







Annual 2014



## Contents

- 5 BASIC MAGNITUDES
  - 6 Financial and non-financial magnitudes
  - **10** Group profile
- 12 CHAIRMAN'S LETTER
- **17** BUSINESS MODEL
  - **18** Identity and commitment
  - 24 Business units
- 38 STRATEGY
  - **39** Market environment
  - **41** Strategic and financial priorities

- 46 CORPORATE GOVERNANCE
  - **47** Corporate governance model
  - **48** Corporate governance bodies
  - **58** Ethical framework
  - **60** Risk Management
- **63** YEAR 2014
  - **64** Period results
  - **83** Customers
  - **85** Human Resources
  - **90** Suppliers
  - 92 Society and environment
- 98 ABOUT
  THIS REPORT



**CORPORATE GOVERNANCE** 

**YEAR 2014** 

**ABOUT THIS REPORT** 



**Group profile** 

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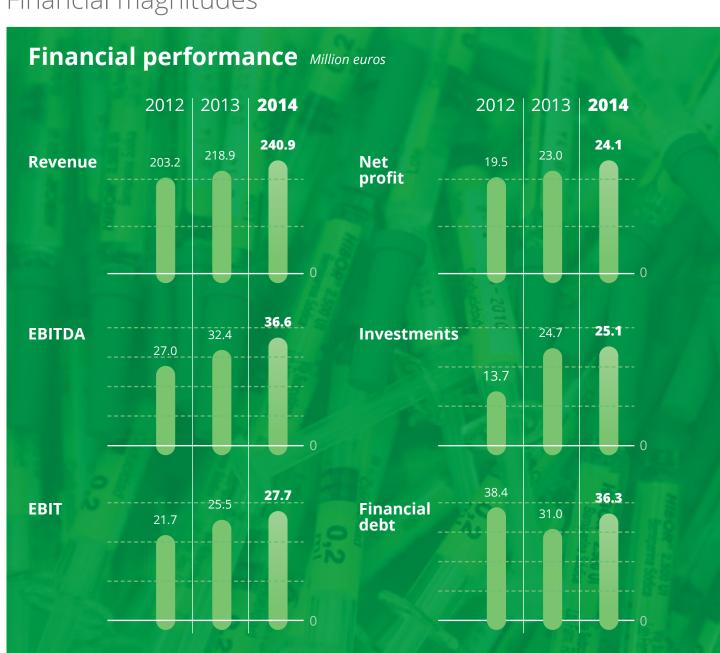
STRATEGY

**CORPORATE GOVERNANCE** 

**ABOUT THIS REPORT** 

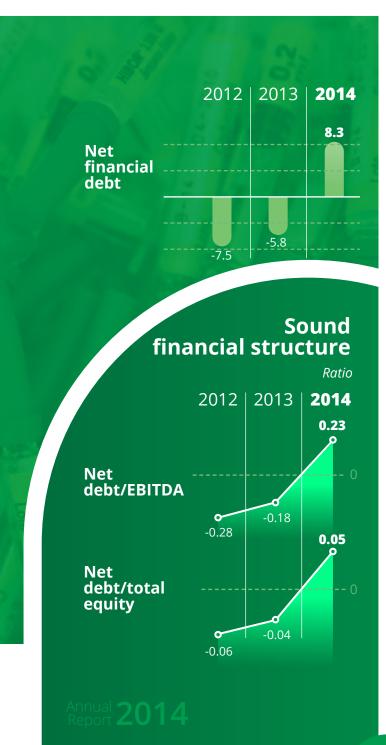


# Financial and non-financial magnitudes Financial magnitudes









## **Stock market** information

Number of shares	50,000,000	
Listing price at closing	10.30 euros	
Capitalization as of 31/12	515,000,000 euros	
Total dividend	8,450,000 euros	
Dividend per share paid in 2014 on 2013 earnings	0.1612 euros	
Dividend per share proposed on 2014 earnings	0.1690 euros	
Pay out (as % of consolidated net profit	35%	
Earnings per share	0.48 euros	
PER (Price-earnings ratio)	21.4	

**ABOUT THIS REPORT** 

### STRATEGY CORPORATE GOVERNANCE

### Non-financial magnitudes









### **Community**

Economic value generated and distributed

Million euros

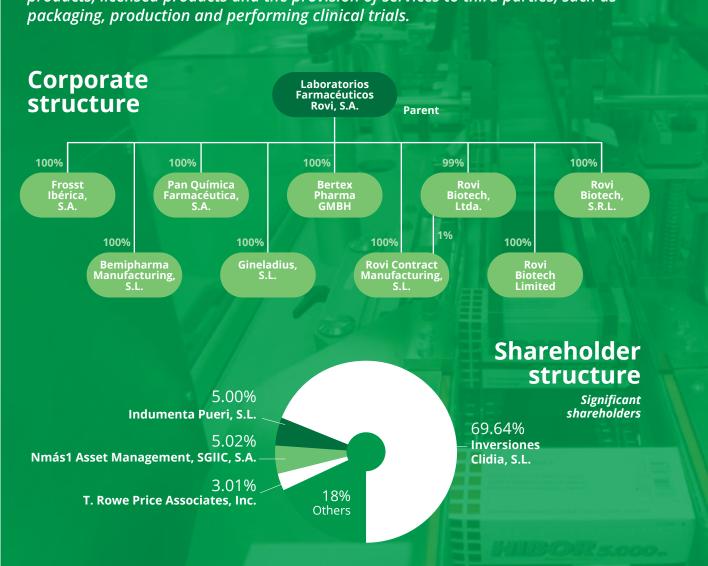
	2012	2013	2014
Economic value generated	204.5	220.3	240.9
Economic value di	stributed		
Shareholders	6.8	8.1	8.5
Suppliers	114.7	121.8	134.3
Society	1.3	1.2	1.5
R&D	9.2	10.5	12
Employees	53.5	55.6	58.1
Capital providers	0.8	1.2	2.1
Amortizations and depreciations	5.3	6.9	8.9
Reserves	12.9	15.0	15.6





### Group profile





(\*) Inversiones Clidia, S.L. is 52.29% owned by Juan López-Belmonte López.

(\*\*) Nmas1 Asset Management, SGIIC, S.A. is a collective investments institutions management company, that shareholders of QMC II Iberian Capital Fund FIL and QMC II Iberian, S.L. have delegated shareholding management in ROVI and that, therefore, exercises voting rights corresponding to the mentioned shareholders.





## Corporate data

#### Name

Laboratorios Farmacéuticos Rovi, S.A.

### Address

Julián Camarillo, 35 28037 MADRID. Spain

#### Telephone

34 91 372 62 30

### Web page

www.rovi.es

### Share capital

3,000,000.00 euros

### Number of shares

50,000,000

#### Nominal

0.06€ share

#### Activity

Manufacturing and marketing of pharmaceutical products and services for third parties.

#### Markets

ROVI group is directly present in Spain and Portugal and its shares are listed in stocks markets of Barcelona, Bilbao, Valencia and Madrid.

### **History**

oundation of the company. • 1946	Foundation of the company.		
Beginning of research in low molecular weight heparins.	low molecular weight		
duction of Bemiparin in the panish market and start of activities in Portugal.	Introduction of Bemiparin in the Spanish market and start of activities in Portugal.		
	Internationalization of ROVI following approval of Bemiparin abroad.		
sed international coverage to 59 countries. 2003	Increased international coverage to 59 countries.		
uction of R&D&I centre and ifacturing plant in Granada. 2006	Construction of R&D&I centre and manufacturing plant in Granada.		
Marketing agreement with Laboratoires Servier for Corlentor.	Marketing agreement with Laboratoires Servier for Corlentor.		
egic agreement with Merck Sharp & Dohme ("MSD").	Strategic agreement with Merck Sharp & Dohme ("MSD").		
FDA approval for injectables plant. <b>2012</b>	FDA approval for injectables plant.		
Agreements to market products from Novartis and Medice.	Agreements to market products from Novartis and Medice.		
Registration process of a bio-similar of 2014 noxaparin in EMA and FDA.			

Annual 2014





Annual 2014



For yet another year, I have the honour to address you to make assessment of the evolution of ROVI's business in 2014. The information we are making available for you is part of the commitment to transparency and good corporate governance that we have undertaken with the shareholders and all the groups of interest of our company. With this in mind, this year I am glad to present our first integrated report, whose main objective is to maintain reliable and relevant information of the group activity during past year, as well as its main strategic lines for the coming years.

ROVI has closed 2014 with the best results since its Initial Public Offering. EBITDA increased 13% reaching the record figure of 36.6 million euros. Furthermore, net profit increased in 5% to 24.1 million, an all-time high figure in the history of the group. This evolution is mainly due to the strength of our main products, which have continued gaining market share in its corresponding markets, and also to our contract manufacturing business, in which were closing new agreements. Growth in both areas drove up total revenues to 240.9 million euros, exceeding in more than double the figure of 2007, when ROVI started its Initial Public Offering (IPO).

These results are more commendable than ever, as they have been produced in a very difficult environment for the sector. Although in 2014 Spanish economy registered some growth four consecutive quarters ever since the crisis started, this recovery has not really been reflected in the pharmaceutical industry, still affected by the tough measures approved in the last years to reduce deficit. In fact,

the pharmaceutical market has experienced a drop of 26% since its historical maximum of May 2010 until December 2014. To this reduction has to be added an additional discount between 7,5% and 15% that innovative products have to credit back to Government to contribute to deficit's sustainability. Prospects for this year are not much better, according to Farmaindustria that predicts another reduction of 2% of pharmaceutical expenditure.

However, these difficulties are having a restrained impact in the company's accounts, thanks to the strength of its business model. Our growth is based in actions like opening new markets by strategic alliances, obtaining long term contracts in the contract manufacturing business and the development of a diversified portfolio of products protected by long term patents. The success of this strategy is reflected in the fact that the sales of prescription based products raised 60% between 2010 and 2014, what means exceeding industry average in 83 basic points.

This growth has also been reflected in our team, that have kept growing in the last years, despite the economic crisis. During last year, the company hired 128 people increasing the workforce to a total of 1,109 employees. This represents 100% growth since 2007.

These results would have not been possible without our strong commitment with research and development, to which we destine 7% of the sales of our pharmaceutical products, although this figure could increase in the future. Currently, the R&D&I is being focused in investigation of heparins and drugs release ISM technology, in which significant progress is





being achieved. We are very excited with the potential of the ISM technology and we hope to start with phase III of the project in 2015. Additionally we have pending the authorization to market a biosimilar of enoxaparin, an antithrombotic, in Europe and in the U.S.A.

In the research field, we would like to highlight that ROVI participates in R&D&I projects in other centres, universities and companies of the sector. In particular, we participate since 2006 as partner in the research activates of CENIT consortium, since 2007 in the Melius Consortium, since 2009 in the CeyeC Consortium, since 2011 we lead SNC Integra Consortium and since 2013 in Adelis Consortium.

### New launches

Our commitment to reach new agreements with other laboratories to market its drugs in Spain has strengthened our portfolio. The results of this effort have been the recent launches of products like Volutsa, Ulunar Breezhaler and Hirobriz Breezhaler, which count now with good sales prospects.

I am pleased to highlight the soundness of our balance, as well as our capacity to generate cash, that allow us to finance our growth organically and position us in a favourable position to make the most of current competitive environment. We will be vigilant to potential opportunities to expand our sales and the profitability of our assets.

Looking at 2015, we are confident that the growth of our operating income will keep the trend of the



We are confident that the growth of our operating income will keep the trend of the last two years

last two years. We hope that our growth will mainly come from our flagship product,
Bemiparin, from obtaining new distribution licence agreements, from the existing portfolio of specialty products and from new customers in the contract manufacturing area.

In this sense, it should be noted the last strategic agreements that are going to contribute developing ROVI´s business. From one side, we have obtained the approval of the registration of Bemiparin in China and Brazil, allowing starting with the marketing stage in both countries this year. This way, Bemiparin keeps being consolidated as one of the main treatments to venous thromboembolic disease in the 53 countries where is currently present. On the other side, in the contract manufacturing area, we have renewed the agreement with MSD, which will be extended until March 2020. This renewal is the result of the efforts of the company to maintain customer´s loyalty in this area.

These sound results as well as good prospects have reflected in the market value of the share, which has been generating value for shareholder. During 2014 the shares of ROVI quoted a revaluation over 3%, an evolution in line with Ibex 35 and that was significantly better than the Ibex small cap index, which had a drop of almost 8% during the year. To reward the support and loyalty of shareholders, ROVI will propose in the next General Meeting of Shareholders a dividend of 0.1690 euros per share on 2014 earnings, what means an increase of 5%.

Sustainability of shareholder remuneration is ensured thanks to the solvency of the company. Even though ROVI increased its debt in 5.3 million euros during 2014, the group position is still secure. In fact, 43% of the debt has been contracted with public administration, with a 0% rate, while bank debt has very favourable conditions.

I would like to end expressing my deep appreciation and gratitude to the huge effort of more than 1,000 people that currently form part of ROVI. Their commitment and enthusiasm in our mission have been the driving force of the Company and are, undoubtedly, the best guarantee that year 2015 will be again a year of growth and success. I would also like to thank shareholders for their loyalty to ROVI and their trust in the Board of Directors.

