



First Half 2015 Financial Results

30th July 2015



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



ROVI – First Half 2015 Financial Results

ROVI reports an operating revenue growth of 4%, led by the strength of the toll manufacturing business

- **Operating revenue increased by 4% to 121.3 million euros in the six-month period ending 30 June 2015, mainly driven by the strength of the toll manufacturing business which grew by 11%, and by the specialty pharmaceutical business, where sales rose 2%. Total revenue increased by 3% to 121.9 million euros in the first half of 2015.**
- **ROVI expects operating revenue to grow from mid to high single digit for the full year 2015, despite (i) a 0.8% slight rise in Spanish pharmaceutical market according to Farmaindustria¹, and (ii) zero to negative spending growth on medicine in Spain for the period 2014-2018 forecast by IMS Health².**
- **Sales of Bemiparin in Spain performed well in the six-month period ending 30 June 2015, with a 7% increase to 24.9 million euros.**
- **Sales of Vytorin[®], Orvatez[®] and Absorcol[®], the first of the five licenses of Merck Sharp & Dohme (MSD), increased by 10% to 11.1 million euros in the first half of 2015. 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, increase by 4% to 3.9 million euros in the first half of 2015. Sales of Volutsa[®], from Astellas Pharma, reached 1.1 million euros in the six-month period ending 30 June 2015.**
- **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 2.6 million euros in the first half of 2015.**

¹<http://www.farmaindustria.es/web/indicador/analisis-de-la-evolucion-del-gasto-farmaceutico-publico-en-espana-mes-mes-2/>

²<http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=266e05267ae a9410VgnVCM10000076192ca2RCRD&vgnnextchannel=736de5fda6370410VgnVCM10000076192ca2RCRD&vgnnextfmt=default>



- **In the first half of 2015, EBITDA was impacted by (i) a 62% reduction in the Other income (subsidies) item, (ii) a 33% increase in Research and Development expenses, mainly as a result of the development of the ISM-Risperidone Phase II study and (iii) recent product launches such as Hirobriz, Ulunar, Volutsa and Orvatez which contributed selling, general and administrative expenses of 2.9 million euros.**
- **EBITDA decreased by 7% to 19.5 million euros in the six-month period ending 30 June 2015, compared to the same period the previous year, reflecting a 1.9 percentage point fall in the EBITDA margin to 16.1% in the first half of 2015 down from 18.0% in the first half of 2014. However, maintaining, in the first half of 2015, the same amount of Research and Development expenses that was registered in the first half of 2014 and excluding the impact of (i) Other income, in the six-month periods ending 30 June 2015 and 30 June 2014, and (ii) recent product launches, in the first half of 2015, EBITDA would increase by 23% to 23.8 million euros, reflecting a 3.0 percentage point rise in the EBITDA margin to 19.6% in the first half of 2015 up from 16.6% in the first half of 2014.**
- **Net profit declined to 13.6 million euros in the first half of 2015, a 9% decrease compared to the same period the previous year. However, maintaining, in the first half of 2015, the same amount of Research and Development expenses that was registered in the first half of 2014 and excluding the impact of (i) Other income, in the six-month periods ending 30 June 2015 and 30 June 2014, and (ii) recent product launches, in the first half of 2015, net profit would increase by 31% to 17.6 million euros.**

Madrid (Spain), 30th July 2015, 8:00 AM CET - ROVI released today its financial results for the first half of 2015.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that *"in the first half of 2015, we reached 4% operating revenue growth mainly driven by the strength of our toll manufacturing area, especially of the injectables plant, and our specialty pharmaceutical business. Sales of the specialty pharmaceutical area rose 2% in the first half of 2015 despite the difficulties that the Spanish pharmaceutical market is going through. Prescription-based pharmaceutical market covering the 6-month period ending June 2015 decreased by -0.2%, according to IMS. Nevertheless, we forecast to continue to grow thanks to, among others, our flagship product, Bemiparin, which is contributing to this growth. In particular, in the first half of 2015, Bemiparin sales increased by 7% in the domestic market. Furthermore, we expect (i) our entrance in the respiratory market through the launch of Hirobriz® Breezhaler® and Ulunar® Breezhaler®, from Novartis, in Spain in December 2014,*



