

# ANNUAL REPORT

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ANNUAL ACCOUNTS



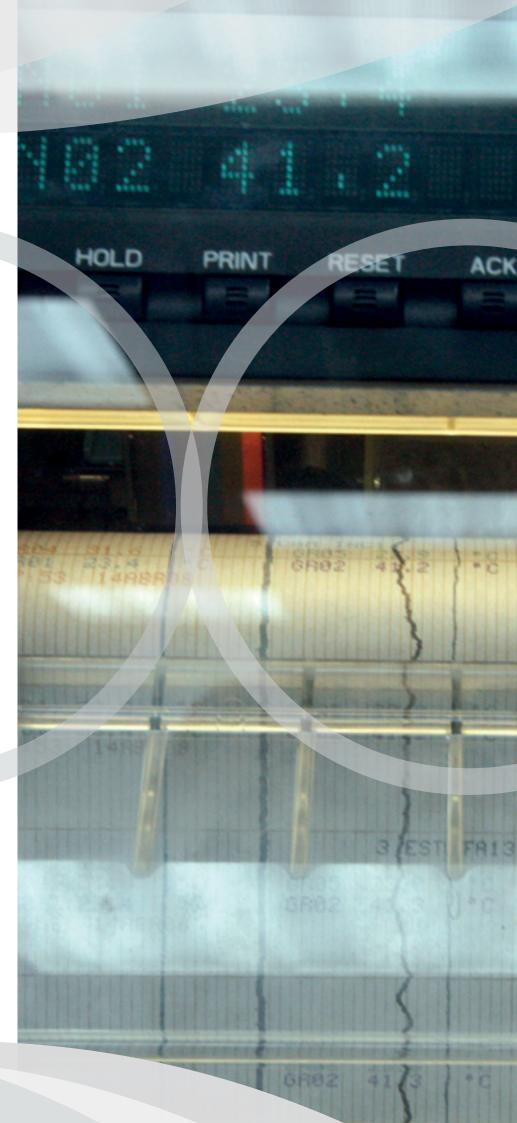
CORPORATE GOVERNANCE ANNUAL ACCOUNTS





### BASIC MAGNITUDES

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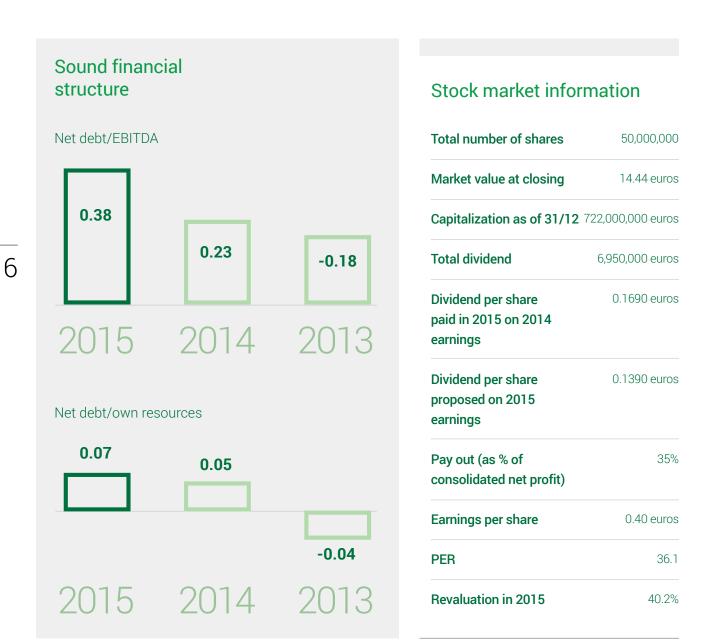
# Financial and non-financial magnitudes

### Financial magnitudes in million euros



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### Non-financial magnitudes

Human resources		
	2015	2014
Average number of employees	1,102	1,082
Net job creation	20	112
Diversity (men/ women)	495 / 607	480 / 602
By geography		
Madrid	835	809
Granada	54	54
Alcalá de Henares	213	219
Hours of training	9,000	85,330
Rotation	2.89%	2.49%
Accident rate	2.9%	1.6%
Absenteeism rate	3.42%	2.00%

Environment		
	2015	2014
CO2 emissions Tons	8,219.76	5,123.88
Waste generation, recycling Tons	519.06	838.22
Generation of non-hazardous residues Tons	852.58	817.52
Electrical power consumed kWh	16,659,473	17,668,424
Natural gas consumed <sup>kWh</sup>	20,778,025	4,221,476
Fuel consumption Litres	394,677	417,055

Community	Economic value generated (million euros) Value distributed (million euros)	247.0	240.9	220.3	
	Shareholders	7.0	8.5	8.1	
	Suppliers	137.0	134.3	121.8	
	Society	1.1	1.5	1.2	
	R&D	16.5	12.0	10.5	
	Employees	61.8	58.1	55.6	
	Capital Suppliers	0.9	2.1	1.2	
	Amortizations and depreciations	10.0	8.9	6.9	
	Reserves (retained value)	12.8	15.6	15.0	
		2015	2014	2013	



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## Group profile

ROVI is a specialty pharmaceutical company engaged in the research, development, manufacturing and commercialization of small molecule and specialty biologic drugs. Its activity comprises the commercialization of own products, licensed products and the provision of services to third parties, such as packaging, filling, production and performing clinical trials.

In its own products portfolio highlights Bemiparin, currently distributed in over 50 countries by strategic alliances and it has become one of first therapeutic proposals for the prevention and treatment of the Venous Thromboembolic Disease.

On the other side, the company offers wide range of products to third parties, from the production, filling, packaging and distribution of the product to performing clinical trials.

### Corporate data

#### Name:

Laboratorios Farmacéuticos Rovi, S.A.

Address:

Julián Camarillo, 35 28037 MADRID. Spain

Telephone: 34 91 375 62 30

Web page: www.rovi.es

Share capital: 3,000,000.00 euros

Number of shares: **50,000,000** 

Nominal:

0.06€ per share

#### Activity:

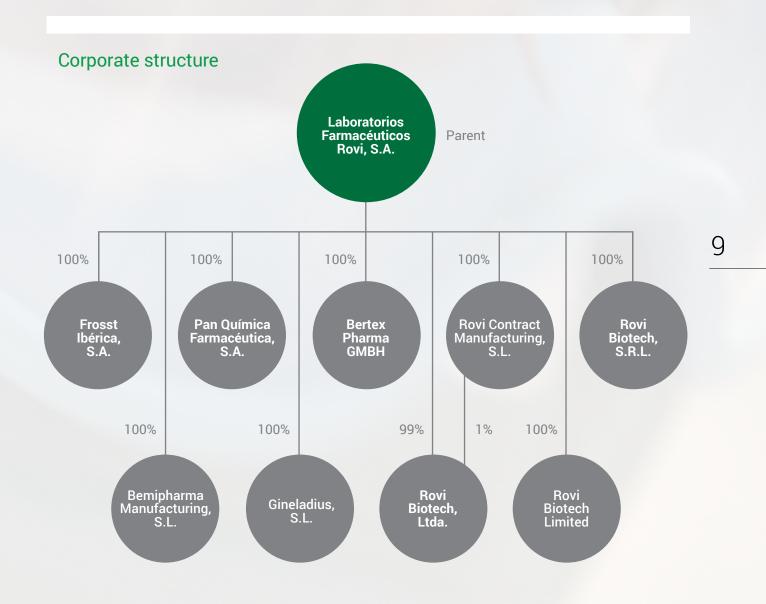
Manufacturing and marketing of pharmaceutical products and services for third parties.

