

Full Year 2013 Results

27 February 2014



Laboratorios Farmacéuticos Rovi, S.A. and SubsidiariesInvestor Relations



ROVI – Full Year 2013 Results

ROVI reports an EBITDA growth of 20% and a net profit growth of 18%, underpinned by outstanding Bemiparin sales

- Operating revenue increased by 8% to 217.6 million euros in 2013, mainly driven by the strength of the prescription-based pharmaceutical business, where sales rose 14%, clearly outperforming the market.
- ➤ The 2013 guidance (mid-to-high single digit growth rate in operating revenues) has been achieved, despite the drop of 6% experienced by the Spanish pharmaceutical market in 2013.
- 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, and (ii) the continued decreases in the pharmacy retail market at least until 2016 forecast by IMS Health.
- ➤ Sales of Bemiparin had an outstanding performance in 2013, with a 20% increase to 66.7 million euros; this growth came both from sales in Spain (+20%) and from international sales (+20%).
- Sales of Corlentor[®], from Servier, grew by 31% to 12.0 million euros in 2013. Sales of Absorcol[®] and Vytorin[®], the first of the five licenses of Merck Sharp & Dohme (MSD), increased by 43% to 17.6 million euros in 2013.
- ➤ EBITDA increased by 20% to 32.4 million euros in 2013, surpassing the 30.0 million euro milestone for the first time ever in ROVI's history. EBITDA margin stood at 14.9%, reflecting a 1.5 percentage point rise from 13.4% in the previous year.
- Net profit increased by 18% to 23.0 million euros in 2013, compared to the previous year. Thanks to this positive performance, 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).



Madrid (Spain), 27 February 2014, 8:00 AM CET - ROVI released today its financial results for the fiscal year ending on 31 December 2013.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that "in 2013, we reached an excellent 8% operating revenue growth mainly driven by the strength of our specialty pharmaceutical area. We achieved this significant operating revenue growth despite the drop of 6% experienced by the Spanish pharmaceutical market in 2013, what means four years in a row of declines and an accumulate reduction of 27% since year 2009 or a cut of more than 3.300 million euros in annual pharmaceutical expenditure. In addition, and according to Farmaindustria¹, the Spanish pharmaceutical market will experience a new contraction in 2014. Nevertheless, and despite of the difficult situation that the pharmaceutical industry is going through, we forecast to continue growing.

Once again Bemiparin led the growth with a 20% increase in sales, and both in the domestic and in the international markets. We expect the continued internationalisation of our flagship product to be one of the Company's growth engines in the medium term.

Furthermore, the agreement with MSD allowed us to strengthen our toll manufacturing area, as it has been reflected in the results of the 2010-2013 period (136.8 million euros accumulated revenue in the mentioned period, amounting to 18% of total operating revenue). In 2013, sales of this area became weaker as a consequence of lower volumes manufactured for MSD compared to the exceptional high levels reached in 2012. Nevertheless, we expect our ability to acquire new clients, as we have already shown in the past, will allow us to get back to growth shortly. In addition, the MSD agreement helped us to reinforce our specialty pharmaceutical area, as we showed with the launch, in January 2011, of Vytorin® and Absorcol®, the first of the five licenses from MSD that will contribute to our growth in the coming years. This launch required a significant investment effort in human capital in 2011 in order to address new prescribers, but this effort has resulted in a significant sales growth (+73% GAGR 2011-2013) and in coming years we expect higher sales and relevant operating leverage. 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 ISM® technology, especially with the Risperidone-ISM® project development, whose phase II trial is planned to start 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".