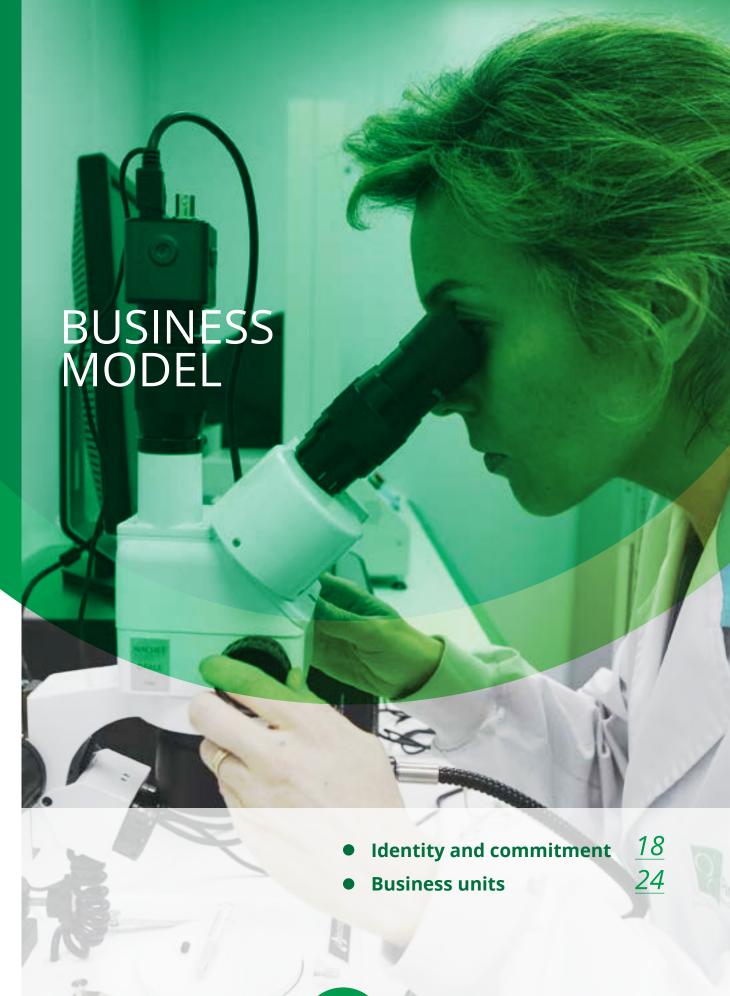


Juan López-Belmonte López CHAIRMAN



**CORPORATE GOVERNANCE** 

YEAR 2014



**YEAR 2014** 



# Identity and Mission, commitment vision and values

### MISSION:

To work for the wellbeing of society, promoting human health through the production of drugs and health products. We research for better health.

### **VISION:**

ROVI aspires to be recognized as a reference for research and production of products aimed at improving the health.

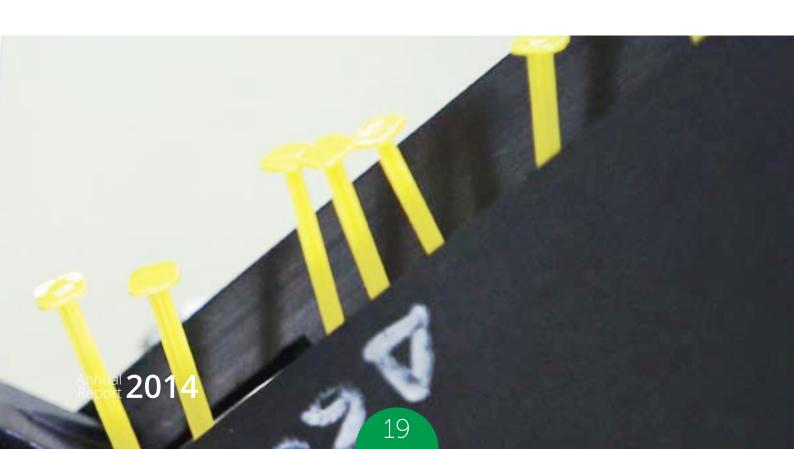




### **Values**

- All of us are the main asset of the company.
- We feel changes as real opportunities for development.
- 3 Is important to feel that every day we learn something and we learn something new.
- We like to assume responsibilities from start to finish.
- 5 We know that we must win the trust of patients every day.

- We make our customers concerns our own and share their successes.
- Our diversity in training, experience and points of view make us to be better.
- We are committed to innovative drugs as engine of growth of ROVI.
- We establish strict ethical standards for ourselves and contributors.
- Our ultimate success depends on effort of all.







### CSR (Corporate Social Responsibility), a commitment with society

In the business strategy of ROVI, Corporate Social Responsibility (CSR) is crucial to ensure company's sustainability in the long term and to strengthen confidence of the groups of interest.

ROVI considers that CSR is a commitment to society, given the importance of its work and product to improve health and quality of life of people. Therefore, in recent years, has developed an intense activity to support research and promote prevention and knowledge of certain diseases.

The company incorporates CSR in its governance, management and daily activity. CSR strategy decisions are responsibility of the Management Committee, and ultimately, on the Board of Directors.

ROVI´s commitment with ethical management and transparency is evident in the development of its internal codes. Additionally, ROVI has applied for SA-8000 standard for the scale and impact of its activities, products and services on the workplace, contributing to reinforce its acting principles:

- Compliance with national and international legislation.
- Establish reviewing mechanism for responsible management to constantly improve.
- Allocate necessary resources to comply with ethical, social, work and environmental commitments.
- Take part in organizations and forums, national and international, promoting and supporting





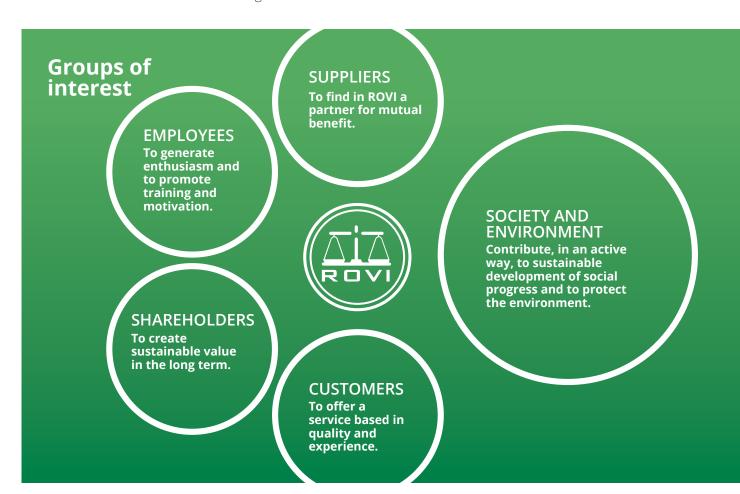
environmental protection programs, as well as human rights, and labour laws.

- Encourage the involvement in CSR of all people working in ROVI through training and communication.
- Promote ROVI's values in relation with Corporate Social Responsibility between suppliers and subcontractors of goods and services.
- Keep communication channels open with all groups of interest of ROVI, in order to improve a dialogue mechanism and mutual understanding so that the

needs of these groups are taking into account in ROVI's strategic and operational development.

### Groups of interest

Knowing the expectations is part of ROVI´s CSR strategy, for this reason, the company tries to keep a constant and fluid dialogue to detect and respond to their interests, ensuring long term business viability. The company has identified five collectives contributing directly or indirectly to the good progress of activities:





The company
has established
communication and
consultation channels to
be aware of the needs of
the groups of interest

The company has established communication and consultation channels to be aware of the needs of the groups of interest and give answers to their expectations.

For its employees, the company has an intranet available, so that the different departments share information, and encourage this way the knowledge of the company activity in the different areas. Another utility of this platform is to facilitate the interaction and dialogue and facilitate employee's work performance. Generating trust and positive feelings toward the brand is one of the main values of the company in its internal organization. In addition, there are suggestion boxes placed at the facilities, to enable anonymous communications for improvements.

Since its Initial Public Offering, ROVI has maintained a commitment for transparency with the shareholders, informing them regularly of its activities. The company has made available for shareholders a direct communication channel enabling an e-mail address ir@rovi.es and information can also be requested through its corporate web site [http://www.rovi.es/







ROVI has a corporate procedure that manages certifications and system qualifications requests

inversores/solicitudInformacion.php?idiomalD=2]. There is also available an e-mail alert system [http:// www.rovi.es/inversores/alertasEmail.php] to automatically receive financial information of ROVI. In addition, during 2014 the company carried out 4 roadshows, participated in 9 events with investors and received 12 visits of investors at its facilities, which represented more than 100 invertors informed.

Furthermore, all relevant information of the group, presentations and economic-financial legal documents and of corporate governance are available to the public in the corporate website www.rovi.es.

For information requests about: certifications and system qualifications, products information and delivery times, among others, of any of the companies of the group, ROVI has a corporate procedure (SOPc813 "Communication, participation and consultation") that manages these data. Most of the requests by this procedure have been about certifications and authorizations. For this reason the corporate website **www.rovi.es** has available to public the certificates from all the companies of the Group.

**ABOUT THIS REPORT** 



# Business Three pillars units of growth

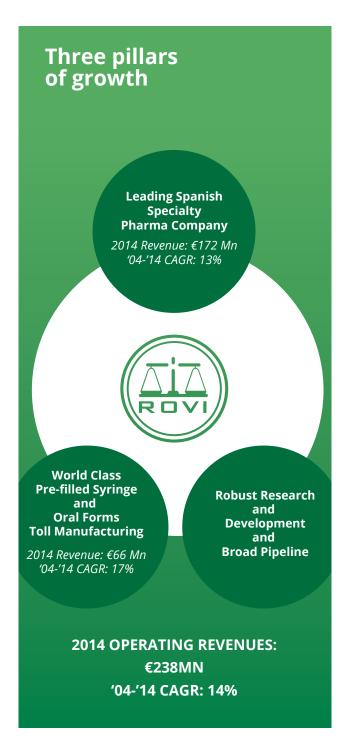
ROVI is a leading company in pharmaceutical specialties engaged in the research, development, manufacturing and marketing of small molecule and specialty biologic drugs.

The group has three pillars of growth: pharmaceutical specialties, with a diversified portfolio with own and third party products; the manufacture for third parties of prefilled syringes and oral solid forms, and a sound low-risk R&D policy. Based in these three pillars, ROVI´s business has a resilient profile that has allowed increasing its benefits during the lasts years, despite of the difficult scenario the sector is facing, aggravated by the public sector cuts in pharmaceutical spending.



**BASIC MAGNITUDES** 





### Competitive advantages

ROVI business has a number of competitive advantages that have allow the company to position as one of the leaders in its market segment, a sector that, additionally, has strong entrance barriers.

Unique knowledge of LMWH: Since it was founded in 1946, ROVI's business has been mainly focused in the research and development of

heparin based drugs, an anticoagulant of rapid effect, and since 1981 its fractionated derivatives, Low Molecular Weight Heparin (LMWH). Thanks this almost 70 years of experience, ROVI's main product, Bemiparin, has positioned as one of the main treatments worldwide for the Venous Thromboembolic Disease.

Patent protected diversified portfolio: The company has a diversified portfolio divided into seven franchises, integrated by its own products and others marketed under

licence. These products cover growing demand needs and are not practically affected by the reference prices system in Spain, so the cuts in pharmaceutical public spending have had less impact in the company's accounts. Additionally, there will not be significant patents expirations until 2017.

Infrastructure with operational benefits: ROVI is one of the major players in the contract manufacturing business. The company is one of world leaders in the production of prefilled

syringes. It is a solid and long term business, as there are just a few companies offering this type of services at international level, contracts are long term oriented, and entry requirements are difficult. Furthermore, ROVI has one of the largest



solid oral forms manufacturing plants in Europe to manufacture solid oral forms and exports to more than 40 countries. Both plants are approved by European Regulators –European Medicines Agency (EMA) – and American – Food and Drug Administration (FDA)–.

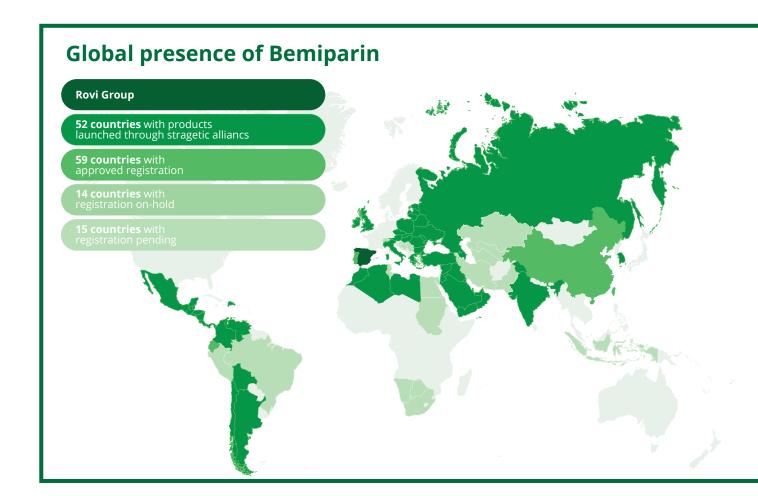


**Low risk innovation**: The Company allocates a substantial part of its income to research, as a low-risk strategy, focusing in chronic diseases with broad medical requirements.



**International expansion**: One of the main objectives of ROVI's strategy is expand its international presence, landing in new markets, always having in mind its policy of minimizing risks.

Currently, Bemiparin is present in more than 80 countries – whether in pre-registration, registration or marketing stage – through strategic alliances with 22 international partners. This way, it has positioned itself as one the leading therapeutic proposals for prevention and treatment of venous thromboembolic disease in 53 countries.







# Pharmaceutical specialties

ROVI has a diversified portfolio including around thirty products of its own and marketed under licence. This portfolio has a defensive profile, as is not affected by reference prices in Spain and there will not be any significant patent expiration until 2017.

Below are the most important products in terms of its contribution to the EBITDA of the group.

#### **Hibor®**

Hibor (Bemiparin) is a low molecular weight heparin (rapid anticoagulant effect) indicated for the prevention and treatment of Venous Thromboembolism (VTD) both in surgical patients and the treatment of acute long term patients that have undergone a VTD process. Venous Thromboembolic Disease 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 the consequences

of thromboembolism evolution, including grow, progression and fragmentation. In the latter case, some fragments may break loose and reach lung, causing pulmonary embolism. Just in Spain, it is estimated that there are almost 65,000 cases of Deep Venous Thrombosis every year and 25,000 cases of Pulmonary Embolism (data from Thromb Haemost 2000, 2001 and 2005).

In the last years, Bemiparin has positioned as one of the main answers internationally to fight against this disease, after expanding its presence to 53 countries through a network of strategic alliances. Currently, Bemiparin is the main product of ROVI and represents 31% of the operating revenue of the group.

### Hirobriz® Breezhaler® and Ulunar® Breezhaler®

In the last quarter of 2014, ROVI started to market Hirobriz Breehaler (indacaterol maleate) and Ulunar Breezhaler (indacaterol maleate and glycopyrronium bromide) in Spain. Both active ingredients are long acting bronchodilators, indicated in the maintenance treatment of Chronic Obstructive Pulmonary Disease **STRATEGY** 





(COPD), in adult patients, and are administered by inhalation through the Breezhaler device. ROVI markets both products under a licence from Novartis.

