



Nine-month period ended 30 September 2014 Results

6 November 2014



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



ROVI – Nine-month period ended 30 September 2014 Financial Results

ROVI reports an operating revenue growth of 8%, led by the strength of pharmaceutical specialties business, and an EBITDA growth of 14%

- **Operating revenue increased by 8% to 173.3 million euros in the nine-month period ended 30 September 2014, mainly driven by the strength of the prescription-based pharmaceutical business, where sales rose 9%, clearly outperforming the market, and by the toll manufacturing business which grew by 6%. Total revenue increased by 8% to 175.5 million euros in the nine-month period ended 30 September 2014.**
- **ROVI expects operating revenue to grow from mid to high single digit for the full year 2015, despite (i) a 2% contraction in the Spanish pharmaceutical market according to Farmaindustria¹, and (ii) the continued decreases in the pharmacy retail market at least until 2017 forecast by IMS Health².**
- **Sales of Bemiparin had an outstanding performance in the nine-month period ended 30 September 2014, with a 8% increase to 53.0 million euros; this growth came both from sales in Spain (+9%) and from international sales (+6%).**
- **Sales of Corlantor[®], from Servier, grew by 19% to 10.1 million euros in the nine-month period ended 30 September 2014. Sales of Absorcol[®] and Vytorin[®], the first of the five licenses of Merck Sharp & Dohme (MSD), increased by 19% to 15.3 million euros in the nine-month period ended 30 September 2014. Sales of Medicebran[®] and Medikinet[®], 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 5.1 million euros in the nine-month period ended 30 September 2014.**
- **EBITDA increased by 14% to 28.9 million euros in the nine-month period ended 30 September 2014, compared to the same period of the previous year, reflecting a 0.9 percentage points rise in the EBITDA margin to 16.7% in the**

¹ <http://www.farmaindustria.es/web/indicadores/mercado-farmaceutico/>

² <http://www.farmaindustria.es/web/documentos/boletines/> (boletín nº 108, April 2014)



nine-month period ended 30 September 2014 up from 15.8% in same period of the previous year.

- **Net profit increased by 6% to 19.9 million euros in the nine-month period ended 30 September 2014, compared to the same period last year.**

Madrid (Spain), 6 November 2014, 8:00 AM CET - ROVI released today its financial results for the nine-month period ended on 30 September 2014.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that *"in the nine-month period ended 30 September 2014, we reached an 8% operating revenue growth mainly driven by the strength of our specialty pharmaceutical area and our toll manufacturing area, specially of the injectables plant. Sales of prescription-based pharmaceutical products rose 9% in this period despite the difficulties that the Spanish pharmaceutical market is going through. Pharmaceutical expenditure covering 12-month period ending August 2014 decreased by more than 3.4 billion euros (-27%) compared to historic maximum reached in May 2010. Nevertheless, we forecast to continue growing thanks to, among others, our flagship product, Bemiparin, which is contributing significantly to this growth. In the nine-month period ended 30 September 2014, Bemiparin sales increased by 9% in the domestic market and 6% in the international market. 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 5 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 our long acting injectable technology (ISM®); we expect to start a phase III trial with our ISM® technology in 2015 as well as to develop new phase I and advanced pre-clinical studies for other candidates next year".



1. Financial highlights

€ million	9M 2014	9M 2013	Growth	% Growth
Operating revenue	173.3	160.9	12.4	8%
Other income	2.2	1.1	1.1	102%
Total revenue	175.5	162.0	13.5	8%
Cost of sales	-69.8	-61.7	-8.1	13%
Gross profit	105.7	100.3	5.3	5%
% margin	61.0%	62.3%		-1.4pp
R&D expenses	-8.9	-7.8	-1.1	14%
Other SG&A	-67.9	-67.1	-0.8	1%
EBITDA	28.9	25.4	3.5	14%
% margin	16.7%	15.8%		0.9pp
EBIT	22.4	20.5	1.9	10%
% margin	12.9%	12.7%		0.2pp
Net profit	19.9	18.7	1.2	6%

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 nine months of 2014 and the comparative information for 2013 (balance sheet) and for the first nine months 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 8% to 173.3 million euros in the nine-month period ended 30 September 2014, driven by the strength of the specialty pharmaceutical business, where sales rose 9% to 124.9 million euros, and by the toll manufacturing business which grew by 6% to 48.2 million euros.

