



Full Year 2014 Results

26 February 2015



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



ROVI – Full Year 2014 Financial Results

ROVI reports total revenue growth of 10% and recurrent EBITDA growth of 18%, reaching record EBITDA and net profit figures

- Operating revenue increased by 9% to 238.0 million euros in 2014, mainly driven by the strength of the prescription-based pharmaceutical business, where sales rose 11%, clearly outperforming the market, and by the toll manufacturing business which grew by 9%. Total revenue increased by 10% to 240.9 million euros in 2014, more than doubling total revenue for 2007 when ROVI held its IPO.
- The 2014 guidance (mid-to-high single digit growth rate in operating revenues) was achieved reaching the highest part of the range, compared to the slight increase of 2% experienced by the Spanish pharmaceutical market in 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) a zero to negative spending growth on medicines in Spain for the period 2014-2018 forecast by IMS Health².
- Sales of Bemiparin had an outstanding performance in 2014, with a 9% increase to 72.7 million euros; this growth came both from sales in Spain (+9%) and from international sales (+8%).
- Sales of Corlantor[®], from Servier, grew by 15% to 13.9 million euros in 2014. Sales of Absorcol[®] and Vytorin[®], the first of the five licenses of Merck Sharp & Dohme (MSD), increased by 20% to 21.2 million euros in 2014.
- Sales of Hirobriz[®] Breezhaler[®] and Ulunar[®] Breezhaler[®], both inhaled bronchodilators from Novartis for patients with respiratory difficulties due to a pulmonary disease known as Chronic Obstructive Pulmonary Disease (COPD),

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

²<http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=266e05267ae9410VgnVCM10000076192ca2RCRD&vgnnextchannel=736de5fda6370410VgnVCM10000076192ca2RCRD&vgnnextfmt=default>



launched in Spain in the fourth quarter of 2014, reached 2.1 million euros in 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 7.5 million euros in 2014.**
- **EBITDA increased by 13% to 36.6 million euros in 2014, reaching the highest EBITDA figure in ROVI's history. EBITDA margin stood at 15.4%, reflecting a 0.5 percentage points rise from 14.9% in 2013. The 2013 EBITDA figure includes a one-off profit of 1.4 million euros as a result of Frosst Ibérica tax inspection for the tax periods 2006, 2007 and 2008. This one-off profit is related to the compensation received from the owner of Frosst Ibérica during the years inspected due to the reduction in the negative tax bases from those years. Excluding the impact of this one-off profit registered in 2013, EBITDA increased by 18% in 2014 reflecting a 1.1 percentage points rise in the EBITDA margin to 15.4% from 14.3% in 2013.**
- **Net profit increased by 5% to 24.1 million euros in 2014, which also represented a record figure in ROVI's history. Excluding the impact of the one-off income of 1.4 million euros registered in 2013, net profit increased by 11% in 2014. Thanks to this positive performance, ROVI will propose to the Shareholders General Meeting a dividend of 0.1690 euros per share on 2014 earnings. This dividend would mean an increase of 5% compared to the dividend on 2013 earnings (€0.1612).**

Madrid (Spain), 26 February 2015, 8:00 AM CET - ROVI released today its financial results for the fiscal year ending on 31 December 2014.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that *"in 2014, we reached an important 9% operating revenue growth mainly driven by the strength of our specialty pharmaceutical area and our toll manufacturing area, especially of the injectables plant. Sales of prescription-based pharmaceutical products rose 11% in 2014 despite the difficulties that the Spanish pharmaceutical market is going through. Pharmaceutical expenditure covering 12-month period ending December 2014 decreased by more than 3.3 billion euros (-26%) 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 2014, Bemiparin sales increased by 9% in the domestic market*



and 8% 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 marketing of Medicebran® and Medikinet®, from Medice, on exclusivity basis in Spain from December 2013, and the entrance in the respiratory field through the launch of Hirobriz® Breezhaler® and Ulunar® Breezhaler®, from Novartis, in Spain in the fourth quarter of 2014, 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 a new phase I study for another candidate next year. Likewise, in 2014 we filed an application with the European health authorities and the FDA to obtain authorisation for the marketing of a low-molecular-weight heparin, a biosimilar of enoxaparin, both in Europe and the United States. They are currently in the assessment process in Europe and in the validation phase in the United States. We are hopeful of obtaining authorisation to market this product and the European registration process is expected to take between five and twelve months".