### Absorcol® and Vytorin®

Absorcol (ezetimibe) and Vytorin (ezetimibe and simvastatine) are products indicated as adjunctive therapy to diet in patients with hipercholesterolaemia. It represents the first of the five licences of MSD that ROVI distributes in Spain under a co-marketing agreement since January 2011.

### **Corlentor®**

Corlentor (ivabradine) is a prescription product for chronic stable angina pectoris and chronic heart failure that ROVI markets under a licence of Laboratorios Servier since 2007.

### Medikinet® and Medicebran®

Medikinet (methylphenidate hydrochloride with modified release) and Medicebran (methylphenidate hydrochloride for immediate release) are prescription products indicated for the treatment of the ADHD (Attention Deficit Hiperactivity Disorder) in children and teenagers. Both products are from the company Medice that ROVI distributes, on exclusivity basis, in Spain since December 2013.

#### **Exxiv®**

Exxiv (etoricoxib) is a selective COX-2 inhibitor, an antiinflammatory indicated for the symptomatic relief of arthritis, rheumatoid arthritis, ankylosing spondylitis, and the pain and signs of inflammation associated with acute gouty arthritis and for the short-term treatment of moderate pain associated with dental surgery. It is a research product of Merck Sharp & Dohme marketed in Spain by ROVI since 2008.



ROVI offers the unification of all contract manufacturing services by the same company

### **Thymanax®**

Thymanax (agomelatine) is an antidepressant indicated for adults with major depressive episodes. It is a research product of Laboratorios Servier distributed by ROVI in Spain under a co-marketing agreement since March 2010.

#### **Volutsa®**

In the first quarter of 2015, ROVI started to market Volutsa (solifenacin succinate and tamsulosin hydrochloride), a product of Astellas Pharma indicated for the treatment of moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia (BPH) in men who are not adequately responding to treatment with monotherapy.

### Imaging contrast media agents and other hospital products

ROVI is one of the leading companies of the market in the commercialization of contrast media agents, hospital

use products for imaging diagnosis (computerized tomography, magnetic resonance imaging, ultrasound scan etc.). This area, that represents more than 10% of company's revenue, includes a wide range of product's portfolio, like the ones commercialized under licence of Bracco: Iomeron® and Iopamiro® (for computerized tomography and intervention), Multihance® and Prohance® (for Magnetic Resonance Imaging), Sonovue® (for ultrasounds) and Bracco Injeenering: EmpowerCTA+®, EmpowerMR® and CT Exprès (contrast injection systems and compatible disposable material).

Hospital division product's portfolio is completed with health products for care and maintenance of intravenous catheters (Fibrilin® and Fibrilin Salino®).

### Contract Manufacturing

ROVI has managed to be well-placed to take advantage of the growing demand of pharmaceutical companies to outsource their manufacturing processes. This way, the company makes the most of the high manufacturing capacities available at its facilities providing a full range of manufacturing services of injectables, suppositories and oral solid forms.

The company, through its two manufacturing plants: one dedicated to injectables (Rovi Contract Manufacturing) and the other specialized in solid oral forms (Frosst Ibérica), offer contracts manufacturing services to third parties in a wide range of pharmaceutical forms, including pre-filled syringes, vials, suppositories, tablets, coated tablets, hard capsules and sachets.

ROVI offers the unification of all services by the same company, from the development of the project until to the final release of a product, including preliminary clinical trials, stability studies, and chronological





physical-chemical and microbiological analysis, with the corresponding savings in time and money for the customers. This way, a customized service is offered to customers, depending on their needs.

The contracts signed with the customer for whom ROVI manufactures usually last between 3 and 5 years average, what contributes to a remarkable incomes steadiness. Additionally, the long regulatory process that a pharmaceutical company has to go through to carry out a change of manufacturer, turns contract manufacturing business in a "lifetime customer value" business model, as long as the service offered optimally fulfil customer requirements.

Contract Manufacturing is divided in:

Injectables

ROVI is currently one of the leading manufacturers of pre-filled syringes in Europe in terms of number of nits manufactured (filled) yearly, with an annual

units manufactured (filled) yearly, with an annual production capacity of 150 million units. There are

not many contract manufacturing competitors of pre-filled syringes worldwide as the entry barriers in this business are high, due to the biological nature of the drugs that are manufactured and the aseptic conditions required (filling of product in sterile rooms controlled microbiology) for the filling of pre-filled syringes.

The company has a plant specialized in filling and packaging of parenteral solutions in prefilled SCF syringes from 0,5ml to 20ml (filled from 0,2ml to 20ml) and vials from 2ml to 10ml. These syringes and vials are filled in aseptic conditions in sterile areas. If needed terminal sterilization can be performed, and it is offered the possibility of adding safety devices to syringes.

The total annual capacity of vials is 40 millions, while suppositories capacity rises to 150 millions.

The plant is approved by European and USA authorities. Also has the approval from authorities from Corea, Brasil, Countries of Gulf, as well as ISO9001, ISO14001 and OSHAS certifications.



ROVI is currently one of the leading manufacturers of pre-filled syringes in Europe

### Solid forms plant

ROVI also has a solid forms plant with a long tradition in the manufacture of pharmaceutical products and that uses state of the art technology to manufacture oral formulations (tablets, coated tablets, hard capsules and sachets).

The plant, with 83.000 square metres, counts with a global annual capacity of 3 billion tablets, 300 million hard capsule and 30 million sachets in different manufacturing lines. Additionally, it has a large size warehouse, with a storage capacity of 9.000 pallets.

In order to provide to all the markets this plant is approved by European and USA authorities. It also holds approval from Japanese, Mexican, Brasilian, Kenyan Belarusain and Gulf countries authorities.

Clinical trials

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

ROVI CM offers a wide range of services for the performance of clinical trials, product preparation and filling, labelling, 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.

### **Development**

ROVI offers 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.

# Commitment to research

Research and development are strategic to compete in the current market and differentiate ourselves from the other companies of the sector. ROVI is a company committed to innovation, with more than 180 granted patents and over 40 pending applications. The success of this policy can be clearly seen in the extraction of the first second generation low molecular weight heparin, Bemiparin, that has become the main product of the company, and is currently present in 53 countries.

In 2014, the group invested in R&D&I a 5% of the operating income, with an increase of 14% in research

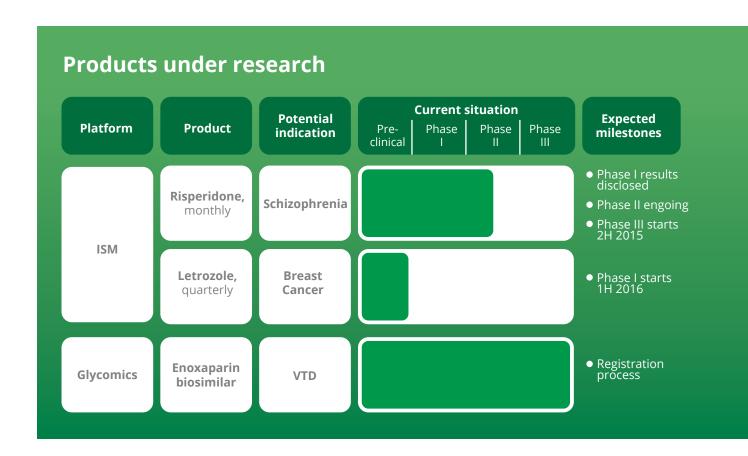




Research expenditure increased by 14% in 2014

expenditure respect previous year, evidenced by a focused investment in the ISM Risperidone project. Due to these investments, 52% of our current income from pharmaceutical specialties area corresponds to own products.

ROVI owns two R&D&I centres and is present in the creation of major national research consortia. It has participated since 2006 as partner in research activities of the Spanish Strategic Consortium for Technical Research (CENIT), in the Consortium Melius 2007 and in the consortium CeyeC 2009. Since 2011, leads actively other research consortia including the SNC\_Integra and ADELIS, both framed in the FEDER-INNTERCONECTA program for Andalucía.







### Areas of Research

Investigation activities are mainly focused in three areas: drugs delivery technology, glycomics, and multilayer technologies to develop urethral catheters.

Drugs delivery technology

Drug administration has direct effects in drug's efficacy as is influenced by factors such as concentration and absorption by organism. Research on this field allows minimizing certain factors such as active substance degradation, preventing side effects and increasing bio-availability (drug's ability to act with the adequate dose).

ROVI has developed a leading-edge research line of prolonged released or depot systems, by using ISM® technology. This way, the product is reconstituted before administration to an injectable fluid that precipitates inside the muscle after being injected, resulting in the formation of solid/semisolid implants by solvent diffusion to body fluids.

ISM® technology overcomes most of the current difficulties associated with oral and parenteral extended release formulation presenting advantages such as easy administration, offering highly effective encapsulation, improvement in the stability of the active substance, and better control of drug´s initial release, among others.

This approach allows ROVI to enter and compete in new therapeutic areas, like psychiatry and oncology.



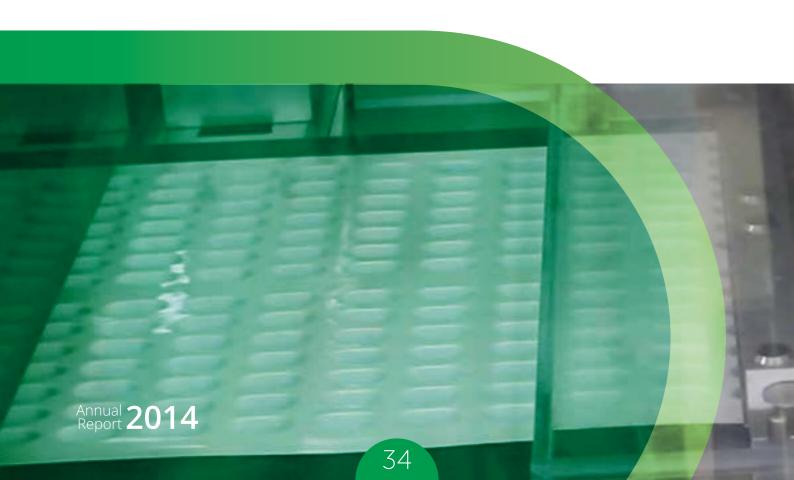
In 2014, ROVI achieved two crucial milestones in the development of the platform with the active substance of Risperidone (Risperidone-ISM®), for the treatment of schizophrenia:

- The final results of the new phase I multicentre study coded as "PRISMA-1" (Pharmacokinetic evaluation of Risperidone ISM long-Acting injection – 1) were communicated on December 2014. PRISMA-1 is a parallel study, randomized and open, to evaluate the pharmacokinetic profile, safety and tolerability of a single intramuscular injection of Risperidone ISM® at three different concentrations (50 mg, 75 mg and 100 mg) in 36 patients with schizophrenia or schizoaffective disorder¹. The results of the pharmacokinetic study PRISMA-1 confirm that the ISM® technology provides a sustained release of risperidone, reaching therapeutic levels from day one and allowing a monthly administration without the need for supplementary oral risperidone during the first weeks or initial dose injections.

- Subsequently, ROVI has carried out the recruitment of patients for the study coded as "PRISMA-2". It is a Phase II multicentre trial in several centres of U.S.A to evaluate the safety and pharmacokinetic profile of Risperidone with the ISM® administration system after the administration of four intramuscular doses (gluteal or deltoid) monthly in schizophrenic patients. The results of this study are expected for the third quarter of 2015.

Both PRISMA-1 and PRISMA-2 studies will provide reliable information to adjust the final design of the phase III program, expected to start in the second half of 2015.

Additionally, related to the developments that ROVI has with the ISM® platform, it is expected that the first clinical trials in humans will start with active ingredient letrozol (an aromatase inhibitor for the treatment of breast cancer) in the first half of 2016.





### Glicomycs

The glycomics is the study and characterization of the sugars making up a cell, like the glycosaminoglycans (GAG), that as well as its role in the regulation of blood coagulation, are involved in processes like cell growth, immune response and inflammation. In order to exercise these functions, GAGs have to interact with numerous proteins. 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.

The degree of specialization and knowledge achieved in this area, allows considering 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 2014, ROVI achieved two crucial milestones in the development of the platform Risperidone- ISM®

As result of the efforts and investment made in this area, ROVI has developed a biosimilar and generic

(1) Pharmacokinetic, Safety, and Tolerability Study of Risperidone ISM® at Different Dose Strengths (PRISMA-1). [http://www.clinicaltrials.gov/show/NCT01788774]. (2) Pharmacokinetics and Tolerability Study of Risperidone ISM® in Schizophrenia (PRISMA-2). [http://clinicaltrials.gov/show/NCT02086786].





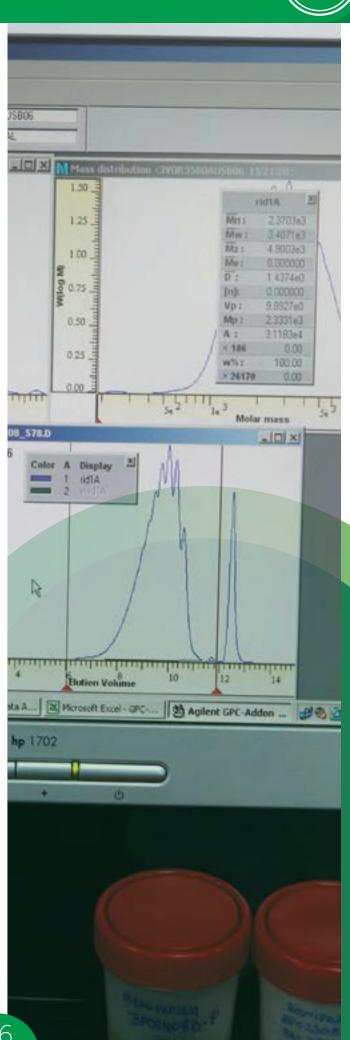
of enoxaparin (a low molecular weight heparin with anti-thrombotic effect) for which requested, in 2014, the marketing authorization from European and USA authorities. On February 9th, 2015, after the completion of the validation phase, it started the assessment process for Europe to obtain the mentioned marketing authorization. It is expected that the European registration process could last from five to twelve months. The request for the marketing authorization of the same drug from the FDA is currently in the validation phase.