Sales of **prescription-based pharmaceutical** products rose 9% to 101.0 million euros in the nine-month period ended 30 September 2014.

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, had a positive performance in the nine-month period ended 30 September 2014, with sales up 8% to 53.0 million euros. Sales of Bemiparin in Spain (**Hibor**[®]) increased by 9% to 34.4 million euros, while international sales had a 6% rise to 18.6 million euros in the nine-month period ended 30 September 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 in the first quarter of 2015.

Sales of **Vytorin**[®] and **Absorcol**[®], the first of the five licenses of MSD, launched in January 2011, increased by 19% to 15.3 million euros in the nine-month period ended 30 September 2014.

Sales of **Corlantor**[®], a specialty product for stable angina and chronic heart failure from Laboratoires Servier, rose 19% to 10.1 million euros in the nine-month period ended 30 September 2014.

Sales of **Medicebran**[®] and **Medikinet**[®], 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 5.1 million euros in the nine-month period ended 30 September 2014.

In November 2013, ROVI announced it had signed an agreement with Novartis Farmacéutica, S.A. for marketing **Hirobriz**[®] **Breezhaler**[®] and **Ulunar**[®] **Breezhaler**[®] 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 was waiting for the approval as local marketer for Hirobriz[®] Breezhaler[®] (which was obtained in September), therefore no sales were registered in the nine-month period ended 30 September 2014. **ROVI expects to start commercialization of Hirobriz[®] Breezhaler[®] and Ulunar[®] Breezhaler[®] in the last quarter of 2014.**

Sales of **Thymanax**[®], an innovative antidepressant from Laboratoires Servier and for which ROVI has a co-marketing agreement covering Spain, decreased by 7% to 7.8 million euros in the nine-month period ended 30 September 2014.

Sales of **Exxiv**[®], a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 2% to 5.1 million euros in the nine-month period ended 30 September 2014, mainly due to a continued deceleration of the COX-2 market.

Sales of **Osseor**[®], a specialty product for the treatment of postmenopausal osteoporosis from Laboratoires Servier, decreased by 72% to 0.9 million euros in the nine-month period ended 30 September 2014. This reduction is mainly 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 21st 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, as long as there is another 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 has been minimum for ROVI.

This new package of measures is added to the four Royal Decree Laws approved since 2010 which have led to significant reductions of public pharmaceutical expenditure in the last 4 years. Pharmaceutical expenditure covering 12-month period ending August 2014 decreased by more than 3.4 billion euros (-27%) compared to historic maximum reached in May 2010. In addition, on 15th July of 2014, a new update of the reference price system of medicines in the Spanish National Health System was published in the Official State Gazette (BOE) (see <http://www.boe.es/boe/dias/2014/07/15/pdfs/BOE-A-2014-7472.pdf>) and it is already in force with a minimum impact for ROVI.

These measures will contribute to a Spanish pharmaceutical market slight rise of 1% in 2014 and a fall of 2% in 2015, according to Farmaindustria¹. In addition, continued decreases in the pharmacy retail market at least until 2017 are forecast by IMS Health². 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 5% to 18.2 million euros in the nine-month period ended 30 September 2014.

Sales of **over-the-counter pharmaceutical products** ("OTC") **and other** increased by 11% to 5.7 million euros in the nine-month period ended 30 September 2014 compared to the same period of the previous year, mainly as consequence of a better performance of EnerZona[®], a range of products based on the principles of the Zone Diet.

Toll manufacturing sales increased by 6% to 48.2 million euros in the nine-month period ended 30 September 2014 compared to the same period of the previous year. The positive evolution of the injectables plant, whose revenue increased by 17% to 19.7 million euros in the nine-month period ended 30 September 2014 largely offset the 0.3 million euros revenue decline in the Frosst Ibérica plant to 28.5 million euros in the nine-month period ended 30 September 2014, as a consequence of a lower production for Merck Sharp and Dohme (MSD).

