million	Q1 2014	Q1 2013	Growth	% Growth
Operating revenue	57.6	53.8	3.8	7%
Other income	0.9	0.3	0.6	195%
<b>Total revenue</b>	<b>58.6</b>	<b>54.1</b>	<b>4.5</b>	<b>8%</b>
Raw materials used and changes in inventories	(23.5)	(22.4)	(1.1)	5%
<b>Gross profit</b>	<b>35.1</b>	<b>31.7</b>	<b>3.4</b>	<b>11%</b>
<i>% margin</i>	<i>60.9%</i>	<i>59.0%</i>		1.9pp
R&D expenses	(3.0)	(2.6)	(0.4)	14%
Other SG&A	(23.2)	(21.5)	(1.6)	8%
<b>EBITDA</b>	<b>9.0</b>	<b>7.6</b>	<b>1.4</b>	<b>18%</b>
<i>% margin</i>	<i>15.6%</i>	<i>14.1%</i>		1.5pp
<b>EBIT</b>	<b>6.9</b>	<b>6.0</b>	<b>0.9</b>	<b>15%</b>
<i>% margin</i>	<i>12.0%</i>	<i>11.1%</i>		0.8pp
<b>Net profit</b>	<b>5.9</b>	<b>5.3</b>	<b>0.6</b>	<b>11%</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 quarter of 2014 and the comparative information for 2013 (balance sheet) and for the first quarter of 2013 (consolidated income statement and cash flow statement) are attached to this report (see Appendix 1).

## 2. Performance of the Group

**Operating revenue** increased by 7% to 57.6 million euros in the three-month period ended 31 March 2014, driven by the strength of the specialty pharmaceutical business, where sales rose 11% to 42.2 million euros.

Sales of **prescription-based pharmaceutical** products rose 13% to 34.6 million euros in the first quarter of 2014.

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, had a very positive performance in the three-month period ended 31 March 2014, with sales up 12% to 18.6 million euros. Sales of Bemiparin in Spain (**Hibor**<sup>®</sup>) increased by 10% to 11.4 million euros, while international sales had a 13% rise to 7.2 million euros in the first quarter of 2014 supported



by the increased presence of Bemiparin, through strategic alliances, in countries where it was already present. Besides, ROVI has obtained registration approval in China and will launch Bemiparin in the Chinese market already in 2014.

Sales of **Vytorin**<sup>®</sup> and **Absorcol**<sup>®</sup>, the first of the five licenses of MSD, launched in January 2011, increased by 25% to 4.8 million euros in the three-month period ended 31 March 2014.

Sales of **Corlontor**<sup>®</sup>, a specialty product for stable angina and chronic heart failure from Laboratoires Servier, rose 22% to 3.2 million euros in the first quarter of 2014.

Sales of **Medicebran**<sup>®</sup> and **Medikinet**<sup>®</sup>, specialty products from Medice indicated for the treatment of ADHD (Attention Deficit and Hyperactivity Disorder) in children and teenagers, launched in December 2013 and marketed on exclusivity basis by ROVI in Spain, reached 1.8 million euros in the three-month period ended 31 March 2014.

In November 2013, ROVI announced it had signed an agreement with Novartis Farmacéutica, S.A. for marketing **Hirobriz**<sup>®</sup> **Breezhaler**<sup>®</sup> and **Ulunar**<sup>®</sup> **Breezhaler**<sup>®</sup> in Spain. Both products are inhaled bronchodilators for patients with respiratory difficulties due to a pulmonary disease known as Chronic Obstructive Pulmonary Disease (COPD). ROVI is waiting for the local representative change approval for Hirobriz<sup>®</sup> Breezhaler<sup>®</sup>, therefore no sales were registered in the first quarter of 2014. ROVI expects to start commercialization of Hirobriz<sup>®</sup> Breezhaler<sup>®</sup> by mid 2014 and Ulunar<sup>®</sup> Breezhaler<sup>®</sup> by beginning 2015.

Sales of **Thymanax**<sup>®</sup>, an innovative antidepressant from Laboratoires Servier, launched in March 2010 and for which ROVI has a co-marketing agreement covering Spain, decreased by 2% to 2.6 million euros in the first quarter of 2014.

Sales of **Exxiv**<sup>®</sup>, a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 5% to 1.7 million euros in the three-month period ended 31 March 2014, mainly due to a continued deceleration of the COX-2 market.

