

2012

ANNUAL REPORT

ROVI





2012

ANNUAL REPORT

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Juan López-Belmonte López
Chairman

One more year, as the President of ROVI, I have the great pleasure to highlight the good results our company has achieved: ROVI increases its benefits. We, as ordinary citizens, are willing to hear some economic good news, as an incentive to keep working hard.

We are the people that have always supported ROVI: shareholders, employees, suppliers...and have the good news that, once again, balances are reflecting the figures and facts of everything that happened during the whole year, and as it should be, have been approved and signed by our auditors, with unqualified audit report.

During this year, ROVI has increased its level of net employment in 65 people, with a total workforce of 899 employees, has reached a turnover of 201.9 million euros, a net profit of 19.5 million euros and, as you know, the results for the first quarter of the current year 2013 have been excellent as well.

My duty as President is to ensure our accounts honesty to all our directors, employees, shareholders and suppliers. To do this, we incorporated years ago the highest level in principles and recommendations and the best corporate governance practices and internal monitoring systems of financial information.

Particularly, the company constantly monitors and control the recommendations of Good Governance Unified Code ("CUBG") published by the Spanish National Stock Market Commission, and the indicators proposed by this Commission to guide description for preparation of Internal Control over Financial Reporting (SCIF), and the results are reported in the Annual Report of Corporate Governance, published yearly by the company.

The company considers these practices as a system to generate value and security for its shareholders.

In this devastating scenario of Spanish economy, here is ROVI, making profits, despite the difficulties in the pharma sector.

In the Spanish pharmaceutical industry, current events show a 20% decrease of the market, as result of the Royal Decrees and specially the 7.5% and 15% discounts, leaving us and all pharmaceutical industry in a turnover similar to the one of 2008.

ROVI is the 24th in the ranking of prescription products (IMS of March 2013), and with a positive growth that will allow us to keep climbing positions.

Together with our marketing and sales success in Spain and abroad, we have to add the success of our net benefit: this year we have exceeded in 8% the previous year. The awards achieved, such as the Medal of Faculty of Pharmacy at Alcala de Henares University and Social Council Award at the University of Granada, are an acknowledgement to our work and an intangible support, improving ROVI's brand awareness and understanding between health professionals and citizenship.

I would also like to highlight from past year's events the fact that we have renewed the highest rating in Profarma Plan, a joint program set up by the Ministry of Industry, Tourism and Commerce, the Ministry of Health and Social Policy and the Ministry of Science and Innovation in order to promote competitiveness in the Pharmaceutical Industry. This is like the honour roll of Spanish pharmaceutical industry and can only be accessed by companies with the following activities:

- Research;
- National Manufacturing; and
- Export.

It is so easy to list it but so hard to achieve. Today the government says that Spanish trade balance is favourable. This is particularly so because companies like ourselves have been making our way at three areas. ROVI is currently present in 51 countries, we manufacture our products in Madrid, Alcala de Henares and Granada, in our three manufacturing plants.

Another problem Spain is facing is industrial deficit, as these last few years we have been dedicated to import, and I would like to take the opportunity to appeal to the Health and Economy Ministries to help companies like us, with manufacturing facili-

ties, because we are the ones that could employ people, and unfortunately for our country it has the highest unemployment rate and a large number of unemployed could find a job in industry.

In the current circumstances of the country, the grants for innovation have been reduced and this is big mistake, as if we do not carry out research we do not export. Exportation is the result of an added value, and this added value is the result of innovation. Innovation can not be interrupted or improvised, because among other reasons, it takes the most important resource: human talent; people trained at our universities, costing a lot of money to our society, that need to be employed and if they can not find a job will have to go abroad.

These difficulties are not new, it has been happening for the last five years, and if crisis go on for a period of time, we will find ourselves in a critical situation for research.

In ROVI we are focused on research and we hope to reap the benefits, although is early, but we are confident that will give us a higher revenue for exportation.

I would like to appeal from here to the Ministries of Health and Economy. To the Ministry of Health to continue assessing and recognizing innovations, particularly in the countries of origin. To the Ministry of Economy, to continue providing funds to the companies that patents their products on behalf of the kingdom of Spain. I would ask them to keep acting as an engine.

Finally would like to express my deep appreciation and gratitude to the almost one thousand people that form ROVI today, for their huge effort. Their commitment and enthusiasm towards our mission have been the drivers of the company, and with no doubt, the best guarantee that 2013 will be again a year of growth and success for us.

I would also like to thank shareholders for their loyalty and trust in ROVI and its Board of Directors.

ROVI in 2012



Main numbers

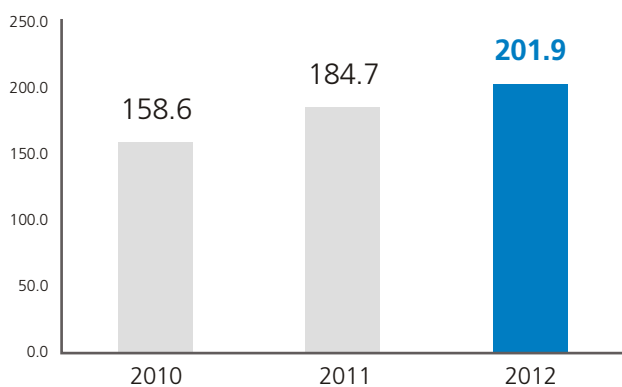
2012 was a significant and positive year for ROVI...

- Results in line with strategic targets.
- Significant increase in sales of prescription-based pharmaceutical products (**10%**), driven by the strength of Bemiparin, our flagship product, with sales up **10%**.
- Market share of Bemiparin at **24%** in Spain.
- Launch of Bemiparin in **6** new countries.
- Excellent performance of the last products launched:
 - Sales of Thymanax[®], an innovative antidepressant from Laboratoires Servier, launched in March 2010 and for which ROVI has a co-marketing agreement covering Spain, increased by **35%** to 11.6 million euros in 2012.
 - Sales of Vytorin[®] and Absorcol[®], the first of the five licenses of MSD, launched in January 2011, increased by **2.2** times to 12.4 million euros in 2012.
 - Sales of Corlantor[®], a specialty product for stable angina and chronic heart failure from Laboratoires Servier, rose **29%** to 9.2 million euros in 2012.

- Toll manufacturing sales increased by **34%** to 63.2 million euros in 2012 compared with the previous year, mainly as a result of the contribution of Frosst Ibérica plant whose revenue amounted to 44.1 million euros in 2012.
- Obtaining of the **FDA approval** for the injectables plant.
- Dividend proposal of **35%** of consolidated net profit for 2012 at the General Meeting of Shareholders.
- Payment of a gross dividend of **0.1366** euros per share on 2012 earnings. This proposed dividend would mean an increase of **8%** compared to the dividend on 2011 earnings.



...which delivered



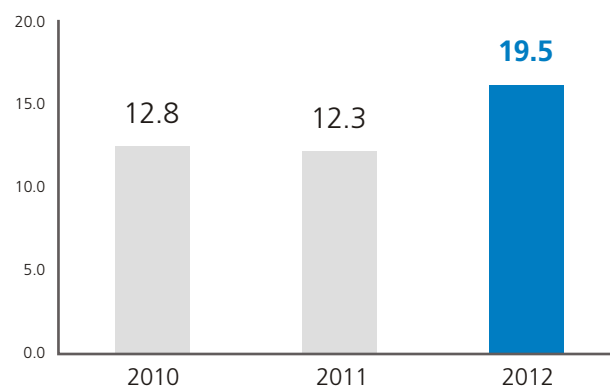
Operating revenues of **201.9** million euros

Growth of **9%** in 2012

Recurrent net profit of **19.5** million euros

Growth of **59%** in 2012

Note: Recurrent net profit excludes a one-off profit of €11.8m registered in 2010, caused by the Frosst Ibérica integration, and the sale of Fitoladius to a third party in 2011, which contributed revenue of 5.6 million euros.





ROVI in 2012

2012, the year in headlines

January

Enerzona launches
a new dietetic product
on to the market:
Cheesecake Snack
PM Farma
20 January, 2012



February

The EC authorises
the use of Corlentor
(ROVI) to treat cardiac
insufficiency
Expansión
15 February, 2012



ROVI earned 18.1
million euros in 2011
Globedia
21 February, 2012



March

Reducing cholesterol might prevent cerebrovascular diseases and ischemic cardiopathy in chronic kidney patients

Medicina 21
14 March, 2012

ROVI will manufacture for the United States

Negocio
20 March, 2012

An excess of perspiration may have a negative effect on self-esteem

Noticias de Salud
27 March, 2012



April

Ivabradine reduces the death rate by 40% in cases of cardiac insufficiency

Diario Médico
4 April, 2012

Agomelatine: an anti-depressant that does not deteriorate the sexual response

Psiquiatría.com
23 April, 2012

The pharmaceutical company ROVI earned 5.3 million euros up to March, a rise of 8%

La información.com
30 April, 2012



May

ROVI: "we are growing thanks to the lever that international sales provide"

Diario Financiero
4 May, 2012

Agomelatine improves the functionality of the patient with depression from the first few weeks of treatment

Europa Press
29 May, 2012



June

The European guide to cardiac insufficiency includes "Corlentor" (ROVI) as a treatment

Diario de Salud
 13 June, 2012

ROVI will pay a dividend of 0.1269 euros on 4 July

Lainformación.com
 13 June, 2012

ROVI's sales grew by 16% in 2011, in spite of the cutbacks in the sector

Diario Medico
 14 June, 2012



July

ROVI increased its net profit by 1%, to 13 million, in the first six months

El Economista
 26 July, 2012



August

ROVI has collected payment of 12.4 million euros from outstanding invoices from the Autonomous Regions

Invertia
 6 August, 2012



September

Yesterday, Tuesday, Esperanza Aguirre visited the laboratory of the Madrid pharmaceutical company ROVI in Alcalá de Henares

Sanifax
 5 September, 2012

ROVI obtains authorisation to market its injectables in the United States

Cinco Dias
 19 September, 2012

Solutions for growth outside Spain

El Mundo
 20 September, 2012



October

Heparin may reduce neurological deterioration after a stroke

Hospimedica.es
15 October, 2012

lvabradine reduces the number of recurrent hospitalisations due to cardiac insufficiency and improves the quality of life

El Médico Interactivo
23 October, 2012



November

ROVI raises its profit by 6%, up to 16.6 million euros, in the first nine months

Europa Press
8 November, 2012

ROVI says its operating revenue has risen by 10%

PM Farma
8 November, 2012

"To be Spanish and show sales growth of 10% is something to be proud of"

Diario Financiero
19 November, 2012



December

Half young Spanish sportspeople show problems related to cardiovascular risk

Europa Press
7 December, 2012

ROVI distributes a dividend and reinvests in order to grow

Expansión
8 December, 2012



Activities report

R&D



ROVI, committed to research

During the 20th and 21st centuries, the so-called “knowledge society” has displaced the former model of industrial society. While in the past the wealth of countries was generated by large farms and huge factories, nowadays national wealth stems, among others, from the research and innovation carried out at small or large technological centres that each contribute with their achievements to the increased productivity of their respective economies.

It is clear that the countries with the greatest growth are those where companies have been successful and have been able to generate added-value products that are then exported to the rest of the world.

This has led us to the conclusion that the companies that operate successfully in modern society are those that are rich in knowledge. Today, the success of companies is based above all on the achievements of their industrial research and innovation.

ROVI is a company that is committed to research. Its success can be clearly seen in the extraction of the first second generation low molecular weight heparin, Bemiparin (HIBOR®), currently present in 51 countries.

In view of ROVI's research commitment, it is essential to protect any inventions that might arise in the course of this research and this protection is mainly achieved through the patent system.

The generation of patents titles and industrial know-how is a clear reflection of the innovative work carried out by ROVI. The laboratory currently has a solid patent portfolio, comprising more than 130 granted patents and over 40 pending applications.

Our innovative approach

ROVI has always stood out for our highly defined approach to innovation and our commitment to investment in research, as we believe that the future of the company depends on carrying out these activities. Research and innovation are essential and strategic in order to compete in the modern market, and are crucial in order to differentiate ourselves from other companies in the sector.

With this in mind, ROVI has two R&D&I centres following the recent creation of a new research centre covering more than 1,300 m² located in the Parque Tecnológico de las Ciencias de la Salud de Granada, the most important Spanish Biopharmaceutical cluster.

Since 2006, ROVI has been present in the creation of major national research consortia. In 2006, the research activities of the NANOFARMA Consortium began as part of a large

biomedicine project focused on research into controlled drug release within the framework of the CENIT programme (the Spanish National Strategic Consortia for Technical Research), an initiative of the current government included within the "Ingenio 2010" Programme.

ROVI has also been playing an active role in other consortia and national plans, including the MELIUS CENIT Consortium of pharmaceutical and bio-technological companies, in 2009 the CEYEC CENIT Consortium and, since 2011 as leader of the SNCintegra (FEDER Innterconecta) consortium and the National PROFARMA Plan to encourage R&D&I in the pharmaceutical industry, in which ROVI has obtained, for the seventh year in a row, the recognition of "excellent," based on our ongoing research efforts in R&D&I, the quality of the projects under way and the recent internationalization of our products.



Our research

1.- DRUG DELIVERY TECHNOLOGIES

One of the most important stages in the development of a drug is the study of how it should be administered. The right administration has a direct effect on the drug's efficacy, as it influences factors such as its pharmacokinetics, pharmacodynamics, safety, immunogenicity, and bio-recognition of the drug, among others. On the other hand, investigation in this field also enables the minimization of such fac-

tors as degradation of the active substance, allows the prevention of side effects and increases the bio-availability of the drug in the body.

ROVI has developed a leading-edge research line in the field of prolonged release or depot systems, by using the ISM[®] technology. This technology is based in the formation of "in situ" forming implants for long-term release of drugs.



1.1. Extended release systems: ISM[®] (In Situ Microparticles system)

In situ forming systems (ISM[®]) have emerged as a very attractive possibility for the extended release of bioactive macromolecules.

Over the last few years, the development of the ISM[®] technological platform has been very fast and has made it possible for depot formulations to become a scientific fact. A depot injection is generally a subcutaneous or intramuscular injection of a pharmacologically active agent that releases the active substance in a constant flow over a long period of time.

Our ISM[®] technology is based on a solid and stable polymeric matrix system of drug, excipients and solvent. The product is reconstituted before administration to an injectable fluid that precipitates in situ (inside the body) after the injection, resulting in the formation of solid/semisolid implants, by solvent diffusion to body fluids.

ISM[®] technology overcomes most of the current difficulties associated with the oral and parenteral extended release formulation combining the advantages of existing techno-

logies such as preformed microparticles and implants. Our technology allows the extended delivery of compounds administered by parenteral via with the following key advantages: less variability, enhanced stability, rapid reconstitution and easier injectability, making it easier for the patient to follow the prescribed treatment.

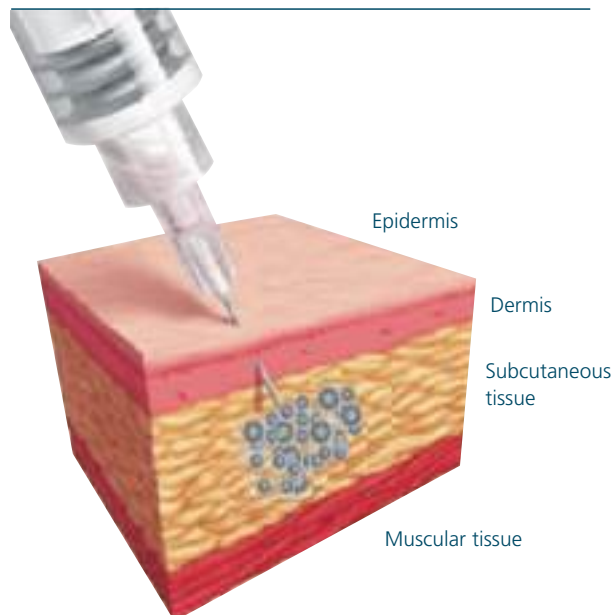
Our ISM[®] systems have the following advantages over technologies existing in the market: (I) ease administration as it is less painful, (II) zero-order kinetics, (III) reduction of the burst effect in drug release and greater reproducibility in the release profiles, (IV) highly effective encapsulation, (V) high performing process and, finally, (VI) improvement in the stability of the active substance.

The establishment of this novel field of research in ROVI arose from the interest showed by the company in the development of formulations with the aim of allowing periodic administration of formulations which are administered daily in chronic and prolonged treatments, improving the patient's quality of life. This novel approach allows ROVI to enter and compete in new therapeutic areas. Extended release formulations based on ISM[®] technology are currently being developed for psychiatric and oncologic drugs due to their industrial potential, commercial and sanitary interest.

The development of ISM[®] technological platform arose from the interest showed by the company in the development of formulations with the aim of allowing periodic administration of formulations which are administered daily in chronic and prolonged treatments, improving the patient's quality of life

In September 2010, the experimental stage began for the first Phase I trial of Risperidone-ISM[®] on healthy volunteers, the first candidate for this drug delivery system. This first trial aimed mainly to evaluate the pharmacokinetics and the tolerability of a single intramuscular administration of risperidone in an ISM[®] formulation. This trial has served not only to confirm this innovative depot formulation for the monthly administration of a recognised anti-psychotic the pharmacokinetic profile, but also it has served as proof of concept for validating ISM[®] technology as a technological platform for future pharmacological candidates. In this regard, two new formulations with ISM[®], for the monthly administration of another widely used anti-psychotic (paliperidone), and for the quarterly administration of a recognised aromatase inhibitor (letrozole) that is currently used extensively on the treatment of hormone-dependent breast cancer, are already in an advanced pre-clinical phase.

On the other hand, during 2012 ROVI undertook important investments in order to build a manufacturing plant for new medicines in Madrid, using the ISM[®] technology, which will be equipped with a very innovative, and unique in its class, machinery for filling solid compounds in syringes under good manufacturing practices. Thanks to these new facilities, ROVI will be prepared to supply with quality and agility the needed samples for carrying out the clinical trials within the next years, and in the future, the industrial production of commercial batches.



1.2. Clinical research: ISM[®] (In Situ Microparticles system)

ROVI has already initiated the research program with this technological platform for some compounds and currently there are several projects on different development phases:

- **Risperidone ISM[®]**: in 2010, the clinical testing stage began for the first Phase I trial of Risperidone ISM[®] on healthy volunteers and finished by the end of the first quarter of 2011. This first trial aimed mainly to evaluate the pharmacokinetics and the tolerability of a single intramuscular administration of risperidone in an ISM formulation¹. In July 2011, ROVI disclosed the positive results obtained from this phase I clinical trial². The analysis of the data showed that ISM technology enables the sustained delivery of risperidone from day one, which will allow for once-monthly administration without the need for supplementary oral risperidone in the first weeks. These characteristics will facilitate the adherence with treatment of schizophrenic patients, and represent an improvement on the risperidone formulations that are currently available in the market. The full results were presented at the 3rd European Conference on Schizophrenia Research held in Berlin in September 2011³.



After obtaining these favourable results, in 2012 ROVI has held meetings with the Spanish Agency of Medicines and the U.S. *Food and Drug Administration* in order to get scientific and regulatory advice on the clinical development of Risperidone ISM[®]. In addition, in 2012 it was obtained the approval for starting up the PRISMA-1 study⁴, a new multicentre, international, phase I study to evaluate the pharmacokinetic profile and safety of single doses of Risperidone ISM[®] at different concentrations administered to schizophrenic patients. It is planned as well to initiate in 2013 the PRISMA-2 study, which is a multicentre, phase II clinical trial intended to evaluate the pharmacokinetics and safety of Risperidone ISM[®] after multiple monthly injections.

• **Paliperidone ISM[®]**: during 2012 the preclinical development of another widely used antipsychotic has been starting for the once monthly administration of paliperidone by the patented ROVI's technology ISM[®]. It is expected to start the development in humans by the first half of 2014.

• **Letrozole ISM[®]**: ROVI is also dedicating its efforts for the development of a novel formulation for a quarterly injection of a well-recognised aromatase inhibitor, letrozole. The project is already in an advance pre-clinical phase under animal testing. Letrozole is currently considered as a key therapy for the treatment of the hormone-dependent breast cancer and the ISM[®] technology may provide better compliance and additional benefits to those patients who are suffering from this type of tumour.

- (1) Trial of Risperidone ISM[®]. ClinicalTrials.gov, National Institutes of Health; NCT01320410
[\[http://www.clinicaltrials.gov/ct2/show/NCT01320410?term=NCT01320410&rank=1\]](http://www.clinicaltrials.gov/ct2/show/NCT01320410?term=NCT01320410&rank=1).
- (2) Laboratorios Farmacéuticos Rovi, S.A. ROVI announces positive results from the Phase I trial for the monthly injectable formulation of Risperidone-ISM. Press release, July 11, 2011
[\[http://www.rovi.es/otros/89.pdf\]](http://www.rovi.es/otros/89.pdf).
- (3) 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.
- (4) Pharmacokinetic, Safety, and Tolerability Study of Risperidone ISM[®] at Different Dose Strengths (PRISMA-1). ClinicalTrials.gov, National Institutes of Health; NCT01788774
[\[http://www.clinicaltrials.gov/ct2/show/record/NCT01788774?term=NCT01788774&rank=1\]](http://www.clinicaltrials.gov/ct2/show/record/NCT01788774?term=NCT01788774&rank=1).