#### Markets:

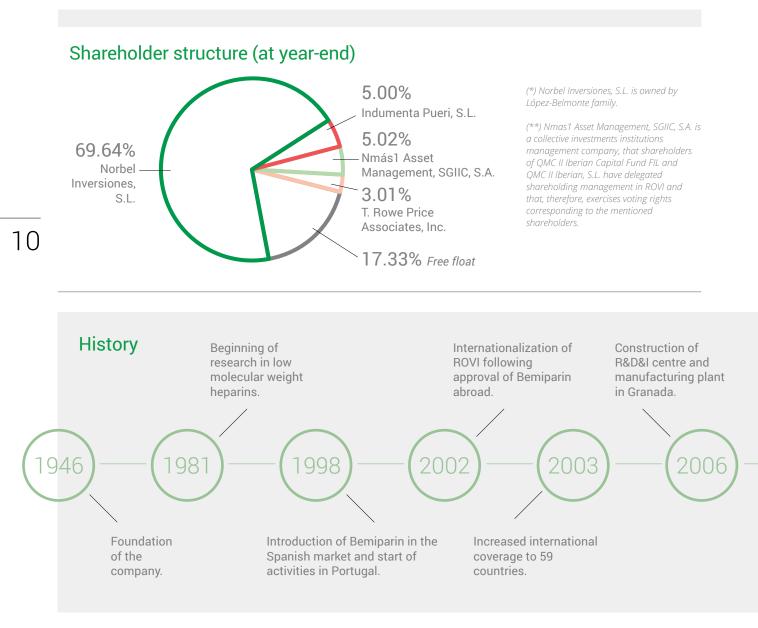
ROVI group is directly present in Spain and Portugal and its shares are listed in stocks markets of Barcelona, Bilbao, Valencia and Madrid.

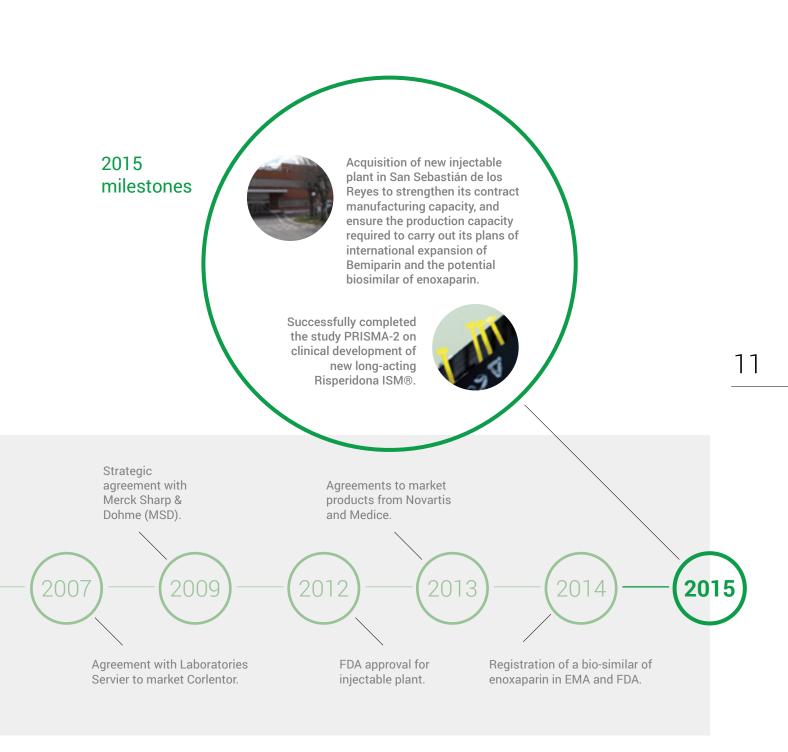


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### CHAIRMAN'S STATEMENT





Dear shareholders,

It is a great pleasure for me to present the Annual Report 2015 of Laboratorios ROVI. You will find in it outlined information of the most relevant aspects of the past period, in relation to the activities developed and about the evolution of business and corporate policies.

Following the footsteps of the previous one, this reports presents, in an integrated manner, clear and relevant information about the activity of the company during 2015 both in financial and non financial aspects. We understand that a global vision of the business and its impact on the environment allowing an appropriate and simultaneous assessment on the development of the company and the progress in its sustainability strategy.

But, before we get into the detailed reading of the Report, let me comment on the most relevant aspects about the information included.

In the area of financial performance, it has to be said that ROVI continues on the path of sustained growth of the last years despite of the difficult economic and regulatory environment in which we find ourselves. Total revenue have been the highest in the company's history, with an increase of 3% compared to the previous year, totalling 247 million euros. To give a comparative reference, this figure represents more than double the income obtained in 2007, year in which the company started its Initial Public Offering (IPO).

The revenue growth is motivated by the strategy of strengthening two of our pillars: the contract manufacturing of injectables business, whose sales increased



### **G** TOTAL REVENUE HAVE BEEN THE HIGHEST IN THE COMPANY'S HISTORY"

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by 10%, and the pharmaceutical specialties business, through the launching of four new products, which have good sales prospects. In fact, the sales of pharmaceutical prescription based products grew 7%, reaching 150.5 million euros in 2015.

The sales of Bemiparin, our leading product, also had a positive performance in Spain during 2015, with a growth of 5%, to reach 50.4 million euros. International sales of the product remained stable and the total sales increased 3% in 2015, to reach 75.1 million euros.

With this approach, and looking at 2016, we are trusting that the growth rate of operating income of ROVI will be between 5% and 9%, despite is expected by Farmaindustria just a slight increase of 0.6% in the Spanish pharmaceutical market and the forecast of IMS Health for the pharmaceutical expenditure in Spain points to a annual growth rate of between 1.3% and 1.6% for the period 2016-2019.

The soundness of our balance sheet and our cash generation capacity have allowed promoting the organic growth of the company. This growth is motivated by the launch of new products –as the recent case of Volutsa®, Ulunar®, Hirobriz®, Orvatez® or Medikinet®–, with which we intend to achieve an advantageous position in the current competitive environment.

Our financial strength has also allowed us to seek inorganic growth. In this sense, the most remarkable fact of the year has been the acquisition of a new injectable plant in San Sebastián de los Reyes that strengthens our contract manufacturing capacity, underpins the growth of Bemiparin and of the potential biosimilar of enoxaparin. THE SOUNDNESS OF OUR BALANCE SHEET AND OUR CASH GENERATION CAPACITY HAVE ALLOWED PROMOTING THE ORGANIC GROWTH"

#### Innovation, vital to ROVI

In the area of innovation and technology, we have managed to complete a new phase in the clinical development of the long lasting injectable Risperidone ISM® after successfully completing the study PRISMA-2. Likewise, we are expecting to obtain the marketing authorization from the European Health authorities to market a new low molecular weight heparin, biosimilar of enoxaparin, in Europe in 2016.

ROVI's involvement with innovation has been reflected in our figures: the investment in R&D raised 37%, to reach 16.5 million euros. This data is particularly revealing comparing it with general, business and administration expenses that just increased 4% in 2015, and mainly due to the new products launches.

The investment that we have made during 2015 in research and development is motivated by our firm commitment to market own quality and successful



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products in the immediate future. The 16.5 million invested had a negative impact in the figure of EBITDA, that has been reduced by 13% compared to the previous year, totalling 31.8 million euros. We are convinced that in this area we will soon recover the path of sustained growth.

The good results of ROVI had also a positive impact on the share value, which has continued generating value for the shareholder. During 2015, ROVI's shares recorded a high appreciation of 40.2%. For this reason, and in order to reward the trust and loyalty of shareholders, we will propose at the General Meeting of Shareholders a dividend of 0.1390 euros per share on 2015 earnings.

ROVI's good financial results are accompanied by a consistent performance in the non financial aspects of the company, i.e., those which are linked to our commitment with society, with the health and quality of people's life, as well as with the environment. ROVI continues making progress in the management and communication of the relevant issues to its groups of interest, aiming to make this commitment with sustainability more evident and effective, as reflected in this report.

My obligation as President is to guarantee to directors, employees, shareholders and suppliers the transparency of our accounts. For that, we have incorporated years ago the highest standards in practices, principles and recommendations in terms of corporate governance and internal control system on financial information. In particular, the Company makes an appropriate monitoring and control of compliance with the recommendations of the Code of Governance of Listed Companies published by the National Securities Market Commission and the



indicators proposed by this same Commission in its guidelines for the preparation of the description of the Internal Financial Information Control System (SCIIF); these aspects are included in the Corporate Governance Annual Report that the Company publishes every year. The Company considers these practices as a system to generate value and peace of mind for its shareholders.

I conclude by stressing that ROVI has a great potential for the future, not only because of its development capacity, but also because of the high level of professionalism and commitment of the people that form part of the company. Without the involvement and effort of the people who make its teams, none of these results would have been possible.