## Multilayer technologies used to develop urethral catheters

One of the most relevant aspects in the use of stents and urethral catheters is the high prevalence of bacteria that in some cases can lead to the appearance of clinical symptoms and complications, including sepsis and death. Currently, the incidence of urinary tract infections is still very high as biofilm formation makes difficult to eradicate microorganisms with antibiotic treatment.

In this sense, in 2014 ROVI has continued with the preclinical development of its multilayer technology that uses polymeric layers that bioerode under the influence of bacterial metabolism. This erosion provides important advantages over the current state of technology, reducing bacterial adhesion, facilitating biofilm elimination, reducing encrustations and avoiding catheter blockage.

The development of this line of investigation provides ROVI the possibility to extend patent's portfolio both of patents and of commercial products of the company in the field of medical devices in an innovative and competitive way as this technology is intended as a platform for future developments.







## Production Plants and R&D centres

ROVI has two research and development centres and three manufacturing plants for its own products and for contract manufacturing to third parties. The work performed in these facilities is crucial for the development of the group.

The three manufacturing plants and the two R&D centres are crucial for the ROVI activity





# Market environment

In 2014 Spanish economy accumulated four consecutive quarters of growth, for the first time since the outbreak of the economic crisis. This recovery process has taken place in an environment of tension relief by the financial markets, a progressive normalization of external finance flow and an improved confidence on performance of the labour market.

However, economic growth is moving slowly to the pharmaceutical sector, where still are noticed the effects of the efforts made for deficit reduction. According to data from Farmaindustria<sup>3</sup>, although in Spain public pharmaceutical expenditure accumulated during 12 months at the end of December 2014 was registering a growth of 2%, still is 26% lower than its historical maximum of 2010.

Additionally, it is expected a fall in the pharmaceutical spending of 2% in 2015, according to Farmaindustria<sup>3</sup>. Likewise, the forecast of IMS Health<sup>4</sup>, related to the expenditure in pharmaceutical drugs in Spain, points to a zero to negative growth rate for the period 2014-2018. Despite the difficult situation the pharmaceutical industry is going through, ROVI expects to carry on growing.

The current difficulties of the sector have a reduced impact on ROVI´s business, which is not virtually affected by the reference price system in Spain. In fact, during the last decade the group has registered an annual sustained growing rate of 14%. Likewise, prescription products of ROVI have increased 60% in the period 2010-2014, outperforming the market in 83 percentage points in the same period.

## New decree in Spain

On March 21st, 2014, the Spanish Government approved a new Royal Decree that regulates the

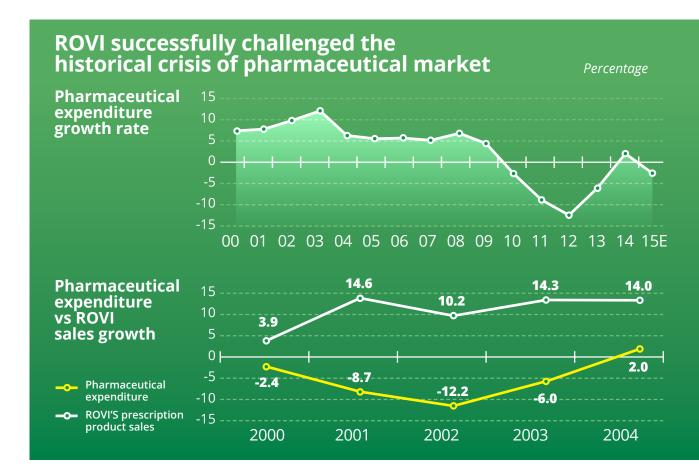




reference prices system and homogeneous group systems in the National Health System (see http://www.boe.es/boe/dias/2014/03/25/pdfs/BOE-A-2014-3189.pdf).

From these measures, we should note the application of the new system to the drugs that have been authorized for more than 10 years, even if it does not exist a generic, as long as there is another drug, other than the original and its licences, with the same active principle and route of administration, and the reduction of the price of reference to the lowest one of European Union; however the impact of these measures has not been relevant for ROVI.

This new package of measures is added to the four Royal Decrees approved since 2010 that have led to important reductions in the pharmaceutical public spending in the last four years. On December 2014, the pharmaceutical spending to 12 months was lower than the historical maximum reached in May 2010 in more than 3,300 million euros (-26%). Additionally, on July 15th of 2014 was published in the Official State Bulletin (BOE) a new update of reference pricing system for medicines in the National Health System (see http://www.boe.es/boe/dias/2014/07/15/pdfs/BOE-A-2014-7472.pdf), that already came into effect without a significant impact for ROVI. Such measures contributed to a slight increase of 2% of the Spanish pharmaceutical market in 2014.



Annual 2014
Report 2014







## Strategic and financial priorities

Growth strategy of ROVI is based in:

- Searching for new marketing opportunities of contract manufacturing.
- Obtaining approval for marketing authorizations of own molecules abroad.
- Reinforce contract manufacturing area through the diversification of customers and services.
- Commercialize new therapeutic indications and advance in the formulation of new products as well as the development of new drugs release system, owned by ROVI, with the main objective of improving patient's adherence to treatment.
- Continue with the investment in R&D&I.





ROVI has obtained the approval for Bemiparin registration in China and will introduce it to this market in 2015

product in important markets, like Brasil, South Africa and Indonesia, among others that will contribute to give a definitive boost to the globalization process of innovative second generation molecule.

harmaceutical

Contract

## Pharmaceutical specialties

In this area ROVI counts as driving force with products like Bemiparin, the existing product portfolio of pharmaceutical specialties (among others, Vytorin®, Absorcol®, Corlentor® and imaging diagnostic media products), and last launches like Volutsa®, Ulunar®, Hirobriz®, Medikinet®, Medicebran® and new licences for products distribution.

Additionally, the agreement reached with MSD in 2009 will allow ROVI to launch four additional products between 2015 and 2019, what will contribute to the sustained growth of the company in the long term. Pharmaceutical specialties commercialized in Spain are of high strategic value and contribute to give ROVI a wider scope for the coming years. Therefore, in the years ahead ROVI hopes to be able to commercialize its own new products, as a result of its success in R&D&I.

ROVI is focused in taking its main product, Bemiparin, to an international level, as one of the drivers of

In the area of Contract Manufacturing, ROVI works to strengthen its operations through the acquisition of new customers that contribute to maximize the potential of the two manufacturing plants, both injectables plant and solid forms one. Both plants are approved by the USA FDA and the European health authorities, and have significant production capacity

long term growth. 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 worldwide. In 2001, ROVI

decided to trade internationally Bemiparin, and

ever since, has increased its presence, whether in pre-registration, registration or marketing stage, to a total of 82 countries. Additionally, ROVI has obtained the approval for Bemiparin registration in China and will introduce it to this market in the second quarter of 2015. It is expected to consolidate the international expansion of Bemiparin with the introduction of the

One of the results of the effort in keeping customer's loyalty in this area has been the re-negotiation of the contract with MSD to extend formulation and packaging services of products Maxalt® and Maxalt-MLT® until March 2020.

and offer a service based on excellence.

#### R&D&I

Manufacturing

The success of ROVI is based on the continuous effort in R&D&I. ROVI is company committed to research, mainly focusing in glycomics and ISM® platform, a





drug release system, owned by ROVI, with the objective of improving patient's adherence to treatment.

As part of this approach, on December 2014, ROVI announced positive results from the Phase I trial of its most advanced candidate for drug release platform, Risperidone ISM®. Currently, a phase II trial is being developed in several USA centres, and the results are expected by the third quarter of 2015. ROVI plans to start phase III of Risperidone ISM® project in 2015, if the results of the ongoing study are positive.

In addition, the first clinical trial in humans with Letrozol ISM® (an aromatase inhibitor for the treatment of breast cancer) is expected to start in the first half of 2016.

In the field of glycomics, that represent for the company its fundamentals, ROVI has invested considerable efforts and investments to develop new antithrombotic products based in heparin derived products. In this line, in 2014 ROVI applied to the European Health Authorities the request for the marketing authorization of low molecular weight heparin, a biosimilar of enoxaparin. On February 9th, 2015, after concluding the validation phase, started the evaluation process to obtain this approval in Europe. It is estimated that the European registration process of the mentioned drug could last from five to twelve months. Furthermore, it should be noted that the result of the registration process (that could be positive or negative) cannot be anticipated until the same is concluded. In 2014, ROVI also applied for the marketing authorization of the same drug in the USA to the FDA (in this case as generic of enoxaparin). In this case, the application is in the validation stage.

ROVI is confident with the potential of its current pipeline of R&D&I projects, making important investment efforts and trusts they will be company's growth engines in the future.







# Goals and prospects

Thanks to the good work of the management team and employees dedication, operating revenue of ROVI increased 9% last year. This way, the group fulfilled its expectations of reaching an operating revenue growth rate of mid to high single digit of the first ten (i.e. the ten between 0 and 10%).

After meeting financial objectives proposed for 2014, the group is confident in achieving a similar evolution for this period. Thus, we expect to achieve in 2015 a percentage of a mid-to-high single digit growth rate in operating revenues (i.e. the ten between 0 and 10%) despite the forecast of Farmaindustria<sup>5</sup> that expects a reduction in the Spanish pharmaceutical market of 2% and the IMS Health<sup>6</sup> forecast for the pharmaceutical expenditure in Spain, that points to a zero or negative growth rate for the period 2014-2018.



(5) http://www.farmaindustria.es/web/indicadores/mercado-farmaceutico/ (6) http://www.imshealth.com/portal/site/imshealth/menuitem.762a961 826aad98f53c753c71ad8c22a/?vgnextoid=266e05267aea9410VgnVCM 10000076192ca2RCRD

BASIC MAGNITUDES CHAIRMAN'S LETTER BUSINESS MODEL

**STRATEGY** CORPORATE GOVERNANCE YEAR 2014 ABOUT THIS REPORT







CORPORATE GOVERNANCE

**YEAR 2014** 

**ABOUT THIS REPORT** 



	Corporate governance model	<u>4/</u>
•	Corporate governance bodies	<u>48</u>
•	Ethical framework	<u>58</u>
		<b>C</b> 0

• Risk Management



## Corporate governance model

The Corporate Governance of Laboratorios ROVI takes into account the effective recommendations both at international and national level and, in particular, is adapted to the Unified Code of Good Governance of Listed Companies approved in 2013. This model guarantees an ethical behaviour by the company, what allows preserving the trust generated to the groups of interest and security to shareholders. ROVI has planned to adapt this year its internal regulation to the new recommendations included in the recently approved Code of Good Governance of Listed Companies by Spanish National Stock Market Commission (CNMV).

The main governing bodies of ROVI are the General Meeting of Shareholders and the Board of Directors. The powers and functioning of each of them is regulated by the Company Statutes, the Regulations of the Board of Directors and of the General Meeting of Shareholders and are available to be consulted in the company's website.

The Board of Directors is the highest management body of ROVI and is responsible for defining the corporate strategy and monitors that management meets set objectives.

The Good Governance requires that the groups of interest have access to the relevant information both in relation to the rules and practice of governance as on the results obtained. For this reason, ROVI presents annually a Report of Corporate Governance and an Annual Report of Directors Remuneration. Additionally submits periodical information on the relevant results of the company to the National Stock Market Commission (CNMV) and prepares a Management Report that accompanies annual accounts. This information is available on the corporate website **www.rovi.es**.



## governance bodies

## **Corporate** General Meeting of Shareholders

The General Meeting of Shareholders (AGM) is the main governing body of the company. Meetings are held, at least, once a year at the General Shareholders Meeting within the first six months of each financial year to review corporate management, and to approve, - if applicable - annual accounts and decide upon the distribution of results and other matters within its competence. Extraordinary Shareholders Meetings are those not included in the above paragraph.

### Right to assist without limitation

All shareholders that hold, at least, one share, have the right to assist to the AGM, ordinary or extraordinary, as long as the share is registered in the corresponding entry register at least five days prior to the date set for the AGM, on first call.





## **General Shareholders Meeting 2014**

On June 12th of 2014 ROVI held the General Shareholders Meeting. This was established with a total of 45,178,094 shares (33,554,416 present and 11,623,678 represented) forming a quorum of 90.356% of shared capital (67.109% present and 23.247% represented).

The agreements established by the Meeting are below:

- Approve Annual Accounts Report of the Company and consolidated with its subsidiaries, as well as the Individual and Consolidated Management Reports, with its subsidiaries, all of them corresponding to the year ending December 31st 2013.
- Approve a payment of a gross dividend of 0.1612 euros per share, which was effective on July 3rd, 2014.
- Approve management and performance of the Board of Directors during the year ending on December 31st, 2013.
- Approve annual retribution of the members of the Board of Directors for the year 2014.
- Approve, with advisory status, the Annual Remunerations Reports of the Company directors.

## Board of Directors

The Board of Administration is the highest decisionmaking, supervisory and controlling body of the company, except on those issues competence of the General Holders Meeting (AGM). Currently is made The Board of Directors
undertook a self assessment
of their activities, based
on the report prepared
by the Appointments and
Remuneration Committee

up for the four top executives of the company, and by two independent directors of recognized professional prestige. All of them have been appointed on the basis of merit, regardless gender. In accordance with Company Statutes, must be composed by no less than five and no more than fifteen, following the recommendations of corporate governance respect the quantitative composition of the Board of Directors.

As the highest decision-making body, delegates management of company's ordinary business to the management team and focus its activity in supervisory functions. This involves guiding ROVI's policies, monitor management activity, evaluate director's performance, and in general, take the most relevant decisions for the company and liaise with shareholders.

In the exercise of his functions, ensures regulatory compliance and social and ethical commitments. Likewise, ensures that no other person or reduced group of people hold the power of decision or is subject to counterweights and controls, and that





no shareholder receives privilege treatment vis-á-vis the rest.

Among his responsibilities is developing a strategic plan, as well as management objectives and annual budget. Also, defines the Group´s structure, investments policy, and establish dividend´s policy, corporate governance and social responsibility. It also establishes and reviews control and risk management policies, as well as period monitoring of internal information and control systems.

In 2014 the Board of Directors held 4 meetings, all them chaired by the President. The percentage of assistance over the total of votes was 100%.

The Board of Directors undertook a self assessment of their activities, based on the report prepared by the Appointments and Remuneration Committee that did not result in significant changes in the internal organization or in procedures related to their activity.