(ii) our entrance in the urology field through the launch of Volutsa®, from Astellas Pharma, in Spain in February 2015, and (iii) the strengthening of the hipercolesterolaemia franchise through the launch of Orvatez®, from MSD, in Spain in June 2015, to contribute to growth in the coming years. These new launches cover growing demand needs and have required a significant investment in order to gain a share in their various market segments but we expect that our effort will provide us a sustainable and profitable growth opportunity in the future. In addition, the MSD agreement will allow us to launch four additional new products in the next 4 years, underpinning our belief in the sustainability of our long term outlook. All these new product launches will lead us to extend the average life of our product portfolio by several years. Also, we are confident of the potential of our current pipeline of R&D projects, making important investment efforts as we trust they will be the company's growth engine in the future. 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 the first half of 2016 as well as to develop a new phase I study for another candidate also next year. Likewise, we are hopeful of obtaining authorization to market a biosimilar of enoxaparin in Europe in the medium term".

1. Financial highlights

€ million	H1 2015	H1 2014	Growth	% Growth
Operating revenue	121.3	116.3	5.0	4%
Other income	0.6	1.6	-1.0	-62%
Total revenue	121.9	117.9	4.0	3%
Cost of sales	-47.8	-46.3	-1.5	3%
Gross profit	74.1	71.6	2.4	3%
% margin	61.1%	61.6%		-0.5pp
R&D expenses	-7.9	-5.9	-2.0	33%
Other SG&A	-46.7	-44.8	-1.9	4%
EBITDA	19.5	20.9	-1.4	-7%
% margin	16.1%	18.0%		-1.9pp
EBIT	14.6	16.6	-2.0	-12%
% margin	12.1%	14.3%		-2.3pp
Net profit	13.6	15.0	-1.4	-9%

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 half of 2015 and the comparative information for 2014 (balance sheet) and for the first half of 2014 (consolidated income statement and cash flow statement) are attached to this report (see Appendix 1).

2. Performance of the Group

Operating revenue increased by 4% to 121.3 million euros in the six-month period ending 30 June 2015, mainly driven by the strength of the toll manufacturing business which grew by 11%, and by the specialty pharmaceutical business, where sales rose 2%. Total revenue increased by 3% to 121.9 million euros in the first half of 2015.

Sales of **prescription-based pharmaceutical** products rose 1% to 70.9 million euros in the six-month period ending 30 June 2015.

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, performed well in Spain in the first half of 2015, with sales up 7% to 24.9 million euros. International sales decreased by 14% to 11.9 million euros. This decrease was specifically linked to the first half of 2015 and ROVI expects Bemiparin marketing in China and Brasil, forecast for the second half of 2015, as well as the launch of the product in new countries, such as Qatar in the first half of 2015, to contribute to stable sales in 2015. Bemiparin total sales decreased by 1% to 36.8 million euros in the first half of 2015.

Sales of **Vytorin**[®], **Orvatez**[®] and **Absorcol**[®], the first of the five licenses of MSD, indicated as adjunctive therapy to diet in patients with hypercholesterolemia, increased by 10% to 11.1 million euros in the first half of 2015.

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 2.6 million euros in the first half of 2015.

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, increased by 4% to 3.9 million euros in the first half of 2015.

Sales of **Corlontor**[®], a specialty product for stable angina and chronic heart failure from Laboratoires Servier, decreased by 3% to 6.6 million euros in the six-month period ending 30 June 2015.



Sales of **Volutsa**[®], a specialty product from Astellas indicated for the treatment of moderate to severe storage symptoms and voiding symptoms associated with benign prostatic hyperplasia, launched in Spain in February 2015, reached 1.1 million euros in the first half of 2015 (see section 6.4).

Sales of **Exxiv**[®], a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 11% to 3.1 million euros in the six-month period ending 30 June 2015, mainly due to a continued deceleration of the COX-2 market.

Sales of **Thymanax**[®], an innovative antidepressant from Laboratoires Servier and for which ROVI has a co-marketing agreement covering Spain, decreased by 26% to 3.9 million euros in the six-month period ending 30 June 2015.