These nearly 1,100 professionals that currently form part of ROVI allow us to face with guarantees the demands of a global competitive market and to continue striving to create value beyond the economic results.

(hun Jahn

Juan López-Belmonte López Chairman



### ABOUT THIS REPORT



The current Annual Report includes relevant information of ROVI on financial aspects, strategic, and ESG (environmental, social and corporate governance) during the period 2015. The previous one was prepared in 2015, including data of calendar year 2014. The information provided in this document relates to the company as a whole, except in those data which is specified a different parameter in particular.

The structure of the information here contained follows the frame [IR] of the Integrated International Reporting Council (IIRC) and, for the non financial aspects, the guidelines for preparation of Sustainability Report of the Global Reporting Initiative (GRI) version 4.

This Annual Report contains forward looking statements. Such information involve 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 of the results, expressed or implied by such forward looking statements.

The information included in this report represents ROVI 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.

Any enquiry referred to this report can be addressed to:

#### **Investors relations**

C/ Alfonso Gómez, 45 A 28037 Madrid Tel: + 34 91 244 44 22 Fax: + 34 91 304 78 81 Email: *ir@rovi.es* 





### BUSINESS MODEL

## **19** Identity and commitment

**28** Business units



# Identity and commitment

### Mission, 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 We make our customers concerns our own and share their successes. company. We feel the changes as real opportunities Our diversity in training, experience and for development. points of view makes us better. Is important to feel that every day we We are committed to innovative drugs as engine of growth. learn something new. We like to assume responsibilities from We establish strict ethical standards for ourselves and our partners. start to finish. We know that we must win the trust of Our final success depends on the effort of all

of us.

patients every day.







# The CSR, a commitment to all 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 stakeholders.

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 reflected in the CSR policy approved by the Board of Directors during 2015.

#### Objectives of CSR policy and supporting tools

All the companies that form ROVI's group, aware of the improvement of health that their products provide, want to give answers to certain social demands in relation to the impact of its activities in society and environment.

For that, the economic development of ROVI must be compatible with ethical standards, social, work, environmental and respect to human rights. The knowledge, dissemination and implementation of these values, that express the commitment of the group related to CSR, act as guidance for the implementation of these values, that express the commitment of the group in terms of business ethics and CSR, and also for the actions of the Board of Directors and other bodies of ROVI group in their relationships with the stakeholders.

The supporting tools developed are: the Corporate Social Responsibility, the Integrated Management Policy (Environment and Health and Safety at Work), the Code of Ethics and the Corporate Social Responsibility Annual Report. The implementation of these tools must:

- Contribute to achieve the strategic objectives of the group.
- Improve group competitiveness making use of new management practices based on innovation, equal opportunities, productivity, profitability and sustainability.
- Manage with responsibility risks and opportunities arising from the changing environment, as well as maximizing the positive impact of its activity in the different places in which operates, and minimize, as far as possible, negative impacts.
- Promoting a culture of ethical behaviour and increasing corporate transparency to generate credibility and confidence of the groups of interest, among this group is the society as whole.
- Promote trust partnerships and values creation for the groups of interest, providing a balanced and integrated response to all of them.



As a result and in order to develop adequately these objectives, the following principles of actions have been established.

ROVI'S COMMITMENT WITH ETHICAL MANAGEMENT AND TRANSPARENCY IS REFLECTED IN THE CSR POLICY APPROVED IN 2015"



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### **Principles of actions**



Compliance with legal regulations in the places where are based our companies.



#### Support the integration of the principles of the United Nations Global Compact.

Support the integration of the principles of the United Nations Global Compact, by the adoption and dissemination of them, as well as other international instruments, especially in the areas of human rights, working practices, environment and fight against corruption.



### Follow the guidelines of the Code of Ethics.

Follow the guidelines of the Code of Ethics, which includes the commitment of the Company with the principles of business ethic and transparency in fields of action and regulates responsible behaviours of all the professionals of the group in the development of their activities.



### Promote free market practices.

Promote free market practices, rejecting any kind of illegal or fraudulent practice, implementing effective mechanisms of prevention, surveillance and sanction of irregularities.



### Commitment with transparency.

Commitment with transparency as a mean to transmit confidence and credibility to the groups of interest. This will involve:

- a. Disseminate relevant and accurate information to the stakeholders, by the compliance with legal requirements of public information if required.
- **b.** Prepare and public financial and non financial information, using, in the latter case, internationally accepted methods, and subjecting them to the opportune internal and external verification processes that guarantee reliability and promote continuous improvement.



### Improve communication channels and dialogue.

Improve communication channels and dialogue, and promote the relationships of the group with shareholders, investors, employees, customers, suppliers and in general with all the stakeholders. This contributes to reach a synergy between corporate values and social expectations, adapting, as far as possible, group's policies and strategies to their interests, concerns and needs, using all the communication tools available, such as direct contact and the corporate web site.



# Conservation and promotion of the environment.

ROVI develops its activity under the firm commitment of contributing to sustainability from an environmental perspective, materializing this commitment through the integration of environment on its different business areas, biodiversity conservation, prevention of pollution, an efficient management of resources and mitigation of climate change, according to the established by the Group's Environmental Policy.



### Fiscal responsibility.

The taxes that ROVI pays in the places in which develops its activity constitute the main contribution of the group companies to sustain public funds, and therefore, one of its contributions to society.

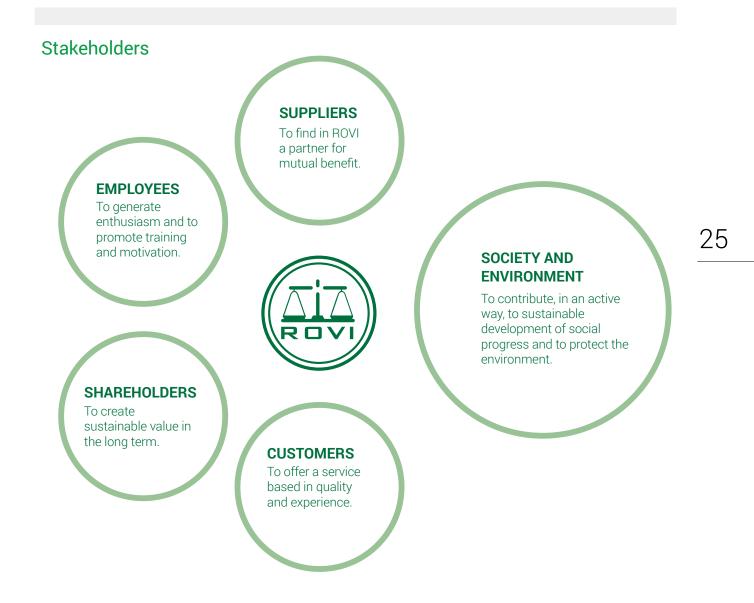


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# Relationship with the stakeholders

Knowing the expectations of the stakeholders is part of the CSR strategy of ROVI, therefore, the company maintains a fluid and constant dialogue to detect and give answers to their interests, ensuring long term business viability. The company has identified five groups that contribute directly or indirectly to the good progress of its activities:

**G** THE COMPANY MAINTAINS A FLUID AND CONSTANT DIALOGUE WITH THE STAKEHOLDERS"





### COMMUNICATION CHANNELS

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

#### **Employees**

For its employees, they can use the suggestion boxes that can be found along the facilities, and aim to facilitate anonymous communications for improvements.

Additionally, ROVI has got available a mechanism that allows employees communicating in a confidential manner, and if appropriate anonymously, any irregularity that could be considered illegal, criminal or that could constitute an infringement of the principles established in the ROVI's Code of Ethics.

The objective of the establishment of this mechanism aims to improve the surveillance and control measures that every company listed must carry out to prevent criminal or illegal activities, which are contrary to its internal ethical principles.

### Suppliers

ROVI's suppliers are a key partner for the company. ROVI sends regularly a voluntary document entitled "CSR commitment" to all suppliers and subcontractors of the entire group, in which they are requested for certifications and the adoption of good practices. Additionally, on site audits are performed to check that all suppliers operate in conformity with national and local regulations, and that there are no significant non compliances in terms of health and safety at work and that there are no practices infringing workers 'rights.