## Power concentration limits

Since the Chairman of the Board of Directors is also the Chief Executive of the Company, independent Director, Mr. Enrique Castellón Leal, who was Vicepresident of the Board during the year 2014, has been appointed in the company Board of Directors meeting of February Coordinating Director, in accordance with the provisions of article 529 of the Spanish Law on Corporations, and is empowered to call Board meetings or to add new items on the agenda, coordinating and giving voice to the concerns of external Directors and lead the Board´s evaluation in accordance to the provisions of article 15 from the Rules of the Board of Directors. Additionally, there are two supportive Chief Executives. This way, it is reduced the risk of concentration of power, as per the recommendations of the Corporate Governance.



### **Board of Directors**

	POSITION	NATURE OF POSITION	APPOINTMENTS AND REMUNERATIONS COMMITTEE	AUDIT COMMITTEE	
Mr. Juan López-Belmonte López	President and Chief Executive Officer	Executive			
Mr. Juan López-Belmonte Encina	Chief Executive Officer	Executive	Secretary		
Mr. Enrique Castellón Leal*	Vicepresident	Independent	President	Member	
Mr. Javier López-Belmonte Encina*	Member	Executive		Secretary	
Mr. Iván López-Belmonte Encina*	Member	Executive			
Mr. Miguel Corsini Freese	Member	Independent	Member	President	
Mr. Gabriel Núñez Fernández	Secretary of Board of Directors				

\*In the meeting of the Boards of Directors held on February 25th, 2015, Mr. Enrique Castellón Leal resigned from his position of Vicepresident and was appointed Coordinating Director. In the mentioned meeting Mr. Iván López-Belmonte Encina and Mr. Javier López-Belmonte Encina were appointed First and Second Vice-president respectively, of the Board of Directors.

## PROFESSIONAL PROFILE OF CHIEF EXECUTIVE OFFICERS

Mr. Juan López-Belmonte López

President and Chief Executive Officer of ROVI since July 27th 2007. He obtained a degree in Economics and Business Studies from the University Complutense of Madrid in 1969. Besides being the Chairman of the Board of Directors of ROVI is also member of the Board of Directors of Farmaindustria, and of the plenary of the Madrid Chamber of Commerce, member of the Board of Directors and of the Executive Committee

of the CEOE, Vicepresident of the Madrid Business Confederation (CEIM) and member of the Management Board of ANEFP. He is shareholder of Inversiones Clidia, S.L. (controlling shareholder of ROVI).

Mr. Juan López-Belmonte Encina

Chief Executive Officer since October 2007. He has worked for the company since 1994 and in October 2001 as appointed Managing Director. He graduated in Economics and Business Studies from the CEU San Pablo of Madrid, specialized in Audit, in 1993. He started his profesional career working in several



The company plans to update the composition and functions of the Appointments and Remunerations Committee and the Audit Committee

international pharmaceutical companies like Nielzen Group, in España; Tyco Group, in the U.S.A; and Boots Pharmaceuticals, in United Kingdom. He is President of R&D&I Committee of the Spanish Confederation of Employers' Organization (CEOE) and Vicepresident of the Governing Board and Board of Directors of Farmaindustria. He is a shareholder of Inversiones Clidia, S.L. (controlling shareholder of ROVI).

#### Mr. Javier López-Belmonte Encina

Chief Financial Officer since 2001. He graduated in Economics and Business Studies in the Colegio Universitario de Estudios Financieros (CUNEF) of Madrid, specializing in Finances, in 1998. He started his professional career in the banking sector, in 1998, working for Argentaria, S.A. in United Kingdom as business analyst and in the pharmaceutical sector in Medeva Pharma. He joined ROVI in 2000. He is a shareholder of Inversiones Clidia, S.L. (controlling shareholder of ROVI).

#### Mr. Iván López-Belmonte Encina

Corporate Development Director since 2007 and Co-General Director since 2001. Graduated in Economics and Business Studies by the Unversidad Complutense de Madrid, specializing in audits, in 1994.

He started his professional career in Germany working in pharmaceutical companies like Amersham and Hexal AG. He works for the company since 1994. He is a shareholder of Inversiones Clidia, S.L. (controlling shareholder of ROVI).

#### Mr. Miguel Corsini Freese

Independent External Director of ROVI. He was appointed Director by cooption on November 12th, 2008 and ratified and the last time that has been re-elected was in the General Meeting of Shareholders held on June 12th of 2014. Mr. Corsini is also Chairman of the Audit Committee and member of the Appointments and Remunerations Committee. Miguel Corsini was Chairman of RENFE and is a member of the Board of Directors of the company Testa Inmuebles en Renta, S.A.

#### Mr. Enrique Castellón Leal

Independent External Director of ROVI. He was appointed Director on October the 24th of 2007, being re-elected for the statutory period of five years in the General Meeting of Shareholders held on June 13th, 2012, and is also a member of the Audit Committee and Chairman of the Appointments and Remuneration Committee. He regularly advises several foundations devoted to research in health sciences and carries out consulting activities in Castellón Abogados. He has worked as consultant in health projects financed for the Interamerican Development Bank (part of the World Bank). He has been appointed General Director, Deputy Director for Health and Social Policies of the Community of Madrid and Undersecretary of the Ministry of Health and Consumers. Likewise, Mr. Castellón is founding partner and Chairman of the Board of Directors of CrossRoadBiotech.

#### **Committees**

With the aim of improving efficacy in the exercise of their functions, the Board of Directors manages its



work through two committees: the Appointments and Remuneration Committee and the Audit Committee.

- Appointments and Remuneration Committee. It is composed by three Directors, the majority of whom are independent. The Chairman will necessarily be an independent Director, and should be re-appointed every four years. 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 director's functions adequately; to establish and review the Company criteria for the management team and its composition and ensure compliance and transparency on the remuneration policy established by management. During the year 2004 four meetings were held.
- Audit Committee. It is composed by three members of the Board of Directors, the majority of whom are independent, appointed based on their knowledge and experience in accounting, audits or risk management areas. 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 Committee meets each quarter in order to review the financial information that as a listed company, the Company is required to publish regularly. In the year 2014 met four times.

The company plans to update the composition and functions of the Appointments and Remunerations Committee and the Audit Committee in the frame of the reform of its internal regulations that is planned to be undertaken to adapt to the amendments introduced in the Corporate Enterprises Act, after approval of the law 31/2014, on December 3rd.







#### STEERING COMMITTEE

During the year 2014, the Steering Committee was composed by 10 members who represent the main organizational areas of ROVI. The Steering Committee, which was leaded by the Chief Executive Officer Mr. Juan López-Belmonte Encina, is the body in which the Board of Directors has delegated the day-to-day management of the company.



- 2 Mr. Javier López-Belmonte Encina. *Chief Financial Officer.*
- 3 Mr. Javier Ángulo García.

  Human Resources Director.
- Mr. Pedro Carretero Trillo.

  Director of Hospitals for Spain and Portugal.
- 5 Mr. Pablo Domínguez Jorge. *Administrative Financial Director.*

CORPORATE GOVERNANCE

YEAR 2014











# Remuneration policy

In accordance with article 45 of company Statutes, the members of the Board of Directors are entitled to be remunerated for the performance of their management duties by an annual fixed amount, in cash, that must be established by the General Meeting of Shareholders. The Board can distribute between the members the remuneration approved by the General Meeting of Shareholders (AGM), taking into account the functions and responsibilities performed by each of them in the Board itself or in the delegated Committees.

Likewise, it is established for the executive directors a variable amount as an incentive linked to the results of the company and the achievement of objectives set that must be in line with company's interest, as well as the professional performance of the beneficiaries, and is not simply derived from the general evolution of the market or from the activity of the company sector.

Additionally, it is expected that in the General Meeting of Shareholders could be established the remuneration systems (i) linked to the listed price of

the shares; or (ii) comprising the delivery of shares of the Company or subsidiaries of the group; or option rights over shares, or other share-based instruments.

The Board of Directors, during the year 2014 has carried out the distribution among its members of the amount of 380,000 euros of the maximum amount of 500,000 euros approved by the General Meeting of Shareholders in favour of the components of the Board of Directors as an annual fixed retribution for the year 2014 for the performance of their management duties, and that has been assigned taking into account the dedication and nature of the services provided by each Director, following a proposal of the Appointments and Remuneration Committee.

Additionally, the Board has agreed the distribution among the Directors of the global fixed annual retribution amount of 959,700 euros as remuneration for the performance of their executive and top management duties, in conformity with the terms of their executive contracts and with the terms and conditions agreed with the Company, taking into consideration the duties and responsibilities performed by each Director and based on the proposal presented by the Appointments and Retributions Committee. Once made the corresponding

**ABOUT THIS REPORT** 



The executive directors have received an amount of 956,835 euros as global fixed retribution

adjustments as per their contracts, the executive directors have received an amount of 956,835 euros as global fixed retribution.

In relation to variable amount incentive to a maximum amount of 479,850 euros approved by the General Meeting of Shareholders (AGM) for the Directors, the Board has carried out a distribution of 383,880 euros, following the proposal of the Appointments and Remuneration Committee, taking into account the results of the Company for the year 2014 and the objectives established for each Director.

For the time being, the Company does not expect substantial changes respect to the retribution policy for the Directors for future periods.

The Board of Directors prepares an annual report over remunerations of Directors, available in the corporate website **www.rovi.es** and in the website of the Spanish National Stock Market Commission, CNMV (www.cnmv.es).

The staff from ROVI, which on December 31st of 2014 were 1,109 employees, received an annual total gross remuneration of around 52 million euros during the year 2014.





# Ethical framework

In order to reassure the values and principles that are the foundation of ROVI´s activities, the group counts with Code of Ethics, approved by the Board of Directors, whose objective is that all interactions with the shareholders and with society in general are ruled by ethic and good practices. This Code of Ethic is mandatory for all employees and serves as guideline in the performance of their duties and in case of conflict of interest.

According to the terms of the code, the Company undertakes to apply the highest ethic standards of transparency in its communications, records of information and reports, both financial and related to its products and activities. This entails the obligation that the preparation of accounts, financial statements, books, registers, and individual or group accounts will comply with all legal requirements and with the correct application of the accounting principles prevailing, with the objective to offer a clear view of the business activities and financial situation of the company.

The Code of Ethics rules establish a channel of complaints that can be used by any employee of the Company in case of detecting violations of the Code.



**CORPORATE GOVERNANCE** 

YEAR 2014







The Code of Ethics rules establish a channel of complaints that can be used by any employee of the Company

In addition, the Company has a specific confidential channel of complaints for financial and accounting irregularities.

The regulation establishes that the Code of Ethics Monitoring Committee is the responsible body to study breaches of the code and propose corrective actions and sanctions, and will issue an annual report for the Chief Executive Officer including all actions developed during the year. The Audit Committee, on its side, ensures the independence of Auditors, in order to guarantee the accuracy of the public information submitted by the company.

The group also strives to monitor and control the recommendations of Unified Code of Good Governance of Listed Companies (and, since February of 2015, The Code of Good Governance has replaced the previous Unified Code). This way, the company has mechanisms to avoid conducts that compromise its shareholders and groups of interest, like concentration of power, lack of transparency or lack of independence of auditors.

Likewise, the company has an anti-bribery and anticorruption policy, applicable to all employees and agents of ROVI, which defines and details the acting guidelines in cases of: bribery, political contributions, charitable contributions and sponsorships, facilitation payments, presents, hospitality and expenses, and control of accounts.

ROVI is committed to actively support the Universal Declaration of Human Rights and requires the compliance of such principles by the employees in the daily activity of the group. The company fights against practices contrary to human dignity and against discrimination at work.

It was not detected any breach in 2014.



## Risk Management

ROVI has a policy for risk management and control to allow identifying, classifying, evaluating and reacting to any possible issue that could threaten the achievement of corporate objectives.

The objectives of this system, supervised by the Audit Committee, are helping to achieve set objectives, to avoid negative impacts derived of materialization of risks, to preserve the image and reputation of the company, to have a continuity in the analysis and detection of possible threats, to obtain reliable information and reinforce the confidence that the company complies with applicable standards.

To do this, once the risk is identified a classification and assessment are made to determine the probability of occurrence and possible impact on the business. Subsequently, it is included in a corporate risk map that is updated annually in which are specified control activities and planned measures or action plans to mitigate possible impact.





The measures to reduce the public expenditure are also contributing to a constant fall in the pharmaceutical demand

#### **Risks identification**

The main risk factors to which the Company considers itself to be exposed in respect of meeting its business objectives are the following:

- Changes in the legislation regulating the market aimed to contain pharmaceutical expense;
- Finalization of contractual relationships with customers representing a significant part of its sales or renewal in less favourable conditions than the current ones;
- Changes in the conditions under which raw materials and other packaging materials needed for manufacturing its products are supplied;
- Late payment on the part of the public authorities in the short term.

As stated previously, ROVI is permanently on the alert and is keeping any risks that may have an adverse effect on its business activities under constant surveillance, applying the appropriate policies and mechanisms to manage them and constantly developing contingency plans that can be used to mitigate or offset their impact. Among them, we highlight the fact that the Company (i) continues, every year, to apply an internal saving policy that is principally based on improving the efficiency of its internal and external operating processes; (ii) is working intensively to maintain a broad and diversified portfolio of products and customers; (iii) is continuing with its target of constantly opening up new markets as a result of its international expansion plan; and (iv) the Company exercises strict credit control and manages its cash effectively, which ensures that sufficient working capital is generated and maintained to allow its day-to-day operations to be carried out.

## Response and monitoring plans for main risks

The steps that the Company follows for risk management are the following:

- 1. **Setting the risk level**. The Audit Committee classifies the risk in the basis of the potential economic impact, calculating probability and making an assessment of losses that could result in case of materializing.
- 2. **Identification and classification**. Using risk maps, the set of factors that could threat the achievement of corporate objectives are identified in an orderly and systematic way. Subsequently, will be classified in operational, technological, financial, legal or reputational.
- 3. **Risk estimate**. Once identified, each of the top executives will proceed to analyse and sort them out according to the "greater exposure" in order to establish control priorities.
- 4. **Determining control objectives**. Measures are taken to deal with possible contingencies the most



The impact of the last political measures has been minimum to ROVI thanks to the young products portfolio

efficient and economic way, minimizing exposure. In parallel, mechanisms should be put into place to allow management to monitor the implementation of actions neutralization and control of efficacy.