¹ http://www.farmaindustria.es/Farma_Public/Imprimir_Public/FARMA_124496?idDoc=FARMA_124496 **ROVI** – Full Year 2013 Results



1. Financial highlights

€ million	2013	2012	Growth	% Growth
Operating revenue	217.6	201.9	15.7	8%
Other income	1.4	1.2	0.1	10%
Total revenue	218.9	203.2	15.8	8%
Raw materials used and changes in inventories	-84.9	-75.5	-9.4	12%
Gross profit	134.1	127.6	6.4	5%
% margin	61.6%	63.2%		<i>-1.6pp</i>
R&D expenses	-10.5	-9.2	-1.2	13%
Other SG&A	-92.6	-92.7	0.1	0%
Other income	1.4	1.3	0.1	10%
EBITDA	32.4	27.0	5.4	20%
% margin	<i>14.9%</i>	<i>13.4%</i>		+1.5pp
EBIT	25.5	21.7	3.8	18%
% margin	11.7%	<i>10.7%</i>		+1.0pp
Net profit	23.0	19.5	3.5	18%

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 2013 and the comparative information for 2012 are attached to this report (see Appendix 1).

2. Performance of the Group

Operating revenue increased by 8% to 217.6 million euros in 2013, driven by the strength of the specialty pharmaceutical business, where sales rose 13% to 156.8 million euros, despite the drop of 6% experienced by the Spanish pharmaceutical market in 2013 compared to the previous year.

Sales of **prescription-based pharmaceutical** products rose 14% to 126.6 million euros in 2013. In September 2012, ROVI and UCB reached an agreement under which they ended their commercial relationship with regards to Cimzia, which had been jointly co-promoted in Spain by ROVI and UCB since June 2010. Excluding the impact of Cimzia co-promotion in 2012, sales of prescription-based pharmaceutical products increased by 15% in 2013.



ROVI's low molecular weight heparin (LMWH), **Bemiparin**, had a very positive performance in 2013, with sales up 20% to 66.7 million euros. Sales of Bemiparin in Spain (**Hibor**®) increased by 20% to 43.8 million euros, while international sales also had a 20% rise to 22.9 million euros in 2013 supported by the increased presence of Bemiparin, through strategic alliances, in countries where it was already present, and by the launch of the product in four new countries during 2013: Romania, South Korea, Lebanon and United Arab Emirates. Besides, ROVI has recently obtained registration approval in China and will launch Bemiparin in the Chinese market already in 2014.

Sales of **Vytorin**[®] and **Absorcol**[®], the first of the five licenses of MSD, launched in January 2011, increased by 43% to 17.6 million euros in 2013.

Sales of **Corlentor**[®], a specialty product for stable angina and chronic heart failure from Laboratoires Servier, rose 31% to 12.0 million euros in 2013.

Sales of **Thymanax**[®], an innovative antidepressant from Laboratoires Servier, launched in March 2010 and for which ROVI has a co-marketing agreement covering Spain, decreased by 1% to 11.5 million euros in 2013 impacted by the latest measures package introduced by the Spanish Government in April 2012 (and effective on 1 July 2012) which is explained below. Nevertheless, sales of Thymanax[®] increased by 5% in the last quarter of 2013.

Sales of **Exxiv**[®], a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 1% to 7.1 million euros in 2013, mainly due to a slight deceleration of the COX-2 market.

Sales of **Osseor**[®], a specialty product for the treatment of postmenopausal osteoporosis from Laboratoires Servier, decreased by 31% to 4.2 million euros in 2013.

On 20th of April of 2012, the Spanish government announced a new package of measures in order to achieve savings of more than 7 billion euros in healthcare expenditure. These new measures were published on the official state gazette on the 24th of April (see http://www.boe.es/boe/dias/2012/04/24/pdfs/BOE-A-2012-5403.pdf).

Among these new measures, (i) the exclusion of some drugs from reimbursement and (ii) the pharmaceutical copayment became more relevant. The list of drugs excluded from reimbursement was published on the 29th of June 2012, without any material impact for the ROVI product portfolio, and the pharmaceutical copayment was effective from the 1st of July 2012. The introduction of the latest package of measures, especially the measure related to the pharmaceutical copayment, meant a monthly pharmaceutical expenditure drop of above 20% on average from July to December 2012 and the number of prescriptions was reduced monthly by 15% on average in the same period. This negative trend continued in 2013; according to the date released by the Ministry of Health, both the Spanish pharmaceutical



market and the number of prescriptions decreased by 6% in 2013 compared to the same period in the previous year. In conclusion, the average monthly pharmaceutical expenditure and the number of prescriptions have decreased by 19% and 14% respectively since the introduction of the latest package of measures (July 2012) and, according to Farmaindustria¹ estimates, pharmaceutical market will fall another 2% in 2014. 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 13% to 23.4 million euros in 2013.