### Shareholders

Since its initial public offering, ROVI has maintained a commitment for transparency with shareholders, informing them regularly of its activities. The company has made available a direct communication channel through the e-mail *ir@rovi.es* and information can also be requested through the *corporate website* (www.rovi.es/inversores/ solicitudInformacion.php). Likewise, shareholders have the possibility of receiving automatically ROVI's financial information via an *e-mail alert system* (www.rovi.es/ inversores/alertasEmail.php).

ROVI considers a priority giving answers to queries and requests formulated by shareholders and investors registered so that they can keep updated about the progress of the group.

In the year 2015, ROVI made public its 'Communication Policy with shareholders, institutional investors and voting advisors' through its *web page* (http://www.rovi.es/inversores/caucesComunicacion.php).

During 2015, ROVI has performed 10 roadshows, has participated in 10 events with investors and advisers and has received 16 visits of investors at its facilities, what represented more than 150 investors being 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).



#### Customers

ROVI's customers have also available a consultation channel for all the requests of information, both for international partners, through an exclusive *web page* (www. bemimed.com), and for direct customers, patients and professionals. Additionally, if there is any complaint, the company initiates an investigation process to identify the cause and to prevent recurrence.

#### Society and environment

The commitment of ROVI with society and with environment protection is firm and constant and is integrated in its daily activity. The environmental policy of the company is based in commitments of continuous improvement, in the compliance of legal requirements and additional voluntary requirements. In relation to environmental queries, ROVI has available a corporate procedure (SOPc813 "Communication, participation and consultation") via which all communications are managed (queries, complaints, etc.) related to the environment and health and safety at work. The quality and health and safety certifications of all the companies of the group are available to the public in the corporate web page (www.rovi.es). Additionally, ROVI devotes part of its resources to promote medical research. During the last years, the company has developed an intense activity to support investigation and promote the prevention and knowledge of certain diseases.

**G** ROVI HAS DEVELOPED AN INTENSE ACTIVITY TO SUPPORT INVESTIGATION AND PROMOTE THE PREVENTION AND KNOWLEDGE OF CERTAIN DISEASES"



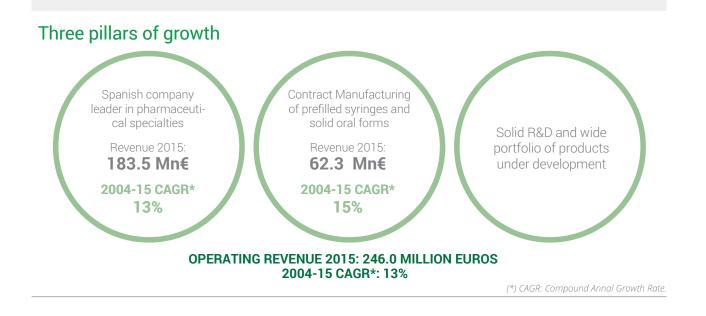
### Business units Three pillars of growth

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 counts with three pillars of growth:



The growth of these pillars provides ROVI with a resilient profile that has allowed increasing its benefits during the last years, despite the difficult scenario the sector is facing, aggravated by the public sector cuts in pharmaceutical spending.





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### Competitive advantages

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

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#### 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. Since October 2005, ROVI has launched nearly 20 products. From here to July 2019 is expected to launch four more new products under MSD licence.

ROVI's activity covers, mainly, seven therapeutic areas with thirty products:

- Cardiovascular
- · Osteoarticular (women's health)
- Respiratory
- Anesthesia pain relief
- Imaging Contrast Media
- Central nervous system
- Primary healthcare

It also counts with an OTC (over-the-counter) product line.



# 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)–.

In 2015, ROVI strengthened its contract manufacturing business with the acquisition of assets of a manufacturing plant in San Sebastián de los Reyes, owned by Crucell, with the essential aim of expanding in the future the production lines of injectables of the group.



#### 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 and establishing international strategic alliances to address the most expensive clinical programs.

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### 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 54 countries.

### Global presence of Bemiparin









# 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 2019.

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.



ROVI HAS A DIVERSIFIED PORTFOLIO INCLUDING THIRTY PRODUCTS "



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 55 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.

In 2015 ROVI acquired a manufacturing plant in San Sebastián de los Reyes (Madrid, España), whose production capacity will reinforce the international expansion of Bemiparin.

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

ROVI started to market Hirobriz Breezhaler (indacaterol maleate) and Ulunar Breezhaler (indacaterol maleate and glycopyrronium bromide) in Spain at the end of 2014. Both active ingredients are long acting bronchodilators, indicated in the maintenance treatment of Chronic Obstructive Pulmonary Disease (COPD), in adult patients, and are administered by inhalation through the Breezhaler device. ROVI markets both products under a licence from Novartis.

### Absorcol®, Vytorin® and Orvatez®

Absorcol (ezetimibe), Vytorin (ezetimibe and simvastatine) and Orvatez (ezetimibe and atorvastatin) are products indicated as adjunctive therapy to diet in patients with hypercholesterolemia. It represents the first of the five licences of MSD that ROVI distributes in Spain under a co-marketing agreement since January 2011, in the case of Absorcol and Vytorin, and from June 2015, in the case of Orvatez.

### **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.

### **Corlentor**®

Corlentor (ivabradine) is a prescription product for chronic stable angina pectoris and chronic heart failure that ROVI markets under a licence of Laboratories 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 anti-inflammatory 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.

### Thymanax®

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

### 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: lomeron® and lopamiro® (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®).

### **OTC Products**

ROVI also counts with a business line of distribution of pharmaceutical products over the counter (OTC), whose principal asset is Enerzone, distributed under Enervit licence. In March 2016, ROVI and Enervit announced the creation of a joint venture for the distribution of nutritional products and other non pharmacological products in Spain and Portugal, thus expanding this collaboration.





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THE COMPANY, THROUGH THREE MANUFACTURING PLANTS, OFFER CONTRACTS MANUFACTURING SERVICES TO THIRD PARTIES IN A WIDE RANGE OF PHARMACEUTICAL FORMS"

### 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 manufacturing plants: two dedicated to injectables (Rovi Contract Manufacturing and a plant in San Sebastián de los Reyes) 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 physicalchemical 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 activity is divided in:



#### INJECTABLES

ROVI is currently one of the leading manufacturers of pre-filled syringes in Europe in terms of number of units manufactured (filled) yearly, with an annual production capacity of 270 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 biologically controlled cleanrooms) for the filling of prefilled 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 60 millions, while suppositories capacity rises to 150 millions.

The plant is approved by European and USA authorities. Also has the approval from authorities from Korea, Brazil,



Gulf countries, as well as ISO9001, ISO14001 and OSHAS certifications.

In June 2015, ROVI reached an agreement with Crucell Spain, S.A. with the acquisition of assets in the manufacturing plant of San Sebastián de los Reyes, with the objective of expanding production lines of injectables of ROVI. Through this operation, ROVI strengthens its contract manufacturing business and ensures the production capacity required to carry out in the future its strategic plans of international expansion.



### ORAL SOLID FORMS

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 3,000 million tablets, 300 million of hard capsules 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, Brazilian, Kenyan Belarusian and Gulf countries authorities.



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.



### **Commitment** with 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 451 patents of wich 314 are granted and 137 are in the process of review and appraisal. 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 55 countries.

In 2015, the group invested in R&D&I 16.5 million euros, that are 6.7% of the operating income, with an increase of 37% in research expenditure respect the previous year. These figures are mainly the result of a focused investment in the ISM Risperidone project. Due to these investments, 50% of our current income from pharmaceutical specialties area corresponds to own products.

ROVI owns three R&D&I centres and two pilot plants for the manufacture of injectable medicinal products under investigation and is present in the creation of major National Strategic Research Consortia (CENIT). It has participated since 2006 as partner in research activities of the consortium CENIT, in the Nanofarma Consortium (2006), in the Consortium Melius (2007) and in the consortium CeyeC (2009). Since 2011, leads actively other research consortia including the SNC\_Integra and ADELIS, (2013), BIOMAP consortium (2015), within the framework of the FEDER-Innterconecta program for Andalucía.