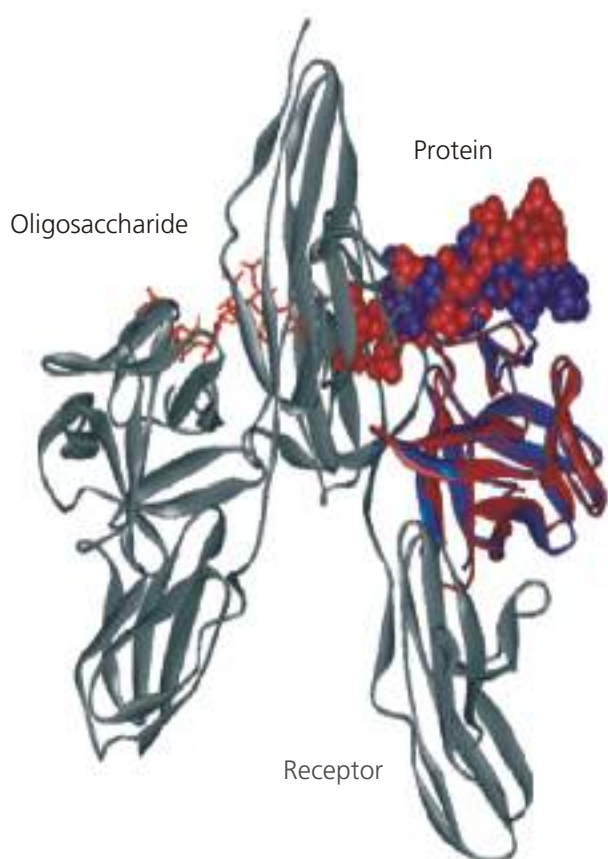
1.3. Pipeline: ISM[®] (In Situ Microparticles system)

Platform	Product	Potential indication	Current situation			
			Pre-clinical	I	II	III
ISM	Risperidone, monthly	Schizophrenia	Pre-clinical	I	II	III
	Paliperidone, monthly	Schizophrenia	Pre-clinical	I	II	III
	Letrozole, quarterly	Breast Cancer	Pre-clinical	I	II	III

2. GLYCOMICS

The extracellular matrix in animal tissues is a medium in which there is intense intercellular communication. This communication takes place through recognition phenomena between biomolecules which, unlike the intracellular interactions, take place in an unconfined medium implying notable requirements in terms of selectivity and specificity. In this context, it is important to highlight the essential role played by carbohydrates as this is the type of biomolecule with the greatest capacity for structural diversity and therefore for transmitting information. For this reason, the new term of glycomics has recently been coined as an innovative solution for seeking out carbohydrates with new activities. Glycomics comprises the study and characterization of the sugars making up a cell.

Glycosaminoglycans (GAGs) constitute the main component in the proteoglycans present in the extracellular matrix. These polysaccharides, apart from their well-known role in the regulation of blood clotting, are involved in the control of a large number of cell signalling processes, including in particular processes for cell growth, differentiation, proliferation, immune response and inflammation. In order to exercise these functions, GAGs have to interact, more or less specifically, with numerous proteins taking part in the



activation or inhibition of the corresponding signalling cascade. Glycomics studies provide very valuable information in this sense, as they allow determination of the receptors taking part in the interaction with each type of GAG.

In 2012, ROVI signed a collaboration agreement with the Department of Biomedical Sciences of the University of Padova (Italy) for studying *in vitro* and animal models whether Bemiparin and some glycosaminoglycan compounds obtained by ROVI could have any effect on the control of the renal fibrosis and the progression of the nephropathy.

2.1. Clinical research: glycomics

The degree of specialization achieved in this area allows consideration of the expansion of applications, indications and alternative mechanisms of action for the heparin-derived products and other glycosaminoglycans, based on both anticoagulant and non-anticoagulant activities.

In October 2011, ROVI announced⁵ the presentation of the results of the final analysis of the “ABEL” clinical trial (**Adjuvant Bemiparin Evaluation study in small cell Lung cancer**) during the XIII National Congress of the Spanish Society of Medical Oncology. The study was aimed to assess the effectiveness and safety of Bemiparin (3,500 IU/day for 26 weeks) in patients with limited small cell lung cancer who are receiving standard anti-tumour treatment (platinum-based chemotherapy and radiotherapy)⁶.



According to the data analysis from a total of 39 patients with limited stage disease of small cell lung cancer (after ending the inclusion of new patients because of a slow recruitment rate), it was shown that the disease progression-free survival time (the primary outcome of the trial) increased by 1.5-fold, and the overall survival time increased by 3.3-fold, in the group of patients who received Bemiparin, compared to the control group without Bemiparin, with no rise in the incidence of haemorrhage⁷.

In the light of these results, and taking into consideration the fact that the time and resources needed to continue with the development of Bemiparin for this new therapeutic

area are significant, ROVI has decided to look for a partner that specialises in oncology, with the appropriate experience and resources for undertaking the clinical development with sufficient guarantees.

In addition, in 2012 ROVI signed another collaboration agreement with the Fundació del Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau for carrying out a randomized controlled clinical study to compare Bemiparin against oral anti-vitamin K in patients with anticoagulation requirements and history of previous gastrointestinal haemorrhage (HEPACO study)⁸.

(5) Laboratorios Farmacéuticos ROVI S.A. The results of the ABEL clinical trial suggest that Bemiparin could be beneficial against small cell lung cancer. Press release, October 19, 2011. <http://www.rovi.es/ficheros/120i.pdf>

(6) Adjuvant Bemiparin in Small Cell Lung Carcinoma (ABEL STUDY). ClinicalTrials.gov, National Institutes of Health; NCT00324558. <http://clinicaltrials.gov/ct/show/NCT00324558?order=2>.

(7) B. Massuti, et al. Phase II, randomized trial of bemiparin associated to chemotherapy in small cell lung cancer: Final results from ABEL study. Oral communication. XIII National Congress of the Spanish Society of Medical Oncology (Málaga, October 19-21, 2011).

(8) Compare VKA vs LMWH in Patients With Anticoagulation Criteria and Episode of Gastrointestinal Bleeding. (Hepaco). ClinicalTrials.gov, National Institutes of Health; NCT01727453 [<http://www.clinicaltrials.gov/ct2/show/NCT01727453?term=bemiparin&recr=Open&rank=3>].

3. MULTILAYER TECHNOLOGIES USED TO DEVELOP URETRAL CATHETERS

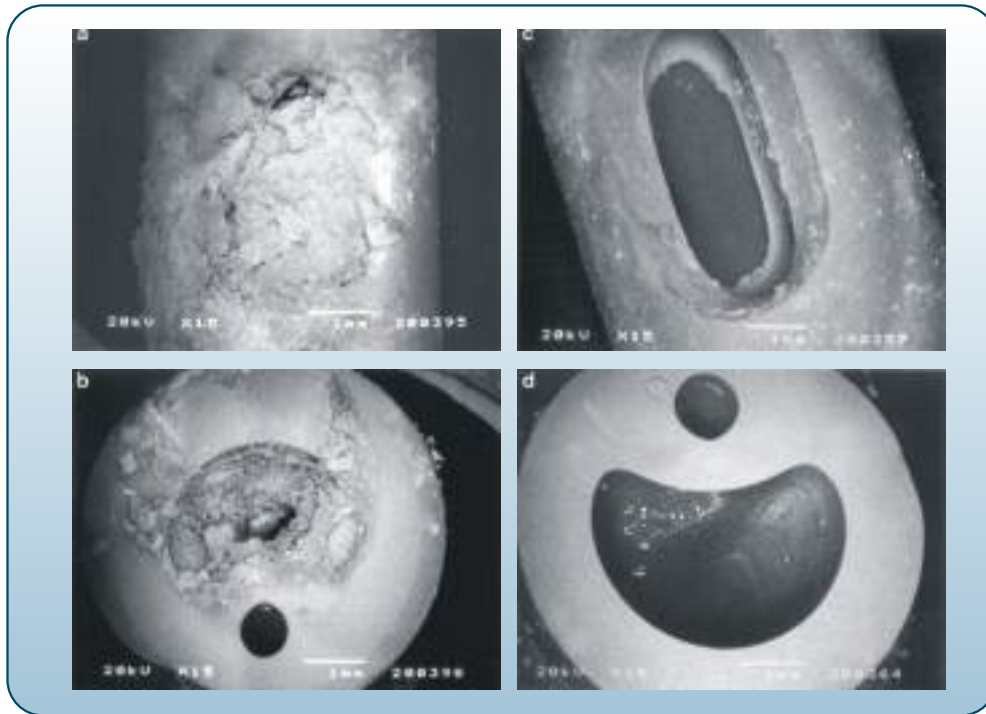
One of the most relevant side effects of using urinary tract catheters is the high prevalence of urinary tract infections that leads to high mortality rates (sepsis and death) and causes significant costs in health care systems. Despite the extensive employment of closed systems or catheters coated with antibacterial compounds to prevent urinary tract infections, the incidence of uretral catheter associated urinary tract infections is still high, as biofilm formation (figure 1) reduces microorganism elimination with the use of antibiotics.

ROVI has recently patented a multilayer technology platform that is currently under development. This technology will be initially used to develop uretral catheters. The development of this technology 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.



Figure 1. Biofilm formation.

Figure 2. Catheter encrustation.



Therefore, urethral catheters based on ROVI's multilayer technology platform will constitute an alternative over existing medical devices, increasing patient's quality of life, reducing the use of antibiotics and reducing catheter substitutions due to blockage and also reducing morbidity and hospitalization associated to the use of these devices.

In 2012, ROVI developed several polymeric compositions and many microbiological trials were performed in order to evaluate performance of each composition on their capacity of avoiding bacterial attachment, promoting biofilm elimination and avoiding the formation of encrustations. These results were also compared over those obtained with materials commonly used in catheter fabrication such as silicone and PVC. ROVI started also in 2012 a scale-up processes study and it developed the first technological beneficial prototypes for in vivo trials and it started also in vivo efficacy studies in animals in 2013, which are currently in the process of being patented.

The development of this innovative research line will provide ROVI with the ability to extend company's patents and commercial products portfolio in the medical devices field in a competitive way, as the technology can be also used as a platform for future developments.

4. NITVIEW® LEDCOMB

New Revolutionary Technology for Effective Lice and Nits Location and Extraction.

In 2012, ROVI signed a worldwide exclusive license for the industrial property rights and manufacturing, distribution and marketing rights assignment of the new system for lice and nits location and extraction Nitview® Ledcomb. After signing the contract, ROVI has been involved in the product development, especially during the technology transfer from the prototype to the final model, as well as during the industrial manufacturing optimization, which has been performed provided that ROVI estimates to proceed with the Spanish and International commercial launch in the second half of 2013.

Nitview® Ledcomb is a Spanish invention system internationally patented (WO2010089433; EP2394528B1; ES1070286U), incorporating an ultraleds torch emitting ultraviolet (UV) light with a wavelength close to visible spectrum (400-405nm, light range naturally visible to the human eye) for an easier location and extraction of lice and nits. The mentioned wavelength is absorbed by the keratin present in the exoskeleton of lice and nits, which emits fluorescence during the exposure, thus facilitating an effective visualization of parasites that allows to remove them in a satisfying way. The ultraleds torch is attached to a detachable comb with micro-channelled teeth (to facilitate nit removal).



Activities report



International

Since 2001 when approval was obtained to launch Bemiparin in the leading European markets, thanks to the first mutual recognition procedure in the United Kingdom, Italy, Austria, Greece, Ireland and Portugal, ROVI has been unstoppable in its efforts to extend the presence of Bemiparin through the international community and share its benefits with doctors and patients all over the world.

Since then, and due to ROVI's dedication and its strategy of opting for the international trade, Bemiparin has extended its presence, whether in pre-registration, registration or marketing stage, to a total of 82 countries thanks to the strategic alliance established with our 19 international partners. ROVI has achieved distribution agreements with highly entrepreneurial pharmaceutical companies that are strongly committed to health such as: Menarini in Central America and Argentina and via its subsidiary Berlín-Chemie, in Central and Eastern Europe and in CIS countries; Sigma-Tau in Italy; Gerot Lannach in Austria; Vianex in Greece; Dem Ilac in Turkey; Hikma in the Middle East and North Africa; Elder Pharmaceuticals in India; Aspen Pharmacare in South Africa; and UCB in Mexico.

The successful conclusion of a new mutual recognition procedure in 8 Eastern European countries, allowed ROVI in 2006 and 2007 to introduce Bemiparin into new European markets such as Czech Republic, Hungary, Slovakia, Poland, the Baltic States (Lithuania, Latvia and Estonia), which in 2008 were joined by Ukraine and Bulgaria and finally Slovenia in 2009.

The period between 2008 and 2011 has been very active for Bemiparin internationally, with the incorporation of new international partners (Apsen in Brazil, UCB in Mexico, CSC Angellini in Romania, Laboratorios Biopas in Venezuela, Haji Medicine Co. in Pakistan, PT Dexta Medica in Indonesia and Iberma in Morocco) and new launches in Russia, Belarus, Bolivia, Bahrein, Turkey, Ukraine, Kuwait, Yemen, Algeria, Bulgaria, Colombia, Morocco, Chile, Georgia and Moldavia.



In 2012, the international expansion of Bemiparin was consolidated with the signature of agreements with companies like STADA in Vietnam, Filipinas, Thailand, Singapore and Malaysia, Il-Sung in South Korea and Livar in Iran and the launches in countries like Mexico, Venezuela, Saudi Arabia, Syria, Oman and Iraq, which, without any doubt, have contributed to impulse the globalization process of our innovative second generation molecule.

This way, Bemiparin has positioned itself as one of the leading therapeutic proposals to prevent and treat venous thromboembolic disease (VTD) in the 51 countries, including Spain, where it is currently marketed.

In terms of the activities carried out this year for the international scientific community, we should highlight the participation of Bemiparin in the thirteenth edition of the EFORT (European Federation of National Associations of Othopaedics and Traumatology) congress in May, where Bemiparin organized a workshop for all the international doctors invited by our partners. Likewise, ROVI participated in the XXII ICT (International Congress on Thrombosis) organized by the MLTD (Mediterranean League against Thromboembolic Disease) with a stand in the exhibition area, a meeting point for our international partners and their doctors.

Furthermore, we supported our partner in Central America, Menarini, in the organization of the Third Conference of Multidisciplinary Experts in Thromboprophylaxis in El Salvador with the participation of opinion leaders from this region. In Italy, ROVI participated with a symposium in the sixth edition of the ICTHIC (International Conference on Thrombosis and Hemostasis Issues in Cancer).

As it is becoming traditional, in May took place the fourth edition of the prestigious "Anti-Thrombosis Masterclass" held in Santiago de Compostela, Spain. This is the most outstanding conference in which Bemiparin is present and in this last edition had an audience of 120 of the most significant international opinion leaders. The year concluded with the meeting "Bemiparin. Meet the experts" in Prague, Czech Republic where 100 international doctors were brought together.

The development of our web page www.bemiparin.com in 2008, with exclusive access for international partners, and the launch in 2009 of another portal called Bemimed ("Bemiparin International Medical Information"), has allowed us to position the molecule in a digital and interactive environment, making use of new technologies to promote not only the exchange of promotional and scientific information about our molecule with our international partners but also the spreading of the latest advances on venous thromboembolic disease and the use of Bemiparin with our scientific community. During 2011, the private portal for our partners and doctors experienced a significant increase in terms of registered users, mainly due to the constant updates provided on scientific publications and information about our international activities for healthcare professionals.

In 2013, ROVI has aimed to boost the use of this web site for both the partner and doctors' access with new contents, in order to be useful to spread the knowledge of the product and the VTD in the daily clinical practice.



Activities report

Products



Hibor®

CARDIOVASCULAR

Venous thromboembolic disease (VTD) includes deep-vein thrombosis in the lower or upper limbs (DVT) and pulmonary embolism (PE). VTD is a serious and potentially fatal process, characterized by the formation of a fibrin clot, thrombosis, inside the veins of the deep vein system, with all the consequences of the evolution of venous thromboses, including growth, progression and fragmentation. In the latter case, some of the fragments may break loose and reach the lung, causing PE.

In Spain the data handled indicate around 65,000 cases of DVT and 25,000 of PE per year, giving a total incidence of 90,000 cases per year (Thromb Haemost 2000, 2001 and 2005).

Hibor (Bemiparin) is a low molecular weight heparin ("LMWH") indicated for preventing and treating venous thromboembolic disease (TED), both in surgical and medical patients, and for the intense and long-term treatment of patients who have suffered a TED process.

It is also indicated for preventing coagulation in the extracorporeal circuit during haemodialysis.

Hibor (Bemiparin) has consolidated its position in the market for anti-thrombosis drugs as the second most-sold LMWH in Spain (IMS, December 2012).

It has a significant international presence. The product has been approved in 56 countries in 4 continents, and is also in the approval process in several countries.



Corlontor (ivabradine) is indicated for:

- **Treatment of coronary artery disease**

Symptomatic treatment of chronic stable angina pectoris in adults with coronary artery disease with normal sinus rhythm:

- in adults unable to tolerate or with a contraindication to the use of beta-blockers;
- or in combination with beta-blockers in patients inadequately controlled with an optimal beta-blockers dose and whose heart rate is > 60 bpm (beats per minute);

- **Treatment of chronic heart failure**

Ivabradine is indicated in patients with chronic heart failure in NYHA II to IV with systolic dysfunction, in patients in sinus rhythm with heart rate ≥ 75 bpm:

- in combination with standard therapy including beta-blocker therapy;
- or when beta-blocker therapy is contraindicated or not tolerated.

Corlontor is supplied in film-coated tablets containing 5 mg and 7.5 mg of ivabradine. It is a product developed by Les Laboratoires Servier and marketed in Spain by Laboratorios Farmacéuticos Rovi, S.A.

The epidemiology data on stable angina in Spain, gathered in the "OFRECE" study (<http://www.secardiologia.es/formacion-y-becas/elearning/webinars/4508-resultados-del-estudio-ofrece>), on the situation of ischaemic cardiopathy in this country, estimate its prevalence at between 600,000 and 700,000 patients.

Chronic heart failure affects 1.2 million patients in Spain (10% of the population over 60 years of age) (Muñiz et al. Rev. Esp Cardiol supl. 2006;6:2F-8F; INE (National Institute of Statistics) 2011). It is a disabling condition and, despite improvements in treatment and management, generally has a poor prognosis, with a survival of only 50% after five years from the diagnosis. In Spain, heart failure is the fourth cause of mortality, which means 15% of all the cardiovascular deaths, and it is the first cause of hospitalization (INE (National Institute of Statistics) 2011).





Ameride®

CARDIOVASCULAR

Ameride is indicated for the treatment of hypertension (high blood pressure) especially in patients with low potassium levels, edema with a coronary origin (swelling of ankles, feet or legs, due to retention of water), and ascites (accumulation of water in the abdomen) due to a cirrhosis (liver disease).

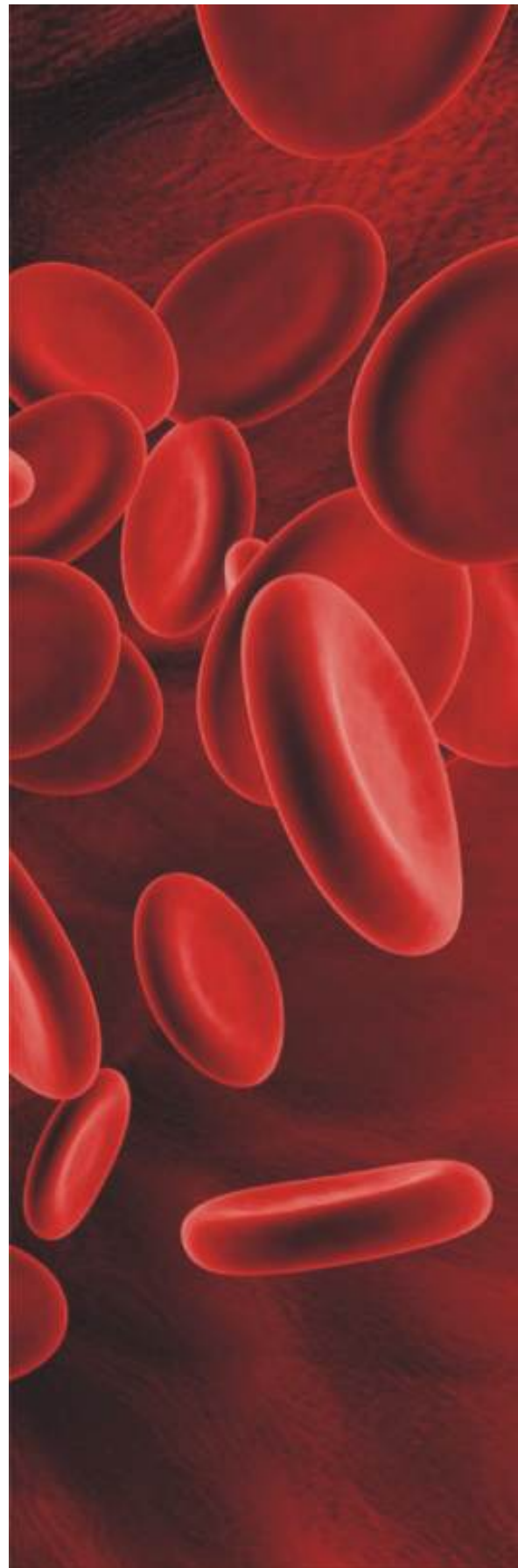
Ameride is a combination of amiloride hydrochloride and hydrochlorothiazide. The component amiloride that is contained in Ameride belongs to the antidiuretic type of agents (potassium conserving); amiloride is also a weak diuretic. The component hydrochlorothiazide in Ameride belongs to the diuretic (thiazide) group of drugs. Ameride acts by making the kidneys eliminate more water and salt and retain more potassium. This helps to reduce hypertension and some forms of edema, while at the same time helping to maintain normal levels of potassium in the blood.