Sales of **Osseor**<sup>®</sup>, a specialty product for the treatment of postmenopausal osteoporosis from Laboratoires Servier, decreased by 76% to 0.3 million euros in the first quarter of 2014. This reduction is partially explained by the decision taken by the EMA (European Medicines Agency) in February 2014 to maintain the authorization to commercialize strontium ranelate (Osseor) but with additional restrictions to its indication and limiting the use of the product to hospitals.

On 21<sup>st</sup> March of 2014, the Spanish government approved a Royal Decree regulating the Reference Price System and homogenous groups of medicines in the Spanish National Health System (see <http://www.boe.es/boe/dias/2014/03/25/pdfs/BOE-A-2014-3189.pdf>).



Among these new measures, (i) the incorporation to the system of those medicines that have been authorized for more than ten-years, although there is not a generic, given there is other medicine, which is different from the original and its licences, with the same active principle and method of administration and (ii) the reduction of the reference price to the lowest of the European Union. The impact of these measures will be minimum for ROVI.

This new package of measures is added to the four Royal Decree Laws approved since 2010 which have led to reductions of public pharmaceutical expenditure by 28% since that year. These measures will contribute to the Spanish pharmaceutical market fall of another 2% in 2014, according to Farmaindustria<sup>1</sup>. Despite the difficult situation that the pharmaceutical industry is going through, ROVI forecasts to continue growing.

Sales of **contrast imaging agents** and other hospital products increased by 4% to 6.0 million euros in the first quarter of 2014.

Sales of **over-the-counter pharmaceutical products** ("OTC") **and other** increased by 9% to 1.6 million euros in the first quarter of 2014 compared to the same period of the previous year, mainly as consequence of a better performance of EnerZona<sup>®</sup>, a range of products based on the principles of the Zone Diet.

**Toll manufacturing** sales decreased by 3% to 15.3 million euros in the first quarter of 2014 compared to the same period of the previous year. The positive evolution of the injectables plant, whose revenue increased by 16% to 4.4 million euros in the three-month period ended 31 March 2014, was offset by a 1.1 million euros revenue decline in the Frosst Ibérica plant to 10.9 million euros in the first quarter of 2014, as a consequence of a lower production for Merck Sharp and Dohme (MSD).

Recently, Frosst Ibérica has signed a partial renewal agreement for the current manufacturing and packaging agreement<sup>1</sup> with MSD for an additional five years period, that is, until 31 March 2020. This renewal is related to the product formulation activities and to the packaging activities for MSD's MAXALT<sup>TM3</sup> (rizatriptan benzoate) tablets and MAXALT-MLT<sup>TM</sup> (rizatriptan benzoate) orally disintegrating tablets. The current contract will remain in force (i) until April 2015 for the packaging activities of products to be sold outside Spain, and (ii) until 31 March 2017 for the packaging activities of the products intended to be marketed in Spain, in both cases as initially expected. Thanks to this renewal, Frosst Ibérica keeps a significant part of its turnover until April 2020.

<sup>1</sup> [http://www.farmaindustria.es/Farma\\_Public/Imprimir\\_Public/FARMA\\_124496?idDoc=FARMA\\_124496](http://www.farmaindustria.es/Farma_Public/Imprimir_Public/FARMA_124496?idDoc=FARMA_124496)

<sup>2</sup> <http://www.rovi.es/ficheros/notas/ingles/87i.pdf>

<sup>3</sup> MAXALT and MAXALT-MLT are trademarks of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co..

**Sales outside Spain** represented 36% of operating revenue in the first quarter of 2014 compared to 40% in the first quarter of 2013. This reduction is mainly due to the increase registered in domestic sales of pharmaceutical products.

**Gross profit** increased by 11% to 35.1 million euros in the three-month period ended 31 March 2014, reflecting an increase of 1.9 percentage points in the gross margin to 60.9% in the first quarter of 2014 from 59.0% in the first quarter of 2013. The decrease of the Bemiparin raw material cost impacted positively in the first quarter of 2014 gross margin.

**Research and development expenses** increased by 14% to 3.0 million euros in the first quarter of 2014, reflecting ROVI investments in products that are under development, mainly related to the Risperidone-ISM<sup>®</sup> project.

**Selling, general and administrative expenses** increased by 8% to 23.2 million euros in the three-month period ended 31 March 2014, compared to the same period of the previous year, mainly due to an increase in personnel costs.