IN 2015, THE GROUP INVESTED IN R&D&I 16.5 MILLION EUROS, THAT ARE 6.7% OF THE OPERATING INCOME, WITH AN INCREASE OF 37%"





On the other hand, ROVI maintains collaboration agreements with universities in order to join efforts that increase scientific, technological and formative activities that contribute disseminating knowledge. The University of Granada and ROVI cooperate in research and personnel training activities for scientific personnel. In particular, there are two projects under development: Integra SNS\_Integra and ADELIS (both within the framework of FEDER-Innterconecta program). The group also maintains an agreement with the "Centro de Investigaciones Biomédicas del CSIC" and with the University of La Rioja (UNIR). ROVI started to build in 2015, a new plant that will allow manufacturing products with ISM® technology for high strength active ingredients, like Letrozole.



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### Products under investigation

		Current situation					
Platform	Product	Potential indication	Pre-clinical I II III	Expected benchmarks			
ISM	<b>Risperidone</b> Monthly	Schizophrenia		<ul> <li>Announcemen of results F II</li> <li>F III will start in the second half 2016</li> </ul>			
	<b>Letrozole</b> Quarterly	Breast cancer		• F I will start in the second half of 2016			
Glycomics	<b>Enoxaparin</b> biosimilar	Thrombosis		• Registration phase			



#### **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.





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#### ISM® TECHNOLOGY ALLOWS ROVI TO ENTER AND COMPETE IN NEW THERAPEUTIC AREAS, LIKE PSYCHIATRY AND ONCOLOGY"

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This approach allows ROVI to enter and compete in new therapeutic areas, like psychiatry and oncology. In 2015, ROVI achieved two crucial milestones in the development of the platform with the active substance of Risperidone (Risperidone- ISM®), for the treatment of schizophrenia:

 As part of the clinical development of the new long acting injectable Risperidone ISM®, ROVI completed successfully the study PRISMA-2. The study PRISMA-2 is a clinical phase II trial parallel and open performed in four US centres. The main objective of this trial was to evaluate safety and pharmacokinetic profile, as well as exploring effectiveness of multiple doses of Risperidone ISM® in patients with stable schizophrenia<sup>1</sup>. Seventy seven schizophrenic patients were

administered intramuscularly and randomly, four monthly doses of 75 mg de Risperidone ISM®, without including any oral supplement of risperidone. All the subjects reached therapeutic levels in plasma (that is, above 7.5 ng/ml for the active fraction) between 2 and 8 hours after the administration of the drug. Plasma concentrations were kept above therapeutic levels during the dosing periods of 4 weeks. No significant variations were observed along the study, both in the Positive and Negative Syndromes Scale (PANSS) and in the Scale to evaluate Extrapyramidal Syndromes. Likewise, it was checked that Risperidone ISM® is safe and well tolerated. Therefore, it was concluded that Risperidone ISM® reached therapeutic levels in plasma from the first hours after the administration of the drug, without requiring including a supplement of oral risperidone, and provided a extended release, along the dosing period of 4 weeks and, with multiple intramuscular injections, regardless of the area used for the injection (gluteal or deltoids). These final positive results were presented in the 24° European Psychiatry Congress on March, 2016<sup>2</sup>.

 The results of the study PRISMA-2, together with data of previous studies, have been already submitted to the European Medicines Agency (EMA) and to the US Food and Drug Administration (FDA) in order to request scientific advice about the design of the phase III clinical study, that is expected to begin by the second half of 2016.



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

Anta L, Llaudó J, Ayani I, Gorostidi B, Monreal M, Martínez-González J, Ochoa L, Gutierro I. Pharmacokinetics, Safety, And Tolerability Of Four 28 Days Cycle Intramuscular Injections For Risperidone-Ism 75 Mg In Patients With Schizophrenia: A Phase-2 Randomized Study (PRISMA-2). European Psychiatry.2016; 33S: S285. [24th European Congress of Psychiatry, Madrid (Spain)].

#### Glycomics

Ο'

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.

As a result of the effort and the investment on this area, ROVI has developed an enoxaparin biosimilar (a low molecular weight heparin with antithrombotic effect) for which requested, in 2014, the marketing authorization to the European health authorities.

On February 9th of 2015, after the completion of the validation phase, it started the assessment process in Europe to obtain the marketing authorization of the mentioned low molecular weight heparin, biosimilar of enoxaparina. The evaluation process is ongoing within the pre-established timelines.

### 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 2015 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.

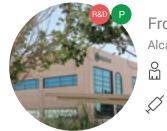
Although ROVI already has a portfolio of 14 international patent applications, the development of this line of investigation provides ROVI the possibility to extend patent's portfolio both of patents and of commercial products of the company in the field of medical devices in an innovative and competitive way as this technology is intended as a platform for future developments.



### **Production plants and R&D centres**

ROVI has three research and development centres and four 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.

### Production plants and R&D centres



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Frosst Ibérica Alcalá de Henares

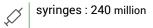
Å 213

> tablets : 3 billion hard capsules : 300 million sachets: 30 million



Production plant of Bemiparin Granada

Å 54





**ROVI Contract** Manufacturing Madrid ല്ല 364

> syringes: 150 million suppositories : 150 million



New injectable plant San Sebastián de los Reyes Å

4

Ø syringes : 120 million vials : 60 million

R&D R&D centre

Production plant

Employees on average

Ě

Annual production capacity



**THE NEW INJECTABLE PLANT IN SAN SEBASTIÁN DE LOS REYES STRENGTHENS MANUFACTURING CAPACITY AND REINFORCES THE GROUP'S EXPANSION PLAN"** 

ANNUAL REPORT 2015

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## STRATEGY

- Market environment
- Strategic and financial priorities



# Market environment

The Spanish economy closed 2015 with a remarkable advance; the GDP increased 3.2%, the highest rise since the onset of the crisis in 2007. This economic strength is mainly attributed to the improvement of private consumption and business investments.

However, this economic growth is hardly reflected in the pharmaceutical sector, in which can still be noticed the effects of the containment of the deficit. The public pharmaceutical expenditure accumulated of 12 months to the end of December 2015 registered, in Spain, a growth of 1.8%, but still is 33% below its all-times highs of 2010. The increase in pharmaceutical expenditure in 2015 is a result of the 1.5% increase in the number of prescriptions and the 0.3% increase in the average expenditure per prescription.

# Growth rate of pharmaceutical market

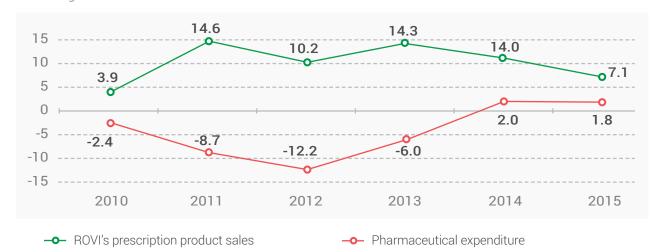
Percentage



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# ROVI sales growth vs. pharmaceutical expenditure growth

Percentage



Data provided by IMS Health indicate that the innovative products market in Spain decreased 0.9% in 2015 versus the previous year. However, the sales of pharmaceutical products with prescription for ROVI increased 7% in 2015, exceeding the market in 7.9 percentage points.

In addition, according to Farmaindustria<sup>3</sup>, it is expected an annual increase of 0.6% of the pharmaceutical expenditure in 2016. Likewise, IMS Health<sup>4</sup> forecast for the pharmaceutical expenditure in Spain points to an annual growth rate of between 1.3% and 1.6% for the period 2016-2019. Despite the difficult situation that the pharmaceutical industry is going through, ROVI expects to growth at higher rates than the growth forecasts for the pharmaceutical expenditure.

4. IMS Health, Market Prognosis Septiembre 2015.

In the classification of laboratories according to the data of IMS Health of December 2015, ROVI moves from position 23 to the 22 in figures (values) and in units moves from position 27 to the 23.