Prinivil® and Prinivil® Plus

CARDIOVASCULAR

Prinivil contains lisinopril and belongs to a group of drugs which are known as inhibitors of the angiotensin converting enzyme (ACE inhibitors). Prinivil is indicated for the treatment of hypertension (high blood pressure), for the treatment of symptomatic heart failure, the short term treatment of acute myocardial infarction, and the treatment of complications related to the type II diabetes kidney in patients with hypertension.

Prinivil Plus contains two different active principles: (i) the component lisinopril, a drug which belongs to the group of ACE inhibitors, and (ii) the component hydrochlorothiazide, which belongs to the diuretic group. Lisinopril dilates blood vessels and facilitates the pumping of blood from the heart to all parts of the body. Hydrochlorothiazide enables the kidneys to let pass more water and salt. Combined, both components work to reduce high blood pressure.



Vytorin®

CARDIOVASCULAR / PRIMARY CARE

Hypercholesterolaemia

Vytorin is indicated as adjunctive therapy to diet for use in patients with primary (heterozygous familial and non-familial) hypercholesterolaemia or mixed hyperlipidaemia where use of a combination product is appropriate:

- patients not appropriately controlled with a statin alone; and
- patients already treated with a statin and ezetimibe.

Vytorin contains ezetimibe and simvastatin. Simvastatin (20-40 mg) has been shown to reduce the frequency of cardiovascular events. A beneficial effect of ezetimibe on cardiovascular morbidity and mortality has not yet been demonstrated.

Homozygous familial hypercholesterolaemia (HoFH)

Vytorin is indicated as adjunctive therapy to diet for use in patients with HoFH. Patients may also receive adjunctive treatments (e.g. low density lipoprotein [LDL] apheresis).

Vytorin is marketed in tablets containing 10 mg of ezetimibe and 20 mg of simvastatin and in tablets containing 10 mg of ezetimibe and 40 mg of simvastatin.

It is a product developed by Merck Sharp & Dohme and marketed in Spain by ROVI since 2011.



Absorcol®

CARDIOVASCULAR / PRIMARY CARE

Primary hypercholesterolaemia

Absorcol co-administered with a HMG-CoA reductase inhibitor (statin) is indicated as adjunctive therapy to diet for use in patients with primary (heterozygous familial and non-familial) hypercholesterolaemia who are not appropriately controlled with a statin alone.

Absorcol monotherapy is indicated as adjunctive therapy to diet for use in patients with primary (heterozygous familial and non-familial) hypercholesterolaemia in whom a statin is considered inappropriate or is not tolerated.

Homozygous familial hypercholesterolaemia (HoFH)

Absorcol co-administered with a statin, is indicated as adjunctive therapy to diet for use in patients with HoFH.

Patients may also receive other adjunctive treatments (e.g., LDL apheresis).

Homozygous sitosterolaemia (phytosterolaemia)

Absorcol is indicated as adjunctive therapy to diet for use in patients with homozygous familial sitosterolaemia.

A beneficial effect of Absorcol on cardiovascular morbidity and mortality has not yet been demonstrated.

Absorcol is supplied in tablets containing 10 mg of ezetimibe. It is a product developed by Merck Sharp & Dohme and marketed in Spain by ROVI since 2011.



Osseor®

OSTEOARTICULAR

Osseor, whose main active ingredient is strontium ranelate, is indicated for the treatment of osteoporosis in postmenopausal women in order to decrease the risk of spinal or hip fractures. It is also indicated for the treatment of osteoporosis in men with a high risk of fracture.

It is the result of research at Les Laboratoires Servier and has been marketed by ROVI since 2005.

Osteoporosis is a skeletal disease characterized by lowered bone resistance that predisposes people to an increased risk of fracture. Of the 3.5 million people who suffer from osteoporosis in Spain, only 18% are diagnosed. Approximately 33% of women aged between 60 and 70 and 66% of women over 80 years of age have osteoporosis. It is calculated that 47% of women may suffer an osteoporotic fracture (Rev Clin Esp. 2003; 203 (10): 496-506; Rev Clin Esp. 2008; 208 Supl 1:1-24).

The Spanish osteoporosis market involves around 10.5 million treatments each year, which represented around 251 million euros in 2012. Osseor has a market share by value of around 2.6% (IMS, MAT December 2012).



Bertanel®

OSTEOARTICULAR

Bertanel is a parenteral methotrexate, indicated for:

- active rheumatoid arthritis in adult patients when treatment with disease-modifying antirheumatic drugs (DMARDs) is indicated;
- polyarthritic forms of severe active juvenile idiopathic arthritis (JIA), when the response to non-steroidal anti-inflammatory drugs (NSAIDs) has been inadequate; and
- severe recalcitrant incapacitating psoriasis that doesn't respond properly to other therapies such as phototherapy, PUVA and retinoids, and severe psoriatic arthritis in adults.

Bertanel is supplied in prefilled syringes. It is a product that has been developed by EBEWE Pharma and has been marketed by ROVI in Spain since September 2010.



Calcio and Vitamina D3 ROVI®

OSTEOARTICULAR

ROVI Calcium and Vitamin D3 is indicated to correct a combined deficiency of calcium and vitamin D in the elderly, and as vitamin D and calcium supplement, as an adjuvant to specific therapy, for the treatment of osteoporosis in patients with manifest deficiency of combined calcium and vitamin D or a high risk of this deficiency.

In adults, the daily calcium requirement is 1,000 mg while in the elderly and post-menopausal women, it is at least 1,200 mg. Likewise, it is advisable for adults older than 50 to ingest 800-1000 IU/day of vitamin D ("National Osteoporosis Foundation's Updated Recommendations for Calcium and Vitamin D3 Intake", reviewed October 2008).



Glufan®

OSTEOARTICULAR

Glufan is indicated for relieving symptoms of mild to moderate degenerative osteoarthritis.



Exxiv®

PAIN RELIEF

Exxiv is a selective COX-2 inhibitor indicated for the symptomatic relief of osteoarthritis (OA), rheumatoid arthritis (RA), ankylosing spondylitis, and the pain and signs of inflammation associated with acute gouty arthritis.

The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks.

Exxiv offers different concentrations based on the disease

for which symptoms are to be treated. It is supplied in film-coated tablets containing 30 mg and 60 mg (both indicated for osteoarthritis), 90 mg (for rheumatoid arthritis and ankylosing spondylitis), and 120 mg of etoricoxib (acute gouty arthritis, only for 8 days of treatment).

It is a product developed by Merck Sharp & Dohme and marketed in Spain by ROVI since 2008.





Thymanax®

CENTRAL NERVOUS SYSTEM

Thymanax is an antidepressant which is indicated for adults with major depressive episodes. It is the result of research at Les Laboratoires Servier and has been marketed by ROVI since 2010.

Depression is currently one of the main challenges of Spanish public health, and is the cause of significant suffering for an increasing number of patients and also for their families, with a major impact on their quality of life. In addition, depression is accompanied by high socio-economic costs, due to its consequences both in social and labour areas. The WHO (World Health Organisation) calculates that in 2020 major depression will be the second largest cause of disability, behind cardiovascular diseases (Murray CJ, Lopez AD. Alternative projections of mortality and disability by cause 1990-2020: Global Burden of Disease Study. Lancet 1997;349(9064):1498-504).

Tryptizol®

CENTRAL NERVOUS SYSTEM

Tryptizol belongs to a group of drugs known as tricyclic antidepressants and contains amitriptyline.

It is indicated for the treatment of depression, nocturnal enuresis (involuntary release of urine in sleep) when organic pathology has been excluded, and chronic neuropathic pain (pain caused by damage to the nervous system).



Activities report

Hospital division



Sonovue®

IMAGING DIAGNOSTIC AREA
IMAGING CONTRAST MEDIA

Sonovue, marketed by ROVI under a license from Bracco Imaging S.p.A., is a medicinal product for diagnostic use only, used in order to enhance the ultrasound imaging of the echogenicity of the blood, which results in an improved signal to noise ratio.

Sonovue is indicated for:

- **Echocardiography**

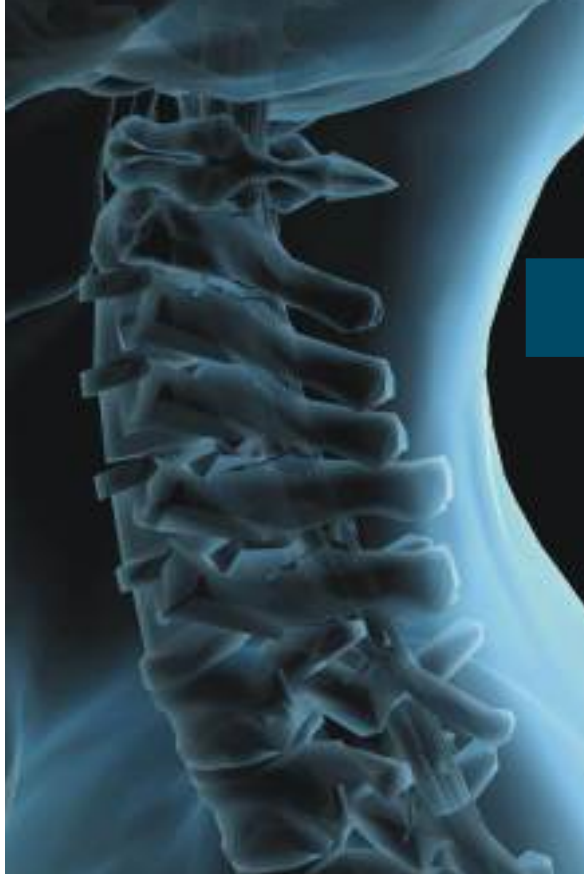
Sonovue is a transpulmonary echocardiographic contrast agent for use in patients with suspected or established cardiovascular disease to provide opacification of cardiac chambers and enhance left ventricular endocardial border delineation.

- **Doppler of macrovasculature**

Sonovue increases the accuracy in detection or exclusion of abnormalities in cerebral arteries and extracranial carotid of peripheral arteries by improving the Doppler signal to noise ratio. Sonovue increases the quality of the Doppler flow image and the duration of clinically useful signal enhancement in portal vein assessment.

- **Doppler of microvasculature**

Sonovue improves the display of the vascularity of liver and breast lesions during Doppler sonography, leading to more specific lesion characterization.



lomon® and lopamiro®

IMAGING DIAGNOSTIC AREA
IMAGING CONTRAST MEDIA

lomon and lopamiro are two nonionic iodinated radiographic contrast media for diagnosis by computerized tomography or X-ray diagnostic techniques. These two products are marketed by ROVI, under licenses from Bracco Imaging S.p.A.

Presentations:

- lomon: from 200 mg/ml to 400 mg/ml concentration, in glass bottles quantities from 50 to 500 ml.
- lopamiro: 300 mg/ml and 370 mg/ml concentration, in glass bottles quantities from 30 to 100 ml.

Multihance® and Prohance®

IMAGING DIAGNOSTIC AREA
IMAGING CONTRAST MEDIA

Multihance and Prohance, both marketed by ROVI under a license from Bracco Imaging S.p.A.

Multihance is a paramagnetic contrast agent for use in diagnostic magnetic resonance imaging (MRI) indicated for:

- MRI of the liver for the detection of focal liver lesions in patients with known or suspected primary liver cancer (eg. hepatocellular carcinoma) or metastatic disease.
- MRI of the brain and spine where it improves the detection of lesions and provides diagnostic information additional to that obtained with unenhanced MRI.
- Contrast-enhanced MR-angiography where it improves the diagnostic accuracy for detecting clinically significant steno-occlusive vascular disease in patients with suspected or known vascular disease of the abdominal or peripheral arteries.

Multihance is commercialized in 10, 15 and 20 ml glass vials. Our presentations offer extends to marketing Multihance in prefilled syringes of 10, 15 and 20 ml.

Prohance, using Magnetic Resonance Imaging (MRI), provides contrast enhancement of the brain, spine and surrounding tissues resulting in improved visualization

(compared with unenhanced MRI) of lesions with abnormal vascularity or those thought to cause a disruption of the normal blood-brain barrier. Prohance can also be used for whole body MRI including the head, neck, liver, breast, musculoskeletal system and soft tissue pathologies.

Prohance is commercialized in 10, 15, 20 and 50 ml glass vials and 10 and 17 ml pre-filled glass syringes.





EmpowerCTA® and EmpowerMR®

IMAGING DIAGNOSTIC AREA
CONTRAST INJECTION SYSTEMS

ROVI commercializes EmpowerCTA and EmpowerMR injectors under a license from ACIST Medical Systems.

EmpowerCTA is a dual-syringe, fixed-rate contrast injector for CT procedures.

The EmpowerMR Hydraulic Contrast Injection System is used for MR procedures.



Hepadren®

HAEMODIALYSIS AREA
LOW MOLECULAR WEIGHT HEPARIN

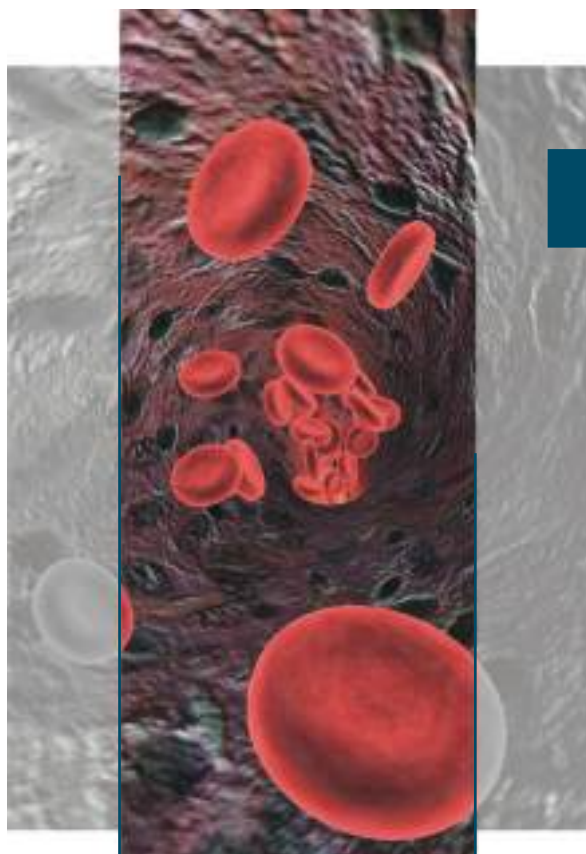
Hepadren is a low molecular weight heparin targeted especially at the nephrology area, for the prevention of clotting in the extracorporeal circuit during haemodialysis.



Fibrilin®

VASCULAR ACCESS AREA

Fibrilin is a ROVI health-care product that has been marketed since November, 2001. It is used for catheter maintenance, preventing the accumulation of fibrin in intravenous peripheral and central catheters, thus avoiding blockage and infection of the catheter



Siklos®

ORPHAN MEDICINES

Siklos is a drug indicated for the prevention of painful and recurrent blood vessels crisis, such as the acute thoracic syndrome in children and adults who suffer from symptomatic drepanocytosis anaemia.

Siklos is supplied in film-coated tablets, with three slots on each side, containing 1,000 mg of hydroxycarbamide. The tablet can be divided into four equal parts.

As the drepanocytosis anaemia is a rare disease in Europe, Siklos is considered an orphan medicine by the European Medicines Agency.



Activities report

Vaccines

Pneumovax® 23

Pneumovax 23 vaccine vial is indicated for active immunization against illness caused by the serotypes of pneumococci included in the vaccine. The product has been marketed by ROVI from 2009 under a co-marketing agreement with Sanofi Pasteur MSD.

Pneumovax is prepared using purified pneumococcal capsular polysaccharide antigens, derived from the 23 serotypes which represent about 90% of the types of the pneumococcal invading disease.

Pneumococcal illness is caused by streptococcus pneumoniae and is a global health problem. In Spain, streptococcus pneumoniae is responsible for 20-30% of all cases of pneumonia, of which 5-20% develop bacteremia (Vila Córcoles A. and colleagues. Effectiveness of the anti-pneumococcal vaccine in patients older than 65. Medifam 2003; 13(4):297-304).



Activities report

OTC

EnerZona®

Enerzona Omega 3 Rx is a highly-concentrated and purified fish-oil supplement that allows us to provide an effective dose in a simple way while avoiding the pollutants in fish.

There are also a wide range of sweet and savoury products to help us maintain the 40-30-30 balance, so as to be able to follow the Zone Diet easily and maximize the benefits obtained.

The sweet products include: chocolate biscuits, coconut or oatcakes; snacks are available in coconut, chocolate, yoghurt, orange, vanilla and cheese cake flavours; minirocks are available in soy and chocolate; and instant meals can be strawberry, cappuccino or chocolate flavour. The savoury options include snacks with a black olive or Mediterranean flavours, soy chips and mushroom and vegetable creams.

Enerzone Whey 90% and Enerzone Soy 90% are pure sources of protein.





Perspirex®

In any situation, including long working days, stress, crowds, events and special occasions, very uncomfortable episodes of sweating can occur.

Perspirex is an antiperspirant treatment developed to control excessive sweating from the armpits. The active substances it contains reduce sweating, physically speaking a minor problem but one which produces a serious social impact.

Perspirex is the market leader in this sector. There is also a hands and feet lotion.



Dentimelo®



Dentimelo is a low molecular weight hyaluronic acid which protects oral mucosa.

The low molecular weight hyaluronic acid, with film-forming properties, promotes the process of skin re-epithelialization.

Dentimelo is indicated to promote the physiological process of repair of oral mucosal lesions and gums, whatever their origin.

There are two presentations, gel and fluid.

Coldpack®

ColdPack is a cold bag, used for local application, which mitigates pain and relieves the nerve endings of the affected area. It also reduces inflammation alleviating the sharp sensation experienced with headaches or inflammations due to injuries.

ColdPack can also be used as a hot bag to relieve other pains.





Activities report

Portugal



ROVI Portugal was established in April 1999, to deal with marketing of the Italian company Bracco's contrast media already sold in Spain.

ROVI and Bracco are now both very successful brands in Portugal. ROVI has increased and consolidated its stake in the contrast media market, leveraging its knowledge of hospital pharmacies and radiologists.

In 2007, we launched in Portugal the first product developed by ROVI, Fibrilin[®], which received an excellent response from the market.

Currently, ROVI Portugal prepares the launch of the ROVI main product, Bemiparin, and it has high expectations regarding the success of the product.

ROVI Portugal is enjoying solid yearly growth rates and is outperforming the market, despite difficult economic and political conditions.

Specialization in the hospital market, more dynamic commercial strategies and new products have contributed to the growth of ROVI and to its excellent reputation in a market that is particularly important to the Company.

Activities report



Contract manufacturing

ROVI offers contract manufacturing services in a wide range of pharmaceutical forms, including pre-filled syringes, vials, suppositories, tablets and capsules through our two contract manufacturing plants: ROVI Contract Manufacturing (injectables plant) and Frosst Ibérica (Solid forms plant).

Our main characteristics are:

- quality in products and service;
- an independent company with significant production capacity;
- flexible, committed and totally transparent with our clients;
- confidentiality at the core of how we operate; and
- our commitment to meet the requirements of our customers.

From one single company, ROVI provides the full range of services, from the development of a project to the final release of a product, including preliminary clinical trials, stability studies, and physical-chemical and microbiological analyses, with the corresponding savings in time and money for our clients.

The flexibility and versatility of ROVI allow us to offer customers all or any of the many services involved in the manufacturing of a pharmaceutical product; a personalized menu for the specific needs of each client.

ROVI is currently one of the largest manufacturers of pre-filled syringes worldwide, with total yearly capacity of 180 million pre-filled syringes. The total yearly capacity of vials is 40 million units and 150 million units of suppositories. ROVI also owns one of the largest FDA approved plants for solid forms in Europe with annual capacity for 3 billion tablets.



Injectables plant (ROVI Contract Manufacturing)



We are specialized in filling and packaging parenteral solutions in prefilled SCF syringes from 0.5ml to 20ml (filled from 0.2 ml to 20ml) and vials from 2ml to 7ml.

ASEPTIC FILLING AND TERMINAL STERILISATION

Syringes and vials are filled in aseptic conditions in sterile areas. If needed, terminal sterilisation can be performed in a brand new counter-pressure autoclave.

SAFETY DEVICES

An increasing number of countries are implementing legislation that requires the use of integrated safety devices, in order to minimize the risk of accidental needle stick injury.

We offer the possibility of adding safety devices to preloaded syringes, using new fully automatic equipment that can handle up to 21,000 units per hour.