**EBITDA** increased by 18% to 9.0 million euros in the three-month period ended 31 March 2014, compared to the same period of the previous year, reflecting a 1.5 percentage points rise in the EBITDA margin to 15.6% in the first quarter of 2014 up from 14.1% in the first quarter of 2013.

**Depreciation and amortisation expenses** increased by 31% to 2.1 million euros in the first quarter of 2014, mainly as a result of the new property plant and equipment and intangible assets purchases made during the last twelve months.

**EBIT** increased by 15% to 6.9 million euros in the three-month period ended 31 March 2014, compared to the same period of the previous year, reflecting a 0.8 percentage point rise in the EBIT margin to 12.0% up from 11.1% in the first quarter of 2013.

**Financial expense** increased by 43% in the first quarter of 2014, compared to the same period of the previous year. The financial expense line mainly includes the implicit interests registered as a result of the recognition at fair value of the reimbursable loans, at zero interest rate, granted by Public Administrations.

**Financial income** increased by 67% in the first quarter of 2014, compared to the same period of the previous year, mainly as a result of higher returns on financial investments.

The **effective tax rate** was 4.8% in the first quarter of 2014 compared to 3.1% in the first quarter of 2013. This favourable effective tax rate is due to the deduction of existing research and development expenses and the capitalisation of negative tax bases resulting from the



Frosst Ibérica, S.A. integration. As of 31 December 2013, Frosst Ibérica negative tax bases amounted to 57.5 million euros, of which 7.4 million euros will be used in the 2013 income tax and 1.9 million euros in the first quarter of 2014.

**Net profit** amounted to 5.9 million euros, an 11% increase compared to the same period of the previous year.

ROVI will pay a **dividend** of 0.1612 euros per share on 2013 earnings if the Shareholders General Meeting approves the application of the 2013 profit, under proposal of ROVI's Board of Directors. This proposed dividend would mean an increase of 18% compared to the dividend on 2012 earnings (0.1366 euros per share) and implies a 35% pay-out.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that, *"we are satisfied with the results for the first quarter of 2014. Operating revenue increased by 7% compared to the same period of the previous year, this way fulfilling our 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. EBITDA margin increased in the first quarter of 2014, mainly as a result of the operating leverage contributed by our last product launches. It is very gratifying to witness 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<sup>®</sup>, Medikinet<sup>®</sup> or Ulunar<sup>®</sup> and Hirobriz<sup>®</sup>, 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 improve the utilisation of our asset base"*.

### 3. Balance Sheet items

#### 3.1 Capital expenditure

ROVI invested 1.7 million euros in the first quarter of 2014, compared to 1.5 million euros in the first quarter of 2013. Of this amount:

- 0.8 million euros corresponds to investment capex related to the injectables facility mainly due to the preparation of the plant for the development of the ISM<sup>®</sup> project, versus 0.5 million euros in the first quarter of 2013;
- 0.3 million euros and 0.1 million euros correspond to investment capex related to the Granada and Alcalá (Frosst Ibérica) facilities respectively; and
- 0.5 million euros corresponds to expenditure on maintenance and other, vs. 1.0 million euros in the first quarter of 2013.



ROVI expects capital expenditure for 2014 to be below the 2013 figure (24.7 million euros), but above the 2012 level (13.7 million euros) due to the investments related to the Risperidone-ISM<sup>®</sup> project.

### 3.2 Debt

As of 31 March 2014, ROVI had total debt of 30.2 million euros, a 2% reduction versus the 31.0 million euros of total debt at the end of 2013. Debt with public administration represented, as of 31 March 2014, 82% of total debt while 97% of total debt is 0% interest rate debt.

<i>In thousand euros</i>	<b>31 March 14</b>	<b>31 December 13</b>
Bank borrowings	1,051	1,212
Debt with public administration	24,933	25,606
Debt from purchase of shares	4,244	4,160
<b>Total</b>	<b>30,228</b>	<b>30,978</b>

The debt from purchase of shares registered as of 31 March 2014 corresponds to the outstanding payment related to the Frosst Ibérica acquisition, which includes the payment of 0.7 million euros for the Frosst Ibérica shares acquisition (the first four payments, of 0.7 million euros each one, were executed on 31 March 2010, 31 March 2011, 20 April 2012 and 2 April 2013) and the payment of 3.5 million euros for the Frosst Ibérica working capital (the first three payments of 3.2 million euros each one were executed on 31 March 2011, 12 April 2012 and 2 April 2013). The outstanding debt of 4.2 million euros was paid on 3 April 2014.