According to IMS, Spanish prescription-based pharmaceutical market decreased by 0.2% in the first half of 2015 compared to the same period the previous year. Nevertheless, ROVI prescription-based pharmaceutical product sales rose 1% in the first half of 2015, beating the market by 1.2 percentage points.

Also, prescription-based pharmaceutical market covering the 12-month period ending June 2015 remained flat compared to the same period the previous year. However, ROVI prescription-based pharmaceutical product sales rose 6% in the last year.

In addition, a slight 0.8% annual increase of Spanish pharmaceutical expenditure is expected for 2015 and 2016, according to Farmaindustria¹, and zero to negative spending growth on medicine in Spain for the period 2014-2018 is forecast by IMS Health². Despite the difficult situation that the pharmaceutical industry is still going through, ROVI forecasts to continue to grow.

Sales of **contrast imaging agents** and other hospital products increased by 6% to 13.2 million euros in the six-month period ending 30 June 2015.

Sales of **over-the-counter pharmaceutical products** ("OTC") and **other** decreased by 1% to 3.8 million euros in the six-month period ending 30 June 2015 compared to the same period the previous year. EnerZona[®], a range of products based on the principles of the Zone Diet, performed well with sales up 6% to 2.1 million euros.

Toll manufacturing sales increased by 11% to 33.3 million euros in the six-month period ending 30 June 2015 compared to the same period the previous year. The positive evolution

¹<http://www.farmaindustria.es/web/indicador/analisis-de-la-evolucion-del-gasto-farmacologico-publico-en-espana-mes-mes-2/>

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

of the injectables plant, whose revenue increased by 57% to 14.6 million euros in the first half of 2015 largely offset the 2.0 million euros revenue decline in the Frosst Ibérica plant to 18.7 million euros in the first half of 2015, as a consequence of a lower production for Merck Sharp and Dohme (MSD).

Sales outside Spain decreased by 2% to 43.2 million euros in the first half of 2015 compared with the same period of previous year. Sales outside Spain represented 36% of operating revenue in the first half of 2015 compared to 38% in the first half of 2014.

Other income (subsidies) decreased by 62% to 0.6 million euros in the first half of 2015 from 1.6 million euros in the first half of 2014.

Gross profit increased by 3% to 74.1 million euros in the six-month period ending 30 June 2015, reflecting a decrease of 0.5 percentage points in the gross margin to 61.1% in the first half of 2015 from 61.6% in the first half of 2014. However, excluding the impact of the Other income (subsidies) item, gross margin would increase to 60.6% in the first half of 2015 from 60.2% in the first half of 2014. The decrease of the Bemiparin raw material cost impacted positively in the first half of 2015 gross margin.

Research and development expenses increased by 33% to 7.9 million euros in the six-month period ending 30 June 2015 mainly due to (i) the development of the PRISMA-2 study, a phase II trial carried out in several USA centres for evaluating the safety and pharmacokinetics of Risperidone-ISM[®] and (ii) the performing of development activities of the formulation for the Risperidone-ISM[®] phase III trial and the Letrozole-ISM[®] phase I trial.

Selling, general and administrative expenses (SG&A) increased by 4% to 46.7 million euros in the six-month period ending 30 June 2015, compared to the same period the previous year, mainly due to recent product launches such as Hirobriz, Ulunar, Volutsa and Orvatez. However, excluding the impact of the launches mentioned above, which contributed expenses of 2.9 million euros in the first half of 2015, selling, general and administrative expenses would decrease by 2% to 43.7 million euros in the first half of 2015. Also, the SG&A rise in the first half of 2015 reflected ROVI investment effort in human capital to address pneumologists and primary care, main targets of Hirobriz and Ulunar products, and to participate in the development of the ISM project.

EBITDA decreased by 7% to 19.5 million euros in the six-month period ending 30 June 2015, compared to the same period the previous year, reflecting a 1.9 percentage point fall in the EBITDA margin to 16.1% in the first half of 2015 down from 18.0% in the first half of 2014. However, maintaining, in the first half of 2015, the same amount of Research and Development expenses that was registered in the first half of 2014 and excluding the impact of (i) Other income, in the six-month periods ending 30 June 2015 and 30 June 2014, and (ii)

recent product launches, in the first half of 2015, EBITDA would increase by 23% to 23.8 million euros, reflecting a 3.0 percentage point rise in the EBITDA margin to 19.6% in the first half of 2015 up from 16.6% in the first half of 2014 (see "w/o impacts" columns of the table below).