#### **BEMIPARIN MARKET**

Bemiparin, a low molecular weight heparin of ROVI's own research, is present in 55 countries around the world. Its main market is Spain, where represents 67% of the sales of the product. Outside Spain, ROVI markets Bemiparin through international partners. The sales of the mentioned product outside Spain amounted to 24.7 million euros in 2015, representing 33% of the sales of the product and 10% of the group's

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http://www.farmaindustria.es/web/documento/indicadores-basicos-del-sectorla-industria-farmaceutica-espanola-y-su-mercado-en-cifras/.

sales. During the year 2015, the international sales were affected by devaluations of currencies in emerging countries, main markets of ROVI. Although our international partners are the ones that assume the risk of the exchange rate, as ROVI invoices in euros, currencies' crisis in these countries has affected the sales of ROVI's reference product. Also, the conflict between Ukraine and Russia, two countries where Bemiparin was present in 2014, has a negative impact on the international sales of the product. These negative impacts had a positive counterpart in the last quarter of 2015 with the launching of the product in China and Brazil, two large emerging countries where the market of low molecular weight heparin is yet to be developed. Those launches that contributed with sales of 0.9 million euros during 2015 financial year allowed ROVI to maintain stable sales during the year.

China is considered as one of most strategic markets for the future growth of the pharmaceutical business. Already listed as the third largest world market, only behind of the USA and Japan. The sales have been increasing at annual rate of almost 25% since 2009. In this regard, consulting company Global Data stated that in 2020 Chinese pharmaceutical market will be worth approximately 315 billion dollars.

Brazil is the largest pharmaceutical market of South America. With an accelerated growth during the last years, the Brazilian pharmaceutical industry recovered regional leadership and is presented as the highest expectation of growth for the coming years. IN THE LAST QUARTER OF 2015, BEMIPARIN WAS LAUNCHED IN CHINA AND BRAZIL, TWO STRATEGIC EMERGING COUNTRIES"

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# Strategic and financial priorities

For 2016, ROVI expects a mid-to-high single digit growth rate for the operating revenue, despite that Farmaindustria<sup>5</sup> just predicts a slight increase of the Spanish pharmaceutical market of 0.6% and the forecast of IMS Health<sup>6</sup> for the pharmaceutical expenditure in Spain points to an annual growth rate of between 1.3% and 1.6% for the period of 2016-2019.

5. http://www.farmaindustria.es/web/documento/indicadores-basicos-del-sectorla-industria-farmaceutica-espanola-y-sumercado-en-cifras/.

6. IMS Health, Market Prognosis. Septiembre 2015.

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#### PHARMACEUTICAL SPECIALTIES

In this area, ROVI counts as driving force with Bemiparin, the new agreements for distribution of products (Volutsa®, Orvatez®, Ulunar® and Hirobriz®), the contribution of Vytorin® and Absorcol®, the existing product portfolio of pharmaceutical specialties and the new licences for products distribution.

In addition, the agreement reached with MSD in 2009 will allow ROVI to launch four additional products between 2015 and 2019, which will contribute to a sustained growth of the company in the long term.

Pharmaceutical specialties commercialized in Spain are high strategic value products 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 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 88 countries.

#### CONTRACT MANUFACTURING

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 injectable plant and solid forms one.

Both plants are approved by the USA FDA and the European health authorities, and have significant production capacity and offer a service based on excellence.

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.

In June 2015, ROVI acquired assets of a manufacturing plant of injectables in San Sebastián de los Reyes, owned by Crucell, with the main purpose of extending the production lines of injectables of ROVI's Group. Through this acquision, ROVI will strengthen its capacity to perform contract manufacturing operations, trying to achieve effectiveness and allowing long term growth.



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ROVI IS BUILDING A NEW PLANT THAT WILL ALLOW TO MANUFACTURE NEW PRODUCTS WITH ISM® TECHNOLOGY"

#### R&D&I

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.

Accordingly, as part of the clinical development of the new long acting injectable Risperidone ISM®, ROVI successfully end the study PRISMA-2 in 2015. This study is a clinical trial phase II parallel and open performed in four USA centres. The main objective has consisted in evaluating safety and pharmacokinetic profile, as well as exploring the efficacy of multiple intramuscular doses of Risperidone ISM® in patients with stable schizophrenia<sup>7</sup>. Final positive results were presented in the 24° European Congress of Psychiatry on March 2016<sup>8</sup>. Likewise, recruitment of patients for the development of the phase III of Risperidone ISM® is expected to start by the third quarter of 2016.

ROVI is building a new plant that will allow to manufacture new products with ISM® technology for high strength APIs, such as Letrozole. After completing regulatory non clinical studies for Letrozole ISM®, this product will initiate the clinical development phase. This new manufacturing plant will produce the medication for the first study in humans with Letrozole ISM®, that will start in the second half of 2016.

Regarding the area of glycomics, on the 9th of February of 2015, after the completion of the validation phase, it was started the assessment process in Europe to obtain the marketing authorization by ROVI of a new low molecular weight heparin, biosimilar of heparin. This evaluation process in progress according to the established schedule and we hope that we will obtain the marketing authorization for the mentioned biosimilar in Europe in 2016.

- Pharmacokinetics and Tolerability Study of Risperidone ISM® in Schizophrenia (PRISMA-2). [http://clinicaltrials.gov/show/NCT02086786].
- Anta L, Llaudó J, Ayani I, Gorostidi B, Monreal M, Martínez-González J, Ochoa L, Gutierro I. Pharmacokinetics, Safety, And Tolerability Of Four 28 Days Cycle Intramuscular Injections For Risperidone-Ism 75 Mg In Patients With Scipophrenia: A Phase-2 Randomized Study (PRISMA-2). European Psychiatry.2016; 33S: S285. [24th European Congress of Psychiatry, Madrid (Spain)].



### CORPORATE GOVERNANCE

- **55** Corporate Governance Model
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## 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 on February 2015. This model guarantees an ethical behaviour by the company, what allows preserving the trust generated to the groups of interest and security to shareholders.

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 stakeholders have

BY THE COMPANY"

**G** ROVI'S CORPORATE GOVERNANCE MODEL GUARANTEES AN ETHICAL BEHAVIOUR

access to the relevant information both in relation to the rules and practice of governance and on the results obtained. For this reason, ROVI presents annually a Report of Corporate Governance and an Annual Report of Directors Remuneration. Additionally, the Company 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).

As well as the governing bodies described above, ROVI counts with Steering Committee in charge of the day to day management of the company and that is formed by 12 executives led by the CEO.



# Corporate Governance Bodies

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### **General Meeting of** Shareholders

The General Meeting of Shareholders is the main governing body of the company. Meetings are held, at least, once a year at the Annual General Meeting (AGM) 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.

#### Annual General Meeting 2015

On June 9th of 2015 ROVI held the Annual General Meeting. This was established with a total of 44,955,701 shares (36,393,642 present and 8,562,059 represented) forming a quorum 89,911% of shared capital (72.787% present and 17.124% represented).

The agreements established by the Meeting are below:

- Approve Annual Accounts Report of ROVI 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 31st of 2014.
- Approve a payment of a gross dividend of 0.1690 euros per share.
- Approve management and performance of the Board of Directors during the year ending on December 31st, 2014.

- Approve annual retribution of the members of the Board of Directors for the year 2015.
- Approve the modification of Corporate Status of the terms of administrators report prepared for this purpose.
- Approve the modification of the Regulations of the General Meeting in the terms of the administrators report prepared for this purpose.
- Appoint D. José Fernando de Almansa Moreno-Barreda as independent director for the statutory period. Delegate to the Board of Directors the power to increase share capital under the terms and conditions of article 297.1.b) of the Spanish Corporations Law.
- Re-elect PricewaterhouseCoopers Auditores, S.L. as auditors of the company and subsidiaries for the year 2015.
- Delegate the powers for the formalization and registration of the agreements adopted by the General Meeting and to perform the compulsory filling of Annual Accounts.
- Approve, with advisory status, the Annual Remunerations Reports of the Company directors.



#### **Extraordinary Shareholders Meeting**

On the 18th of November of 2015 ROVI celebrated an Extraordinary Shareholders Meeting. This was established with a total of 45,363,105 shares (39,051,281 present and 6,311,824 represented) forming a quorum of 90.726% of shared capital (78.103% present and 12.624% represented).

In particular, all the proposals subjected were adopted and are summarized below:

 Approval of the total split-off of Inversiones Clidia, S.L., company being divided, in favour of Laboratorios Farmacéuticos ROVI, S.A. and Norbel Inversiones, S.L., qualifying companies, according to the terms of the common project of total division formulated by the governing bodies of the mentioned companies, published in ROVI's web page.