1. Financial highlights

€ million	2014	2013	Growth	% Growth
Operating revenue	238.0	217.6	20.5	9%
Other income	2.9	1.4	1.5	110%
Total revenue	240.9	218.9	22.0	10%
Cost of sales	-94.6	-84.9	-9.7	11%
Gross profit	146.3	134.1	12.3	9%
% margin	61.5%	61.6%		-0,1pp
R&D expenses	-12.0	-10.5	-1.5	14%
Other SG&A	-97.8	-92.6	-5.2	6%
Other income	-	1.4	n.a.	n.a.
EBITDA	36.6	32.4	4.2	13%
% margin	15.4%	14.9%		0,5pp
EBIT	27.7	25.5	2.2	9%
% margin	11.6%	11.7%		-0,1pp
Net profit	24.1	23.0	1.1	5%

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 2014 and the comparative information for 2013 are attached to this report (see Appendix 1).

2. Performance of the Group

Operating revenue increased by 9% to 238.0 million euros in 2014, driven by the strength of the specialty pharmaceutical business, where sales rose 10% to 172.2 million euros, and by the toll manufacturing business which grew by 9% to 65.6 million euros. Total revenue increased by 10% to 240.9 million euros in 2014, more than doubling total revenue for 2007 when ROVI held its IPO.

Sales of **prescription-based pharmaceutical** products rose 11% to 140.5 million euros in 2014.

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, had a positive performance in 2014, with sales up 9% to 72.7 million euros. Sales of Bemiparin in Spain (**Hibor**[®]) increased by 9% to 48.0 million euros, while international sales had an 8% rise to 24.7 million euros in 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 expects to launch Bemiparin in the Chinese market in the second quarter of 2015.

Sales of **Vytorin**[®] and **Absorcol**[®], the first of the five licenses of MSD, launched in January 2011, increased by 20% to 21.2 million euros in 2014.

Sales of **Corlentor**[®], a specialty product for stable angina and chronic heart failure from Laboratoires Servier, rose 15% to 13.9 million euros in 2014.

Sales of **Hirobriz**[®] **Breezhaler**[®] and **Ulunar**[®] **Breezhaler**[®], both inhaled bronchodilators from Novartis for patients with respiratory difficulties due to a pulmonary disease known as Chronic Obstructive Pulmonary Disease (COPD), launched in Spain in the fourth quarter of 2014, reached 2.1 million euros in 2014 (see section 6.3).

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 7.5 million euros in 2014.

Sales of **Thymanax**[®], an innovative antidepressant from Laboratoires Servier and for which ROVI has a co-marketing agreement covering Spain, decreased by 11% to 10.2 million euros in 2014.

Sales of **Exxiv**[®], a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 3% to 6.9 million euros in 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 77% to 1.0 million euros in 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 December 2014 decreased by more than 3.3 billion euros (-26%) 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 contributed to a Spanish pharmaceutical market slight rise of 2% in 2014.

In addition, a 2% fall of the Spanish pharmaceutical expenditure is expected for 2015, according to Farmaindustria¹, and a zero to negative spending growth on medicines in Spain for the period 2014-2018 is 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 24.6 million euros in 2014.

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

² <http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=266e05267aea9410VgnVCM10000076192ca2RCRD&vgnnextchannel=736de5fda6370410VgnVCM10000076192ca2RCRD&vgnnextfmt=default>

Sales of **over-the-counter pharmaceutical products** ("OTC") **and other** increased by 4% to 7.1 million euros in 2014 compared to 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 9% to 65.6 million euros in 2014 compared to 2013. The positive evolution of the injectables plant, whose revenue increased by 28% to 28.6 million euros in 2014 largely offset the 1.1 million euros revenue decline in the Frosst Ibérica plant to 37.0 million euros in 2014, as a consequence of a lower production for Merck Sharp and Dohme (MSD).