WATER FOR INJECTION (WFI) IN PREFILLED SYRINGES (PFS)

At our injectable plant recently approved by FDA (September 2012), it manufactures WFI in PFS for reconstitution/dilution drug products.

Water for Injection is produced according to US and European pharmacopoeia requirements. We provide CTD (Common Technical Document) module 3 & DMF (Drug Master File) including 36 months ICH stability data.

The types of syringes and volumes of WFI are as follows:

- 1ml standard syringes filled with 0.5ml of Water for Injection;
- 1.25ml syringes filled with 1ml of Water for Injection;
- 3ml syringes filled with 2ml of Water for Injection;
- 10ml syringes filled with 5ml and 10ml of Water for Injection; and
- 20ml syringes filled with 15ml and 20ml of Water for Injection.

QUALITY

A laboratory was built in 2005 and it includes two independent areas (microbiology and chemistry labs), enabling 24-hour production.

The plant is approved by the European authorities and also by the authorities of South Korea, Brazil and the countries of the Gulf, and it is ISO (9001, 14001, OSHAS) certified.

SUPPOSITORIES

We are also specialist in the manufacturing and packaging of suppositories in aluminum blister packs. Annual capacity: 150 million of suppositories.



Solid forms plant (Frosst Ibérica)

In the agreement reached with Merck Sharp & Dhome (MSD), ROVI acquired in April 2010 the manufacturing and packaging operations of the MSD facility in Alcalá de Henares. This plant has a long tradition of manufacturing excellence in pharmaceutical products and uses state of the art technology – Roller Compaction - for manufacturing oral formulations.

TECHNOLOGY

In an 83,000m² terrain, facilities include:

- Formulation Areas:
 - Dry granulation: highly competitive costs thanks to our high capacity Roller Compactor;
 - Wet granulation (High Shear and Low Shear), including fluid bed drying, milling and ribbon blending;
 - Planetary mixers;
 - Different compression bays for direct compression and granulation compression; and
 - Film coating is also available.
- Packaging Areas:
 - Different high speed blistering lines, flexible blister lines and flexible semiautomatic lines; and
 - Packaging, labeling, marking, overwrapping and casepacking capability for every packaging line. Every line is equipped with high tech vision system capability.

A complete service: production - testing - packaging and storage:

- High total and free capacity available to meet medium to very large production requirements (global capacity 3 billion tablets/year);
- From batches of 100 kg up to batches of 1,000 kg;
- Flexible and/or large volume packaging available to comply with customer needs; and
- Large size warehouse (8,000 pallets) which include a cold room (2 to 8 C°) of 400 pallets.



QUALITY

A brand new quality laboratory was built in 2005 in a separate building (4,600 m²) and includes a microbiology lab, a chemistry lab and quality assurance offices.

In order to provide access to all markets, this plant is GMP and FDA approved. We also hold Japanese, Mexican, Brazilian and Gulf Countries approval.



Clinical trials

Complying with both American and European quality standards, ROVI offers competitive technical support from the standpoints of cost, flexibility and reliability.

ROVI offers a wide range of services for the performance of clinical trials, product preparation and filling, labeling, packaging and logistics, always with the most rigorous quality standards. The machinery used is the same as for an industrial-scale batch, so it complies with the latest European regulations on clinical trials.

ROVI team of experts can advise customers on all aspects from manufacturing to the design of packaging materials to ensure time constraints are met.

For ROVI, every project is the most important, no matter its size.

Product development

ROVI can provide advice on the best strategy to follow, from the introduction of a new product, pre-clinical technical development to a commercial batch. In other words, we are involved in the project management and feasibility studies, launch and preproduction strategies, technological transfer and registration issues.

All of this ensures that the new product complies with all legal requirements and can be launched appropriately in the right place at the right time, with sufficient quantity of products.



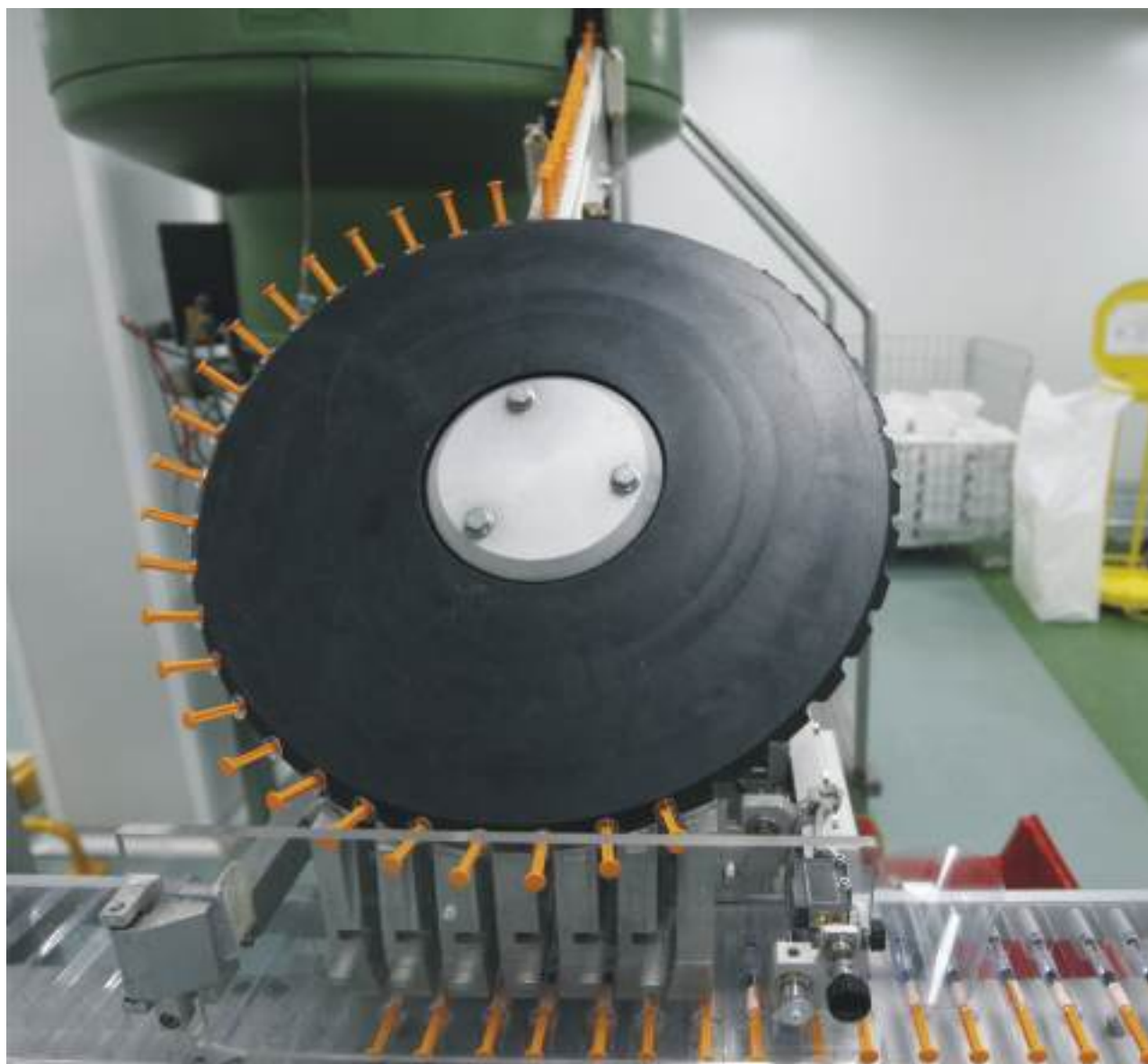
Co-Development Projects

In order to increase the manufacturing of both plants Co-Development services (initial model) are offered:

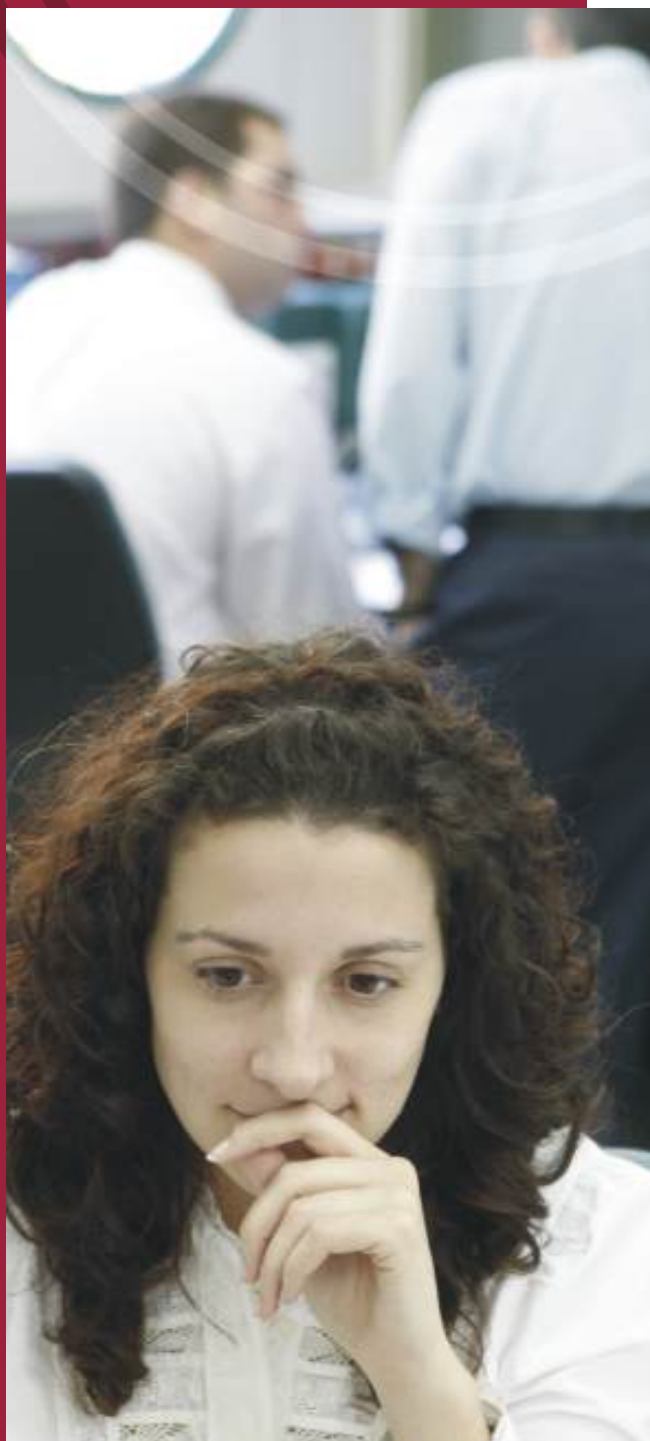
1. Partner chooses and provides the API (active principle);
2. ROVI offers from pre/formulation, scale up, stability batches, regulatory batches, bioequivalence studies if necessary, dossier compilation to manufacturing industrial batches; and
3. Licensing: directly through partner or out-licensing.

We are committed to ensure a personalized service to each partner so we can adapt to variations in our initial Co-development model.

The model proposed is a virtual joint venture with a cost-profit sharing approach.



Management report



- ▣ Operating revenue increased by 9% to 201.9 million euros in 2012, driven by the strength of the toll manufacturing business, where sales rose 34%, and by the specialty pharmaceutical business, which grew by 1%. In the second quarter of 2011, Fitoladius was sold to a third party. This sale contributed revenue of 5.6 million euros. Excluding the impact of Fitoladius in 2011, operating revenue increased by 13% and sales of the specialty pharmaceutical business grew by 6% in 2012.
- ▣ The 2012 guidance, for operating revenue rising from high single digit to low double digit growth and later on July 26, 2012 forecast to reach the low range of the guidance, was achieved. This was despite a monthly pharmaceutical expenditure decrease of more than 20% on average from July to December 2012 and a monthly reduction of the number of prescriptions by 15% on average in the same period, mainly as a result of the latest package of measures which was effective on July 1, 2012.
- ▣ ROVI expects to grow operating revenue from mid to high single digit for 2013, despite the impact of the latest package of measures and the Spanish pharmaceutical market decrease of 13% expected for 2013 according to Farmaindustria¹, the Spanish Pharmaceutical Association.
- ▣ Sales of Bemiparin increased by 10% to 55.7 million euros and sales of Corlontor, from Servier, grew by 29% in 2012. Sales of Thymanax, an innovative antidepressant from Servier that ROVI launched in March 2010, increased by 35% to 11.6 million euros in 2012.

(1) <http://www.coib.org/uploadsBO/Generica/Documents/24-10.PDF>



- ▣ In January 2011, ROVI started the marketing of Absorcol[®], whose active principle is ezetimibe, and Vytorin[®], which combines two active principles, ezetimibe and simvastatin, the first of the five licenses of Merck Sharp & Dohme (MSD), in Spain. Sales of Absorcol[®] and Vytorin[®] increased by 2.2 times to 12.4 million euros in 2012.
- ▣ EBITDA increased by 14% to 27.0 million euros in 2012, compared to the same period of the previous year, impacted by (i) the sale of Fitoladius to a third party in the second quarter of 2011, which contributed revenue of 5.6 million euros in 2011, and (ii) other income registered in 2012 as a result of Frosst Ibérica tax inspection. Excluding the impact of Fitoladius in 2011 and the impact of Frosst Ibérica tax inspection in 2012, EBITDA increased by 46% in 2012, reflecting a stable gross margin of 63.2% in 2012.
- ▣ Net profit increased by 8% to 19.5 million euros in 2012, compared to the previous year, impacted by the sale of Fitoladius in 2011. Excluding the impact of Fitoladius in 2011, net profit increased by 59% in 2012.
- ▣ ROVI will propose to the Shareholders General Meeting a dividend of 0.1366 euros per share on 2012 earnings. This proposed dividend would mean an increase of 8% compared to the dividend on 2011 earnings.



Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that "in 2012, we reached an excellent 9% operating revenue growth driven by the strength of two of our pillars of growth, our specialty pharmaceutical area and our toll manufacturing area. Our young portfolio protected us from the governmental measures which were effective from November 2011, and these measures had an impact of less than 1 million euros on 2012 sales. On 20 April 2012, the Spanish Government announced a new package of measures in order to achieve savings of more than 7 billion euros in healthcare expenditure. Among these new measures, the exclusion of some drugs from reimbursement and the copayment became more relevant. I would like to highlight that no significant ROVI product was affected by the list of drugs excluded from reimbursement, which was published on the 29th of June. The introduction of the latest package of measures, especially the pharmaceutical copayment, which was effective on the 1st of July, meant a monthly pharmaceutical expenditure decrease 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. According to Farmaindustria¹, the Spanish Pharmaceutical Association, the Spanish pharmaceutical market will decrease by 13% in 2013, in line with 2012. Despite the difficult situation that the pharmaceutical industry is going through, we forecast to continue growing but we expect these factors could slow down our growth.

The agreement with MSD will allow us to launch four new products in the next 7 years

Once again Bemiparin led the growth with a 10% increase in sales. Bemiparin sales in Spain rose 3% and outside Spain grew by 26%, highlighting the continued internationalisation of our flagship product as one of the Company's growth engines in the medium term. Furthermore, the agreement with MSD allows us to strengthen our toll manufacturing area, as we have already reflected in the 2010, 2011 and 2012 results, as well as 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. We expect this effort to result in a significant sales growth and operating leverage in the coming years. In addition, the MSD agreement will allow us to launch four additional new products in the next 7 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 III studies are planned to start by the first half of 2013. 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.coib.org/uploads/BO/Generica/Documents/24-10.PDF>

Financial highlights

	2012	2011	Growth	%Growth
Operating revenue	201.9	184.7	17.2	9%
Other income	1.2	3.5	-2.2	-64%
TOTAL REVENUE	203.2	188,2	15.0	8%
Raw materials used and changes in inventories	-75.5	-69.4	-6.1	9%
GROSS PROFIT	127.6	118.7	8.9	8%
% margin	63.2%	64.3%		-1.1pp
R&D expenses	-9.2	-8.4	-0.8	10%
Other SG&A	-92.7	-86,6	-6.1	7%
Other income	1.3	-	-	n.a.
EBITDA	27.0	23.7	3.3	14%
% margin	13.4%	12.8%		0.5pp
EBIT	21.7	19.0	2.7	14%
% margin	10.7%	10.3%		0.5pp
NET PROFIT	19.5	18.1	1.4	8%

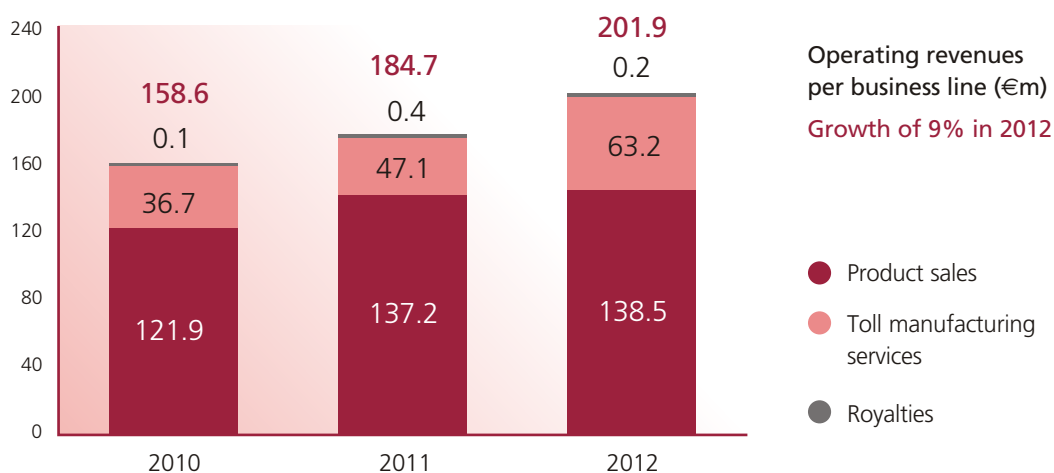
Note: certain numerical figures included in this document have been rounded. Therefore, discrepancies in tables between totals and the sums of the amounts listed may occur due to such rounding.



Good performance across the Group

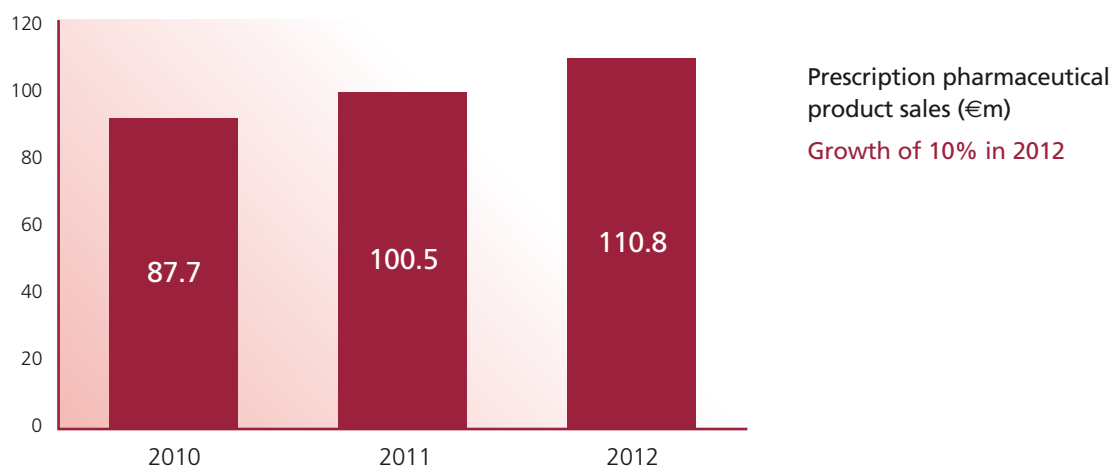
Operating revenue increased by 9% to 201.9 million euros in 2012, driven by the strength of the toll manufacturing business, where sales rose 34%, and by the specialty pharmaceutical business, which grew by 1% in 2012. In the second quarter of 2011, Fitoladius was sold to a third party.

This sale contributed revenue of 5.6 million euros in 2011. Excluding the impact of Fitoladius, operating revenue increased by 13% in 2012, compared to the same period of the previous year, and sales of the specialty pharmaceutical business increased by 6% in the same period.