Sales of **over-the-counter pharmaceutical products** ("OTC") **and Other** declined by 4% to 6.8 million euros in 2013 compared to the previous year, mainly as consequence of the reduction of consumption in the current Spanish economic environment.

Toll manufacturing sales decreased by 4% to 60.4 million euros in 2013 compared to the previous year. The positive evolution of the injectables plant, whose revenue increased by 17% to 22.3 million euros in 2013, was offset by a 6.1 million euros revenue decline in the Frosst Ibérica plant to 38.1 million euros in 2013, as a consequence of a lower production for Merck Sharp and Dohme (MSD) compared to the exceptionally high levels reached in 2012.

Recently, Frosst Ibérica has signed a partial renewal agreement for the current manufacturing and packaging agreement² 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^{TM3} (rizatriptan benzoate) tablets and MAXALT-MLTTM (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.

After 31 March 2015 there will be an increase in the spare capacity at the Frosst Ibérica facility. Nevertheless, ROVI expects to return shortly to the current usage levels by getting new customers and by increasing production to other current customers.

Sales outside Spain represented 37% of operating revenue in 2013 compared to 40% in 2012. This reduction is mainly due to the increase registered in domestic sales of pharmaceutical products.

http://www.farmaindustria.es/Farma_Public/Imprimir_Public/FARMA_124496?idDoc=FARMA_124496

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

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



Gross profit increased by 5% to 134.1 million euros in 2013, reflecting a decrease in the gross margin to 61.6% in 2013 from 63.2% in 2012, mainly as a result of:

- lower margins in the toll manufacturing business due to the increase of the production for clients for which ROVI buys the materials needed in the manufacturing process; and
- the price reduction of the contrast imaging agents and other hospital products that did not impede the achievement of higher sales as consequence of higher volume sold.

The decrease of the Bemiparin raw material cost impacted positively in the 2013 gross margin. During 2013, ROVI bought Bemiparin raw material at around 35 euros per million of international units (vs. close to 40 euros in 2012). ROVI expects an additional slight reduction in Bemiparin raw material cost during 2014.

Research and development expenses increased by 13% to 10.5 million euros in 2013, reflecting ROVI investments in products that are under development, mainly related to the Risperidone-ISM[®] project.

Selling, general and administrative expenses stood at 92.6 million euros in 2013, flat compared to the previous year, despite the increase in sales, thanks to (i) the reduction of the ROVI sales team as a consequence of the end of the commercial relationship with UCB regarding Cimzia in September 2012 and (ii) ROVI's strict cost control policy.

As a result of Frosst Ibérica tax inspection for the tax periods 2006, 2007 and 2008, ROVI registered a compensation of 1.3 million euros in 2012 results on the "**Other income**" item from the owner of Frosst Ibérica during the years inspected, who assumed the payment. On the same line, in 2013 an income of 1.4 million euros was registered related to the compensation received due to the reduction in the negative tax bases from years under inspection.

EBITDA increased by 20% to 32.4 million euros in 2013, compared to the previous year, reflecting a 1.5 percentage point rise in the EBITDA margin to 14.9% up from 13.4% in 2012, thanks to the increase in sales and the operating leverage of the business.

Depreciation and amortisation expenses increased by 31% to 6.9 million euros in 2013, mainly as a result of the new property plant and equipment and intangible assets purchases made during the last twelve months (see section 3.1).

EBIT increased by 18% to 25.5 million euros in 2013, compared to the previous year, reflecting a 1.0 percentage point rise in the EBIT margin to 11.7% up from 10.7% in 2012.



Financial expense decreased by 30% in 2013, compared to 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 decreased by 77% in 2013, compared to the previous year, mainly as a result of lower returns on financial investments.

The **effective tax rate** was 5.1% in 2013 compared to 6.4% in 2012. 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.