Sales outside Spain increased by 7% to 85.2 million euros in 2014 compared with the previous year. Sales outside Spain represented 36% of operating revenue in 2014.

Gross profit increased by 9% to 146.3 million euros in 2014, reflecting a decrease of 0.1 percentage points in the gross margin to 61.5% in 2014 from 61.6% in 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 2014 gross margin.

Research and development expenses increased by 14% to 12.0 million euros in 2014, reflecting ROVI investments in products that are under development, mainly related to the Risperidone-ISM[®] project.

Selling, general and administrative expenses increased by 6% to 97.8 million euros in 2014, compared to the same period of the previous year, mainly due to an increase in personnel costs.

As a result of Frosst Ibérica tax inspection for the tax periods 2006, 2007 and 2008, ROVI registered a one-off income of 1.4 million euros in 2013, on the "**Other income**" item, related to the compensation received from the owner of Frosst Ibérica during the years inspected due to the reduction in the negative tax bases from those years.

EBITDA increased by 13% to 36.6 million euros in 2014, reaching the highest EBITDA figure in ROVI's history. EBITDA margin stood at 15.4%, reflecting a 0.5 percentage points rise from 14.9% in 2013. Excluding the impact of the one-off income of 1.4 million euros registered in 2013, EBITDA increased by 18% in 2014 reflecting a 1.1 percentage points rise in the EBITDA margin to 15.4% from 14.3% in 2013.

Depreciation and amortisation expenses increased by 28% to 8.9 million euros in 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 9% to 27.7 million euros in 2014, compared to the previous year, reflecting a 0.1 percentage points decline in the EBIT margin to 11.6% down from 11.7% in 2013. Excluding the impact of the one-off income of 1.4 million euros registered in 2013, EBIT increased by 15% in 2014 reflecting a 0.6 percentage points rise in the EBIT margin to 11.6% from 11.1% in 2013.

Financial expense increased by 70% in 2014, compared to 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 78% in 2014, compared to 2013, mainly as a result of the registration of interest on late payments from certain hospitals.

The **effective tax rate** was 5.9% in 2014 compared to 5.1% in 2013. 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 2014, Frosst Ibérica negative tax bases amounted to 50.1 million euros, of which 7.7 million euros will be used in the 2014 income tax.

On 27 November 2014, a deep tax reform was approved by law (see <http://www.boe.es/boe/dias/2014/11/28/pdfs/BOE-A-2014-12328.pdf>) in order to simplify taxes, reduce withholding taxes and improve Spanish companies' competitiveness. These tax measures, that have been in force since January 2015, will 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.

Among the tax measures that will 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; and
- ✓ R&D tax credit schedule is maintained.

Net profit increased by 5% to 24.1 million euros in 2014, which also represented a record figure in ROVI's history. Excluding the impact of the one-off income of 1.4 million euros registered in 2013, net profit increased by 11% in 2014.

ROVI will pay a **dividend** of 0.1690 euros per share on 2014 earnings if the Shareholders General Meeting approves the application of the 2014 profit, under proposal of ROVI's Board of Directors. This proposed dividend would mean an increase of 5% compared to the dividend on 2013 earnings (0.1612 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 2014. Operating revenue increased by 9% compared to 2013, fulfilling our expectations and more than doubling total revenue for 2007 when ROVI held its IPO; and also it must be pointed out that net profit represented a record figure in ROVI's history 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 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 Volutsa[®], Ulunar[®], Hirobriz[®], Vytorin[®] or Medikinet[®], 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 25.1 million euros in 2014, compared to 24.7 million euros in 2013. Of this amount:

- 12.7 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 8.4 million euros in 2013;
- 4.6 million euros corresponds to investment capex related to the Granada facility mainly for the future implementation of a third production line, versus 0.5 million euros in 2013;
- 2.3 million euros corresponds to investment capex related to the Alcalá (Frosst Ibérica) facility, versus 2.0 million euros in 2013; and
- 5.5 million euros corresponds to expenditure on maintenance and other, vs. 13.8 million euros in 2013 (include capex invested for the exercise of the Purchase Option over Rhodogil).