€ million	Reported		w/o impacts			
	H1 2015	H1 2014	H1 2015	H1 2014	Growth	% Growth
Operating revenue	121.3	116.3	121.3	116.3	5.0	4%
Other income	0.6	1.6	-	-	-	-
Total revenue	121.9	117.9	121.3	116.3	5.0	4%
Cost of sales	-47.8	-46.3	-47.8	-46.3	-1.5	3%
Gross profit	74.1	71.6	73.5	70.0	3.4	5%
<i>% margin</i>	<i>61.1%</i>	<i>61.6%</i>	<i>60.6%</i>	<i>60.2%</i>		0.4pp
R&D expenses	-7.9	-5.9	-5.9	-5.9	-	-
Other SG&A	-46.7	-44.8	-43.7	-44.8	1.1	-2%
EBITDA	19.5	20.9	23.8	19.3	4.5	23%
<i>% margin</i>	<i>16.1%</i>	<i>18.0%</i>	<i>19.6%</i>	<i>16.6%</i>		3.0pp

Depreciation and amortisation expenses increased by 15% to 4.9 million euros in the first half of 2015, mainly as a result of the new property, plant and equipment and intangible assets purchases made during the last twelve months.

EBIT decreased by 12% to 14.6 million euros in the first half of 2015, compared to the first half of 2014, reflecting a 2.3 percentage point decline in the EBIT margin to 12.1% down from 14.3% in the first half of 2014. However, maintaining, in the first half of 2015, the same amount of Research and Development expenses that was registered in the first half of 2014 and excluding the impact of (i) Other income, in the six-month periods ending 30 June 2015 and 30 June 2014, and (ii) recent product launches, in the first half of 2015, EBIT would increase by 25% to 18.9 million euros, reflecting a 2.6 percentage point rise in the EBIT margin to 15.6% in the first half of 2015 up from 13.0% in the first half of 2014.

Financial expense decreased by 44% in the first half of 2015, compared to the same period the previous year, mainly due to the registration, in the first half of 2014, of the interests related to the return of the 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 decreased by 11% in the first half of 2015, compared to the first half of 2014, mainly as a result of the reduction of interest on late payments from certain hospitals registered in the first half of 2015.

The **effective tax rate** was 5.1% in the first half of 2015 compared to 5.6% in the first half of 2014. 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 were used in the 2014 income tax and 3.8 million euros in the first half of 2015.

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. Then, 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 declined to 13.6 million euros in the first half of 2015, a 9% decrease compared to the same period the previous year. However, maintaining, in the first half of 2015, the same amount of Research and Development expenses that was registered in the first half of 2014 and excluding the impact of (i) Other income, in the six-month periods ending 30 June 2015 and 30 June 2014, and (ii) recent product launches, in the first half of 2015, net profit would increase by 31% to 17.6 million euros.



€ million	Reported		w/o impacts			
	H1 2015	H1 2014	H1 2015	H1 2014	Growth	% Growth
Operating revenue	121.3	116.3	121.3	116.3	5.0	4%
Other income	0.6	1.6	-	-	-	-
Total revenue	121.9	117.9	121.3	116.3	5.0	4%
Cost of sales	-47.8	-46.3	-47.8	-46.3	-1.5	3%
Gross profit	74.1	71.6	73.5	70.0	3.4	5%
% margin	61.1%	61.6%	60.6%	60.2%		0.4pp
R&D expenses	-7.9	-5.9	-5.9	-5.9	-	-
Other SG&A	-46.7	-44.8	-43.7	-44.8	1.1	-2%
EBITDA	19.5	20.9	23.8	19.3	4.5	23%
% margin	16.1%	18.0%	19.6%	16.6%		3.0pp
EBIT	14.6	16.6	18.9	15.1	3.8	25%
% margin	12.1%	14.3%	15.6%	13.0%		2.6pp
Net profit	13.6	15.0	17.6	13.5	4.2	31%

The ROVI General Shareholders Meeting, on 9 June 2015, approved the payment of a **gross dividend** of 0.1690 euros per share on 2014 earnings. This dividend was paid on 2 July 2015 and it meant an increase of 5% compared to the dividend on 2013 earnings (0.1612 euros per share).