¹ <http://www.farmaindustria.es/web/indicadores/mercado-farmaceutico/>

² <http://www.farmaindustria.es/web/documentos/boletines/> (boletín nº 108, April 2014)

Sales outside Spain increased by 3% to 63.1 million euros in the nine-month period ended 30 September 2014 compared with the same period of the previous year. Sales outside Spain represented 36% of operating revenue in the nine-month period ended 30 September 2014.

Gross profit increased by 5% to 105.7 million euros in the nine-month period ended 30 September 2014, reflecting a decrease of 1.4 percentage points in the gross margin to 61.0% in the nine-month period ended 30 September 2014 from 62.3% in the nine-month period ended 30 September 2013. This gross margin reduction is mainly due to the increase in volumes manufactured for clients being invoiced for materials in the injectables plant, contributing with lower margins. The decrease of the Bemiparin raw material cost impacted positively in the nine-month period ended 30 September 2014 gross margin.

Research and development expenses increased by 14% to 8.9 million euros in the nine-month period ended 30 September 2014, reflecting ROVI investments in products that are under development, mainly related to the Risperidone-ISM[®] project.

Selling, general and administrative expenses increased by 1% to 67.9 million euros in the nine-month period ended 30 September 2014, compared to the same period of the previous year, mainly due to an increase in personnel costs.

EBITDA increased by 14% to 28.9 million euros in the nine-month period ended 30 September 2014, compared to the same period of the previous year, reflecting a 0.9 percentage points rise in the EBITDA margin to 16.7% in the nine-month period ended 30 September 2014 up from 15.8% in the same period of the previous year.

Depreciation and amortisation expenses increased by 31% to 6.5 million euros in the nine-month period ended 30 September 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 10% to 22.4 million euros in the nine-month period ended 30 September 2014, compared to the same period of the previous year, reflecting a 0.2 percentage points rise in the EBIT margin to 12.9% up from 12.7% in the nine-month period ended 30 September 2013.

Financial expense increased by 57% in the nine-month period ended 30 September 2014, compared to the same period of the previous year mainly due to the registration of the interests related to the return of the outstanding amount (10.4 million euros) of a 11.9 million euros loan granted by the Ministry of Health, Social Services and Equality for the development of the vaccine project in 2009. The financial expense line also includes the implicit interests registered as a result of the recognition at fair value of reimbursable loans, at zero interest rate, granted by Public Administrations.



Financial income increased by 92% in the nine-month period ended 30 September 2014, compared to the same period of the previous year, mainly as a result of the registration of interest on late payments from certain hospitals.

The **effective tax rate** was 5.2% in the nine-month period ended 30 September 2014 compared to 4.1% in the same period of the previous year. This favourable effective tax rate is due to the deduction of existing research and development expenses and the capitalisation of negative tax bases from Frosst Ibérica, S.A. As of 31 December 2013, Frosst Ibérica negative tax bases amounted to 57.5 million euros, of which 7.4 million euros were used in the 2013 income tax and 6.2 million euros to be used in the nine-month period ended 30 September 2014.

On 20 June 2014, the Spanish Government announced a deep tax reform, to be introduced from January 2015, in order to simplify taxes, reduce retentions and improve Spanish companies' competitiveness (see [http://www.minhap.gob.es/Documentacion/Publico/GabineteMinistro/Varios/Reforma%20Fiscal%20\(en%20ingl%C3%A9s\).pdf](http://www.minhap.gob.es/Documentacion/Publico/GabineteMinistro/Varios/Reforma%20Fiscal%20(en%20ingl%C3%A9s).pdf)). These suggested tax measures would positively affect ROVI income statement and income tax payable rate. ROVI expects to maintain an effective tax rate from mid to high single digit for the following years.

The tax reform content is still pending to be approved. Among the suggested tax measures that would affect corporate income tax, it should be noted that:

- ✓ the tax rate is reduced from 30% to 28% in 2015 and to 25% from 2016;
- ✓ tax losses may offset positive taxable income faster and without time limit from 2016; and
- ✓ R&D tax credit schedule is maintained.

Net profit amounted to 19.9 million euros, a 6% increase compared to the same period of the previous year.