• Delegate the powers for the formalization and registration of the agreements adopted by the General Meeting.

### **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 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.

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.

Its responsibilities are defined in article 5 of the Board of Directors' Regulations, among others, and in particular, 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 2015, the Board of Administration held 9 meetings, all of them chaired by the President. The percentage of assistance over the total 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.

The Coordinating Director, D. Enrique Castellón Leal, 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.

	Position	Nature of the position	Appointments and Remunerations Committee	Audit Committee
Mr. Juan López-Belmonte López	President	Dominical		
Mr. Juan López-Belmonte Encina	Chief Executive Officer	Executive		
Mr. Iván López-Belmonte Encina	First Vice-president	Executive		
Mr. Javier López-Belmonte Encina	Second Vice-president	Executive		
Mr. Miguel Corsini Freese	Member	Independent	President	Member and Secretary
Mr. José Fernando de Almansa Moreno-Barreda	Member	Independent	Member	Member
Mr. Enrique Castellón Leal	Coordinating Director	Independent	Member and Secretary	President
Mr. Gabriel Núñez Fernández	Secretary non-member			





#### PROFESSIONAL PROFILE OF CHIEF EXECUTIVE OFFICERS



#### Mr. Juan López-Belmonte López

Chairman of ROVI for 21 years now. He obtained a degree in Economics and Business Studies from the University Complutense of Madrid in 1969 and he is also an Insurance Actuary. 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 and member of Management Board of IFEMA. He is shareholder of Norbel Inversiones S.L. (controlling shareholder of ROVI).



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#### 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 professional career working in several 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 Norbel Inversiones 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 Vicepresident of the Madrid Confederation of Employers and Industries (CEIM) and he is also a shareholder of Norbel Inversiones 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 Norbel Inversiones S.L. (controlling shareholder of ROVI).





#### Mr. Miguel Corsini Freese

Independent Director. Currently member of the Executive Committee of the Confederation of Employers and Industries (CEIM) and is a member of the Executive Board of the Spanish Confederations of Employers' Organization (CEOE). He holds a Law degree and is an expert in Labour Law. His professional career has been linked for years to Renfe, as he was the Chairman of the Board of Directors between 1996 and 2004. On October 2007 was appointed First Vice-President of the Chamber of Commerce of Madrid. He is a member of the Board of Directors of several companies, such as Legalitas and Azvi, as well as the Chairman of Cetren.



#### Mr. José Fernando de Almansa Moreno-Barreda

Independent director. Degree in Law by the University of Deusto (Bilbao).

Diplomatic. He entered the Diplomatic Corps on the 2nd of December of 1974. From 1976 to 1992 has held different positions: Secretary of the Spanish Embassy in Brussels, Cultural Advisor of the Spanish Embassy in Mexico, Managing Director of the Section of Coordination of Sub-directorate General of Eastern Europe, Director of Atlantic Affairs in the Directorate-General for External Affairs, Political Advisor of the Permanent Representation of Spain for North Atlantic Council in Brussels, Minister-Counsellor of the Spanish Embassy in the former Soviet Union, Secretary General of the National Commission of the Fifth Centenary of the Discovery of America, and Deputy Director of Eastern Europe under the General Directorate of European Foreign Affairs. From 1993 to 2002, was appointed by his Majesty King Juan Carlos I, head of the Royal House, with Rank of Minister, being appointed Private Counsellor of His Majesty The King Juan Carlos I.



#### Mr. Enrique Castellón Leal

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Independent External Director of ROVI. Founding partner and president of the Board of Directors of CrossRoadBiotech SCR. He holds a degree in Medicine and Surgery and Internal Medicine Specialist by the University Complutense of Madrid and in Economics and Business Sciences by the University Autónoma of Madrid. Master in Public Health y Master in Health Policy and Management by the Harvard University. He worked as physician in the Internal Medicine Service of the Hospital Clínico San Carlos of Madrid, member of the Medical Inspectors of the Healthcare System, Managing Director of the Galician Health Service, Vicecounsellor of Healthand Social Services of the Comunidad de Madrid and Deputy Secretary of the Ministry of Health and Consumer Affairs. Likewise, he regularly advises several foundations devoted to the research 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).



#### COMMITTEES

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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 a 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 2005 seven 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 2015 met seven times.

#### **BOARD OF DIRECTORS**

During the year 2015, the Board of Directors was composed by 12 members who represent the main organizational areas of ROVI. The Board of Directors, which is 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.

- Mr. Juan López-Belmonte Encina. *Chief Executive Officer.*
- **Mr. Iván López-Belmonte Encina.** *Co-General Director and Director of Corporate Development.*
- Mr. Javier López-Belmonte Encina. Chief Financial Officer.
- Mr. Javier Ángulo García. Human Resources Director.
- Mr. Pedro Carretero Trillo. Director of Hospitals Network.
- Mr. Miguel Ángel Castillo Román. International Business Development Director.

- Mr. Pablo Domínguez Jorge. Administrative Financial Director.
- **Mr. José Eduardo González Martínez.** Deputy General Manager and Institutional Relations and Communication Director.
- Mr. Ibón Gutierro Adúriz. Corporate Research & Development Director.
- Mr. Fernando Martínez Morales. Sales Director Line B.
- Ms. Maite Muñoz Pineda. Sales Director Lines C and D.
- Mr. Miguel Ángel Ortega Sánchez. Industrial Director.

#### INTEGRATION OF CSR IN ROVI'S MANAGEMENT

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



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**Mr. Miguel Ángel Ortega Sánchez** Industrial Director

2 Mr. Javier Ángulo García Human Resources Director

**B** Mr. Fernando Martínez Morales Sales Director Line B **Mr. José Eduardo González Martínez** Deputy General Manager and Institutional Relations and Communication Director



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Mr. Pablo Domínguez Jorge Administrative Financial Director



Mr. Javier López-Belmonte Encina Chief Financial Officer

Mr. Juan López-Belmonte Encina Chief Executive Officer



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8 Mr. Ibón Gutierro Adúriz Corporate Research & Development Director

Mr. Miguel Ángel Castillo Román International Business Development Director

Mr. Pedro Carretero Trillo Director of Hospitals Network

Mr. Iván López-Belmonte Encina Co-General Director and Director of Corporate Development



Ms. Maite Muñoz Pineda 2 Mis. Waite Waite2 Finese Sales Director Lines C and D



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> THE BOARD OF DIRECTORS, DURING THE YEAR 2015, HAS CARRIED OUT THE DISTRIBUTION AMONG ITS MEMBERS OF THE AMOUNT OF 401,146 EUROS"

# 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 Annual General Meeting (AGM). The Board can distribute between the members the remuneration approved by the AGM, taking into account the functions and responsibilities performed by each of them in the Board itself or other objective circumstances that the Board of Administration considers relevant.

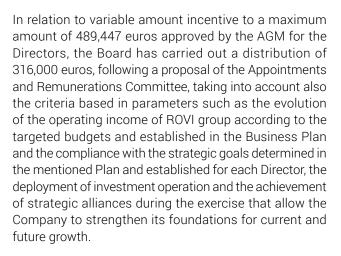


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Likewise, it is established for the executive directors a variable amount as an incentive linked to the results of the company and the achievement of objectives set that must be in line with company's interest, as well as the professional performance 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 AGM 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 2015, has carried out the distribution among its members of the amount of 401,146 euros of the maximum amount of 560,000 euros approved by the AGM in favour of the components of the Board of Directors as an annual fixed retribution for the year 2015 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 978,894 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 adjustments as per their contracts, the executive directors have received an amount of 925,254 euros as global fixed retribution.



The Board of Directors prepares an annual report about the remunerations of Directors, available in the *corporate website* (www.rovi.es) and in the *CNMV* (www.cnmv.es).

The staff from ROVI, which on the 31st of December 2015 was 1,098 employees, received an annual total gross remuneration of around 51 million euros during the year 2015.



# 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. 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 anti-corruption 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 2015.



# 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.



#### **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.

Fiscal risk inherent to the activity of companies of the size and complexity of the company.