3.2 Debt

As of 31 December 2014, ROVI had total debt of 36.3 million euros. Debt with public administration, which is 0% interest rate debt, represented 43% of total debt as of 31 December 2014.

<i>In thousand euros</i>	31 December 14	31 December 13
Bank borrowings	20,560	1,212
Debt with public administration	15,746	25,606
Debt from purchase of shares	-	4,160
Total	36,306	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 9.9 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 2014, total debt increased only by 5.3 million euros as of 31 December 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) decreased to -1.6 million euros in 2014 from 5.5 million euros in 2013 mainly due to (i) the increase of 8.8 million euros in the "inventories" item, compared to an increase of 2.5 million euros in 2013, as a result of increasing Bemiparin production in 2014 and (ii) the increase of 7.8 million euros in the "trade and other receivables" item in 2014, compared to an increase of 1.5 million euros in 2013 as a result of the collection of 8.1 million euros from the Spanish Public Administrations within the execution of the "Payment to Suppliers Plan" in 2013.

3.4 Net and gross cash position

As of 31 December 2014, ROVI had a gross cash position of 28.0 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 -8.3 million euros, compared to 5.8 million euros as of 31 December 2013.

3.5 Working capital

The increase in working capital in 2014 was mainly due to a 8.8 million euros increase in inventories as a result of increasing Bemiparin production in this period. In addition, the “trade and other receivables” item increased by 7.8 million euros in 2014. Cash and cash equivalents increased by 7.3 million euros in 2014 and the “trade and other payables” line increased by 11.5 million euros.

As of 31 December 2014, Social Security and Public Administrations total debt with ROVI amounted to 12.4 million euros, of which 10.7 million euros in Spain and the other 1.7 million euros in Portugal. Almost all this debt is expected to be collected through the usual channels.

4. 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 Farmaindustria¹, and (ii) a zero to negative spending growth on medicines in Spain for the period 2014-2018 forecast by IMS Health².

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

5. Research and Development update

The R&D programs of ROVI are mainly focused on the Glycomics and the ISM[®] platforms, the latest an own proprietary drug delivery system aimed to improve patients’ therapeutic compliance.

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

² <http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=266e05267ae9410VgnVCM10000076192ca2RCRD&vgnnextchannel=736de5fda6370410VgnVCM10000076192ca2RCRD&vgnnextfmt=default>

In 2014, ROVI has made notable steps forward in the development of the ISM® platform. On one hand, ROVI has built in Madrid a manufacturing plant for new medicines using the ISM® technology, which is equipped with a very innovative, and unique in its class, machinery for filling solid compounds in syringes under good manufacturing practices.

On the other hand, two key milestones were achieved last year:

- The final results of the new phase I multicentre trial PRISMA-1 (*Pharmacokinetic evaluation of Risperidone ISM long-Acting injection - 1*) were communicated last December, 2014. PRISMA-1 is an open label, randomized, parallel study, to evaluate the pharmacokinetics, safety and tolerability of one intramuscular injection of Risperidone ISM® at three different concentrations (50 mg, 75 mg y 100 mg) in 36 patients with schizophrenia or schizoaffective disorder¹. The results of PRISMA-1 pharmacokinetic study confirm that ISM® technology provides sustained delivery of risperidone, reaching therapeutic levels from day one and enabling administration once-monthly without the need for supplementary oral risperidone during the first weeks or initial dose injections (see also section 6.2).
- The patients' enrolment of the PRISMA-2 study² was complete; this is a phase II trial carried out 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 2H2015.

Finally, Glycomics represents the fundamentals of the company, and for this reason ROVI has been dedicating noteworthy efforts and investments during the past years for developing new antithrombotic products based on heparin derivatives. Accordingly, in 2014 ROVI 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. On the 9th of February, after the end of the validation phase, the assessment process started in order for ROVI to be granted the Marketing Authorisation in Europe of this drug. The European registration process for this drug is expected to take between five and twelve months. It should be noted in any case that the assessment process is subject to interruptions and extensions if the European health authorities require additional information. Likewise, it should be pointed out that the outcome of the registration process (which may be favourable or unfavourable) cannot be known until it concludes. In addition, in 2014 ROVI also filed an application with the FDA (U.S. Food and Drug Administration) to obtain authorisation to market the same drug and said

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

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

application is currently in the validation phase. ROVI will continue to inform on the European evaluation process, as well as on the registration process of the same drug before the FDA (U.S. Food and Drug Administration), as the calendar for registration, in both Europe and the United States, progresses.