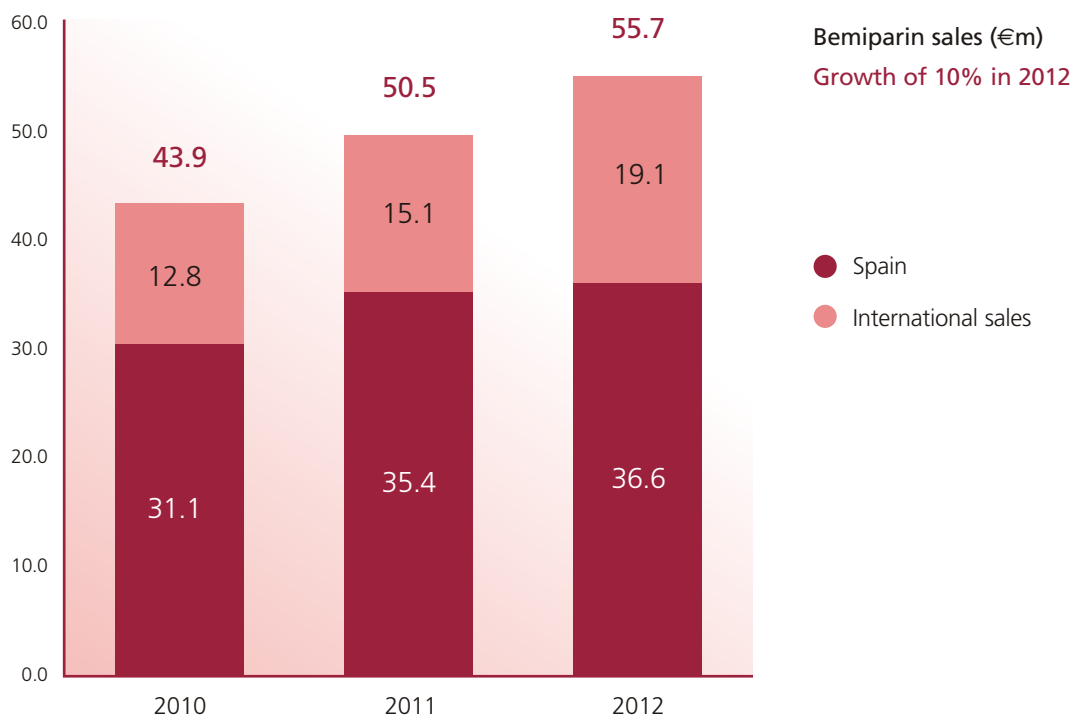
Sales of **prescription-based pharmaceutical products** rose 10% to 110.8 million euros in 2012. In the second quarter of 2011, Fitoladius was sold to a third party and, in June 2011, EMLA was stopped to be marketed and started

to be only promoted. Excluding the impact of Fitoladius and EMLA distribution in 2011, sales of prescription-based pharmaceutical products increased by 14% in 2012.



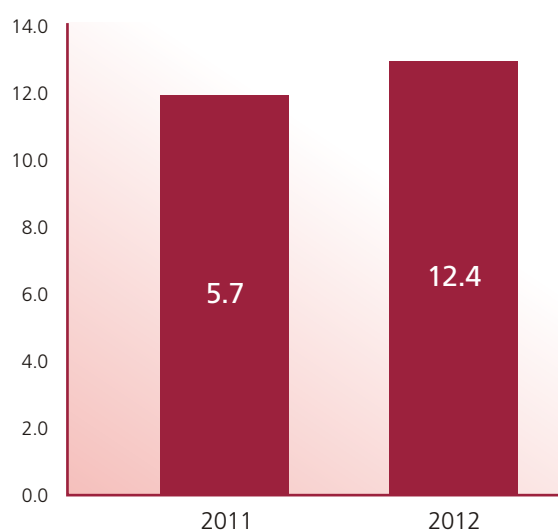
ROVI's low molecular weight heparin (LMWH), **Bemiparin**, maintained a growth rate, with sales up 10% to 55.7 million euros. Sales of Bemiparin in Spain (**Hibor**[®]) increased by 3% to 36.6 million euros, while international sales rose 26% to 19.1 million euros in 2012 supported by the

increased presence of Bemiparin, through strategic alliances, in countries where it was already present, and by the launch of the product in six new countries, Mexico, Venezuela, Saudi Arabia, Iraq, Syria and Oman, during 2012.



Sales of **Vytorin**[®] and **Absorcol**[®], the first of the five licenses of MSD, launched in January 2011, increased by 2.2 times to 12.4 million euros in 2012.

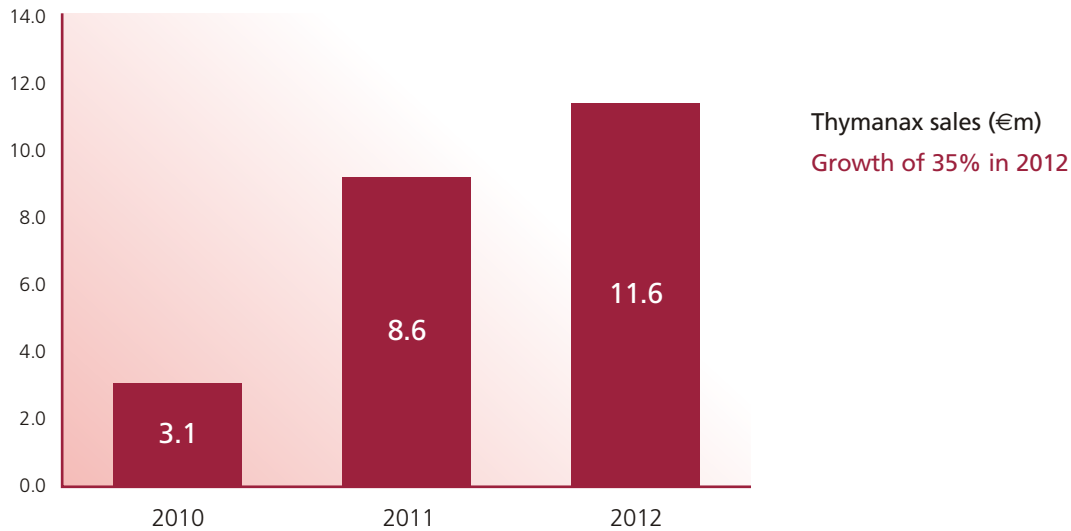
Vytorin and Absorcol sales (€m)
Growth of 2.2 times in 2012





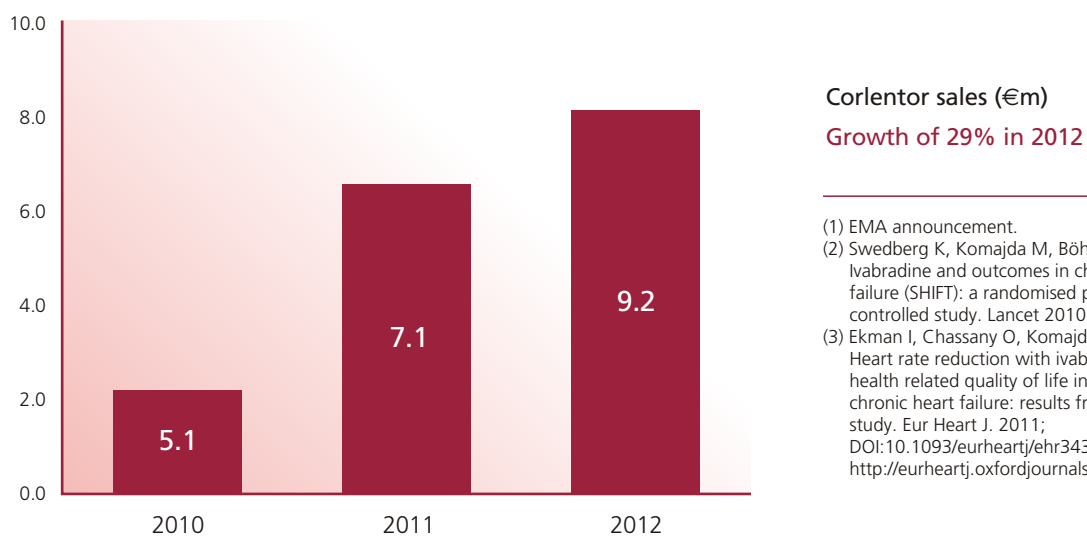
Sales of **Thymanax**[®], an innovative antidepressant from Laboratoires Servier, launched in March 2010 and for which

ROVI has a co-marketing agreement covering Spain, increased by 35% to 11.6 million euros in 2012.



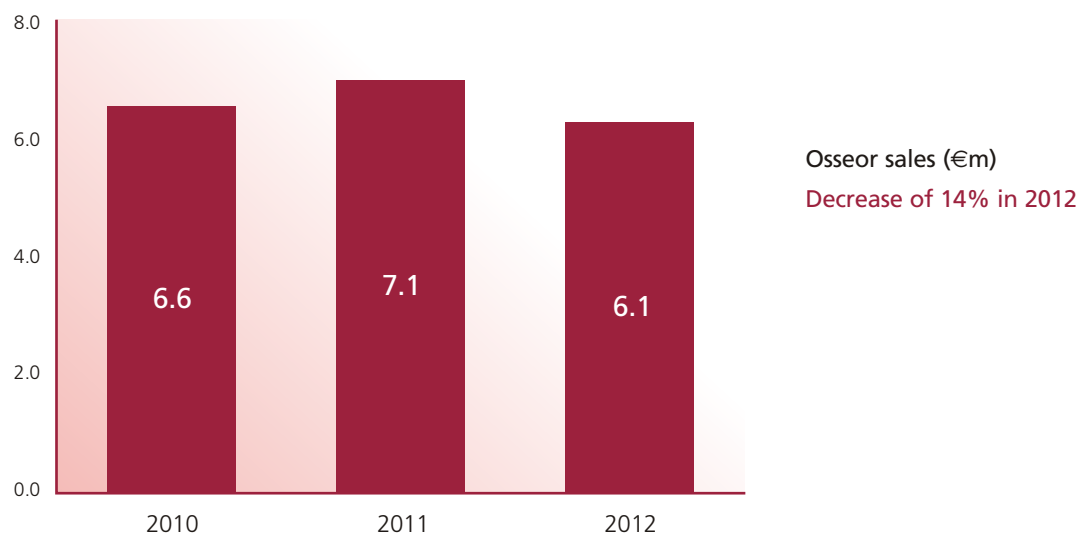
Sales of **Corlentor**[®], a specialty product for stable angina and chronic heart failure from Laboratoires Servier, rose 29% to 9.2 million euros in 2012. In February 2012, Corlentor was approved by the European Commission for the treatment of patients with chronic heart failure¹. The European Commission's decision to authorise this new indication for Corlentor followed the review of data from the SHIFT trial, the largest-ever morbi-mortality study of treat-

ments for chronic heart failure involving more than 6000 patients. It demonstrated that the treatment significantly reduced the risk of death and hospitalisation from heart failure, and improved the quality of life of people living with the disease.^{2,3} This reduction in mortality was highly significant in patients with a heart rate of 75 beats per minute (bpm), or above, for whom Corlentor is now indicated.



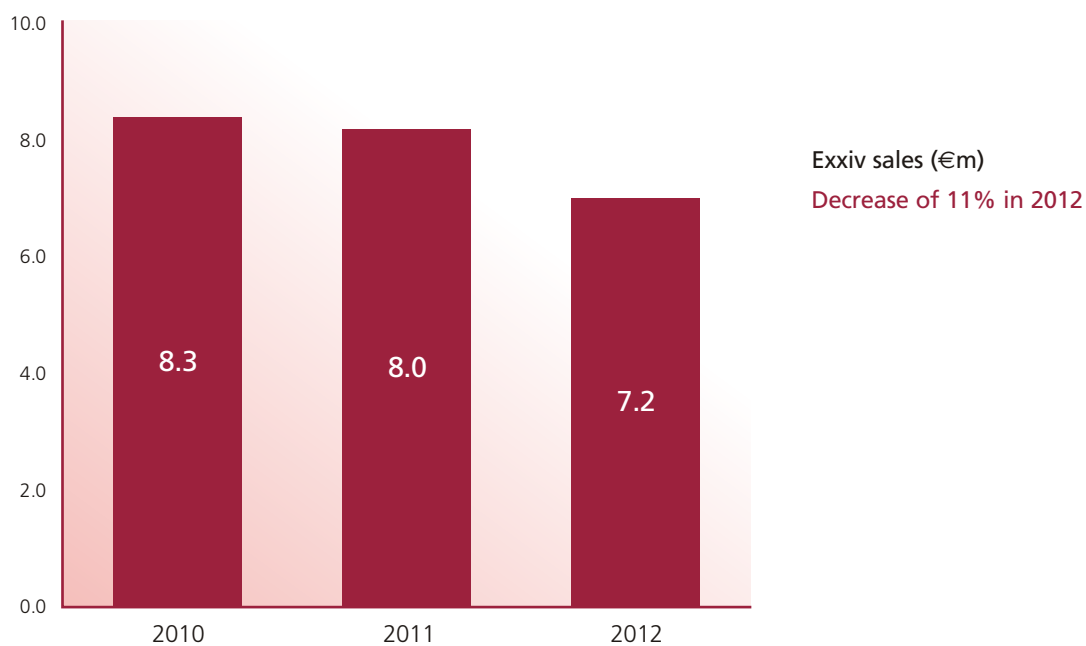
(1) EMA announcement.
 (2) Swedberg K, Komajda M, Böhm M et al. Ivabradine and outcomes in chronic heart failure (SHIFT): a randomised placebo-controlled study. *Lancet* 2010; 376:875-85.
 (3) Ekman I, Chassany O, Komajda M et al. Heart rate reduction with ivabradine and health related quality of life in patients with chronic heart failure: results from the SHIFT study. *Eur Heart J*. 2011; DOI:10.1093/eurheartj/ehr343. Available at: <http://eurheartj.oxfordjournals.org>

Sales of **Osseor**[®], a specialty product for the treatment of postmenopausal osteoporosis from Laboratoires Servier, decreased by 14% to 6.1 million euros in 2012.



Sales of **Exxiv**[®], a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 11% to 7.2 million

euros in 2012, mainly due to a slight deceleration of the COX-2 market.





On 21st of July of 2011, the Spanish government announced a package of measures to reduce the pharmaceutical expenditure (see <http://www.msps.es/gabinete/Prensa/notaPrensa/desarrolloNotaPrensa.jsp?id=2165>). The impact for ROVI of these measures, which were effective from November 2011, on 2012 sales was less than 1 million euros.

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 (see <http://www.mssi.gob.es/profesionales/farmacia/pdf/ProyectoResolucionExclusion.pdf>), without any material impact for the ROVI product portfolio, and the pharmaceutical copayment was effective from the 1st of July. The introduction of the latest package of measures, especially of the pharmaceutical copayment, meant a monthly pharmaceutical expenditure decrease 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. In addition, according to Farmaindustria¹, the Spanish Pharmaceutical Association, the Spanish pharmaceutical market will decrease by 13% in 2013, in line with 2012. Despite the difficult situation that the pharmaceutical industry is going through, ROVI forecasts to continue growing but it expects these factors could slow down its growth.

In the second quarter of 2011, **Fitoladius**[®] product was sold to a third party. This sale contributed revenue of 5.6 million euros in 2011. Revenue related to Fitoladius distribution amounted to 0.7 million euros in 2011.

In 2012, ROVI did not register sales from the **EMLA**[®] distribution, a topical anaesthetic licensed by AstraZeneca that has been marketed by ROVI since 1998. In June 2011, the

EMLA[®] distribution agreement with AstraZeneca was replaced by a promotion agreement. Revenue related to EMLA[®] promotion amounted to 1.3 million euros in 2012. Revenue related to EMLA[®] distribution (in the first half of 2011) and promotion (in the second half of 2011) amounted to 3.7 million euros in 2011.

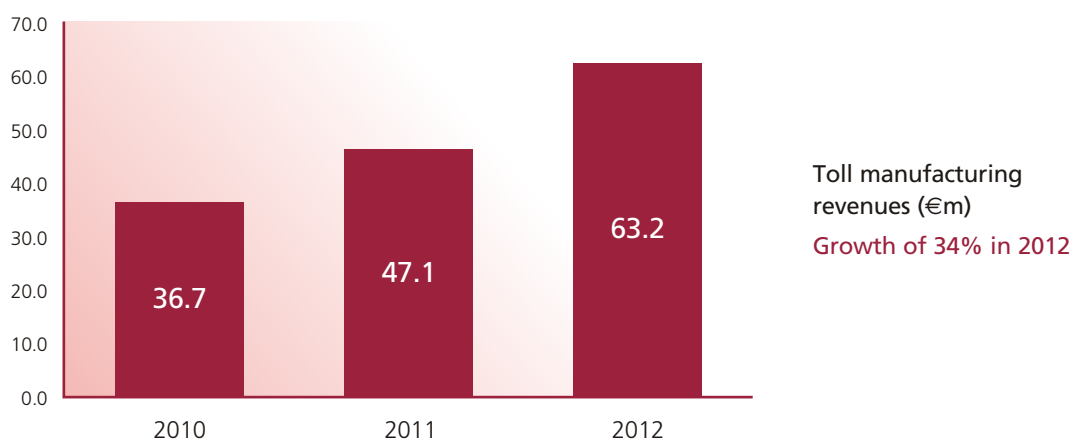
Sales of **Pneumovax**^{®-23}, a non recurrent vaccine that helps to protect against serious infections caused by the bacterium pneumococcus, licensed by Sanofi Pasteur MSD in July 2008 for marketing by ROVI, reached 0.4 million euros in 2012 compared to 1.2 million euros in 2011 due to budget constraints from the Spanish government.

Sales of **over-the-counter pharmaceutical products** declined by 14% to 5.9 million euros in 2012 compared to the previous year. This was mainly as consequence of the reduction of consumption in the current Spanish economic environment.

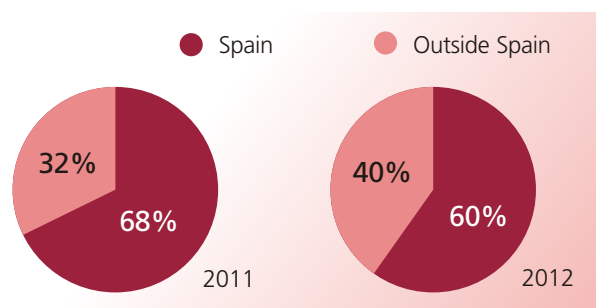
Sales of **contrast imaging agents and other hospital products** decreased by 6% to 20.7 million euros in 2012.

Toll manufacturing sales increased by 34% to 63.2 million euros in 2012 compared with the previous year, mainly as a result of the contribution of the Frosst Ibérica plant whose revenue amounted to 44.1 million euros in 2012. The Frosst Ibérica plant has current manufacturing capabilities of 3 billion of tablets and 100 million of boxes. ROVI counted on a spare capacity of 50% in this plant when it was acquired in the second quarter of 2010. The company is using this spare capacity and it has been reduced by more than 30% since the plant acquisition. For the time being, the spare capacity is less than 20% in this plant which will allow ROVI to continue acquiring new customers in order to maximise the potential of the acquired infrastructure. In January 2011, ROVI signed an agreement with Farmalíder, a pharmaceutical company specialised in the development of branded, OTC, value-added, and traditional generic products, for the manufacturing, research and conditioning of pharmaceutical specialties based on Ibuprofen and Paracetamol. Farmalíder has undertaken to work towards providing ROVI with annual manufacturing that will represent an increase in the production of the plant of Frosst Ibérica by 10% to 15%.

(1) <http://www.coib.org/uploadsBO/Generica/Documents/24-10.PDF>



Sales outside Spain increased by 36% to 81.3 million euros in 2012 compared with the previous year. Sales outside Spain represented 40% of operating revenue in 2012 compared to 32% in 2011.

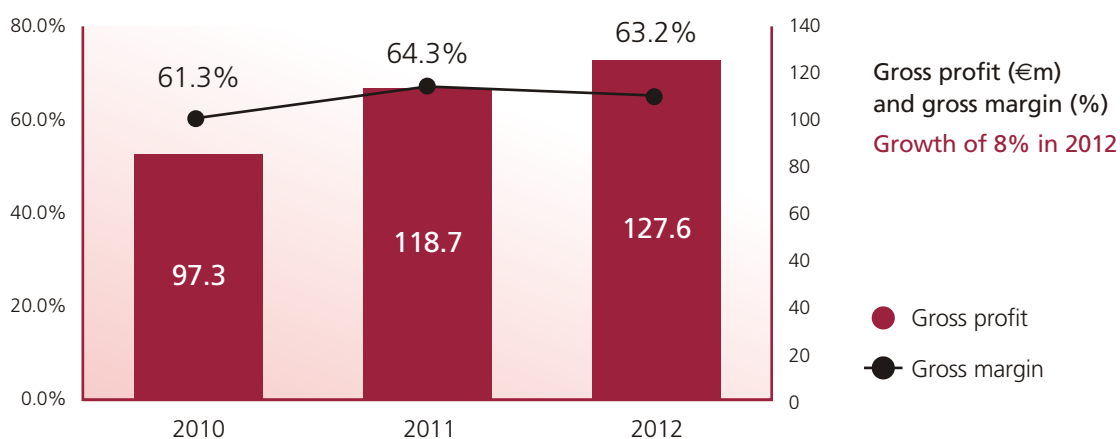


Gross profit increased by 8% to 127.6 million euros in 2012, reflecting a decrease in the gross margin to 63.2% in 2012, from 64.3% in 2011, mainly as a result of the Fitoladius sale to a third party in the second quarter of 2011 and of the reduction of other income (subsidies) in 2012.