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that, "operating revenue increased by 4%, compared to the first half of 2014, despite the difficulties in the economic and regulatory environments. We attribute this out-performance to the strength of our injectable toll manufacturing business as well as of our leading products, which continue to enjoy good sales prospects. Our commitment to reach new agreements with other laboratories to market its drugs in Spain as well as our focus on R&D to commercialise our own products led us to significantly invest in the first half of 2015, impacting the EBITDA figure. Nevertheless, we expect EBITDA to recover the path of sustained growth shortly. It is very gratifying to witness the strength of our balance sheet and our excellent capacity to generate cash, which allows us to finance organic growth through the launch of new products, such as Volutsa[®], Ulunar[®], Hirobriz[®], Orvatez[®], 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 8.9 million euros in the first half of 2015, compared to 6.6 million euros in the first half of 2014. Of this amount:

- 1.1 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 3.0 million euros in the first half of 2014;
- 1.0 million euros corresponds to investment capex related to the Granada facility, versus 1.8 million euros in the first half of 2014;
- 1.4 million euros corresponds to investment capex related to the Alcalá (Frosst Ibérica) facility, versus 0.4 million euros in the first half of 2014; and
- 1.4 million euros corresponds to expenditure on maintenance and other, vs. 1.4 million euros in the first half of 2014.
- The rest of the capex invested in 2015 corresponds mainly to the acquisition of assets of a manufacturing plant in San Sebastián de los Reyes (see section 6.3).

3.2 Debt

As of 30 June 2015, ROVI had total debt of 35.0 million euros. Debt with public administration, which is 0% interest rate debt, represented 42% of total debt as of 30 June 2015.

<i>In thousand euros</i>	30 June 15	31 December 14
Bank borrowings	20,377	20,560
Debt with public administration	14,660	15,746
Total	35,037	36,306

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 to 4.6 million euros in the first half of 2015 from 2.6 million euros in the first half of 2014 mainly due to (i) the decrease of 0.7 million euros in the "trade and other receivables" item in the first half of 2015, compared to an increase of 7.1 million euros in the first half of 2014 and (ii) the increase of 2.4 million euros in the "inventories" item, compared to an increase of 7.3 million euros in the first half of 2014 as a result of a larger Bemiparin production in the first half of last year.

3.4 Net and gross cash position

As of 30 June 2015, ROVI had a gross cash position of 27.1 million euros, compared to 28.0 million euros as of 31 December 2014, 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 -7.9 million euros, compared to -8.3 million euros as of 31 December 2014.

3.5 Working capital

The decrease in working capital in the first half of 2015 was mainly due to (i) an increase in the "trade and other payables" line of 3.9 million euros and (ii) a decrease in the "trade and other receivables" item of 0.7 million euros. "Inventories" increased by 2.4 million euros mainly as a result of the stock of the products recently launched, Hirobriz, Ulunar, Volutsa and Orvatez, and "Cash and cash equivalents" decreased by 1.0 million euros in the first half of 2015.

As of 30 June 2015, Social Security and Public Administrations total debt with ROVI amounted to 11.6 million euros, of which 10.2 million euros in Spain and the other 1.4 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 0.8% slight rise in Spanish pharmaceutical market according to Farmaindustria¹, and (ii) zero to negative spending growth on medicine in Spain for the period 2014-2018 forecast by IMS Health².

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

¹ <http://www.farmaindustria.es/web/indicador/analisis-de-la-evolucion-del-gasto-farmaceutico-publico-en-espana-mes-mes-2/>

² <http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vqnextoid=266e05267aea9410VqnVCM10000076192ca2RCRD&vqnextchannel=736de5fda6370410VqnVCM10000076192ca2RCRD&vqnextfmt=default>

5. Research and Development update

As it has been previously commented, 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.