The ROVI General Shareholders Meeting, on 12 June 2014, approved the payment of a **gross dividend** of 0.1612 euros per share on 2013 earnings. This dividend was paid on 3 July 2014 and it meant an increase of 18% compared to the dividend on 2012 earnings (0.1366 euros per share).

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that, "*we are satisfied with the results for the nine-month period ended 30 September 2014. Operating revenue increased by 8% compared to the same period of the previous year, 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 nine-month period ended 30*

September 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 Vytorin[®], Medikinet[®] or Ulunar[®] and Hirobriz[®], 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 12.2 million euros in the nine-month period ended 30 September 2014, compared to 12.8 million euros in the nine-month period ended 30 September 2013. Of this amount:

- 6.4 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[®] project, versus 4.3 million euros in the nine-month period ended 30 September 2013;
- 2.2 million euros corresponds to investment capex related to the Granada facility mainly for the future implementation of a third production line, versus 0.4 million euros in the nine-month period ended 30 September 2013;
- 1.2 million euros corresponds to investment capex related to the Alcalá (Frosst Ibérica) facility, versus 0.8 million euros in the nine-month period ended 30 September 2013; and
- 2.4 million euros corresponds to expenditure on maintenance and other, vs. 7.2 million euros in the nine-month period ended 30 September 2013 (include capex invested for the exercise of the Purchase Option over Rhodogil).

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[®] project.

3.2 Debt

As of 30 September 2014, ROVI had total debt of 37.3 million euros. Debt with public administration, which is 0% interest rate debt, represented 44% of total debt as of 30 September 2014.

<i>In thousand euros</i>	30 September 14	31 December 13
Bank borrowings	20,725	1,212
Debt with public administration	16,568	25,606
Debt from purchase of shares	-	4,160
Total	37,293	30,978

The increase in bank borrowings is due to the collection of 20 million euros, of which 12 million euros came from European Investment Bank funds (through banking institutions) with interest rates ranging from 1.95% to 2.15% and payment calendars between 24 and 48 months with lack periods between 12 and 24 months.

In addition, debt with public administration was reduced by 9.0 million euros mainly due to the return of the outstanding amount (10.4 million euros) of a 11.9 million euros loan granted by the Ministry of Health, Social Services and Equality for the development of the vaccine project in 2009.

The debt from purchase of shares registered as of 31 December 2013 corresponded to the outstanding payment related to the Frosst Ibérica acquisition, which included the payment for the Frosst Ibérica shares acquisition and for the working capital. The outstanding debt of 4.2 million euros as of 31 December 2013 was paid on 3 April 2014.

Despite the new banking debt (20 million euros) obtained in the third quarter of 2014, total debt increased only by 6.3 million euros as of 30 September 2014 compared to total debt as of 31 December 2013.

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) increased by 26% up to 5.3 million euros in the nine-month period ended 30 September 2014 from 4.2 million euros in the same period of the previous year mainly as a result of (i) the decrease of 3.8 million euros in the "trade and other payables" item, compared to an increase of 7.0 million euros in the nine-month period ended 30 September 2013, and (ii) the increase of 1.1 million euros in the "trade and other receivables" item in the nine-month period ended 30 September 2014, compared to an increase of 12.1 million euros in the same period of the previous year.

3.4 Net and gross cash position

As of 30 September 2014, ROVI had a gross cash position of 36.1 million euros, compared to 36.7 million euros as of 31 December 2013, and net cash position (available-for-sale financial assets plus deposits plus cash and cash equivalents minus short term and long term financial debt) of -1.2 million euros, compared to 5.8 million euros as of 31 December 2013.

3.5 Working capital

The increase in working capital in the nine-month period ended 30 September 2014 was mainly due to a 4.7 million euros increase in inventories as a result of increasing Bemiparin production in this period. The "trade and other payables" item decreased by 3.8 million euros in the same period. Cash and cash equivalents increased by 8.8 million euros in the nine-month period ended 30 September 2014 and the "trade and other receivables" line increased by 1.1 million euros.