On the 13th July 2012, the Spanish Government approved by law a package of tax measures (http://www.boe.es/boe/dias/2012/07/14/pdfs/BOE-A-2012-9364.pdf) in order to guarantee budgetary stability and to promote competitiveness. Among these tax measures, the limitation of the negative tax bases to be offset, which was reduced to 25% from 50%, and the tax rate increase for the payment on account, from 27% to 29% for ROVI, as well as the minimum disbursement for this payment, from 8% to 12%, affect ROVI's income tax payable rate.

On the 27th December 2012, the Spanish Government approved by law a new package of tax measures (http://www.boe.es/boe/dias/2012/12/28/pdfs/BOE-A-2012-15650.pdf) in order to consolidate public finance and to promote economic activity. Among these tax measures, the limitation of up to 70% of the deduction in the tax base of amortization, both for tangible and intangible assets related to the periods 2013 and 2014, affects ROVI's income tax payable rate.

As a consequence of the signature, on 15 February 2013, of the Conformity Assessment arising from the corporate income tax inspection of ROVI group for the periods 2007 and 2008, the Group recorded a corporate income tax expense of 109 thousand euros in 2013. On the same date, the VAT tax inspection of ROVI group for the same periods ended without any payments to be assumed.

Net profit amounted to 23.0 million euros, an 18% increase compared to 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 2013. Operating revenue increased by 8% compared to 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 2013, 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 24.7 million euros in 2013, compared to 13.7 million euros in 2012. Of this amount:

- 8.4 million euros corresponds to investment capex related to the injectables facility mainly due to the acquisition of two inspection machines and to the preparation of the plant for the development of the ISM[®] project, versus 3.9 million euros in 2012 (mainly investments in order to prepare the plant for the FDA inspection);
- 2.0 million euros corresponds to investment capex related to the Alcalá facility (Frosst Ibérica), versus 3.7 million euros in 2012 (mainly in a new manufacturing module);
- 0.5 million euros corresponds to investment capex related to the Granada facility, versus 2.5 million euros in 2012 (when it was implemented a second production line); and
- 2.7 million euros corresponds to expenditure on maintenance, vs. 3.6 million euros in 2012.

The rest of the capex invested in 2013 corresponds to the exercise of the Purchase Option over Rhodogil[®] (see section 6.1) and to the new distribution agreements (see sections 6.2 and 6.3).

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 31 December 2013, ROVI had total debt of 31.0 million euros, a 19% reduction versus the 38.4 million euros of total debt at the end of 2012. Debt with public administration represented, as of 31 December 2013, 83% of total debt while 96% of total debt is 0% interest rate debt.

In thousand euros	31 December 13	31 December 12
Bank borrowings	1,212	2,813
Debt with public administration	25,606	27,505
Debt from purchase of shares	4,160	8,072
Total	30,978	38,390

The debt from purchase of shares registered as of 31 December 2013 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 will be paid on 31 March 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 5.5 million euros in 2013 from 7.3 million euros in 2012, mainly as a result of (i) the 80% capital expenditure increase in 2013 compared to the previous year, and (ii) the collection of 8.1 million euros from the Spanish Public Administrations within the execution of the "Payment to Suppliers Plan" in 2013, which corresponded to pending invoices due for collection by 31st of May 2013, compared to 13.5 million euros collected in 2012 from de Autonomous Regions within the first phase of the "Payment to Suppliers Plan".

Net cash generated from operating activities rose 10.2 million euros to 29.8 million euros, although this increase was offset by the 11.0 million euros higher capex due to the purchase of new products and in-license agreements.

3.4 Net and gross cash position

As of 31 December 2013, ROVI had a gross cash position of 36.7 million euros, compared to 45.9 million euros as of 31 December 2012, and a net cash position (available-for-sale



financial assets plus deposits plus cash and cash equivalents minus short term and long term financial debt) of 5.8 million euros, compared to 7.5 million euros as of 31 December 2012, providing it with a high level of financial flexibility.