### 3.3 Free cash flow

Free cash flow (net cash generated (used) from operating activities minus (plus) property, plant and equipment and intangible assets purchases (sales) plus interest received) decreased to -5.0 million euros in the first quarter of 2014 from 4.7 million euros in the first quarter of 2013, mostly as a result of an inventory increase of 2.7 million euros in the first quarter of 2014 (mainly due to a larger Bemiparin production) compared to an inventory reduction of 4.7 million euros in the first quarter of 2013 (as a consequence of a high stock level at the end of 2012).

### 3.4 Net and gross cash position

As of 31 March 2014, ROVI had a gross cash position of 30.2 million euros, compared to 36.7 million euros as of 31 December 2013, and a zero net cash position (available-for-sale financial assets plus deposits plus cash and cash equivalents minus short term and long term financial debt), compared to 5.8 million euros as of 31 December 2013.

### 3.5 Working capital

The increase in working capital in the first quarter of 2014 was mainly due to a 7.0 million euros increase in the "trade and other receivables" item. Inventories increased by 2.7 million euros in the same period mainly due to a larger Bemiparin production in the first quarter of 2014. Cash and cash equivalents decreased by 6.5 million euros in the first quarter of 2014 and the "trade and other payables" line decreased by 4.2 million euros in the mentioned period.

As of 31 March 2014, Social Security and Public Administrations total debt with ROVI amounted to 9.4 million euros, of which 7.9 million euros in Spain and the other 1.5 million euros in Portugal. All this debt is expected to be collected through the usual channels.

## 4. Guidance for 2014

For 2014, ROVI expects a **mid-to-high single digit growth rate for the operating revenue** despite (i) a 2% contraction in the Spanish pharmaceutical market as forecast by Farmaindustria<sup>1</sup>, the Spanish Pharmaceutical Association, and (ii) the continued decreases in the pharmacy retail market at least until 2016 forecast by IMS Health<sup>2</sup>.

ROVI expects its growth drivers to be Bemiparin, the new license agreements (Medikinet<sup>®</sup> and Hirobriz<sup>®</sup>), its existing portfolio of specialty pharmaceuticals, contribution from recent launches such as Vytorin<sup>®</sup> and Absorcol<sup>®</sup>, new product distribution licenses and new contracts in the toll manufacturing area.

## 5. Research and Development update

As it has been previously informed, ROVI has made remarkable progress in its most advanced candidate for the own proprietary drug delivery platform, Risperidone ISM<sup>®</sup>, a long-acting injectable second-generation antipsychotic drug.

ROVI is building in Madrid a manufacturing plant for new medicines using the ISM<sup>®</sup> technology; this is being equipped with a very innovative, and unique in its class, machinery for filling solid compounds in syringes under good manufacturing practices.

---

<sup>1</sup> [http://www.farmaindustria.es/Farma\\_Public/Imprimir\\_Public/FARMA\\_124496?idDoc=FARMA\\_124496](http://www.farmaindustria.es/Farma_Public/Imprimir_Public/FARMA_124496?idDoc=FARMA_124496)

<sup>2</sup> IMS Market Prognosis March 2013

The ISM<sup>®</sup> technology was initially validated by a “proof of concept” phase I study on healthy subjects, and in 2013 the new phase I multicentre trial PRISMA-1 (*Pharmacokinetic evaluation of Risperidone ISM long-Acting injection - 1*) started and patients’ enrolment has been successfully accomplished. The PRISMA-1 is an open-label, randomized, parallel study to evaluate the pharmacokinetics, safety, and tolerability of a single intramuscular injection of Risperidone ISM<sup>®</sup> at three different dose strengths in subjects with schizophrenia or schizoaffective disorder<sup>1</sup>; after a recent interim analysis it has been decided not to perform an additional escalating-dose stage, since the initial selected doses have achieved the optimal plasma levels and preliminary PK data have shown dose-proportionality. Consequently, the final results of the PRISMA-1 trial are expected by the 3Q2014.

Besides, the patients’ enrolment of the phase II trial PRISMA-2<sup>2</sup> has already started in several USA centres for evaluating the safety and pharmacokinetics of Risperidone ISM<sup>®</sup> after four monthly intramuscular doses (gluteus or deltoids) in schizophrenic subjects. The results from this study are expected by the first half of 2015.

Both PRISMA-1 and 2 studies, along with a thorough population pharmacokinetics modelling, will provide trustworthy information for tuning the final design of the phase III program, which is planned to start in 2015.