- 5. **Change detection**. All departments have periodic information systems, that appropriately detect the changes produced.
- 6. Information of the Audit Committee. Once risks have been estimated and assessed, top executives will communicate to the Audit Committee those that have been considered high and medium risk, as well as measures planned for its neutralization and evaluation. Furthermore, Audit Committee will keep the Board of Directors properly informed about the risk detected and the measures approved to deal with them.

#### Risks arising in 2014

Measures approved by the Government of Spain and Regional Governments to reduce deficit in the public Health sector:

• The measures for the reduction in pharmaceutical expenditure that have been affecting the

pharmaceutical sector in last years have caused a significant fall in the public pharmaceutical expenditure since year 2010.

• On the other side, the measures to reduce the public expenditure in the Autonomous Communities are also contributing to a constant fall in the pharmaceutical demand according to the budgetary adjustments of the mentioned Communities, and that usually affect, significantly, the pharmaceutical part.

The measures implemented by Royal Decrees between 2010 and 2012, along with the new package of measures adopted in 2014 that include the following:

- The application of the new reference price system for generic medicines that have been authorized for more than 10 years, although there is not a generic, as long as there is another medicine different from the original and its licences, with the same active principle and route of administration.
- The reduction of the reference price to the lowest of the European Union has led to significant reductions in the public pharmaceutical expenditure during the last four years.

Although, in principle, the impact of these last measures has been minimum to ROVI thanks to the young products portfolio, the company keeps working to maintain a well diversified products portfolio in which the drive of innovative and competitive products offset and compensate the slowdown of the products more affected by governmental and local measures for the reduction of pharmaceutical expenditure. Furthermore, the inclusion of new products to the specialties portfolio of the company and the opening and development of new markets in the international expansion process of our main product, Bemiparin, have contributed to that, finally, the Company results have been in line with its forecasts.





### Period results

### Highlighted facts



Positive results for the monthly injectable formulation of Risperidone ISM®, antipsychotic drug for schizophrenic patients.



Presentation of the application to obtain the marketing authorization of a biosimilar of enoxaparin to the European health authorities and to the U.S.A. FDA. This application has been validated in Europe, and is in the assessment phase; and in the U.S.A. is in the validation phase.



Launch in Spain of Hirobriz® Breezhaler® and Ulunar® Breezhaler®, two inhaled bronchodilator for patients with respiratory difficulties due to COPD. **STRATEGY** 

CORPORATE GOVERNANCE



Announcement of new agreement to market Volutsa® in Spain, a drug for the treatment of moderate to severe storage symptoms and voiding systems associated to benign prostatic hyperplasia.







Record results of the company, with 24.1 million euros of net profit and revenues of 240.9 million euros, double compared to 2007, when ROVI carried out an Initial Public Offering (IPO).





ROVI closed the year with the best results of its history

# Financial results

ROVI demonstrated again in 2014 the strength of its business, despite the difficult moment the pharmaceutical sector is going through, still penalized by the containment in public expenditure. The group closed the year with the best results of its history: a record net profit of 24.1 million euros, a 5% more than in 2013; an EBITDA without precedents of 36.6 million, a growth of 13% from the previous year; and a total revenue of 240.9 million, that exceeded and even doubled the figures registered in the year 2007, when ROVI carried out the Initial Public Offering (IPO).

This evolution is mainly due to the strength of the sales of prescription-based pharmaceutical products, whose sales increased 11% outperforming pharmaceutical market behaviour; and also to the contract manufacturing business than increased 9%.

The figures of the previous year included a non recurring income of 1,4 million, as a result of the tax audit performed in Frosst Ibérica for the tax



### **Balance Sheet** of Laboratorios Farmacéuticos ROVI, S.A. and subsidiaries

Thousands of euros	31 December <b>2014</b>	31 December <b>2013</b>	
ASSETS			
Non-current assets	99,287	98,440	
Property, Plant and Equipment	73,593	60,199	
Intangible assets	17,206	14,468	
Deferred tax assets	8,280	7,517	
Avaible-for-sale financial assets	71	16,121	
Trade and other receivables	137	135	
Current assets	162,033	137,483	
Inventoires	67,567	58,747	
Trade and other receivables	63,678	55,919	
Current income tax assets	4,117	3,416	
Cash and cash equivalents	26,671	19,401	
TOTAL ASSETS	261,320	235,923	
EQUITY			
Capital and reserves attributable to shareholders of the company			
Share capital	3,000	3,000	
Legal reserve	600	600	
Treasury shares	(2,813)	(782)	
Retained earnings and voluntary reserves	133,569	118,943	
Profil for the period	24,116	23,022	
Reserve for avaible-for-sale assets	(2)	(319)	
TOTAL EQUITY	158,470	144,464	
LIABILITIES			
Non-current liabilities	40,733	33,119	
Financial debt	32,032	22,578	
Deferred income tax liabilities	1,818	2,637	
Non-current deferred revenues	6,883	7,904	
Current liabilities	62,117	58,340	
Trade and other payables	55,018	43,485	
Financial debt	4,274	8,400	
Current deferred revenues	798	4,084	
Provisions for other liabilities and charges	2,027	2,371	
TOTAL LIABILITIES	102,850	91,459	
TOTAL EQUITY AND LIABILITIES	261,320	235,923	

**BASIC MAGNITUDES** 



### **Consolidated Income Statement** of Laboratorios Farmacéuticos ROVI, S.A. and subsidiaries

Thousands of euros

	Full Year <b>2014</b>	Full Year <b>2013</b>	
Revenue	238,047	217,587	
Cost of sales	(94,578)	(84,895)	
Employee benefit expenses	(58,085)	(55,619)	
Other operating expenses	(51,663)	(47,401)	
Depreciation, amortisation and impairment charges	(8,884)	(6,943)	
Recognition of government grants on non financial non-current assets	and other 2,855	1,358	
Other income	-	1,385	
OPERATING PROFIT	27,692	25,472	
Finance income	545	307	
Finance costs	(2,603)	(1,528)	
FINANCE COSTS - NET	(2,058)	(1,221)	
PROFIT BEFORE INCOME TAX	25,634	24,251	
Income tax	(1,518)	(1,229)	
PROFIT FOR THE PERIOD	24,116	23,022	
Earnings per share (basic and diluted) attributable to the shareholders of the Company (euros):			
- Basic and diluted	0.48	0.46	

### **Sound financial structure**

Ratio

	2014	2013	2012	
NET DEBT/EBITDA	0.23	-0.18	-0.28	
NET DEBT/TOTAL EQUITY	0.05	-0.04	-0.06	

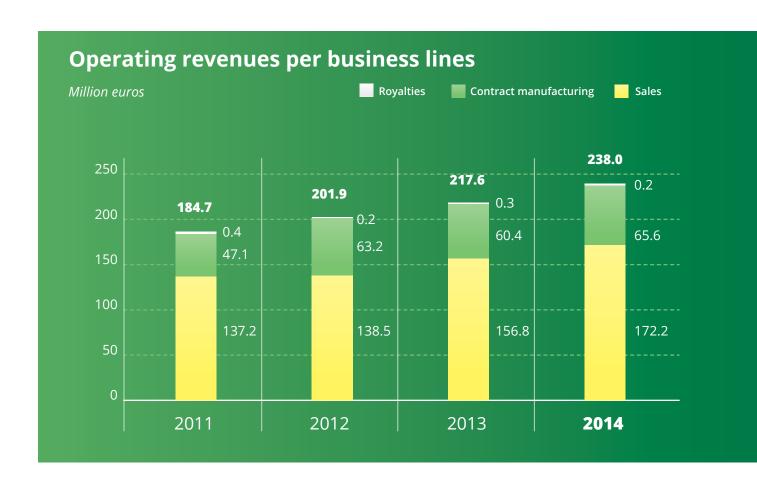


periods 2006, 2007 and 2008. This not recurring income was assumed by the owner of Frosst Ibérica during the periods inspected, as a result of the reduction in the negative taxable income from previous periods inspected. Excluding the impact of this compensation, the EBITDA increased 18%, while the net profit grew 11%.

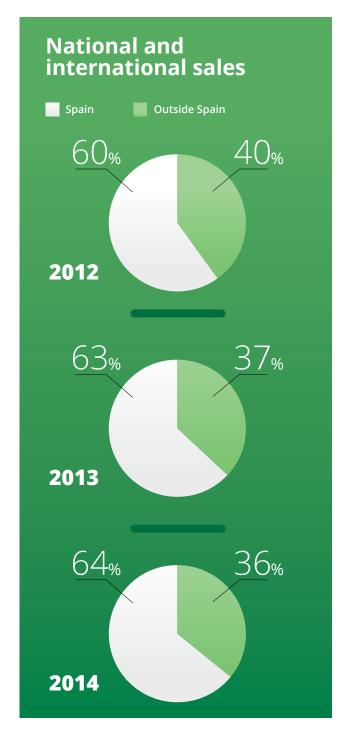
This way, the forecast of the company 2014 has been reached, which pointed to a mid-to-high single digit growth rate for the operating revenue (0%-10%). Operating revenues grew a 9%, a total of 238 million euros, compared to a slight increase of the 2% experienced by the Spanish pharmaceutical market.

#### Positive sales performance

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







The sales of prescription-based pharmaceutical products grew 11% reaching 140.5 million euros

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

#### **Products sales**

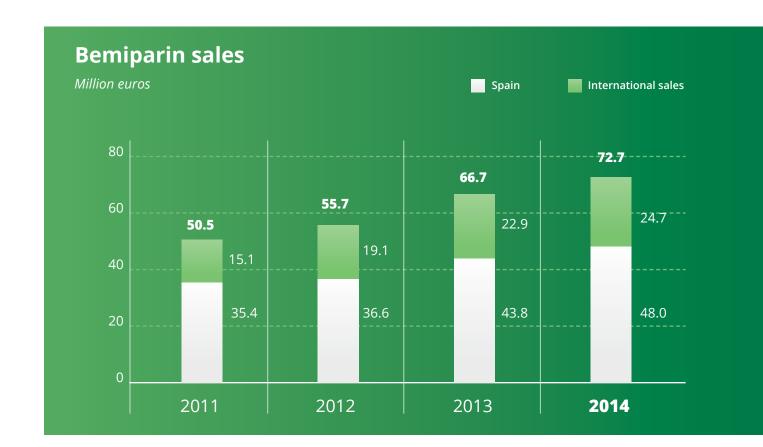
The sales of prescription-based pharmaceutical products grew 11% reaching 140.5 million euros in 2014.

ROVI's low molecular weight heparin (LMWH), Bemiparin, had a positive performance in 2014, with sales up 9% to 72.7 million euros. Sales of Bemiparin in Spain (Hibor®) increased by 9% to 48.0 million euros, while international sales had an 8% rise to 24.7 million euros in 2014 supported by the increased presence of Bemiparin, through strategic alliances, in countries where it was already present. Besides, ROVI has obtained registration approval in China and expects to launch Bemiparin in the Chinese market in the second quarter of 2015

Sales of Hirobriz® Breezhaler® and Ulunar® Breezhaler®, both inhaled bronchodilators from Novartis for patients with respiratory difficulties due to a pulmonary disease known as Chronic







Obstructive Pulmonary Disease (COPD), launched in Spain in the fourth quarter of 2014, reached 2.1 million euros in 2014.

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

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

Sales of Medicebran® and Medikinet®, specialty products from Medice indicated for the treatment of

ADHD (Attention Deficit and Hyperactivity Disorder) in children and teenagers, launched in December 2013 and marketed on exclusivity basis by ROVI in Spain, reached 7.5 million euros in 2014.

Sales of Exxiv®, a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 3% to 6.9 million euros in 2014, mainly due to a continued deceleration of the COX-2 market.

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

**STRATEGY** 

CORPORATE GOVERNANCE

YEAR 2014



Toll manufacturing sales increased by 9% to 65.6 million euros

Sales of contrast imaging agents and other hospital products increased by 5% to 24.6 million euros in 2014.

Sales of over-the-counter pharmaceutical products ("OTC") and other increased by 4% to 7.1 million euros in 2014 compared to the previous year, mainly as consequence of a better performance of EnerZona®, a range of products based on the principles of the Zone Diet.

#### Toll Manufacturing

Toll manufacturing sales increased by 9% to 65.6 million euros in 2014 compared to 2013. The positive evolution of the injectables plant, whose revenue increased by 28% to 28.6 million euros in 2014 largely offset the 1.1 million euros revenue decline in the Frosst Ibérica plant to 37.0 million euros in 2014, as a consequence of a lower production for Merck Sharp and Dohme (MSD).



#### Sound results

**STRATEGY** 

Gross profit increased by 9% to 146.3 million euros in 2014, reflecting a decrease of 0.1 percentage points in the gross margin to 61.5% in 2014 from 61.6% in 2013. This gross margin reduction is mainly due to the increase in volumes manufactured for clients being invoiced for materials in the injectables plant, contributing with lower margins. The decrease of the Bemiparin raw material cost impacted positively in the 2014 gross margin.

Research and development expenses increased by 14% to 12.0 million euros in 2014, reflecting ROVI

investments in products that are under development, mainly related to the Risperidone-ISM® project.

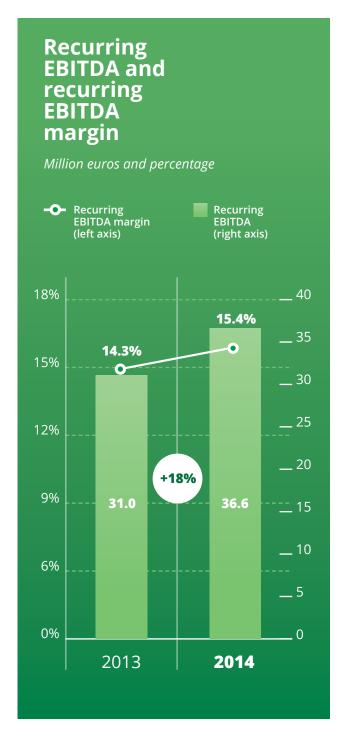
Selling, general and administrative expenses increased by 6% to 97.8 million euros in 2014, compared to the same period of the previous year, mainly due to an increase in personnel costs.

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



**STRATEGY** 





Ibérica during the period inspected, as a result of a reduction of the negative taxable income from previous periods inspected), EBITDA increased by 18% in 2014 reflecting a 1.1 percentage points rise in the EBITDA margin to 15.4% from 14.3% in 2013.