In previous communications, ROVI informed that a manufacturing plant for new medicines using the ISM® technology (equipped with very innovative machinery for filling solid compounds in syringes) has already been built. Besides, the company is currently constructing a new plant that will allow manufacturing new ISM products for high potency active principles, e.g. letrozole. ROVI is presently completing the regulatory non-clinical studies for Letrozole ISM® for progressing into clinical development and this new manufacturing facility will produce the medication for the first study in humans with Letrozole ISM®, planned to be started by 1H2016.

The results from the PRISMA-2 study are expected by the third quarter of 2015, after completing the patients' follow up; this is a phase II clinical 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 subjects¹. The company will request scientific advice to *European Medicines Agency* (EMA) and *US Food and Drug Administration* (FDA) for reviewing all available data from Risperidone ISM® before progressing to phase III, which is planned to start by first half 2016.

On the other hand, ROVI has presented two communications to the 12th European Association for Clinical Pharmacology and Therapeutics (EACPT) Congress recently held in Madrid (June 27-30th, 2015) with regards to the pharmacokinetic profile of its long-acting injectable antipsychotics Risperidone ISM² and ³.

Regarding Glycomics, on last February 9th, after the end of the validation phase, the assessment process started in order for ROVI to be granted the Marketing Authorisation in Europe of a low-molecular-weight heparin, a biosimilar of enoxaparin. ROVI has received a list of objections and questions about this drug from the pertinent European health authorities and is currently working on answering them.

¹ *Pharmacokinetics and Tolerability Study of Risperidone ISM® in Schizophrenia (PRISMA-2)*. [<http://clinicaltrials.gov/show/NCT02086786>].

² *Population pharmacokinetic modeling and simulations of long-acting intramuscular risperidone ISM®*. [[http://www.clinicaltherapeutics.com/article/S0149-2918\(15\)00326-4/pdf](http://www.clinicaltherapeutics.com/article/S0149-2918(15)00326-4/pdf)]

³ *Phase I clinical trial to evaluate the pharmacokinetics, safety, and tolerability of one intramuscular injection of risperidone ISM® at different dose strengths in subjects with Schizophrenia or Schizoaffective disorder (PRISMA-1)*. [[http://www.clinicaltherapeutics.com/article/S0149-2918\(15\)00448-8/pdf](http://www.clinicaltherapeutics.com/article/S0149-2918(15)00448-8/pdf)]

Furthermore, within the field of antithrombotic drugs, an analysis of the aggregated data from several clinical trials with Bemiparin was also presented at the above mentioned European congress¹; the data showed that Bemiparin, in comparison with placebo, did not show an increase of bleeding in elderly and patients with renal impairment, corroborating the safety profile of this second-generation low molecular weight heparin in these special populations.

6. Key operating and financial events

6.1 ROVI signs an agreement with Merus Labs to manufacture Sintrom®

Laboratorios Farmacéuticos Rovi, S.A. ("ROVI" or the "Company") announces today that it has signed an agreement with the company Merus Labs Netherland B.V. ("Merus"), pharmaceutical company specialized in acquisition and licensing to third parties of pharmaceutical products, through which ROVI will manufacture for Merus the pharmaceutical product Sintrom® (acenocoumarol), indicated for the treatment and prophylaxis of thromboembolic disorders.

Under the terms of the contract signed, ROVI will provide Merus manufacturing and packaging services, on an exclusive basis, of the product Sintrom® to supply Spain and Portugal, during a period of five years. In this sense, it is expected that annual production of this product will lead to an increase of, approximately, 25% of the production of the plant of Frosst Ibérica, S.A.

Within the same agreement, it is established that ROVI will provide logistics and distribution services of Sintrom® in Spain, on exclusivity basis, for a period of a year, renewable yearly.

ROVI expects to start providing logistics and distribution services of Sintrom® in the third quarter of 2015, once authorization is obtained from the Spanish Agency of Medicines and Health Products (AEMPS). Likewise, ROVI expects to obtain authorization from the mentioned agency to manufacture this product in the second half of 2016.

Juan López-Belmonte Encina, CEO of ROVI, commented: "we are very pleased to work with Merus, which will contribute to strengthen two main engines of growth of the company: contract manufacturing and pharmaceutical specialties area, providing us a sustainable growth opportunity in the long term".