As of 30 September 2014, Social Security and Public Administrations total debt with ROVI amounted to 11.6 million euros, of which 10.0 million euros in Spain and the other 1.6 million euros in Portugal. Almost 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 slight rise of 1% in the Spanish pharmaceutical market as forecast by Farmaindustria¹, the Spanish Pharmaceutical Association, and (ii) the continued decreases in the pharmacy retail market at least until 2017 forecast by IMS Health².

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

5. Guidance for 2015

ROVI expects **operating revenue to grow from mid to high single digit for the full year 2015**, despite (i) a 2% contraction in the Spanish pharmaceutical market according to

¹ <http://www.farmaindustria.es/web/indicadores/mercado-farmaceutico/>

² <http://www.farmaindustria.es/web/documentos/boletines/> (boletín nº 108, April 2014).

Farmaindustria¹, and (ii) the continued decreases in the pharmacy retail market at least until 2017 forecast by IMS Health².

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

6. 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[®], a long-acting injectable second-generation antipsychotic drug.

ROVI is building in Madrid a manufacturing plant for new medicines using the ISM[®] 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.

The ISM[®] technology was initially validated by a “proof of concept” phase I study on healthy subjects¹, and the new phase I multicentre trial PRISMA-1 (*Pharmacokinetic evaluation of Risperidone ISM long-Acting injection - 1*), which started in 2014, has already finished. 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[®] at three different dose strengths in subjects with schizophrenia or schizoaffective disorder²; final results of the PRISMA-1 trial will be communicated shortly.

On the other hand, the patients’ enrolment of the PRISMA-2 study³ is already complete; this is phase II trial in several USA centres for evaluating the safety and pharmacokinetics of Risperidone ISM[®] after four monthly intramuscular doses (gluteus or deltoids) in schizophrenic subjects. The results from this study are expected by the 3Q2015.

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

¹ Farré M. et al. A clinical trial to evaluate the pharmacokinetics, safety and tolerability of single doses of risperidone with the novel long-acting injectable technology ISM[®] in healthy volunteers. *Eur Arch Psychiatry Clin Neurosci* 2011; 261 (Suppl 1): S57.

² *Pharmacokinetic, Safety, and Tolerability Study of Risperidone ISM[®] at Different Dose Strengths (PRISMA-1)*. [<http://clinicaltrials.gov/show/NCT01788774>].

³ *Pharmacokinetics and Tolerability Study of Risperidone ISM[®] in Schizophrenia (PRISMA-2)*. [<http://clinicaltrials.gov/show/NCT02086786>].

In addition, ROVI has filed an application with the European health authorities to obtain authorisation for the marketing of a low-molecular-weight heparin, a biosimilar of enoxaparin, in Europe. Said application is currently in the validation phase. Notwithstanding, the outcome of the registration and authorisation process (which may be favourable or unfavourable) cannot be known until it concludes. Likewise, ROVI has also filed an application with the FDA (U.S. Food and Drug Administration) to obtain authorisation to market the same drug and said application is currently in the validation phase.

7. Key operating and financial events

7.1 ROVI announces the agreement to market Hirobriz[®] Breezhaler[®] and Ulunar[®] Breezhaler[®] in Spain

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

Under the terms of this marketing agreement, ROVI will undertake the promotion and distribution in Spain both of Hirobriz[®] Breezhaler[®], whose active ingredient is indacaterol maleate, and of Ulunar[®] Breezhaler[®], 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).

Indacaterol maleate delivered through the Breezhaler[®] 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[®] 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[®] Breezhaler[®] is already marketed in Spain, and ROVI will begin marketing it in the last quarter of 2014. Rovi expects to market the combination of indacaterol maleate and glycopyrronium bromide, Ulunar[®] Breezhaler[®], also in the last quarter of 2014.