3.5 Working capital

Working capital during 2013 experienced almost no change as the increase in "inventories" (+2.5 million euros due to a larger Bemiparin production in 2013) and in "trade and other receivables" (+1.5 million euros related to the higher level of sales) was partially offset by an increase in "trade and other payables" (+3.6 million euros).

On the 28th June 2013, the Spanish Government approved by law a financing plan for the payment of suppliers in order to cancel outstanding debts due for collection up until 31st May 2013. This new "Payment to Suppliers Plan" was published in the official state gazette on the 29th of June (see http://www.boe.es/boe/dias/2013/06/29/pdfs/BOE-A-2013-7063.pdf).

On the 10th October 2013, the Spanish Government announced the start of the process for the payment of the last phase of the "2013 Suppliers Plan" for the Autonomous Communities (see http://www.minhap.gob.es/Documentacion/Publico/GabineteMinistro/Notas%20Prensa/2013/S.E.%20ADMINISTRACIONES%20PUBLICAS/10-10-13%20NP%20Plan%20de%20Morosidad.pdf). Within this last phase of the aforementioned "2013 Suppliers Plan", ROVI has collected 8.1 million euros at the end of 2013, remaining only 0.1 million euros of pending invoices due for collection up to 31 May 2013.

As of 31 December 2013, Social Security and Public Administrations total debt with ROVI amounted to 9.0 million euros, of which 7.6 million euros in Spain and the other 1.4 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 Farmaindustria¹, the Spanish Pharmaceutical Association, and (ii) the continued decreases in the pharmacy retail market at least until 2016 forecast by IMS Health².

ROVI expects its growth drivers to be Bemiparin, the new license agreements (Medikinet[®] and Hirobriz[®]), its existing portfolio of specialty pharmaceuticals, contribution from last launches

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¹ http://www.farmaindustria.es/Farma_Public/Imprimir_Public/FARMA_124496?idDoc=FARMA_124496

² IMS Market Prognosis March 2013



such as Vytorin[®] and Absorcol[®], new product distribution licenses and new contracts in the toll manufacturing area.

5. Research and Development update

ROVI's R&D projects keep going mainly focused on the Glycomics and the ISM® platforms, the latest an own proprietary drug delivery system aimed to improve patients' therapeutic compliance.

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.

On the other hand, during 2013, ROVI has made remarkable progress in its most advanced candidate for the aforementioned drug delivery platform, Risperidone ISM $^{\text{@}}$, a long-acting 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 subjects, and in 2013 the new phase I multicentre trial PRISMA-1 (<u>Pharmacokinetic evaluation of Risperidone ISM long-Acting injection - 1</u>) 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® at three different dose strengths in subjects with schizophrenia or schizoaffective disorder¹; it is also considered an additional escalating-dose stage, in case of the initial selected doses might not have achieved the optimal plasma levels (decision to be taken by 1Q2014); the results of the first parallel stage are expected by the first half of 2014 (and alternatively, by the second half of 2014, if the second escalating-dose stage is needed).

Besides, an IND (*Investigational New Drug*) has already been submitted to FDA by last November. This will allow initiating the phase II trial PRISMA-2 in several USA centres for evaluating multiple doses of Risperidone ISM[®] in schizophrenic patients. The results from this study are expected by the first half of 2015.

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¹ Pharmacokinetic, Safety, and Tolerability Study of Risperidone ISM® at Different Dose Strengths (PRISMA-1). [http://www.clinicaltrials.gov/ct2/show/NCT01788774?term=NCT01788774&rank=1].



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.

In addition, the initiation of the first human studies with Paliperidone ISM[®] (another longacting second-generation antipsychotic drug) and Letrozole ISM[®] (an aromatase inhibitor for the treatment of breast cancer) are planned for the first halves of 2014 and 2015, respectively.

Finally, in 2013 there were set the basis for progressing to the production of the first prototypes of urethral catheters using the multilayered technology platform patented by ROVI, which should be ready for animal testing in 2014. The development of this technology still is in a very early stage, and is based on the use of polymer layers that bioerode under the influence of bacterial metabolism. This erosion provides important advantages over the state of the art technologies, reducing bacterial adhesion on the luminal surface and facilitating biofilm elimination and formation of encrustations that lead to catheter blockage. Therefore, this type of catheter could increase patient's quality of life, reduce the use of antibiotics and avoid catheter replacement due to blockage.