## 6. Key operating and financial events

### 6.1 ROVI announces the agreement to market Hirobriz<sup>®</sup> Breezhaler<sup>®</sup> and Ulunar<sup>®</sup> Breezhaler<sup>®</sup> in Spain

In November 2013, ROVI announced it had signed an agreement with Novartis Farmacéutica, S.A. for marketing Hirobriz<sup>®</sup> Breezhaler<sup>®</sup> (Indacaterol maleate) and Ulunar<sup>®</sup> Breezhaler<sup>®</sup> (indacaterol maleate and glycopyrronium bromide) in Spain, which correspond to Novartis’ Onbrez<sup>®</sup> Breezhaler<sup>®</sup> and Ultibro<sup>®</sup> Breezhaler<sup>®</sup> products respectively.

Under the terms of this marketing agreement, ROVI will undertake the promotion and distribution in Spain both of Hirobriz<sup>®</sup> Breezhaler<sup>®</sup>, whose active ingredient is indacaterol maleate, and of Ulunar<sup>®</sup> Breezhaler<sup>®</sup>, which combines indacaterol maleate and glycopyrronium bromide. Both products are inhaled bronchodilators for patients with respiratory difficulties due to a pulmonary disease known as Chronic Obstructive Pulmonary Disease (COPD).

<sup>1</sup> *Pharmacokinetic, Safety, and Tolerability Study of Risperidone ISM<sup>®</sup> at Different Dose Strengths (PRISMA-1)*. [<http://clinicaltrials.gov/show/NCT01788774>].

<sup>2</sup> *Pharmacokinetics and Tolerability Study of Risperidone ISM<sup>®</sup> in Schizophrenia (PRISMA-2)*. [<http://clinicaltrials.gov/show/NCT02086786>].



Indacaterol maleate delivered through the Breezhaler<sup>®</sup> device is indicated for maintenance bronchodilator treatment of airflow obstruction in adult patients with COPD. Indacaterol belongs to a group of bronchodilator drugs called beta2-adrenergic agonists, which, when inhaled, relax the small airway wall muscles of the lungs, helping to open the airways and ease the inflow and outflow of air.

The combination of indacaterol maleate and glycopyrronium bromide delivered through the Breezhaler<sup>®</sup> device is the first once-daily dual bronchodilator for the maintenance treatment of COPD to be approved both in Europe and in Japan. It is expected that dual bronchodilation will set a new standard of care for COPD by combining the proven efficacy benefits and safety profiles of two established treatments for COPD: indacaterol maleate and glycopyrronium bromide.

Hirobriz<sup>®</sup> Breezhaler<sup>®</sup> is already marketed in Spain, and ROVI will begin marketing it by mid 2014. Rovi expects to market the combination of indacaterol maleate and glycopyrronium bromide delivered through the Breezhaler<sup>®</sup> device by beginning 2015.

According to IMS Health data, during the twelve months to September 2013 (MAT September 2013) market sales of inhaled beta 2 stimulants (which include Hirobriz<sup>®</sup> Breezhaler<sup>®</sup>) stood at 39.7 million euros. There are no sales figures in the case of the combination, since it had not yet begun to be marketed in Spain, but the market for anticholinergics (alone and in combination), to which these products will belong, amounts to 156.6 million euros in Spain (MAT September 2013).

## **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>®</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  
+34 913756235  
[jlopez-belmonte@rovi.es](mailto:jlopez-belmonte@rovi.es)  
[www.rovi.es](http://www.rovi.es)

Javier López-Belmonte Encina  
Chief Financial Officer  
+34 913756266  
[javierlbelmonte@rovi.es](mailto:javierlbelmonte@rovi.es)  
[www.rovi.es](http://www.rovi.es)

Marta Campos Martínez  
Investor Relations  
+34 912444422  
[mcampos@rovi.es](mailto:mcampos@rovi.es)  
[www.rovi.es](http://www.rovi.es)

Virginia Pérez Repes  
Investor Relations  
+34 912444422  
[vperez@rovi.es](mailto:vperez@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, 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 MARCH 2014 AND 31 DECEMBER 2013

(Thousands of euros)

	31 March 2014	31 December 2013
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, Plant and Equipment	59,840	60,199
Intangible assets	14,393	14,468
Deferred tax assets	7,806	7,517
Available-for-sale financial assets	16,121	16,121
Financial receivables	135	135
	<b>98,295</b>	<b>98,440</b>
<b>Current assets</b>		
Inventories	61,406	58,747
Trade and other receivables	62,884	55,919
Current income tax assets	1,140	3,416
Cash and cash equivalents	12,866	19,401
	<b>138,296</b>	<b>137,483</b>
<b>Total assets</b>	<b>236,591</b>	<b>235,923</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS AS OF 31 MARCH 2014 AND 31 DECEMBER 2013**