- Excluding the impact of Fitoladius, gross margin remained stable at 63.2% in 2012.
- Excluding the impact of Fitoladius and the impact of other income, which decreased by 64% in 2012,

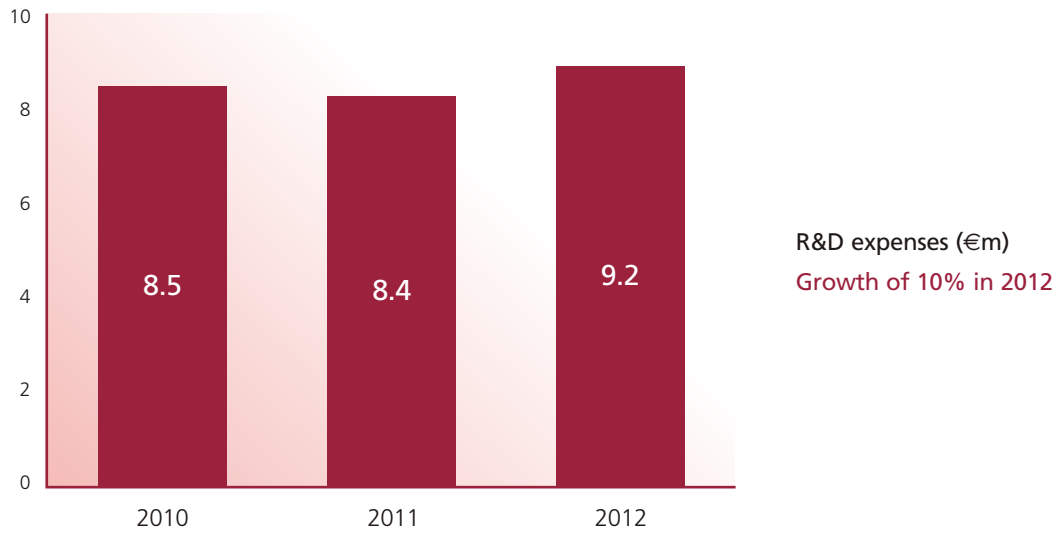
gross margin increased by 1.4 percentage points to 62.6% in 2012 from 61.2% in 2011.

The decrease of the Bemiparin raw material cost impacted positively in the 2012 gross margin. In 2012, ROVI continued to buy Bemiparin raw material for less than 40 euros per million of international units and it expects this stable trend to continue in 2013.



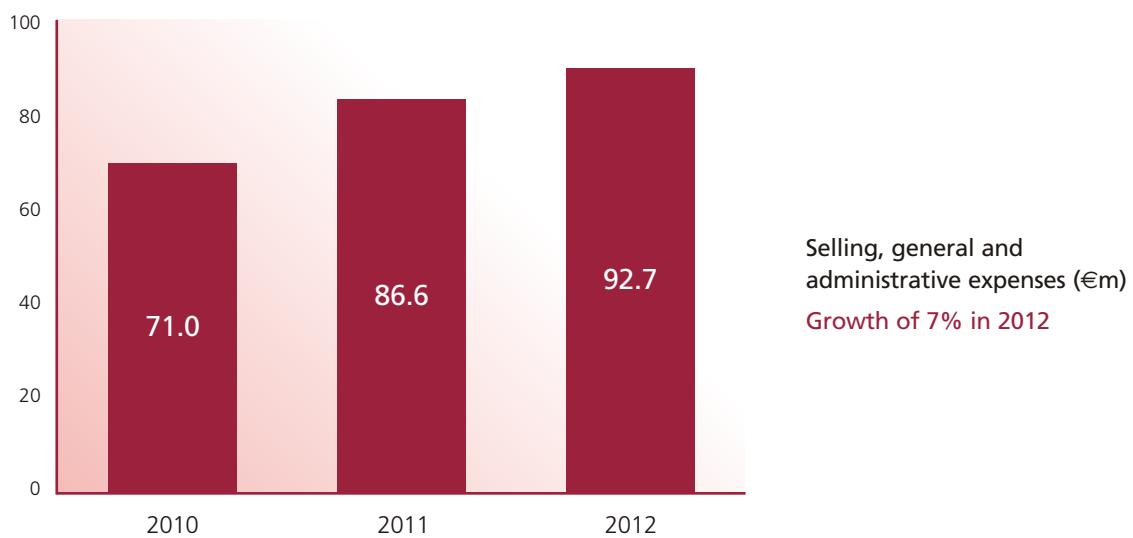


Research and development expenses increased by 10% to 9.2 million euros in 2012, reflecting ROVI investments in products that are under development.



Selling, general and administrative expenses increased by 7% to 92.7 million euros in 2012, compared to the same period of the previous year, mainly as a result of (i) the

increase in the toll manufacturing volumes and (ii) the preparation of the injectables facility for a FDA (US Food and Drug Administration) inspection.

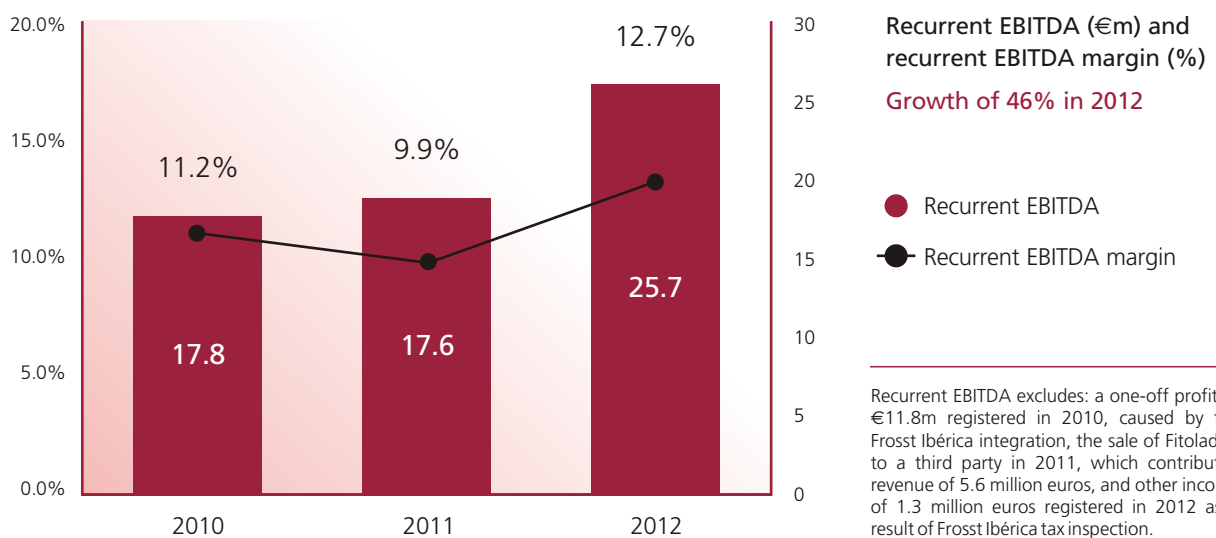
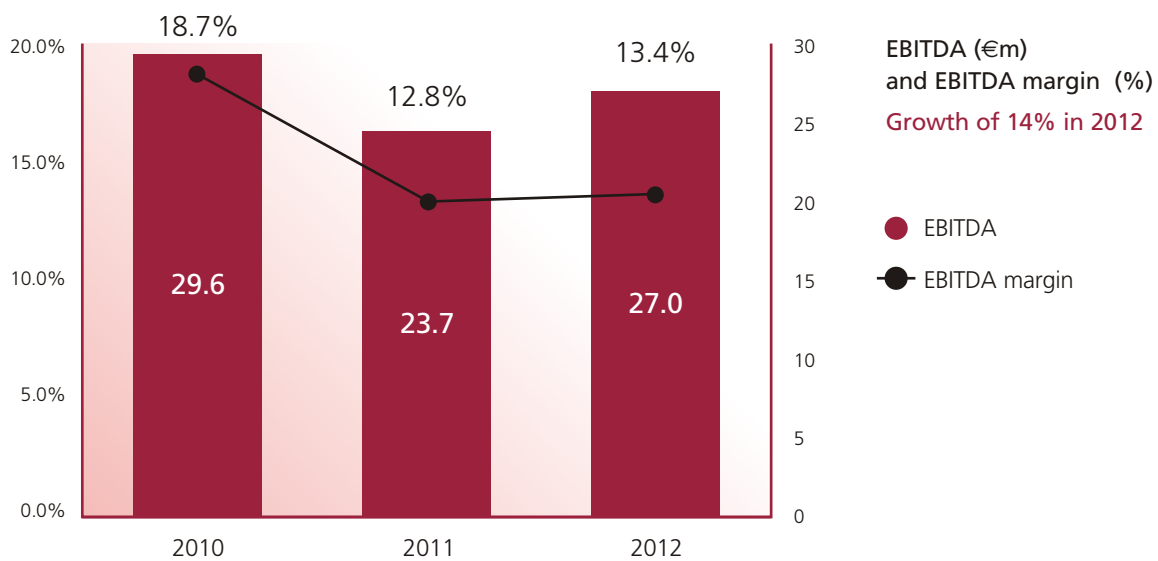


As a result of Frosst Ibérica tax inspection for the period 2006-2008, ROVI registered a compensation of 1.3 million euros in the **other income** item in 2012 from the owner of Frosst Ibérica during the period reviewed, which assumed this payment. As a counterpart for this 1.3 million euros income, an expense was mainly registered in the "income tax" line.

EBITDA increased by 14% to 27.0 million euros in 2012, compared to the previous year, impacted by (i) the Fitoladius

sale to a third party in the second quarter of 2011, which contributed revenue of 5.6 million euros in 2011, and (ii) other income registered in 2012 as a result of Frosst Ibérica tax inspection.

- Excluding the impact of Fitoladius in 2011 and the impact of Frosst Ibérica tax inspection in 2012, EBITDA increased by 46% in 2012, compared to the previous year.



Recurrent EBITDA excludes: a one-off profit of €11.8m registered in 2010, caused by the Frosst Ibérica integration, the sale of Fitoladius to a third party in 2011, which contributed revenue of 5.6 million euros, and other income of 1.3 million euros registered in 2012 as a result of Frosst Ibérica tax inspection.

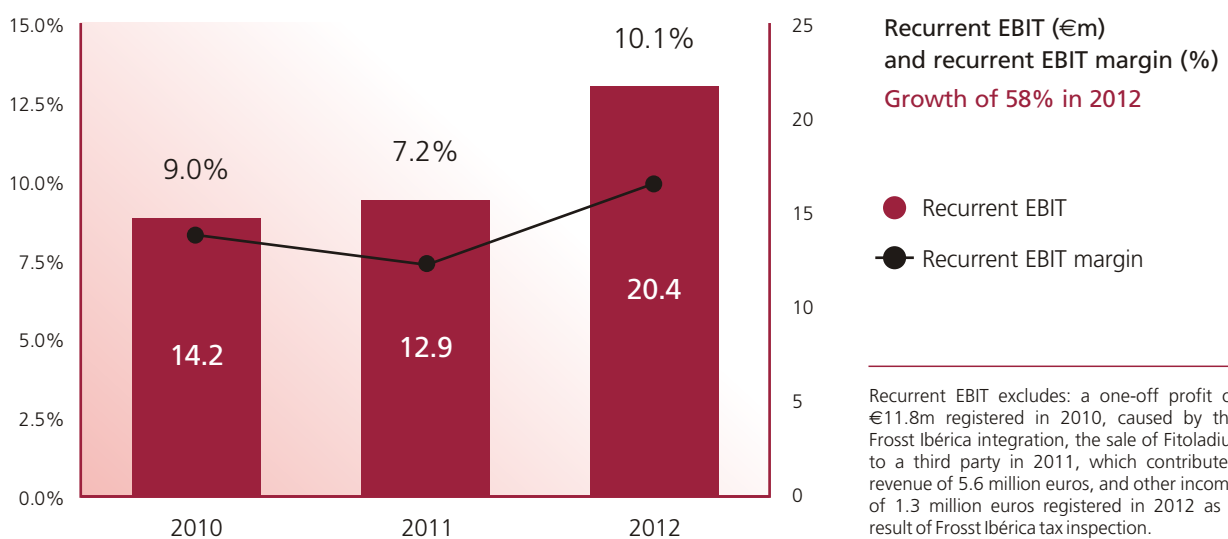
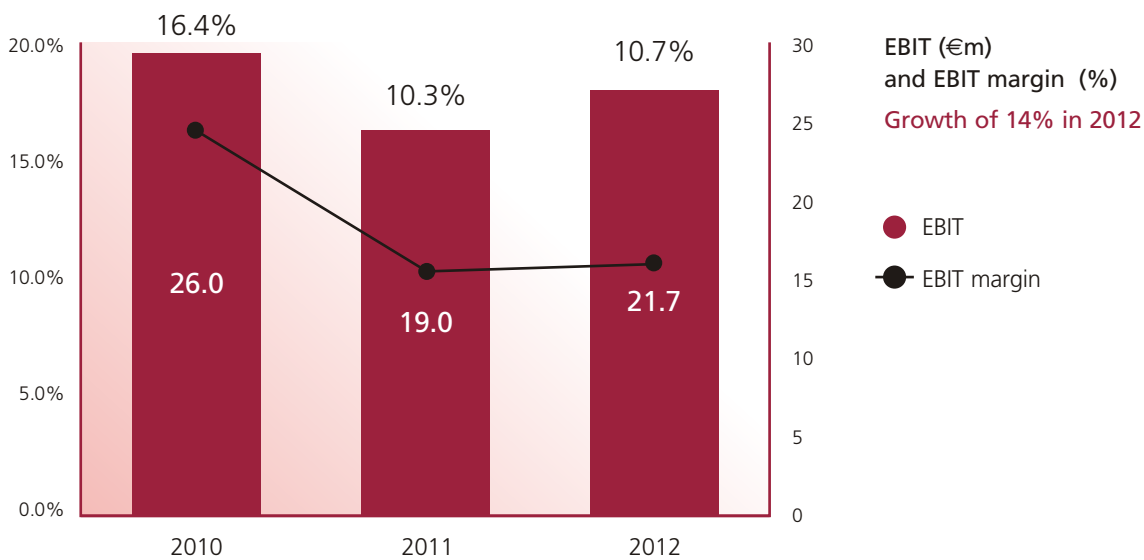


Depreciation and amortisation expenses increased by 13% in 2012, compared to the same period of the previous year, mainly as a result of the new property plant and equipment and intangible assets purchases made during the last twelve months.

EBIT increased by 14% to 21.7 million euros in 2012, compared to the previous year, impacted by (i) the Fitoladius sale

to a third party in the second quarter of 2011 and (ii) other income registered in 2012 as a result of Frosst Ibérica tax inspection.

- Excluding the impact of Fitoladius in 2011 and the impact of Frosst Ibérica tax inspection in 2012, EBIT increased by 58% in 2012, compared to the previous year.



Financial expense decreased by 8% in 2012, compared to the previous year.

The **financial income line** decreased by 42% in 2012, compared to the previous year, mainly as a result of: (i) the reduction in the average amount of deposits in 2012 and (ii) the reduction of delay interests from Court decisions related to pending invoices due for collection from Public Administration in 2012.

The **effective tax rate** was 6.4% in 2012 compared with 4.2% in 2011. This favourable effective tax rate is due to the deduction of existing research and development expenses and the capitalisation of existing negative tax bases resulting from the Frosst Ibérica integration. As of today, Frosst Ibérica negative tax bases amount to 62.8 million euros, of which 5.3 million euros will be used in the 2012 income tax.

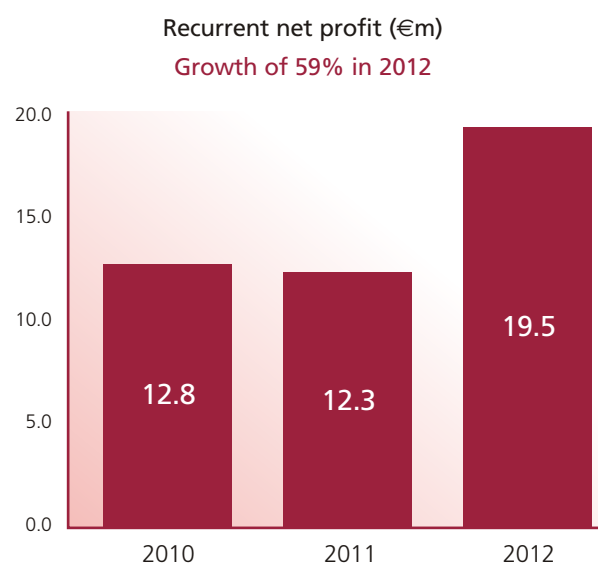
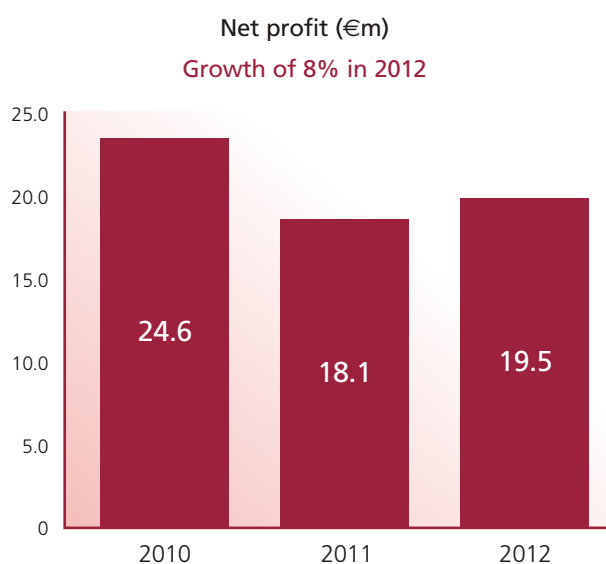
On 19th August 2011, a package of tax measures was approved by law (see <http://www.boe.es/boe/dias/2011/08/20/pdfs/BOE-A-2011-14021.pdf>) affecting tax bases. Previously, ROVI did not pay taxes on Frosst Ibérica profits as this company has negative tax bases and profits could be offset without limit. According to this law, ROVI has to pay taxes on Frosst Ibérica profits as this company can only offset its profits by 50% of the tax bases of the group during the period 2011-2013.

On 30th March 2012, a package of tax measures (see <http://www.boe.es/boe/dias/2012/03/31/pdfs/BOE-A-2012-4441.pdf>) was approved by law in order to reduce Spanish public deficit. Among these tax measures, the elimination of the freedom of depreciation incentive and the reduction of the deductions limits affected 2012 ROVI Group income statement. In addition, these measures will affect ROVI income tax payable rate.

On 13th July 2012, a new package of tax measures (see <http://www.boe.es/boe/dias/2012/07/14/pdfs/BOE-A-2012-9364.pdf>) was approved by law in order to guarantee budgetary stability and to promote competitiveness. Among these new 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%, will affect ROVI income tax payable rate.

The **net profit** of ROVI increased by 8% to 19.5 million euros in 2012, compared to the previous year, impacted by the Fitoladius sale in 2011.

- Excluding the impact of Fitoladius in 2011, net profit increased by 59% in 2012, compared to the previous year.



Recurrent net profit excludes: a one-off profit of €11.8m registered in 2010, caused by the Frosst Ibérica integration, and the sale of Fitoladius to a third party in 2011, which contributed revenue of 5.6 million euros.

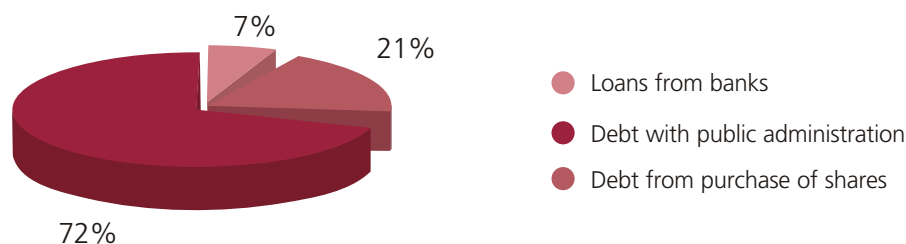


As of 31 December 2012, ROVI had total debt of 38.4 million euros. Debt with public administration represented, as

of 31 December 2012, 72% of total debt and 93% of total debt is 0% interest rate debt.

	31 December 2012	31 December 2011
Loans from banks	2,813	4,799
Debt with public administration	27,505	33,897
Debt from purchase of shares	8,072	11,984
TOTAL	38,390	50,680

Debt breakdown as of 31/12/2012 (%)



As of 31 December 2012, ROVI had a **gross cash position** of 45.9 million euros, compared to 61.7 million euros as of 31 December 2011, and a **net cash position** (financial assets and cash minus short term and long term debt) of 7.5 million euros, compared to 11.0 million euros as of 31 December 2011, providing it with a high level of financial flexibility.

Free cash flow (net cash generated (used) from operating activities plus/minus property, plant and equipment and intangible assets purchases/sales plus interest received) increased by 9% to 7.3 million euros in 2012, mainly as a result of the positive impact on the working capital of collections related to pending invoices from Spanish Public Administrations.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that, "we are satisfied with the results for 2012. Operating revenue increased by 9% from the previous year.

This was in line with 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, and to the contribution of the toll manufacturing business. Margins increased in 2012, excluding the impacts of the Fitoladius sale in 2011 and the decrease of other income in 2012, mainly as a result of the reduction of the Bemiparin raw material costs and of a higher contribution of the toll manufacturing business. We expect to keep margin expansion in 2013. It is very gratifying to witness the growth in 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 and Absorcol, 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 better the utilisation of our asset base".

Guidance for 2012

ROVI expects to **grow operating revenue from mid to high single digit for the full year 2013**, in spite of (i) the impact of the latest package of measures, approved by the Spanish Government on 20 April 2012, which was effective on the 1st of July in order to obtain savings of more than 7 billion euros in healthcare expenditure, and (ii) the decrease of the Spanish pharmaceutical market of 13% expected for 2013, according to Farmaindustria¹, the Spanish Pharmaceutical Association.