6. Key operating and financial events

6.1 ROVI announces the agreement to market Volutsa® in Spain

ROVI announces it has signed an agreement with Astellas Pharma, S.A. (Astellas) to market Volutsa® (solifenacin succinate and tamsulosin hydrochloride) in Spain, which corresponds to Astellas' Vesomni® product.

Under the terms of this marketing agreement, ROVI will undertake the promotion and distribution in Spain of Volutsa®, a modified release tablet containing two active substances, solifenacin and tamsulosin. Solifenacin is an anticholinergic drug and tamsulosin belongs to a drugs group called alpha-antagonists. Volutsa® is indicated for the treatment of moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia (BPH) in men who are not adequately responding to treatment with monotherapy.

When the prostate becomes enlarged, urinary problems (voiding symptoms) such as urinary hesitancy (difficulty to initiate urination), reduction of the flow of urine (weak stream), urine leakage and sensation of incomplete emptying of the bladder, may occur. At the same time, the bladder may also be affected and it contracts spontaneously at times when urination is delayed. This causes bladder (storage) symptoms such as changes in the sensation of the bladder, urgency (having an uncontrollable urge to urinate) and a high urinary frequency to occur. Solifenacin reduces involuntary contractions of the bladder and increases the amount of urine that the bladder can hold. Tamsulosin allows the urine to pass more easily through the urethra, thereby facilitating urination.

ROVI has started to market Volutsa® in the first quarter of 2015, at the same time Astellas has started commercialising Vesomni®.

6.2 ROVI announces new positive results for the monthly injectable formulation of Risperidone-ISM

ROVI informed of the positive results from the clinical trial PRISMA-1, performed with a long acting formulation of risperidone in schizophrenic patients. PRISMA-1 is an open label, randomized, parallel study, to evaluate the pharmacokinetics, safety and tolerability of one

intramuscular injection of Risperidone ISM® at three different concentrations (50 mg, 75 mg y 100 mg) in 36 patients with schizophrenia or schizoaffective disorder¹.

As announced previously, the ISM® technology was validated by the development of a first Phase I study as “proof of concept” in healthy volunteers². Along the same line, the results of PRISMA-1 pharmacokinetic study confirm that ISM® technology provides sustained delivery of risperidone, reaching therapeutic levels from day one and enabling administration once-monthly without the need for supplementary oral risperidone during the first weeks or initial dose injections. Likewise, Risperidone ISM® was, in general terms, well tolerated and the adverse reactions registered were the expected ones of this antipsychotic. Therefore, the pharmacologic profile of Risperidone ISM® would not only facilitate adherence with treatment for schizophrenic patients, but also could be proposed as a correct medication to treat acute exacerbations of the disorder.

Furthermore, it has already been completed patients recruitment of phase II of “PRISMA-2”³ study, in several centres of the U.S.A. to evaluate safety and pharmacokinetic profile of Risperidone ISM® after the administration of four intramuscular doses (gluteal or deltoid injection) of 75 mg monthly in schizophrenic patients. Both PRISMA-1 and PRISMA-2 studies are expected to provide reliable information to adjust the design of phase III program, expected to start in 2015.

6.3 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

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

² *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.*

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

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.