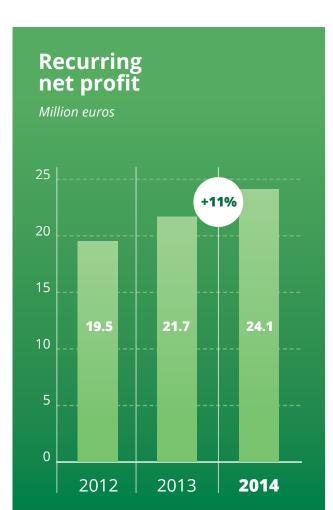
Depreciation and amortisation expenses increased by 28% to 8.9 million euros in 2014, mainly as a result of the new property plant and equipment and intangible assets purchases made during the last twelve months.

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

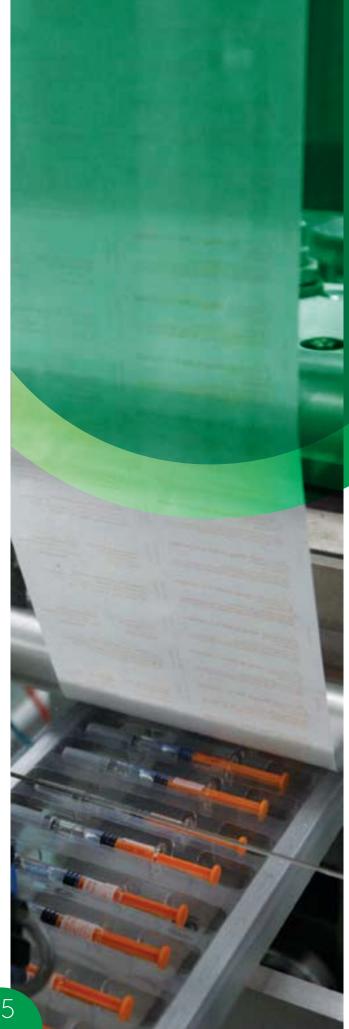
Financial expense increased by 70% in 2014, compared to the previous year, mainly due to the registration of the interests related to the return of the outstanding amount (10.4 million euros) of a 11.9 million euros loan granted by the Ministry of Health, Social Services and Equality for the development of the vaccine project in 2009. The financial expense line also includes the implicit interests registered as a result of the recognition at fair value of reimbursable loans, at zero interest rate, granted by Public Administrations.

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

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



Net profit increased by 5% to 24.1 million euros in 2014, which represented a record figure in ROVI's history



**STRATEGY** 

**CORPORATE GOVERNANCE** 



# **Financial** position

The objective of ROVI regarding 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.

As of December 31st of 2014, ROVI had a total debt of 36.3 million euros, 17% more than in the previous year. Debt with public administration, at 0% interest rate, represented at the time 43% of the total.

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

In addition, debt with public administration was reduced by 9.9 million euros mainly due to the return of the outstanding amount (10.4 million euros) of a 11.9 million euros loan granted by the Ministry of Health, Social Services and Equality for the development of the vaccine project in 2009.

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

Despite the new banking debt (20 million euros) obtained in 2014, total debt increased only by 5.3

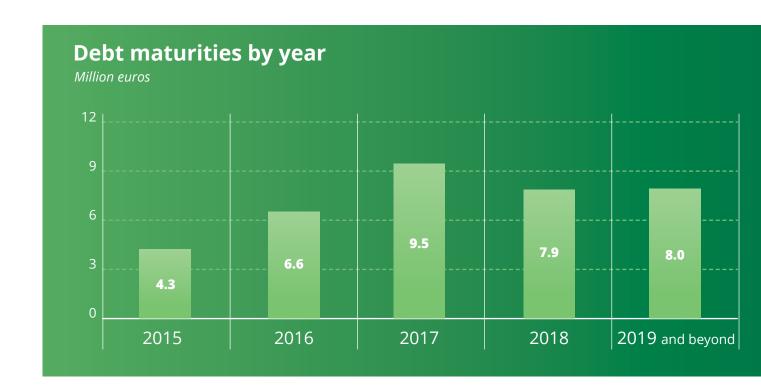


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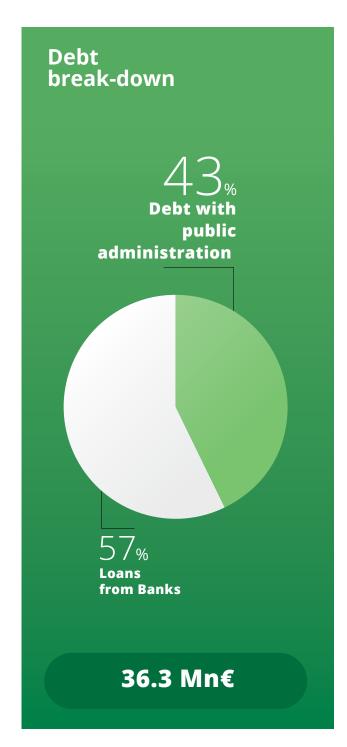
million euros as of 31 December 2014 compared to total debt as of 31 December 2013.

As of 31 December 2014, ROVI had a gross cash position of 28.0 million euros, compared to 36.7 million euros as of 31 December 2013, and net cash position (available-for-sale financial assets plus deposits plus cash and cash equivalents minus short term and long term financial debt) of -8.3 million euros, compared to 5.8 million euros as of 31 December 2013.

Free cash flow (net cash generated (used) from operating activities minus (plus) property, plant and equipment and intangible assets purchases (sales) plus interest received) decreased to -1.6 million euros in 2014 from 5.5 million euros in 2013 mainly due to:







- the increase of 8.8 million euros in the "inventories" item, compared to an increase of 2.5 million euros in 2013, as a result of increasing Bemiparin production in 2014, and
- the increase of 7.8 million euros in the "trade and other receivables" item in 2014, compared to an increase of 1.5 million euros in 2013 as a result of the collection of 8.1 million euros from the Spanish Public Administrations within the execution of the "Payment to Suppliers Plan" in 2013.

#### **Investments**

Research is crucial for the future of ROVI. Therefore, the company increased in 2014 its investments in fixed assets and in R&D&I, to strengthen both its products portfolio as its contract manufacturing services.

ROVI invested 25.1 million euros in 2014, compared to 24.7 million euros in 2013. Of this amount:

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



# **Consolidated statement of cash flow** of Laboratorios Farmacéuticos ROVI, S.A. and subsidiaries

Thousands of euros	Full Year <b>2014</b>	Full Year 2013	
CASH FLOWS FROM OPERATING ACTIVITIES			
Profit before income tax	25,634	24,251	
ADJUSTMENTS FOR NON-MONETARY TRANSACTIONS:			
Amortisation	8,884	6,943	
Interest income	(545)	(307)	
Impairment losses	2,865	1,844	
Interest expense	2,603	1,528	
Net changes in provisions for other liabilities and charges	(344)	720	
Grant for non-financial fixed assets and distribution licence income	(2,268)	(1,127)	
CHANGES IN WORKING CAPITAL	(7.746)	(4, 44,0)	
Trade and other receivables	(7,746)	(1,419)	
Inventories	(11,229)	(3,278)	
Trade and other payables OTHER COLLECTIONS AND PAYMENTS	11,533	3,607	
Collection for distribution licenses	210	70	
Interest paid	(2,658)	(172)	
Income tax cash flow	(3,937)	(2,844)	
NET CASH GENERATED (USED) FROM OPERATING ACTIVITIES	23,002	29,816	
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of intangible assets	(4,201)	(12,005)	
Purchases of property, plant and equipment	(20,853)	(12,678)	
Proceeds of property, plant and equipment	38	40	
Proceeds from sale of available-for-sale financial assets	16,201	11,957	
Contracting short term bank deposits	-	(103)	
Loans granted to related parties	-	(1,050)	
Interest received	365	307	
NET CASH GENERATED (USED) IN INVESTING ACTIVITIES	(8,450)	(13,532)	
CASH FLOWS FROM FINANCING ACTIVITIES			
Repayments of financial debt	(18,907)	(9,384)	
Proceeds from financial debt	21,636	901	
Purchase of treasury shares	(3,345)	(3,466)	
Dividends paid	(8,042)	(6,780)	
Reissue of treasury shares	1,376	5,261	
NET CASH GENERATED (USED) IN FINANCING ACTIVITIES	(7.000)	(13,468)	
IN FINANCING ACTIVITIES	(7,282)	(15,100)	
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS	7,270	2,816	

**ABOUT THIS REPORT** 



# Evolution of main R&D&I projects

### Risperidone ISM®:

Schizophrenia is a chronic, severe and disabling mental disorder that affects to approximately 1% of population. The disease usually starts developing at a critical age for personal development, forcing in many cases to abandon studies or work activity, causing a great deal of suffering for the subject and family environment, as well as an important loss to society. It is estimated that from 3 to 5% of health expenditure is destined to schizophrenia.

ROVI has achieved a significant progress with the most advanced candidate for the drug delivery platform own by the company, Risperidone ISM®, a second

generation anti-psychotic drug of prolonged action, optimum for effective treatment of schizophrenia.

To do this, ROVI has built in Madrid a manufacturing plant of Investigational Medicine Products with the ISM® release system technology, equipped with innovative and unique machinery for the filling of solid compounds in syringes under the guidelines of good manufacturing practices. Also is building a second plant that will allow manufacturing drugs with ISM® technology, that contain high strength active principles (APIs) such as letrozol.

The ISM® technology has been validated by a phase I study that confirms that this technology provides a sustained delivery of risperidone, reaching therapeutic levels from day one and allowing monthly administration without requiring additional oral supplements of risperidone during the first weeks neither initial load injections. The study is in phase





II of investigation and is expected to start phase III in 2015.

#### Letrozol ISM®:

The project of quarterly administration of the well recognised aromatase inhibitor, letrozol, is in an advanced pre-clinical phase under animal testing and is planned to start phase I of the study in the first half of 2016. Letrozol is currently used for the treatment of hormone-dependent breast cancer and the ISM® technology may provide better results and additional benefits for patients suffering this type of tumour.

ROVI has built in Madrid a manufacturing plant with the ISM® release system technology

## Biosimilar of enoxaparin

In 2014, ROVI filed an application to the pharmaceutical authorities in Europe and U.S.A in order to obtain the marketing authorization for a low molecular weight heparin, biosimilar and/or generic of enoxaparin.

It is a new antithrombotic product developed from glycomics area, result of investments and knowledge gained by the company over the years in the field of heparin derived products.





## Trade information

In a year of high volatility for the values of small and medium capitalization, in which Ibex Small Caps registered a drop of 11.5%, ROVI shares were performed excellently and were revalorized 3,2%, up to 10.30 euros. Thanks to this increase, the group shares exceeded the barrier of the 10 euros, for the first time since 2008, and were very close to historical maximum. This good performance reflects the confidence of the market in ROVI´s business,

whose operating incomes have registered an annual sustained growth rate of 14% during the last decade.

As of December 31st of 2014, the capitalization of the group amounted to 515 million, 172 times its accounting value.

ROVI will propose in the General Meeting of Shareholders a dividend on the earnings of year 2014 of 0.1690 euros per share, what means an increase of 5% compared to the dividend paid on the earnings of year 2013.



ımber of shares	50,000,000
isting price at closing	10.30 euros
Capitalization as of 31/12	515,000,000 euros
Total dividend	8,450,000 euros
Dividend by share paid in 2014 on 2013 earnings	0.1612 euros
ividend by share proposed on 2014 earnings	0.1690 euros
ay out (as % of consolidated net profit)	35%
arnings per share	0.48 euros
ER (Price-earnings ratio)	21.4





# Customers

ROVI aims to fulfil the needs and expectations of its customers, whether making an offer of services "on demand" in its contract manufacturing area, as through a product's portfolio whose ultimate objective is to improve quality of life of people.

The company has positioned the customer as the focus of its daily activity, in the conviction that only achieving a high degree of satisfaction and creating solid and trust based relationships in the long term can achieved the growth target established by the group. Furthermore, ROVI is committed to guarantee confidentiality of customer´s data and not to disclose information to third parties.

With this objective, the group considers crucial building long lasting business relationships based





The company has since 2008 an exclusive website for international partners

on closeness, in an attitude of permanent service, and in trust. In this sense, feedback mechanisms and processes are very important, as are one of the best channels for evaluation of services and a tool for constant improvement. To this end, ROVI has been for years undertaking actions to improve communication channels with its customers.

The company has since 2008 an exclusive website for international partners (www.bemimed.com), aiming to strengthen commercial relationships and to create a bidirectional communication channel. Furthermore, since 2009 ROVI has site for health professionals.

This has allowed us to position Bemiparin in an interactive and digital environment, making the most of new technologies to promote both change of scientific and promotional information of the molecule with the private network of partners, and to disseminate the last advances in the treatment for the Venous Thromboembolic Disease and the use of Bemiparin with the scientific community.

Additionally, ROVI participates in specialized events of the industry, such as AEFI, PMFARMA or Asinfarma, with the objective of reinforcing the relationship with health professionals, answer their doubts and recruit talent.

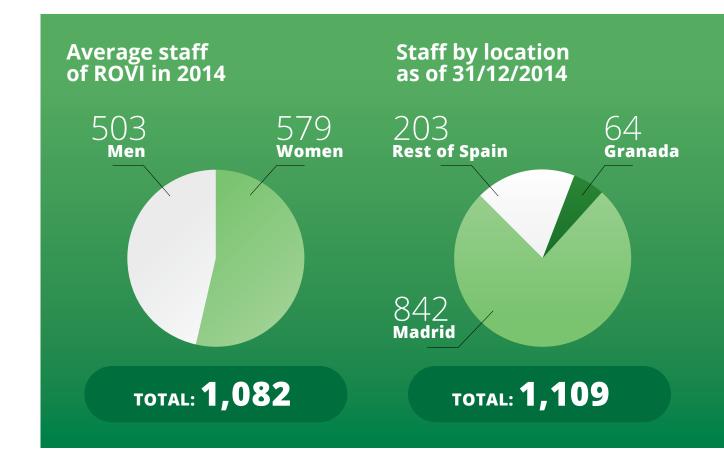




# Human resources

ROVI has exceeded 1,000 employees, being a staff of highly qualified, young and dynamic professionals based on equal opportunities. Employees constitute one of the main pillars of its structure. This is evidenced by the commitment of the company with job creation. During last year, staff increased in more than 13%, after creating 128 jobs, most of them permanent contracts.