¹ *Aggregated Data of Clinical Trials: Bemiparin Bleeding Risk In Elderly And Patients With Renal Impairment.*
[http://www.clinicaltherapeutics.com/article/S0149-2918\(15\)00497-X/pdf](http://www.clinicaltherapeutics.com/article/S0149-2918(15)00497-X/pdf)



6.2 ROVI announces the upcoming marketing of Orvatez® in Spain

ROVI announces it has signed an agreement with Merck Sharp & Dohme S.A. (MSD) to market in Spain Orvatez®, a drug that combines two active principle ingredients, ezetimibe and atorvastatin, which act by inhibiting the two sources of origin of cholesterol. It is indicated for adults patients with primary hypercholesterolemia (increased levels of cholesterol in blood) or mixed (high levels in blood of cholesterol and triglycerides) when the use of product combination is considered adequate. Orvatez® can be used in patients not controlled adequately with a single statine or in patients already treated with statine and ezetimibe. Orvatez® will be marketed in Spain, under a co-marketing regimen with Atozet® which is already being marketed by MSD.

Orvatez® is part of the first of the five marketing agreements that MSD granted ROVI on their products, under the strategic pharmaceutical agreement to market and to manufacture reached on the 23rd of July, 2009, and notified on the next day, on July the 24th 2009, to the National Stock Market Commission as Relevant Fact, with number 111,707.

With Orvatez®, ROVI expands its product's portfolio and strengthen its commitment to the area of hypercholesterolemia in which is currently offering two products of MSD, Absorcol® and Vytorin®, as alternative therapies for cholesterol problems.

Hypercholesterolemia is the presence of increased levels of cholesterol in the blood. It is one of main cardiovascular risk factors. The cardiovascular diseases such as angina pectoris, myocardial infarction, cerebrovascular diseases, and the peripheral vascular disease are one of the main causes of death in our country. In Spain, the CODIMET study evidenced that just 12% of the patients with coronary heart disease or equivalent risk have their LDL cholesterol levels controlled¹.

6.3 ROVI agrees to acquire assets of a manufacturing plant in San Sebastián de los Reyes

As it was communicated to the market on 3 June 2015 through Relevant Fact number 223905, ROVI has reached an agreement with Crucell Spain, S.A. (Crucell) by which it has acquired assets of the manufacturing plant at San Sebastián de los Reyes, owned by Crucell, with the main objective to expand in the future the injectables production lines of ROVI's group (others than the ones being manufactured by Crucell). These production assets will remain inoperative for some time while ROVI carries out investments for necessary and significant

¹ Pérez de Isla L, Saltijeral Cerezo A, Vitale G, Gonzalez Timón B, Torres Do Rego A, Álvarez-Sala LA. Prevalencia del colesterol LDL inadecuado en pacientes con enfermedad coronaria y/o diabetes mellitus tipo 2. Rev Clin Esp 2012; 212:475-81

adaptation and refurbishment. Through this operation, ROVI intends to strengthen its contract manufacturing business and ensure the production capacity required to carry out its future strategic plans of international expansion of Bemiparin and, predictably, marketing and development of its potential new low molecular weight heparin, biosimilar of enoxaparin. Until the to be acquired assets begin to operate and ROVI obtains relevant approvals, ROVI will perform the technical analysis required in order to adapt mentioned assets to ROVI's methodology and procedures.

The assets purchased by ROVI consist in three parcels in San Sebastián de los Reyes and a list of property assets, including: two production lines (one of them high speed) for the filling of syringes, one production line for the filling of vials, a high speed line for the inspection of syringes and other for syringe's packaging.

By this agreement, ROVI will strengthen for the future its capacity to perform contract manufacturing operations as well as its international expansion strategy of Bemiparin and its potential new low molecular weight heparin, thus favouring company's sustained growth in the long term. This agreement is in line with ROVI's global strategy with its current manufacturing model to achieve greater effectiveness and allow its long term growth, while continue with its constant commitment of economic growth in Spain.

The agreement implies an investment by ROVI of approximately 4 million euros. The operation has been financed by available funds from the Company; therefore it has not being required seeking external financing.