ROVI expects its growth drivers to be Bemiparin, its existing portfolio of specialty pharmaceuticals, last launches such as Vytorin, Absorcol and Thymanax, new product distribution licenses and new customers in the toll manufacturing area.

Dividend payment

ROVI will pay a **dividend** of 0.1366 euros per share on 2012 earnings if the Shareholders General Meeting approves the application of the 2012 profit, under proposal of ROVI Board of Directors. This proposed dividend would mean an increase of 8% compared to the dividend on 2011 earnings. In addition, this dividend would imply the pay-out of 35% of consolidated net profit for 2012.

The ROVI General Shareholders Meeting, on 13 June 2012, approved the payment of a gross dividend of 0.1269 euros per share on 2011 earnings. This dividend was paid on 4 July 2012 and it implied the pay-out of 35% of consolidated net profit for 2011.

(1) <http://www.coib.org/uploads/BO/Generica/Documents/24-10.PDF>



Company information

Corporate profile



ROVI is a fully integrated Spanish specialty pharmaceutical company engaged in the research, development, 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 own 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

Company information

The history of ROVI

2000 - 2012

- 2000: start of research into oral administration of Bemiparin.
- 2001: start of research into technology for enhancers for oral absorption of carbohydrates and protein ("EFOCAP").
- 2002: internationalisation of ROVI following overseas approval of Bemiparin.
- 2003: approval of Bemiparin in the UK, Ireland, Portugal, Austria, Greece and Italy.
- 2003: increased international coverage, whether in stages of registration, pre-registration, or marketing, in a total of 59 countries.
- 2003: Prince Felipe prize for Business Excellence in technological Innovation.
- 2004: start of research into technology for release of oral carbohydrates and proteins ("OCAP").
- 2004: sale of the generics division.
- 2005: licensing agreement with Laboratoires Servier for marketing of Osseor.
- 2006: start of construction of R&D centre for Bemiparin in Granada.
- 2007: marketing agreement with Laboratoires Servier for Corlontor.
- 2007: acquisition of Bertex, a German company specialising in technology for release injectable micro-particles.
- 2008: agreement with Sanofi Pasteur MSD for marketing of Pneumovax-23.
- 2008: agreement with Merck Sharp & Dhome International for marketing of EXXIV.
- 2009: strategic pharmaceutical manufacturing and marketing agreement with Merck Sharp & Dohme (MSD) in Spain.
- 2009: signing of a protocol of intentions with the Spanish government for the development of a centre for the research and production of vaccines for seasonal and pandemic flu in Spain.
- 2010: agreement with EBEWE for the marketing of Bertanel and with Laboratoires Servier for the marketing of Thymanax.
- 2011: launch of Absorcol and Vytorin, the first of the five licenses from MSD.
- 2011: agreement of Alentia Biotech, a joint venture of Ferrer and ROVI, with Novartis Vaccines for the transfer of the technology for the production of flu vaccines.
- 2012: obtaining of the FDA approval for the injectables plant.

1990s

- 1994: sale to Pfizer of ROVI glycerine suppositories.
- 1994: award of certificate for Good Practises in Manufacturing for manufacturing and packaging installations.
- 1995: start of supply of high added value packaging services to leading international pharmaceutical companies.
Development of a second generation of low molecular weight heparins, Bemiparin, called Hibor.
- 1998: introduction of Bemiparin in the Spanish market.
Start of activities in Portugal.

1980s

- 1981: start of research into low molecular weight heparins.
Marketing of Bracco Imaging S.p.A. products in Spain.

1940-1970s

Founded in December 1946.

Marketing in Spain of licensed specialised products of international pharmaceutical companies.

Marketing of sodium heparin in the 1950s and 1960s.

Marketing of calcium heparin in the 1960s and 1970s.



Company information

Management team



Mr. Juan López-Belmonte López

He holds a degree in business and economics from the Universidad Complutense de Madrid. He has served as the Chairman of our Board of Directors for over 13 years. He is a member of the Board of Directors of Farmaindustria, the Madrid Chamber of Commerce, the Board of Directors and Executive Committee of Madrid Business Confederation and a member of the Board of Directors of CEIM. He is also a member of the Board of the University-Company Foundation and of the Regional Advisory Council (Central Territory) of BBVA.



Mr. Juan López-Belmonte Encina

He holds a degree in business and economics from CEU San Pablo de Madrid, with an emphasis in auditing. He is a shareholder of Inversiones Clidia, S.L. (and controlling shareholder of the Company) and our Chief Executive Officer. He began his career carrying out diverse roles for various international pharmaceutical companies including the Nielzen Group in Spain, the Tyco Group in the United States and Boots Pharmaceutical in the United Kingdom. He has been with our Company since 1994 and served as General Director from October 2001 and as Chief Executive Officer from October 2007.



Mr. Iván López-Belmonte Encina

He holds a degree in business and economics from the Universidad Complutense de Madrid, with an emphasis in auditing. He is a shareholder of Inversiones Clidia, S.L. (and controlling shareholder of the Company) and our Corporate Development Director. He is also a member of our Board of Directors. He began his career in Germany working for such companies as Amersham, which focuses on nuclear medicine, and Hexal AG, a pharmaceutical company specializing in generics. He joined our Company in 1994 and has served as Co-General Director from 2001 and as Director of Corporate Development from September 2007.



Mr. Javier López-Belmonte Encina

He holds a degree in business and economics from the Colegio Universitario de Estudios Financieros (CUNEF) de Madrid, with an emphasis in finance. He is our Chief Financial Officer and a member of our Board of Directors. He began his career in the banking industry in 1998 as an analyst of the former Argentaria, S.A. in the United Kingdom and also worked for Medeva Pharma in the United Kingdom. He joined our Company in 2000 and served as Chief Executive Officer from 2001.



Mr. Javier Martínez González

A graduate in Medicine and Surgery and a Specialist in Pharmaceutical Medicine from the Faculty of Medicine of the Universidad Complutense of Madrid. He was Doctor in Primary Care and the Special Emergency Service of INSALUD until 1990. He then pursued his professional career in clinical research in the Scientific Department of ALK-Abelló in Madrid and in 1993 joined Laboratorios Pfizer, S.A. as Chief Doctor of the Therapeutic Area. He joined ROVI in 2002 as Medical Director, and is currently Director of Clinical Development.



Mr. Javier Angulo García

A graduate in Law from the University of Deusto, specialising in Financial Law. Until June 2000, he worked in the US multinational Guardian Llodio, as Labour Relations Officer, and from July 2000 until joining ROVI in 2007 he worked in the German multinational pharmaceutical company Schering in Madrid, in the manufacturing and marketing of pharmaceutical products and nuclear medicine equipment, as Director of Administration and Labour Relations. He is currently the Human Resources Director of ROVI.



Mr. José Zapata Prieto

A graduate in Pharmacy from the Universidad Complutense of Madrid (1985-1990). He started his career in the pharmaceutical sector at L'Oréal Cosméticos (1991-1993). He joined ROVI in 1993, where he has worked as Director of Quality, and he has been Industrial Director since April 2008. He holds a Master in the Pharmaceutical and Para-Pharmaceutical Industry from CESIF, a Master in Pharmaceutical Industry Management from IE ("Instituto de Empresa") and completed a Management Development Program at the University of Navarra.



Mr. Fernando Martínez Morales

A graduate in Industrial Technical Engineering from the Universidad Politécnica of Madrid. He has a long track record in the pharmaceutical sector, working at companies which include Laboratorios Andreu (currently Roche), Upjohn Farmoquímica, Juste SAQF, Astrazeneca, where he worked until 2005 as Head of Sales for the four lines of specialists (Oncology, Hospitals, Urology and Psychiatry), and was subsequently Director of Sales at Astellas Pharma. He joined ROVI in March 2007 as Manager of Sales and has been Director of Sales since September 2009.



Mr. Pedro Carretero Trillo

A graduate in Biological Sciences of the Universidad Complutense of Madrid. He holds a Master's in Commercial Management and Marketing from ESIC, ESEM. He was previously employed as a Molecular Biology Sales Professional at Cultek and as National Head of Sales and Marketing for Diabetes at Emminens. He joined ROVI in 2002 as Head of Product for Hibor (Bemiparin) and is currently Director of Hospitals and Institutional Relations for Spain and Portugal.



Mr. Pablo Domínguez Jorge

A graduated in Economics and Business of the Universidad Autónoma of Madrid in 1991 with a Master's in Financial Markets from the Carlos V International Centre in 1992. He started his career at Pfizer España S.A. in 1992 and worked there for 15 years, as Head of Treasury and Client Services. In 2007, he joined AstraZéneca España as National Manager of Hospital Accounts. In July 2008 he moved to ROVI, where he is Administrative Financial Director.



Corporate Social Responsibility



Corporate Social
Responsibility is composed
of the ethical, social
and environmental
commitments
that ROVI has voluntarily
assumed, as an active part
of society, in order
to contribute to
social and economic progress
and to improving
people's quality of life.

Mission, vision and values

MISSION

We want to work for the well-being of society, promoting human health through the production of high quality and reliability drugs, medical devices and brand compression garments.

We research for better health.

VISION

ROVI is recognized as a reference for the research and production of products aimed to the improvement of health.

VALUES

- All of us are the main asset of the company.
- We feel the changes as real opportunities for development.
- It is important to feel that every day we learn something new.
- We like to assume responsibilities from beginning to end.
- We know that we have to earn patients' trust every day.
- We care about our customers concerns and share their successes.
- Our diversity training, experience and viewpoints make us better.
- We are committed to innovative drugs as a driver of growth for ROVI.
- We have strict ethical standards for ourselves and our partners.
- Our ultimate success depends on our common efforts.

Groups of interest

The main groups of interest are:

SHAREHOLDERS
To create more value for the long term

SOCIETY
To contribute, in an active way, to the sustainable development of the Society

ENVIRONMENT
To protect the environment



CUSTOMERS
To offer a service based on quality and excellence

SUPPLIERS
To find in ROVI a partner for the mutual benefit

EMPLOYEES
To generate enthusiasm and to promote training and motivation



In order to meet responsibility with all of them during 2012, ROVI carried out the following actions:

With society

During 2012, ROVI collaborated in various solidarity events by donating more than 3.05% of the profits of the group, double compared to the previous year.

These actions have aimed to promote healthy practices in society collaborating with foundations and institutions.

With the environment

ROVI's commitment to the protection of the environment is strong and constant. One of the key tools to ensure a proper management of the environmental aspects is the implementation of the environmental management system according to the criteria established in the ISO 14001:2004 and the Eco Management and Audit Scheme (EMAS).

MAIN ENVIRONMENTAL IMPACTS	
Waste generation	During 2012, ROVI managed more than 560 tons of dangerous waste
Power consumption	Lay down targets in order to reduce power consumption

With employees

People are the main capital of ROVI. In a company with a long tradition in human resources, corporate values and culture are present every day in every employee.

In order to guarantee the commitment of the management team with the employees, in May 2012 ROVI obtained the certificate of compliance with the SA 8000 standard. This standard set up requirements based on the international human rights and the national labour laws in order to protect and empower the staff of the company, the staff hired by the company as well as the suppliers/subcontractors and sub-suppliers.

- **Equal opportunities for all:** the commitment of ROVI to its employees, who are the key to the success of the company, is based on helping them to advance in their professional careers, balancing their personal and professional lives, and emphasizing employment stability.

	Employees	% men	% women
2007	502	47.8%	52.2%
2008	547	44.8%	55.2%
2009	550	44.5%	55.5%
2010	783	54.3%	45.7%
2011	834	48.8%	51.2%
2012	899	45.3%	54.7%

- **We invest in people:** almost 29,000 hours of training were provided in 2012, which meant 32 hours of training per employee.
- **Security comes first:** for this reason, during 2012, ROVI invested 106,100 euros in preventive actions related to the health and safety of our staff. Several suggestions, made by our staff, were also implemented in order to improve working conditions.



With customers

During 2012, we maintained our customer portfolio with very slight variations. In fact, the number of orders increased by 12.6%.

With suppliers

Because ROVI suppliers are an essential element of the value chain, as they work with us and share in our overall responsibility, and they are a key part of the continuous improvement of our activity, we want ROVI commitments to be complied by them as well.

Therefore, a commitment with CSR was requested to our suppliers, including the non-recruitment of minors and the introduction of patterns for balancing personal and professional lives. Today, almost 50% of them have signed this commitment.

With shareholders

ROVI's main commitment to its shareholders is to create higher value that is sustainable over time.

The 2012 guidance, for operating revenue rising from high single digit to low double digit growth and later on July 26, 2012 forecast to reach the low range of the guidance, was achieved. The company's credibility is based on its continued compliance with what it announces to its shareholders, potential investors and the financial community.



Corporate Governance



Share Capital

As of 31 December 2012, the share capital of Laboratorios Farmacéuticos ROVI, S.A. fully subscribed and paid in and composed of ordinary shares each of nominal value of 0.06 euros, and represented by book entries, was as follows:

Share Capital (euros)
3,000,000.00
Number of shares
50,000,000
Number of voting rights
50,000,000

Holders of Significant Shareholdings

The shareholders of significant stakes in the capital share of Laboratorios Farmacéuticos ROVI, S.A., either directly or indirectly, of above 3% of share capital, of which the Com-

pany is aware, according to the information contained in the official registers of the Comisión Nacional del Mercado de Valores on 31 December 2012, are as follows:

	% direct	% indirect	TOTAL
Inversiones Clidia, S.L.	66.840(*)	-	66.840
Bestinver Gestión, S.A. SGIC	-	5.098	5.098
Norges Bank	3.033	-	3.033

(*) Inversiones Clidia, S.L., which owns 66.840 percent of the capital share of the Company, is 52.288 percent owned by Mr. Juan López-Belmonte López.

Board of Directors

COMPOSITION

In accordance with the Company Statutes, the Board of Directors of Laboratorios Farmacéuticos ROVI, S.A, must be

composed by no less than five and nor more than fifteen members. In accordance with these provisions, the Board of Directors as of 31 December 2012 was composed as follows:

	Member of Board of Directors since	Appointments and Remuneration Committee	Audit Committee	Directors condition	
				Executive	Independent
Mr. Juan López-Belmonte López President and Chief Executive Officer	27/07/2007				
Mr. Juan López-Belmonte Encina Chief Executive Officer	27/07/2007				
Mr. Enrique Castellón Leal Vicepresident	24/10/2007				
Mr. Javier López-Belmonte Encina Director	27/07/2007				
Mr. Iván López-Belmonte Encina Director	27/07/2007				
Mr. Miguel Corsini Freese Director	12/11/2008				
Mr. Jose Félix Gálvez Merino Secretary non director					



Committees of the Board of Directors

APPOINTMENTS AND REMUNERATION COMMITTEE

The Appointments and Remuneration Committee is composed of three directors, the majority of whom are independent. Its main role is to inform and to present to the Board of Directors proposals on appointments and resignations of directors and top managers; to evaluate the competences, know-how and experience necessary on the Board, and the time and dedication that is required of each member to carry out a director's functions adequately; to establish and review the Company criteria to be followed by the management team about its composition; and to monitor and ensure the transparency of the remuneration policy established by management. The Committee makes reports, establishes policies, and makes proposals on the areas of its competence, which are submitted to the Board of Directors for their consideration and, if applicable, approval.

AUDIT COMMITTEE

The Audit Committee is composed of three members of the Board of Directors, the majority of whom are independent, who are appointed based on their know-how and experience in the accounting, auditing, or risk management areas. The Committee meets each quarter in order to review the financial information that as a listed company the Company is required to publish regularly. The Committee, among other functions, monitors the process of preparing the financial information of the Company and the Group and confirms the accuracy of the information, regularly reviews the information and internal control systems and risk management policies, and monitors the independence and effectiveness of internal and external auditors. The Board of Directors must consider and come to decisions on any proposals and reports that are submitted to it by the Committee.



Professional profile of members of the Board of Directors

D. Juan López-Belmonte López

See section "Management Team" (page 62)

D. Javier López-Belmonte Encina

See section "Management Team" (page 62)

D. Juan López-Belmonte Encina

See section "Management Team" (page 62)

D. Iván López-Belmonte Encina

See section "Management Team" (page 62)



Mr. Enrique Castellón Leal

A graduate in Medicine and Surgery and a Specialist in Internal Medicine at the Universidad Complutense of Madrid and in Business and Economics at the Universidad Autónoma of Madrid. He holds a Master's in Public Health and a Master's in Health Policy and Management from Harvard University. He was practitioner in the Internal Medicine Service of the Hospital Clínico San Carlos de Madrid, a member of the Medical Inspectors of Social Security, Director General of the Galician Health Service, Deputy Director for Health and Social Services in the Community of Madrid, and Undersecretary in the Ministry of Health and Consumers. He also regularly advises various foundations which carry out research in health services, and provides consulting services for Castellón Abogados. He has worked as a consultant in health policies for the Interamerican Development Bank (part of the World Bank), and is a founding partner and Chairman of the Board of Directors of CrossRoadBiotech SCR.



Mr. Miguel Corsini Freese

A Law graduate and an expert in employment law. His career was for many years associated with Renfe, where he was Chairman of the Board from 1996 to 2004. He is currently Vice Chairman of the Business Federation of Madrid (CEIM) and a member of the Management Board of the Spanish Confederation of Business Organisations (CEOE). In October 2007, Mr Corsini was appointed first Vice Chairman of the Chamber of Commerce of Madrid. In January 2010, he was appointed member of the Control Commission of Caja Madrid. He is a member of the Board of Directors of various companies, including Mutua Madrileña Automovilista, San José Tecnologías, Testa Inmuebles in Renta (Grupo Sacyr-Vallehermoso), Autoclub Mutua Madrileña, S.L., MM Globalis, S.A.U. de Seguros y Reaseguros y MM Hogar, and S.A.U. de Seguros y Reaseguros.



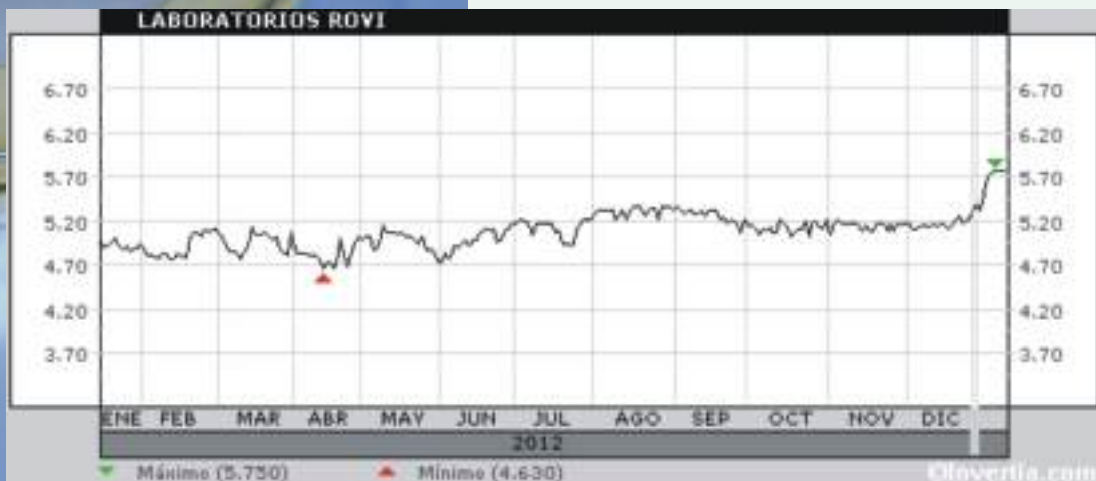
Financial report

Stock market capitalisation

On the December 5th 2007, ROVI carried out an Initial Public Offering (IPO) of shares initially intended for qualified investors in Spain and to qualified institutional investors abroad. The face value of the operation, without including the shares corresponding to the green shoe purchase option, was 17,389,350 shares already issued and in circulation with a nominal value of 0.06 euros per share, giving a total nominal amount of 1,043,361 euros. The offering price for the operation was 9.60 euros per share.

ROVI shares performed better than the IBEX 35 index in 2012. ROVI's share price increased by 4% from 30 December 2011 to 31 December 2012 compared with an IBEX 35 index fall of 5% in the same period.

The following graph shows the fluctuations of the share price in the stock market in 2012.



The following chart shows the performance of the share price of ROVI compared with the IBEX 35 index in 2012.



Activity

Laboratorios Farmacéuticos Rovi, S.A. ("Rovi", "the Parent Company" or "the Company"), the parent company of the Group, was incorporated as a public limited company ("sociedad anónima") in Madrid on 21 December 1946. It is entered in the Companies Register of Madrid, sheet 1,179, folio 197 of volume 713 of Companies Book 283. The registered office of Laboratorios Farmacéuticos Rovi, S.A. is located at Julian Camarillo, 35, Madrid. Its head office is at the same address in Madrid.

The Company's principal activity is the sale of its own pharmaceutical products and the distribution of other products for which it holds licences granted by other laboratories for specific periods, in accordance with the terms and condi-

tions contained in the agreements entered into with said laboratories.

Rovi is the parent of a pharmaceutical business group engaged in the production and sale of pharmaceutical products. The Group's main product is Bemiparin, a low molecular weight heparin, which is marketed in various countries.