ROVI has marketed Hirobriz[®] Breezhaler[®] and the combination of indacaterol maleate and glycopyrronium bromide, Ulunar[®] Breezhaler[®], since 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

For further enquiries, please contact:

Juan López-Belmonte Encina
Chief Executive Officer
+34 913756235
jlopez-belmonte@rovi.es
www.rovi.es

Javier López-Belmonte Encina
Chief Financial Officer
+34 913756266
javierbelmonte@rovi.es
www.rovi.es

Marta Campos Martínez
Investor Relations
+34 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 2014 AND 31 DECEMBER 2013

(Thousands of euros)

	31 December 2014	31 December 2013
ASSETS		
Non-current assets		
Property, Plant and Equipment	73,593	60,199
Intangible assets	17,206	14,468
Deferred tax assets	8,280	7,517
Available-for-sale financial assets	71	16,121
Financial receivables	137	135
	99,287	98,440
Current assets		
Inventories	67,567	58,747
Trade and other receivables	63,678	55,919
Current income tax assets	4,117	3,416
Cash and cash equivalents	26,671	19,401
	162,033	137,483
Total assets	261,320	235,923



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

(Thousands of euros)

	31 December 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	(2,813)	(782)
Retained earnings and voluntary reserves	133,569	118,943
Profit for the period	24,116	23,022
Reserve for available-for-sale assets	(2)	(319)
Total equity	158,470	144,464
LIABILITIES		
Non-current liabilities		
Financial debt	32,032	22,578
Deferred income tax liabilities	1,818	2,637
Non-current deferred revenue	6,883	7,904
	40,733	33,119
Current liabilities		
Trade and other payables	55,018	43,485
Financial debt	4,274	8,400
Current deferred revenue	798	4,084
Provisions for other liabilities and charges	2,027	2,371
	62,117	58,340
Total liabilities	102,850	91,459
Total equity and liabilities	261,320	235,923



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED INCOME STATEMENTS FOR THE FULL YEARS 2014 AND 2013

(Thousands of euros)

	Full Year	
	2014	2013
Revenue	238,047	217,587
Cost of sales	(94,578)	(84,895)
Employee benefit expenses	(58,085)	(55,619)
Other operating expenses	(51,663)	(47,401)
Depreciation, amortisation and impairment charges	(8,884)	(6,943)
Recognition of government grants on non financial non-current assets and other	2,855	1,358
Other income	-	1,385
OPERATING PROFIT	27,692	25,472
Finance income	545	307
Finance costs	(2,603)	(1,528)
FINANCE COSTS - NET	(2,058)	(1,221)
PROFIT BEFORE INCOME TAX	25,634	24,251
Income tax	(1,518)	(1,229)
PROFIT FOR THE PERIOD	24,116	23,022



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED CASH FLOW STATEMENTS FOR THE FULL YEARS 2014 AND 2013

(Thousands of euros)

	Full year	
	2014	2013
Cash flows from operating activities		
Profit before income tax	25,634	24,251
Adjustments for non-monetary transactions:		
Amortisation	8,884	6,943
Interest income	(545)	(307)
Impairment losses	2,865	1,844
Interest expense	2,603	1,528
Net changes in provisions for other liabilities and charges	(344)	720
Grant for non-financial fixed assets and distribution licence income	(2,268)	(1,127)
Changes in working capital		
Trade and other receivables	(7,746)	(1,419)
Inventories	(11,229)	(3,278)
Trade and other payables	11,533	3,607
Other collections and payments		
Collection for distribution licenses	210	70
Interest paid	(2,658)	(172)
Income tax cash flow	(3,937)	(2,844)
Net cash generated (used) from operating activities	23,002	29,816
Cash flows from investing activities		
Purchases of intangible assets	(4,201)	(12,005)
Purchases of property, plant and equipment	(20,853)	(12,678)
Proceeds of property, plant and equipment	38	40
Proceeds from sale of available-for-sale financial assets	16,201	11,957
Contracting short term bank deposits	-	(103)
Loans granted to related parties	-	(1,050)
Interest received	365	307
Net cash generated (used) in investing activities	(8,450)	(13,532)
Cash flows from financing activities		
Repayments of financial debt	(18,907)	(9,384)
Proceeds from financial debt	21,636	901
Purchase of treasury shares	(3,345)	(3,466)
Dividends paid	(8,042)	(6,780)
Reissue of treasury shares	1,376	5,261
Net cash generated (used) in financing activities	(7,282)	(13,468)
Net (decrease)/increase in cash and cash equivalents	7,270	2,816
Cash and cash equivalents at beginning of the period	19,401	16,585
Cash and cash equivalents at end of the period	26,671	19,401