6. Key operating and financial events

6.1 ROVI exercises the Purchase Option held over the health register of Rhodogil[®] in Spain

In June 2013, ROVI and Sanofi announced they had reached an agreement for ROVI to exercise the Purchase Option held over the health register of Rhodogil[®] in Spain, which was owned by Sanofi.

Since July 2003, ROVI had been providing to Sanofi commercial promotion services for Rhodogil $^{\text{@}}$ in Spain. Under the new agreement, Rhodogil $^{\text{@}}$ is directly marketed by ROVI in Spain.

Rhodogil[®] is a synergistic combination of two antibacterial: metronidazole and spiramycin. Is effective against a broad spectrum of germs, especially those associated with infections of the oral cavity (e.g. dental infections).

According to IMS Health data, Rhodogil® sales in Spain reached 3.6 million Euros over the last twelve months to April 2013 (MAT April 2013), and in the case of macrolide antibiotics market and similar (such as Rhodogil®) reached a total 34.1 million Euros, reflecting the product a market share in units of 15% for that period.



6.2 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 promoting it from 1 January 2014. Rovi expects to market the combination of indacaterol maleate and glycopyrronium bromide delivered through the Breezhaler[®] 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[®] 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).



6.3 ROVI announces the exclusive commercialization of Medicebran $^{\rm @}$ and Medikinet $^{\rm @}$ in Spain

In November 2013, ROVI announced it had signed an agreement with MEDICE Arzneimittel Pütter GmbH & Co. KG ("Medice") to market in Spain Medicebran[®] and Medikinet[®], products indicated for the treatment of ADHD (Attention Deficit Hyperactivity Disorder) in children and teenagers.

Under this marketing agreement, ROVI will be in charge of the promotion, distribution and sales, on exclusivity basis, for both Medicebran[®] and Medikinet[®], psychostimulant drugs aimed for the treatment of ADHD in children and teenagers between 6 and 18 years of age. Both products contain the active ingredient hydrochloride methylphenidate; the difference is that Medicebran[®] is an immediate-release drug while Medikinet[®] has a modified release (50% of the dose has immediate release and the other 50% extended release).

These drugs enhance the activity of certain parts of the brain that have low activity, helping to improve the level of attention and the capacity to focus, while reducing impulsive behaviour. Its administration is part of a comprehensive treatment program that typically includes psychological, educational and social therapy.

According to data of IMS Health, the market for psychostimulant medications for children and teenagers reached in Spain, in the 12 month period until September of 2013 (MAT September of 2013), a total figure of 47.8 million Euros, being the joint sales of Medicebran $^{\text{®}}$ and Medikinet $^{\text{®}}$ in this same period 9.6 million Euros, representing a market share of 20%.

6.4 ROVI announces the cancelation of the project of its joint-venture Alentia to build a national production centre of flu vaccines

ROVI and Grupo Ferrer have decided to cancel the project of their joint-venture Alentia, consistent in the construction of a national production centre of flu vaccines. This decision has been taken mainly due to (i) an important reduction in the prices of flu vaccines during the last three campaigns, and (ii) the impossibility to obtain the needed public funding due to the current adverse financial situation of the country (this project required an estimate investment of approximately 92 million euros).