The company is committed with the creation and maintenance of necessary conditions to create a polite working environment, safe, and healthy, that allow the professional´s career development. To do





ROVI has been implemented the flexible shifts to facilitate and contribute to improve quality of life in our employees

this, it has been established a management system, from standard SA-8000, based on international tools and national labour laws to protect the employee.

#### Reconciling family life and work

The commitment of ROVI with the employees is a key to the success of the company. The reconciliation of work and family life is also part of this concern. Wellbeing and health of workers have a direct effect in the creation of value for the company. Since 2012, has been implemented the flexible shifts to facilitate and contribute to improve quality of life in our employees.

#### **Equal opportunities**

The company selects the members of the staff based on their professional achievements and talent. The result of this non discrimination policy can be seen in the staff composition: more than half are women both at group level as in most divisions and in the Portugal office.





## **Employees by company**

		2014			2013		
	TOTAL	PERMANENT	TEMPORARY	TOTAL	PERMANENT	TEMPORARY	
LAB. FCOS. ROVI	430	381	49	405	377	28	
PANQUIMICA	69	67	2	6	6	0	
ROVI CONTRACT MANUFACTURING	393	245	148	331	221	110	
FROSST IBÉRICA	211	184	27	229	197	32	
BEMIPHARMA	6	6	0	10	10	0	
	1,109	883	226	981	811	170	

STAFF INCREASES FROM 2013 TO 2014: 128 ADDITIONAL EMPLOYEES (+13%)

## **Professional training**

Talent and innovation are essential to achieve the strategic objectives of ROVI. The company through its Human Resources departments of its subsidiaries, promotes training of employees with courses that provide the required abilities to perform their work position.

During year 2014, has been nearly 85,330 hours of training, i.e. 78 hours of training per employee. The course includes training for middle management in leadership, team's management, risk prevention, as well as training in new products.

Continuous training is one of the pillars underpinning ROVI's growth in the long term. Therefore, promote professional and personal development in different specialties, in an open working environment, that guarantees equal opportunities, is a main part of the commitment with employees. For this reason, most training imparted is related to our products and quality.

#### Fluent communication

The company has employee suggestion boxes in all the premises. In the same line, we are starting to arrange workshops in some plants for the staff of human resources to study and analyze each proposal, so that we can improve working environment.

#### Safety

ROVI considers a priority the health of its employees, with the conviction that any accident could be avoided. Therefore, as well as working to make safer facilities, the company wants to raise awareness between the staff towards safety as a basic issue.

Control activities that are associated to health and safety risks at work, and those activities whose development could lead to legal breaches or deviations from provisions in the policy is a basic item in the Integrated Management System.





### **Accident rate** in 2014

1.6% **ACCIDENT RATE IN 2014:** 

2.0% ACCIDENT RATE IN 2013:

It is calculated as accidents/average n° of employees x 100.

## **Absenteeism in 2014**

ROVI 1.71% **ROVI CONTRACT MANUFACTURING** 2.34%

FROSST IBÉRICA 1.96%

2.00% **GROUP AVERAGE** 

Similarly, there is a continuous monitoring of the basic points, that guarantees the correct functioning of relevant operational controls, compliance with legal requirements and other requirements subscribed voluntarily by the company and in conformity with the objectives and targets established in terms of Health and Safety and Environment.

To monitor and improve Health and Safety have been developed different procedures that control the following aspects:

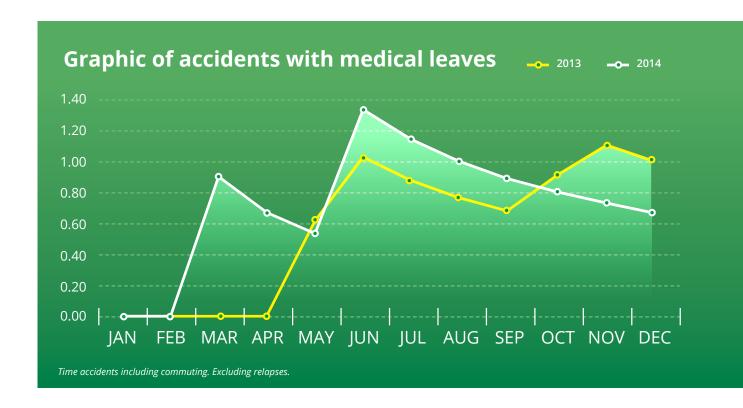


- · Safety inspections of equipment and facilities, as well as other working places.
- · Investigation of accidents.

During year 2014 were invested 1.9 million euros in preventive actions for health and safety, in order to reduce accidents by 20% at group level in itinere compared to 2013 and to improve communication system in case of accident by an employee's fainting if the employee is working on his own.

Likewise, in plants and subsidiaries of the group were undertaken measures as awareness-rising actions in terms of health and safety and environment, investments in equipment and infrastructure or implementation of industrial hygiene programs. They have also been implemented several improvement During year 2014 were invested 1.9 million euros in preventive actions for health and safety

suggestions made by the staff, to improve working conditions.



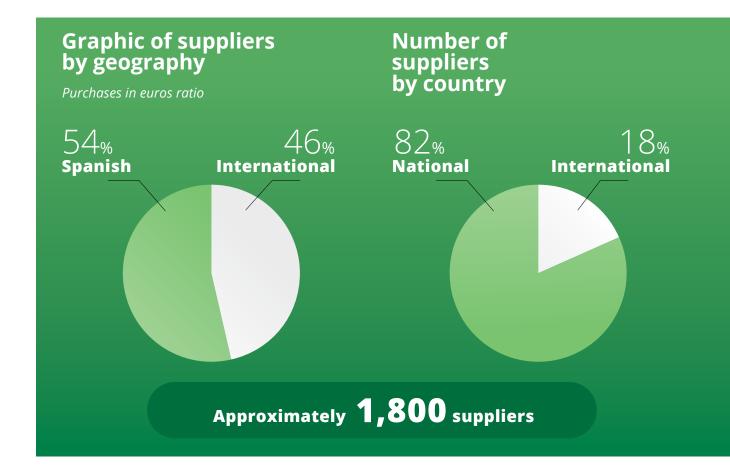




# Suppliers

ROVI has undertaken the commitment to perform a responsible management of its supply chain since suppliers are considered a main factor for the development of its business. With this objective, the group tries to involve all suppliers and subcontractors to adopt good corporate social responsibility practices so that, like ROVI, regulate its business according to the standards included in the certification SA-8000, SGE-21 or similar.

Since 2010, the company has two mechanisms to ensure and promote the adoption of good social corporative practices in its supply chain.







## CSR in the supply chain

In the first place, ROVI sends periodically a voluntary document entitled "CSR commitment" to all group's suppliers and subcontractors, requesting standards certifications such as SA-8000 urging them to adopt good practices. Currently, more than 55% of the companies have signed this commitment with social responsibility, although the objective is that all suppliers are adhered to this commitment.

Additionally, audits take place in-situ in which is verified that all suppliers operate in accordance to national and local regulations, that there are no substantial non-compliance issues in related to health and safety and that there no practices that impair workers rights. Among other aspects, auditors ensure that a safe working environment is provided, that meet health and safety and environment regulations and employees are not subject of abuse or discrimination.

More than 55% of the companies have signed this commitment with social responsibility

ROVI has established as objective for 2015 improve training of auditors that carry out these CSR audits, to gather a more complete and reliable information of its supply chain.



# Society and environment

# Environment

ROVI´s commitment to the protection of the environment is strong and constant and is integrated in the daily activity. The environmental policy of the company is based in continuous improvement commitments, in compliance with legal requirements and additional voluntary requirements. The implementation of power efficiency solutions, the rational management of natural resources and recycling generated waste are the main focus of the environmental strategy of the company.

One of the key issues to ensure proper management of environmental aspects is the implementation of an environmental management system based on



**ABOUT THIS REPORT** 

**BASIC MAGNITUDES** 



	2014	2013	Var.
ROUP			
Water (m³)	115,932	125,853	-8%
Electricity (Kw/h)	17,532,783	17,688,424	-1%
GRANADA			
Water (m³)	10,410	6,322	65%
Network	10,220	6,176	65%
Cistern	190	146	30%
Electricity (Kw/h)	2,174,576	1,976,424	10%
ABORATORIOS FARMACÉUTICOS ROVI - MADRID			
Water (m³)	5,107	7,558	-32%
Electricity (Kw/h)	-	-	-
ROVI CONTRACT MANUFACTURING			
Water (m³)	36,409	42,969	-15%
Electricity (Kw/h)	4,792,008	4,547,702	5%
ROSST IBERICA			
Water (m³)	64,006	69,004	-7%
Electricity (Kw/h)	10,566,199	11,144,298	-5%

Waste man	nagement Kild	grams	
ROVI MADRID	92,684.01	<b>TOTALS 2014</b>	1,478,774.07
ROVI GRANADA	581,412.00	% RESPECT PROFITS	6.14
ROVI CM	92,678.06	<b>TOTALS 2013</b>	1,026,465.00
FROSST	712,000.00	% VARIATION RESPECT 20	13 44%

the criteria established by the international standard ISO 14001:2004 and the Eco Management and Audit Scheme (EMAS) scheme.

These certifications acknowledge the quality of environmental management system of ROVI and support its commitment with the environment beyond

**STRATEGY** 

**CORPORATE GOVERNANCE** 



During the year 2014, 94,469.62 euros were destined to environmental expenses

the current national legislation. For this reason, in all production facilities of ROVI is promoted a production management respectful to the environment, in a constant effort to reduce power consumption and perform a more efficient waste management.

During the year 2014, 94,469.62 euros were destined to environmental expenses, with the objective of improving dangerous waste management and reduce power, water and gas consumption.

Likewise, although water and electricity consumption increased due to the increase of activity in the plant of Granada, in the rest of the plants of the group the environmental objectives were met for 2014. Between other measures, in the plant of Alcalá the consumption of paper was reduced 25% and electricity and water consumption more than 9,8%; in the plant of Madrid paper consumption was reduced 20%, electricity consumption 3% and the relation between the kilogram of dangerous waste by million units manufactured was reduced 2%; and in Granada was reduced 10% of dangerous waste generation and awareness-raising actions related to health and safety increased 20%. In the head office, in Madrid, was





made the measurement of carbon footprint in order to compensate 30% of the same. This compensation will be performed by a project financed to reduce the effect of green house gas emissions (i.e. forestation of an area).

# Society

ROVI devotes part of its resources to promote medical research. During the last years has developed an intense activity to support investigation and promote knowledge and prevention of certain diseases. During 2014, the company donated more than 665,000 euros to institutions (mainly foundations and medical research associations) for this purposes.

In this context, it has launched an International Grants Award for Biomedical Research on Bemiparin, a low molecular weight heparin, indicated in the prophilaxis and treatment of the venous thromboembolic disease. This grants award promotes original and independent research to increase scientific knowledge of Bemiparin, an anti-thrombotic with a unique pharmacologic profile that is currently used in 53 countries.

On the other side, ROVI maintains collaboration agreements with universities in order to join efforts to increase scientific, technological, learning activities and for knowledge dissemination. The University of Granada and ROVI co-operate in research activities and training of scientific personnel. In particular, we have two open projects: Integra SNS\_Integra and

Economic value generated and distributed  Million euros			
	2014	2013	2012
CONOMIC VALUE GENERATED	240.9	220.3	204.5
CONOMIC VALUE DISTRIBUTED			
Shareholders	8.5	8.1	6.8
Suppliers	134.3	121.8	114.7
Society	1.5	1.2	1.3
R&D	12	10.5	9.2
Employees	58.1	55.6	53.5
Capital providers	2.1	1.2	0.8
Amortizations and depreciation	8.9	6.9	5.3
Reserves	15.6	15.0	12.9



ROVI participated in the 150° anniversary of the Spanish Red Cross with a donation for charity social canteens

ADELIS (both framed in the FEDER Interconnecta program).

The group also has an agreement with the Biomedical Research Centre of CSIC and with the University of La Rioja (UNIR).

Aiming those highly qualified students can access work market, to improve their abilities, knowledge and experience, the company has an ongoing students training program in the company. For this, there are about twenty collaboration agreements with Universities and Schools. These practices help students to start their career in a professional working environment.

In 2014, ROVI participated in the 150° anniversary of the Spanish Red Cross with a donation for charity social canteens. Also ROVI collaborated with the *Proyecto Hombre Granada* for the development of programs drug addiction treatment and social reintegration for patients and their families.







#### **Commitment with progress**

As part of the support ROVI provides to promote health practices for society, in 2015 the Management have approved the sponsorship of training activities to support health professionals (trainers, physiotherapists,...) that collaborate with foundations such as "También" and "Deporte y Desafío". They are two private non-profit institutions, whose main objective is social integration of people with disabilities through sports. ROVI will collaborate in activities related to skiing.

Also, and in order to promote the involvement of staff from ROVI in these activities, we have collaborated with this institutions. The first example was the "X Trofeo Santiveri", of alpine skiing adapted, where 6 volunteers from ROVI helped in the previous races and in the completion that took place on 11 and 12 of April, 2015 in the slopes of Sierra Nevada.

BASIC MAGNITUDES

CHAIRMAN'S LETTER

**BUSINESS MODEL** 

STRATEGY

CORPORATE GOVERNANCE

YEAR 2014 ABOUT THIS REPORT



**STRATEGY** 





The current Annual Report includes relevant information of ROVI on financial aspects, strategics, and ESG (environmental, social and corporate governance) during the period 2014. The information provided relates to the company as a whole, except in those data in which is specified a different parameter in particular.

This Annual Report includes forward-looking statements. Such prospective information involving known and unknown risks, uncertainties and other factors that may cause that actual results, performance or achievements of ROVI, or its industrial results, to be materially different, profitability or future achievements, expressed or implied by such forward looking statements. The information included in this report represents ROVI's expectations and prospects at the time of writing this report. ROVI wishes to state that subsequent events and developments may cause these expectations and prospects to change. However, while ROVI may opt to update these forward-looking statements at some point in the future, specifically disclaims any obligation to do so, except in case of substantive changes. These future prospects 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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