(Thousands of euros)

	<b>31 March 2014</b>	<b>31 December 2013</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	(1,208)	(782)
Retained earnings and voluntary reserves	141,965	118,943
Profit for the year	5,930	23,022
Reserve for available-for-sale assets	(319)	(319)
<b>Total equity</b>	<b>149,968</b>	<b>144,464</b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>		
Financial debt	21,510	22,578
Deferred income tax liabilities	2,449	2,637
Non-current deferred revenue	8,582	7,904
	<b>32,541</b>	<b>33,119</b>
<b>Current liabilities</b>		
Trade and other payables	39,250	43,485
Financial debt	8,718	8,400
Current deferred revenue	3,990	4,084
Provisions for other liabilities and charges	2,124	2,371
	<b>54,082</b>	<b>58,340</b>
<b>Total liabilities</b>	<b>86,623</b>	<b>91,459</b>
<b>Total equity and liabilities</b>	<b>236,591</b>	<b>235,923</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED INCOME STATEMENTS FOR THE THREE-MONTH PERIODS ENDED 31**  
**MARCH 2014 AND 31 MARCH 2013**

(Thousands of euros)

	Three-month periods ended 31 March	
	2014	2013
Revenue	57,624	53,781
Changes in inventories	2,659	(4,741)
Raw materials and consumables used	(26,140)	(18,445)
Employee benefit expenses	(14,589)	(12,871)
Other operating expenses	(11,524)	(10,463)
Depreciation, amortisation and impairment charges	(2,090)	(1,594)
Recognition of government grants on non financial non-current assets and other	947	321
<b>OPERATING PROFIT</b>	<b>6,887</b>	<b>5,988</b>
Finance income	185	111
Finance costs	(841)	(589)
<b>FINANCE COSTS - NET</b>	<b>(656)</b>	<b>(478)</b>
<b>PROFIT BEFORE INCOME TAX</b>	<b>6,231</b>	<b>5,510</b>
Income tax	(301)	(172)
<b>PROFIT FOR THE YEAR</b>	<b>5,930</b>	<b>5,338</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED CASH FLOW STATEMENTS FOR THE THREE-MONTH PERIODS ENDED 31**  
**MARCH 2014 AND 31 MARCH 2013**

(Thousands of euros)

	Three-month periods	
	2014	2013
<b>Cash flows from operating activities</b>		
Profit before income tax	6,231	5,510
<b>Adjustments for non-monetary transactions:</b>		
Amortisation	2,090	1,594
Interest income	(185)	(111)
Interest expense	841	589
Net changes in provisions	(247)	28
Grant for non-financial fixed assets and distribution licence income	(1,018)	(283)
<b>Changes in working capital</b>		
Trade and other receivables	(5,469)	(5,419)
Inventories	(2,659)	4,741
Trade and other payables	(4,735)	(2,757)
<b>Other collections and payments</b>		
Collection for distribution licenses	100	-
Interest paid	(6)	(13)
Income tax cash flow	1,500	2,213
<b>Net cash generated (used) from operating activities</b>	<b>(3,557)</b>	<b>6,092</b>
<b>Cash flows from investing activities</b>		
Purchases of intangible assets	(268)	(120)
Purchases of property, plant and equipment	(1,388)	(1,386)
Proceeds from sale of available-for-sale financial assets	-	957
Interest received	185	111
<b>Net cash generated (used) in investing activities</b>	<b>(1,471)</b>	<b>(438)</b>
<b>Cash flows from financing activities</b>		
Repayments of financial debt	(1,091)	(1,313)
Proceeds from financial debt	10	627
Purchase of treasury shares	(426)	(731)
Reissue of treasury shares	-	1,371
<b>Net cash generated in financing activities</b>	<b>(1,507)</b>	<b>(46)</b>
<b>Net (decrease)/increase in cash and cash equivalents</b>	<b>(6,535)</b>	<b>5,608</b>
<b>Cash and cash equivalents at beginning of the period</b>	<b>19,401</b>	<b>16,585</b>
<b>Cash and cash equivalents at end of the period</b>	<b>12,866</b>	<b>22,193</b>