The shares of the Company are listed on the Madrid, Barcelona, Bilbao and Valencia Stock Exchanges and included in the Spanish Stock Exchange Interconnection System (Continuous Market)

THE FOLLOWING FINANCIAL INFORMATION IS EXTRACTED FROM THE ANNUAL ACCOUNTS OF LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES AS OF AND FOR THE YEAR ENDED 31 DECEMBER 2012 AUDITED BY THE AUDITING FIRM OF PRICEWATERHOUSECOOPERS AUDITORES, S.L. THESE ANNUAL ACCOUNTS MAY ALSO BE OBTAINED FROM www.rovi.es.

Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries balance sheet (Thousand euros)

	2012	2011
ASSETS		
Non-current assets		
Property, plant and equipment	53,791	45,857
Intangible assets	3,176	2,736
Deferred tax assets	6,073	4,856
Available-for-sale financial assets	28,148	5,117
Financial receivables	133	325
	91,321	58,891
Current assets		
Inventories	56,225	41,306
Trade and other receivables	54,377	68,698
Current income tax assets	3,855	3,682
Bank deposits	-	6,000
Cash and cash equivalents	16,585	49,491
	131,042	169,177
TOTAL ASSETS	222,363	228,068
EQUITY		
Capital and reserves attributable to Company shareholders		
Share capital	3,000	3,000
Legal reserve	600	600
Treasury shares	(2,060)	(1,922)
Retained earnings and voluntary reserves	105,692	93,920
Profit for the year	19,514	18,127
Reserve for available-for-sale assets	(299)	256
Total equity	126,447	113,981
LIABILITIES		
Non-current liabilities		
Financial debt	29,135	41,246
Deferred income tax liabilities	3,256	3,635
Non-current deferred revenues	(8,393)	12,450
	40,784	57,331
Current liabilities		
Trade and other payables	39,878	41,775
Financial debt	9,255	9,434
Current deferred revenues	4,348	4,298
Provision for other liabilities and charges	1,651	1,249
	55,132	56,756
Total liabilities	95,916	114,087
TOTAL EQUITY AND LIABILITIES	222,363	228,068

Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries income statement (Thousand euros)

Year ended 31 December

	2012	2011
Revenue	201,923	184,706
Changes in inventories	14,919	(518)
Raw materials and consumables used	(90,432)	(68,921)
Employee benefit expenses	(53,546)	(51,133)
Other operating expenses	(48,359)	(43,893)
Depreciation, amortization and impairment charges	(5,320)	(4,709)
Recognition of government grants on non-financial non-current assets and other	1,236	3,453
Other income	1,256	-
OPERATING PROFIT	21,677	18,985
Finance income	1,341	2,319
Finance costs	(2,180)	(2,376)
FINANCE COSTS - NET	(839)	(57)
PROFIT BEFORE INCOME TAX	20,838	18,928
Income tax	(1,324)	(801)
PROFIT FOR THE YEAR FROM CONTINUING OPERATIONS	19,514	18,127
Profit for the year from discontinued operations	-	-
PROFIT FOR THE YEAR	19,514	18,127
Earnings per share (basic and diluted) attributable to the shareholders of the Company (euros):		
Basic and diluted	0.39	0.36

Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries statement of changes in equity (Thousand euros)

	Share capital	Legal reserve	Treasure shares	Retained earnings and voluntary reserves	Profit for the year	Reserve for available-for-sale assets	TOTAL EQUITY
Balance at 1 January, 2011	3,000	600	(1,960)	77,914	24,582	(2)	104,134
Total comprehensive profit for the year	-	-	-	-	18,127	258	18,385
Acquisition of treasury shares	-	-	(147)	-	-	-	(147)
Re-issuance of treasury shares	-	-	185	(29)	-	-	156
Transfer of 2010 profit	-	-	-	24,582	(24,582)	-	-
Dividends 2010	-	-	-	(8,604)	-	-	(8,604)
Dividends treasury shares	-	-	-	57	-	-	57
Balance at 31 December, 2011	3,000	600	(1,922)	93,920	18,127	256	113,981
Total comprehensive profit for the year	-	-	-	-	19,514	(55)	18,959
Acquisition of treasury shares	-	-	(1,838)	-	-	-	(1,838)
Re-issuance of treasury shares	-	-	1,700	(212)	-	-	1,488
Transfer of 2011 profit	-	-	-	18,127	(18,127)	-	-
Dividends 2011	-	-	-	(6,345)	-	-	(6,345)
Dividends treasury shares	-	-	-	45	-	-	45
Sale of 50% Alentia Biotech, S.L.	-	-	-	157	-	-	157
Balance at 31 December, 2012	3,000	600	(2,060)	105,692	19,514	(299)	126,447

Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries cash flow statement (Thousand euros)

Year ended 31 December

	2012	2011
Cash flows from operating activities		
Profit before income tax	20,838	18,928
Adjustments for non-monetary transactions:		
Amortization, depreciation and impairment	5,320	4,709
Interest income	(1,341)	(2,319)
Gains or losses on sales of available-for-sale financial assets	-	(88)
Gains or losses on derecognition of financial assets and liabilities	21	109
Interest expense	2,180	2,376
Net changes in provisions	402	9
Grant on non-financial assets and income from distribution licences	(999)	(2,435)
Changes in working capital		
Trade and other receivables	12,359	(12,598)
Inventories	(14,919)	518
Trade and other payables	(2,074)	4,139
Other collections and payments		
Proceeds from distribution licences	-	700
Interest paid	(105)	(155)
Income tax cash flow	(2,068)	(1,209)
Net cash generated (used) in operating activities	19,614	12,684
Cash flows from investing activities		
Purchases of intangible assets	(915)	(800)
Purchases of property, plant and equipment	(12,805)	(7,553)
Proceeds from sales of property, plant and equipment	26	-
Purchases of available-for-sale financial assets	(30,859)	(6,400)
Proceeds from sale of available-for-sale financial assets	7,737	1,810
Contracting current bank deposits (*)	(1,055)	(6,000)
Liquidating current bank deposits (*)	7,014	25,000
Purchases of other financial assets	-	(65)
Cash decrease due to sale of Alentia Biotech, S.L.	(10,278)	-
Interest received	1,341	2,319
Net cash generated (used) in investing activities	(39,794)	8,311
Cash flows from financing activities		
Repayments of financial debt	(8,833)	(8,613)
Proceeds from financial debt	2,757	12,012
Purchase of treasury shares	(1,838)	(147)
Reissue of treasury shares	1,488	156
Dividends paid	(6,300)	(8,547)
Net cash generated in financing activities	(12,726)	(5,139)
Net (decrease)/increase in cash and cash equivalents	(32,906)	15,856
Cash and cash equivalents at beginning of the year	49,491	33,635
Cash and cash equivalents at end of the year (*)	16,585	49,491

(*) As of 31 December 2011, the Group held current bank deposits maturing at over three months of 6 million euros. These current bank deposits are fully available.

Analysis of the main headings in the balance sheet for Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries (Thousand euros)

Property, plant and equipment

The breakdown of the movement on the different categories of property, plant and equipment is shown below:

	Land and buildings	Technical facilities, machinery & tools	Furniture, fittings and other	IT equipment and vehicles	PPE in progress	Total
Cost or valuation	35,402	85,481	2,739	5,781	238	129,641
Accumulated amortization	(19,673)	(61,368)	(1,721)	(4,220)	-	(86,982)
Net carrying amount 01.01.11	15,729	24,113	1,018	1,561	238	42,659
Additions	-	5,921	29	1,603	-	7,553
Retirements	(3,756)	-	-	-	-	(3,756)
Transfers	-	238	-	-	(238)	-
Eliminations from amortization	3,756	-	-	-	-	3,756
Amortization charge	(792)	(2,612)	(103)	(848)	-	(4,355)
Balance at 31.12.11						
Cost or valuation	31,646	91,640	2,768	7,384	-	133,438
Accumulated amortization	(16,709)	(63,980)	(1,824)	(5,068)	-	(87,581)
Net carrying amount 31.12.11	14,937	27,660	944	2,316	-	45,857
Additions	-	11,151	139	1,515	-	12,805
Retirements	-	(68)	-	-	-	(68)
Eliminations from amortization	-	42	-	-	-	42
Amortization charge	(166)	(3,541)	(94)	(1,044)	-	(4,845)
Balance at 31.12.12						
Cost or valuation	31,646	102,723	2,907	8,899	-	146,175
Accumulated amortization	(16,875)	(67,479)	(1,918)	(6,112)	-	(92,384)
Net carrying amount 31.12.12	14,771	35,244	989	2,787	-	53,791

In 2012 and 2011 there were no impairments of property, plant and equipment.

At 31 December, 2011, the land and constructions item included buildings under finance lease agreements with a net carrying amount of 626 thousand euros. These assets,

which had been fully depreciated at the end of the 2011 reporting period, with an acquisition value of 3,756 thousand euros, were eliminated from the Group's property, plant and equipment on 31 December, 2011, since then, the leases on these buildings have been considered operating leases.

Analysis of the main headings in the balance sheet for Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries (Thousand euros)

Intangible assets

Movement on intangible assets was as follows:

	Patents and industrial property	Trademarks and licences	Computer software	Total
Balances at 01.01.11				
Cost	573	402	5,244	6,219
Accumulated amortization	(10)	(51)	(3,868)	(3,929)
Net carrying amount 01.01.11	563	351	1,376	2,290
Additions 2011	168	-	632	800
Amortization charge	(26)	(16)	(312)	(354)
Balances at 31.12.11				
Cost	741	402	5,876	7,019
Accumulated amortization	(36)	(67)	(4,180)	(4,283)
Net carrying amount 31.12.11	705	335	1,696	2,736
Additions 2012	130	101	684	915
Amortization charge	(36)	(26)	(413)	(475)
Balances at 31.12.12				
Cost	871	503	6,560	7,934
Accumulated amortization	(72)	(93)	(4,593)	(4,758)
Net carrying amount 31.12.12	799	410	1,967	3,176

In previous years, the Group acquired intangible assets for 580 thousand euros relating to patents and industrial property. The acquisition was made through the purchase of 100% of the shares of the German company Bertex Pharma GmbH. As part of the acquisition agreement, a payment of 100 thousand euros was made during the year

2011, meaning an increase of said amount in the value of these intangible assets.

Research and development expenditure incurred in 2012 was 9,248 thousand euros (8,414 thousand euros in 2011).

Analysis of the main headings in the balance sheet for Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries (Thousand euros)

Inventories

	2012	2011
Raw materials & other consumables	15,902	10,481
Work in progress & semi-finished goods	10,078	11,419
Finished goods produced internally	8,601	6,649
Marketing products	21,644	12,757
Total inventories	56,225	41,306

The inventories purchase/sale commitments for the Group at the year end were as normal in its course of its business. Management estimates that meeting these commitments

will not generate losses for the Group. The Group has insurance policies to cover the risks the inventories are exposed to. The insurance cover is considered sufficient.

Trade and other receivables

The breakdown of current trade and other receivables is as follows:

	2012	2011
Trade receivables	45,265	60,540
Less: provision for impairment of receivables	(1,450)	(1,172)
Trade receivables - net	43,815	59,368
Other receivables	209	659
Receivables from related parties	908	743
Deposits	1,119	1,077
Employee advances	144	163
Public authorities	8,315	7,013
Total trade and other receivables	54,510	69,023
Less: Non-current portion: Financial receivables	133	325
Current portion	54,377	68,698

Analysis of the main headings in the balance sheet for Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries (Thousand euros)

Application of profit

The proposed application of the profit for the year 2012 and other reserves of the parent company, determined on the basis of generally-accepted accounting principles in Spain, that will be submitted to the General Meeting of

Shareholders, together with the application approved for 2011 based on the profit of the parent company, is as follows:

	2012	2011
Basis of application		
Profit for the year	20,634	7,704
Application		
Dividend	6,830	6,345
Retained earnings	13,804	1,359
Total application of profit	20,634	7,704

Trade and other payables

The breakdown of current trade and other payables is as follows:

	2012	2011
Trade payables	32,005	33,507
Payables to related parties	1,088	1,128
Outstanding remuneration	3,119	3,732
Public authorities	2,852	3,305
Other payables	814	103
Total trade and other payables	39,878	41,775

Analysis of the main headings in the balance sheet for Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries (Thousand euros)

Financial debt

	2012	2011
Non-current		
Bank borrowings	1,213	2,840
Debt with government entities	24,010	30,582
Debt on acquisition of Frosst Ibérica, S.A.	3,912	7,824
	29,135	41,246
Current		
Bank borrowings	1,600	1,959
Debt with government entities	3,495	3,315
Debt on acquisition of Frosst Ibérica, S.A.	4,160	4,160
	9,255	9,434
Total financial debt	38,390	50,680

At 31 December, 2012, ROVI had a total debt of 38,390 thousand euros. Debt with public administration represented 72% of total debt in 2012, from 67% in 2011. This section mainly contains the reimbursable advances that, since the 2001 financial year, Laboratorios Farmacéuticos ROVI, S.A., along with other companies in the Group since 2007, has been awarded by official national and regional bodies to fund different R&D projects. These reimbursable advances, as they are subsidies, do not accrue any interest charges. As of 31 December, 2012, 93% of the Group total debt is 0% interest rate debt.

Another significant heading among the borrowings is that for bank borrowings, which reflects loans with three financial institutions as of December 31, 2012. Parts of the financial expenses generated by these transactions have also been subsidized by official entities.

The Group's objective in relation to the management of capital is to maintain a low level of leveraging which will make it easier for the Group to obtain additional borrowings if required in order to make new investments. The leverage index or gearing ratio at 31 December 2012 and 2011 were as follows:

	2012	2011
Financial debt	38,390	50,680
Less: Cash and cash equivalents	(16,585)	(49,491)
Net debt	21,805	1,189
Equity	126,447	113,981
Leverage index/gearing ratio	17.24%	1.04%

Analysis of the main headings in the balance sheet for Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries (Thousand euros)

Deferred revenue

	2012	2011
Non-current		
Deferred revenues on distribution licenses	1,005	1,234
Deferred revenues on grants	7,388	11,216
	8,393	12,450
Current		
Deferred revenues on distribution licenses	179	129
Deferred revenues on grants	4,169	4,169
	4,348	4,298
Total deferred revenues	12,741	16,748

The caption "Deferred revenues on distribution licenses" records amounts collected from the rights to market Hibor in a number of countries. The Group defers the revenue over the terms of the contracts, which have a duration of between 10 and 15 years. In 2012, no deferred revenues on distribution licences were recognized in relation to new Hibor distribution contracts.

The "Deferred revenues on grants" caption shows the amounts pending recognition in the income statement for reimbursable and non-reimbursable grants received by the Group. These amounts are credited to the income statement over the useful life of the subsidized assets.

a) The most significant non-reimbursable grants pending recognition in the income statement are related to the construction of the bemiparin plant in Granada, which came into operation in 2009:

- Non-reimbursable grant granted by the Andalusian Innovation and Development Agency (Innovation, Science and Enterprise Department) for 5,431 thousand euros. This grant was received in November 2008 and recognition in the income statement commenced in 2009, when the assets for which it was granted began to be depreciated. The amount recognized for this grant under the caption "Deferred revenues on current and non-current grants" at 31 December, 2012 was 4,399 thousand euros (4,694 thousand euros at 31 December, 2011).
- Also for the construction of the Granada bemiparin plant, the Innovation, Science and Enterprise Department of the Andalusian Regional Government granted the Group a non-reimbursable grant of 2,200 thousand euros. Recognition of this grant in the income statement commenced on 1 January, 2010 and the amount recognized under the caption

Analysis of the main headings in the balance sheet for Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries (Thousand euros)

“Deferred revenues on current and non-current grants” at 31 December, 2012 was 1,784 thousand euros (1,923 thousand euros at 31 December, 2011). This grant had not yet been collected at 31 December, 2012.

b) The most significant amounts recognized as deferred revenues related to reimbursable grants granted by government entities relate to construction of the vaccine plant in Granada:

- In 2009, the Group received a decision whereby the Ministry of Health and Social Policy granted a repayable loan of 11,900 thousand euros for development of the vaccine against seasonal influenza and the construction of a new vaccine production plant in Granada. This loan was collected in 2010. A subsidized interest rate is associated to this loan and is recognized under the caption “Deferred revenues on current and non-current grants” for an amount of 3,285 thousand euros at 31 December, 2012 (3,285 thousand euros at 31 December, 2011).

Analysis of the main items in the income statement for Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries (Thousand euros)

Revenue

	2012	2011
Sale of goods	137,736	129,783
Sale of services	63,128	47,120
Revenue from distribution licenses	179	406
Other revenue	880	7,397
Total revenue	201,923	184,706

Sale of goods by product line

	2012	2011
Pharmaceutical products	110,785	100,512
Contrast agents and other hospital products	20,691	21,941
Non prescription pharmaceutical products	5,907	6,861
Cosmetic medicine products	353	469
Total sale of goods by product line	137,736	129,783

Sales of **prescription-based pharmaceutical products** rose 10% to 110.8 million euros in 2012. In the second quarter of 2011, Fitoladius was sold to a third party and, in June 2011, EMLA was stopped to be marketed and started to be only promoted. Excluding the impact of Fitoladius and EMLA distribution in 2011, sales of prescription-based pharmaceutical products increased by 14% in 2012.

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, maintained a growth rate, with sales up 10% to 55.7 million euros. Sales of Bemiparin in Spain (**Hibor**) increased by 3% to 36.6 million euros, while international sales rose 26% to 19.1 million euros in 2012 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 six new countries, Mexico, Venezuela, Saudi Arabia, Iraq, Syria and Oman, during 2012.

Sales of **Vytorin**® and **Absorcol**®, the first of the five licenses of MSD, launched in January 2011, increased by 2.2 times to 12.4 million euros in 2012.

Sales of **Thymanax**®, an innovative antidepressant from Laboratoires Servier, launched in March 2010 and for which ROVI has a co-marketing agreement covering Spain, increased by 35% to 11.6 million euros in 2012.

Analysis of the main items in the income statement for Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries (Thousand euros)

Sales of **Corlentor**[®], a specialty product for stable angina and chronic heart failure from Laboratoires Servier, rose 29% to 9.2 million euros in 2012. In February 2012, Corlentor[®] was approved by the European Commission for the treatment of patients with chronic heart failure¹. The European Commission's decision to authorise this new indication for Corlentor[®] followed the review of data from the SHIFT trial, the largest-ever morbi-mortality study of treatments for chronic heart failure involving more than 6000 patients. It demonstrated that the treatment significantly reduced the risk of death and hospitalisation from heart failure, and improved the quality of life of people living with the disease.^{2,3} This reduction in mortality was highly significant in patients with a heart rate of 75 beats per minute (bpm), or above, for whom Corlentor[®] is now indicated.

Sales of **Osseor**[®], a specialty product for the treatment of postmenopausal osteoporosis from Laboratoires Servier, decreased by 14% to 6.1 million euros in 2012.

Sales of **Exxiv**[®], a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 11% to 7.2 million euros in 2012, mainly due to a slight deceleration of the COX-2 market.

Sales of **over-the-counter pharmaceutical products** declined by 14% to 5.9 million euros in 2012 compared to the previous year. This was mainly as consequence of the reduction of consumption in the current Spanish economic environment.

Sales of contrast **imaging agents and other hospital products** decreased by 6% to 20.7 million euros in 2012.

1. EMA announcement

2. Swedberg K, Komajda M, Böhm M et al. Ivabradine and outcomes in chronic heart failure (SHIFT): a randomised placebo-controlled study. *Lancet* 2010; 376:875-85

3. Ekman I, Chassany O, Komajda M et al. Heart rate reduction with ivabradine and health related quality of life in patients with chronic heart failure: results from the SHIFT study. *Eur Heart J*. 2011; DOI:10.1093/eurheartj/ehr343. Available at: <http://eurheartj.oxfordjournals.org>

Employee benefit expenses

	2012	2011
Wages and salaries	44,436	42,857
Social security costs	9,059	8,225
Pension costs / defined-contribution pension plans	51	51
Total employee benefit expenses	53,546	51,133

Analysis of the main items in the income statement for Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries (Thousand euros)

Main financial ratios

	2012	2011
Financial ratios (thousand euros)		
Gross profit ¹	127,646	118,720
% Gross profit / Revenues	63%	64%
EBITDA ²	26,997	23,694
% EBITDA / Revenues	13%	13%
Profit for the year	19,514	18,127
Total equity / Total equity and liabilities	57%	50%
Borrowings ³	38,390	50,680
Borrowings / Total equity and liabilities	17%	22%
Working capital ⁴	75,910	112,421
Net cash ⁵	7,462	11,005
% Net cash / Total equity and liabilities	3%	5%

1. Operating revenues (revenues + recognition of government grants on non financial non current assets and others) +/- changes in inventories of finished goods and work in progress - raw materials and consumables used.
2. Calculated as operating profit + depreciation, amortisation and impairment charges.
3. This reflects the total of current and non-current borrowings.
4. Calculated as total current assets - total current liabilities.
5. Net cash includes available-for-sale financial assets, deposits (included within the heading of Trade and other receivables), cash and cash equivalents and derivative financial instruments (net), minus borrowings (bank borrowings, debts with Government entities, third party debts, finance lease liabilities and accrued interests).

Forward-looking statements

This report 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 report represent ROVI's expectations and beliefs as of the date of this report. 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 report.



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