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

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
javierlbelmonte@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 30 JUNE 2015 AND 31 DECEMBER 2014

(Thousands of euros)

	30 June 2015	31 December 2014
ASSETS		
Non-current assets		
Property, Plant and Equipment	77,227	73,593
Intangible assets	17,567	17,206
Deferred tax assets	8,845	8,280
Available-for-sale financial assets	71	71
Financial receivables	138	137
	103,848	99,287
Current assets		
Inventories	69,931	67,567
Trade and other receivables	63,024	63,678
Current income tax assets	2,120	4,117
Cash and cash equivalents	25,673	26,671
	160,748	162,033
Total assets	264,596	261,320



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS AS OF 30 JUNE 2015 AND 31 DECEMBER 2014

(Thousands of euros)

	30 June 2015	31 December 2014
EQUITY		
Capital and reserves attributable to shareholders of the company		
Share capital	3,000	3,000
Legal reserve	600	600
Treasury shares	(7,221)	(2,813)
Retained earnings and voluntary reserves	149,323	133,569
Profit for the period	13,570	24,116
Reserve for available-for-sale assets	(2)	(2)
Total equity	159,270	158,470
LIABILITIES		
Non-current liabilities		
Financial debt	29,194	32,032
Deferred income tax liabilities	1,550	1,818
Non-current deferred revenues	6,436	6,883
	37,180	40,733
Current liabilities		
Trade and other payables	58,951	55,018
Financial debt	5,843	4,274
Current deferred revenues	894	798
Provisions for other liabilities and charges	2,458	2,027
	68,146	62,117
Total liabilities	105,326	102,850
Total equity and liabilities	264,596	261,320



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED INCOME STATEMENTS FOR THE SIX-MONTH PERIODS ENDING 30 JUNE
2015 AND 30 JUNE 2014

(Thousands of euros)

	Six-month periods ending 30 June	
	2015	2014
Revenue	121,257	116,304
Cost of sales	(47,800)	(46,274)
Employee benefit expenses	(30,674)	(28,005)
Other operating expenses	(23,865)	(22,707)
Depreciation, amortisation and impairment charges	(4,907)	(4,249)
Recognition of government grants on non financial non-current assets and other	601	1,579
OPERATING PROFIT	14,612	16,648
Finance income	359	404
Finance costs	(678)	(1,218)
FINANCE COSTS - NET	(319)	(814)
PROFIT BEFORE INCOME TAX	14,293	15,834
Income tax	(723)	(879)
PROFIT FOR THE PERIOD	13,570	14,955



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED CASH FLOW STATEMENTS FOR THE SIX-MONTH PERIODS ENDING 30
JUNE 2015 AND 30 JUNE 2014

(Thousands of euros)

	Six-month periods ending 30 June	
	2015	2014
Cash flows from operating activities		
Profit before income tax	14,293	15,834
Adjustments for non-monetary transactions:		
Amortisation	4,907	4,249
Interest income	(359)	(404)
Impairment	(1,348)	1,374
Interest expense	678	1,218
Net changes in provisions	431	(296)
Grant for non-financial fixed assets and income from distribution licenses	(65)	(1,169)
Changes in working capital		
Trade and other receivables	848	(5,159)
Inventories	(1,447)	(8,239)
Trade and other payables	(5,106)	1,304
Other collections and payments		
Proceeds from distribution licenses	-	200
Interest paid	(199)	(16)
Income tax cash flow	441	(134)
Net cash generated (used) from operating activities	13,074	8,762
Cash flows from investing activities		
Purchases of intangible assets	(1,300)	(980)
Purchases of property, plant and equipment	(7,608)	(5,579)
Proceeds from sale of property, plant and equipment	6	-
Proceeds from sale of available-for-sale financial assets	-	9,590
Contracting current bank deposits	(170)	-
Interest received	401	404
Net cash generated (used) in investing activities	(8,671)	3,435
Cash flows from financing activities		
Repayments of financial debt	(1,386)	(6,763)
Proceeds from financial debt	305	600
Purchase of treasury shares	(4,914)	(1,499)
Reissue of treasury shares	594	1,283
Net cash generated in financing activities	(5,401)	(6,379)
Net (decrease)/increase in cash and cash equivalents	(998)	5,818
Cash and cash equivalents at beginning of the period	26,671	19,401
Cash and cash equivalents at end of the period	25,673	25,219