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 31 DECEMBER 2013 AND 31 DECEMBER 2012

	31 December 2013	31 December 2012
ASSETS		
Non-current assets		
Property, Plant and Equipment	60,199	53,791
Intangible assets	14,468	3,176
Deferred tax assets	7,517	6,073
Available-for-sale financial assets	16,121	28,148
Financial receivables	135	133
	98,440	91,321
Current assets		
Inventories	58,747	56,225
Trade and other receivables	55,919	54,377
Current income tax assets	3,416	3,855
Cash and cash equivalents	19,401	16,585
	137,483	131,042
Total assets	235,923	222,363



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS AS OF 31 DECEMBER 2013 AND 31 DECEMBER 2012

	31 December 2013	31 December 2012
EQUITY		
Capital and reserves attributable to		
shareholders of the company		
Share capital	3,000	3,000
Legal reserve	600	600
Treasury shares	(782)	(2,060)
Retained earnings and voluntary reserves	118,943	105,692
Profit for the year	23,022	19,514
Reserve for available-for-sale assets	(319)	(299)
Total equity	144,464	126,447
LIABILITIES		
Non-current liabilities		
Financial debt	22,578	29,135
Deferred income tax liabilities	2,637	3,256
Non-current deferred revenue	7,904	8,393
	33,119	40,784
Current liabilities		
Trade and other payables	43,485	39,878
Financial debt	8,400	9,255
Current deferred revenue	4,084	4,348
Provisions for other liabilities and charges	2,371	1,651
_	58,340	55,132
Total liabilities	91,459	95,916
Total equity and liabilities	235,923	222,363



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED INCOME STATEMENTS FOR THE FULL YEARS 2013 AND 2012

	Full Year	
	2013	2012
Revenue	217,587	201,923
Cost of sales	(84,895)	(75,513)
Employee benefit expenses	(55,619)	(53,546)
Other operating expenses	(47,401)	(48,359)
Depreciation, amortisation and impairment charges	(6,943)	(5,320)
Recognition of government grants on non financial non- current assets and other	1,358	1,236
Other income	1,385	1,256
OPERATING PROFIT	25,472	21,677
Finance income	307	1,341
Finance costs	(1,528)	(2,180)
FINANCE COSTS - NET	(1,221)	(839)
PROFIT BEFORE INCOME TAX	24,251	20,838
Income tax	(1,229)	(1,324)
PROFIT FOR THE YEAR	23,022	19,514



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED CASH FLOW STATEMENTS FOR THE FULL YEARS 2013 AND 2012

(Thousand of euros)	Fully	Full year	
	2013	2012	
Cash flows from operating activities			
Profit before income tax	24,251	20,838	
Adjustments for non-monetary transactions:			
Amortisation	6,943	5,320	
Interest income	(307)	(1,341)	
Gains or losses on derecognition of financial assets and liabilities	-	21	
Interest expense	1,528	2,180	
Net changes in provisions	720	402	
Grant for non-financial fixed assets and distribution licence income	(1,127)	(999)	
Changes in working capital			
Trade and other receivables	(331)	12,359	
Inventories	(2,522)	(14,919)	
Trade and other payables	3,607	(2,074)	
Other collections and payments			
Collection for distribution licenses	70	-	
Interest paid	(172)	(105)	
Income tax cash flow	(2,844)	(2,068)	
Net cash generated (used) from operating activities	29,816	19,614	
Cash flows from investing activities	(
Purchases of intangible assets	(12,005)	(915)	
Purchases of property, plant and equipment	(12,678)	(12,805)	
Proceeds of property, plant and equipment	40	26	
Purchases of available-for-sale financial assets		(30,859)	
Proceeds from sale of available-for-sale financial assets	11,957	7,737	
Contracting short term bank deposits	(103)	(1,055)	
Liquidating current deposits		7,014	
Loans granted to related parties	(1,050)	-	
Cash decrease due to sale of Alentia Biotech	-	(10,278)	
Interest received	307	1,341	
Net cash generated (used) in investing activities	(13,532)	(39,794)	
Cash flows from financing activities	(0.204)	(0.022)	
Repayments of financial debt	(9,384)	(8,833)	
Proceeds from financial debt	901	2,757	
Purchase of treasury shares	(3,466)	(1,838)	
Reissue of treasury shares	5,261	1,488	
Dividends paid Net cash generated in financing activities	(6,780) (13,468)	(6,300) (12,726)	
Net (decrease)/increase in cash and cash equivalents	2,816	(32,906)	
Cash and cash equivalents at beginning of the year	16,585	49,491	
Cash and cash equivalents at end of the year	19,401	16,585	