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[®] Breezhaler[®]) 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[®] 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



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Forward-looking statements

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

**APPENDIX 1**
LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS AS OF 30 SEPTEMBER 2014 AND 31 DECEMBER 2013

(Thousands of euros)

	30 September 2014	31 December 2013
ASSETS		
Non-current assets		
Property, Plant and Equipment	65,138	60,199
Intangible assets	15,239	14,468
Deferred tax assets	8,518	7,517
Available-for-sale financial assets	6,675	16,121
Financial receivables	136	135
	95,706	98,440
Current assets		
Inventories	63,477	58,747
Trade and other receivables	56,988	55,919
Current income tax assets	917	3,416
Cash and cash equivalents	28,241	19,401
	149,623	137,483
Total assets	245,329	235,923



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS AS OF 30 SEPTEMBER 2014 AND 31 DECEMBER 2013

(Thousands of euros)

	30 September 2014	31 December 2013
EQUITY		
Capital and reserves attributable to shareholders of the company		
Share capital	3,000	3,000
Legal reserve	600	600
Treasury shares	(2,739)	(782)
Retained earnings and voluntary reserves	133,983	118,943
Profit for the period	19,863	23,022
Reserve for available-for-sale assets	(215)	(319)
Total equity	154,492	144,464
LIABILITIES		
Non-current liabilities		
Financial debt	32,884	22,578
Deferred income tax liabilities	2,139	2,637
Non-current deferred revenue	8,992	7,904
	44,015	33,119
Current liabilities		
Trade and other payables	39,665	43,485
Financial debt	4,409	8,400
Current deferred revenue	731	4,084
Provisions for other liabilities and charges	2,017	2,371
	46,822	58,340
Total liabilities	90,837	91,459
Total equity and liabilities	245,329	235,923



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED INCOME STATEMENTS FOR THE NINE-MONTH PERIODS ENDED 30
SEPTEMBER 2014 AND 30 SEPTEMBER 2013

(Thousands of euros)

	Nine-month periods ended 30 September	
	2014	2013
Revenue	173,292	160,927
Cost of sales	(69,801)	(61,680)
Employee benefit expenses	(42,730)	(40,126)
Other operating expenses	(34,029)	(34,775)
Depreciation, amortisation and impairment charges	(6,516)	(4,977)
Recognition of government grants on non financial non-current assets and other	2,187	1,085
OPERATING PROFIT	22,403	20,454
Finance income	512	267
Finance costs	(1,959)	(1,250)
FINANCE COSTS - NET	(1,447)	(983)
PROFIT BEFORE INCOME TAX	20,956	19,471
Income tax	(1,093)	(795)
PROFIT FOR THE PERIOD	19,863	18,676



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED CASH FLOW STATEMENTS FOR THE NINE-MONTH PERIODS ENDED 30
SEPTEMBER 2014 AND 30 SEPTEMBER 2013

(Thousands of euros)

	Nine-month periods ended 30 September	
	2014	2013
Cash flows from operating activities		
Profit before income tax	20,956	19,471
Adjustments for non-monetary transactions:		
Amortisation	6,516	4,977
Interest income	(512)	(267)
Interest expense	1,959	1,250
Net changes in provisions for other liabilities and charges	(354)	694
Grant for non-financial fixed assets and distribution licence income	(1,593)	(1,194)
Changes in working capital		
Trade and other receivables	1,081	(11,719)
Inventories	(4,730)	(4,161)
Trade and other payables	(3,820)	7,009
Other collections and payments		
Collection for distribution licenses	200	70
Interest paid	(2,554)	(165)
Income tax cash flow	(137)	790
Net cash generated (used) from operating activities	17,012	16,755
Cash flows from investing activities		
Purchases of intangible assets	(1,849)	(5,974)
Purchases of property, plant and equipment	(10,377)	(6,836)
Proceeds from sale of available-for-sale financial assets	9,590	8,958
Contracting short term bank deposits	-	(103)
Interest received	512	267
Net cash generated (used) in investing activities	(2,124)	(3,688)
Cash flows from financing activities		
Repayments of financial debt	(17,745)	(8,479)
Proceeds from financial debt	21,636	793
Purchase of treasury shares	(3,177)	(2,344)
Dividends paid	(8,042)	(6,780)
Reissue of treasury shares	1,280	4,223
Net cash generated (used) in financing activities	(6,048)	(12,587)
Net (decrease)/increase in cash and cash equivalents	8,840	480
Cash and cash equivalents at beginning of the period	19,401	16,585
Cash and cash equivalents at end of the period	28,241	17,065