ROVI IS CONTINUING WITH ITS TARGET OF CONSTANTLY OPENING UP NEW MARKETS AND IS WORKING INTENSIVELY TO MAINTAIN A BROAD AND DIVERSIFIED PORTFOLIO"

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. The company has a comprehensive risk control system in matters of taxation and external financial advisors that review the preparation and presentation of the different taxes as well as decision making on fiscal matters.

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### 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 probaaking an assessment of losses that

bility 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, among the financial or economic contingent liabilities, tax duties and other off balance sheet risks.



#### 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 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, those will be sent to

the Control and Risk Management Responsible to inform to the Audit Committee, as well as the measures planned for its evaluation and planned for its neutralization and evaluation, so that the Committee can discuss and evaluate in the framework of the general strategy and corporate objectives, as well as monitoring the evolution and mitigation of the impact. Furthermore, Audit Committee will keep the Board of Directors properly informed about the risk detected and the measures approved to deal with them.



#### **Risk arising in 2015**

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 the last years by Royal Decrees-Laws 4 and 8/2010, 9/2011, 16/2012 and, in particular, by the Royal Decree 177/2014, of the 21st of March, that regulates the reference price system and of homogeneous groups in the Health National System, and certain information systems in terms of financing and prices of medicines and health products and the successive Ministerial Orders by which is updated the reference price system on the National Health System, has lead to the most significant reduction in the pharmaceutical expenditure in our country since 2010. The effects of the reduction on the average expenditure per prescription of the measures approved during the year 2014 started being noticed from September of that that period and have been extended during the year 2015, although the impact for the company has been minimum as it only applies to four products that were already affected by discounts established in previous Royal Decrees. Respect to the new Order of reference prices approved in the year 2015, that includes a price reduction in several products of the Company, also is not expected a significant impact as they are products already affected by previous Royal Decrees.

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.

**G** THE MEASURES TO REDUCE THE PUBLIC EXPENDITURE IN THE AUTONOMOUS COMMUNITIES ARE ALSO CONTRIBUTING TO A CONSTANT FALL IN THE PHARMACEUTICAL DEMAND"



Although, in principle, the impact of these last measures has been minimum to ROVI thanks to the new 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.

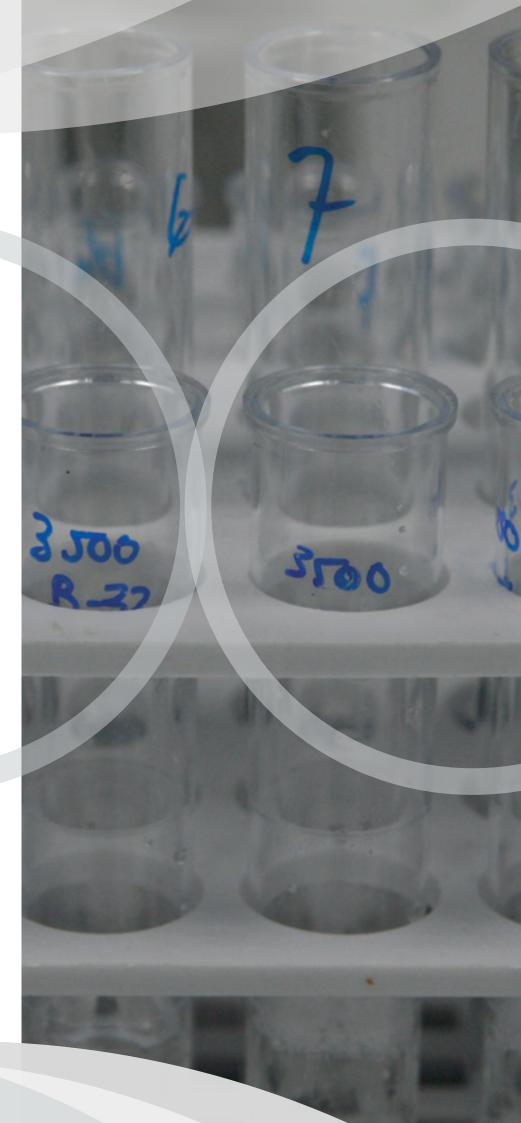


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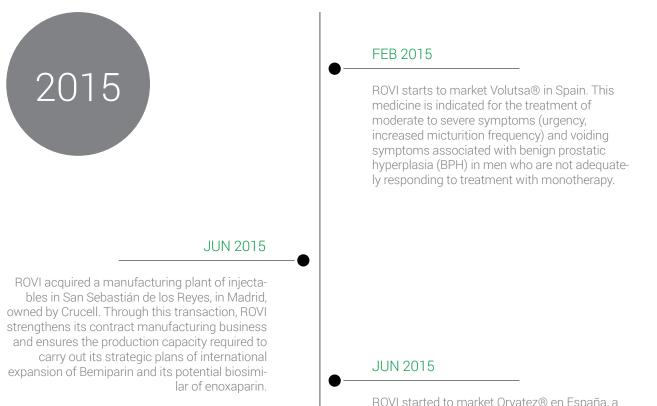


# YEAR 2015

- 75 Period results
- 90 Customers
- 93 Employees
- 100 Suppliers
- **104** Environment and society

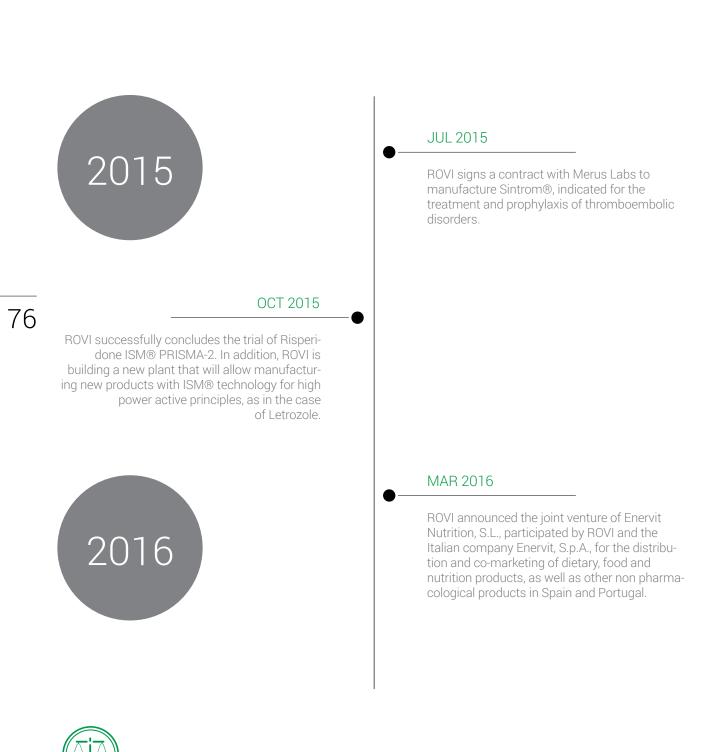


# Period results Highlighted facts



ROVI started to market Orvatez® en España, a product that combines two active principles, ezetimibe and simvastatine that act by inhibiting the two sources of origin of cholesterol.





# Economic results

ROVI demonstrated again in 2015 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 good results: total revenues were increased 3% in 2015 to reach the figure of 247.0 million euros, more than double the figure of total income registered in 2007 when ROVI carried out the Initial Public Offering (IPO).

EBITDA, by contrast, has been affected in 2015. The main causes were: (i) a reduction of 65% of the grants, (ii) an increase of 37% in the expenditure of research and development mainly due to the progress of the phase II study of Risperidone-ISM® and (iii) the launches of products as Hirobriz®, Ulunar®, Volutsa® and Orvatez®, that involved general, sales and administration expenses amounting 3.3 million euros in 2015.

With all this, EBITDA decreased 13% to 31.8 million euros, and implied a reduction in the EBITDA margin of 2.4 percentage points down to 12.9% in 2015. However, if the same amount of expenses in research and development were to be kept in 2015 than in 2014 and excluding, in 2015 and 2014, the impact of other income and launches of new products, the EBITDA would have increased 11% to a total of 38.6 million euros, what would have meant a growth in the EBITDA margin of 1 percentage point to 15.7% in 2015 from the 14.6% in 2014.

Net profit, for its part, decreased to 19.8 million euros in 2015, a drop of 18% respect the previous year. Again, if



the same expenditure in research and development of 2014 would have been maintained in 2015, and excluding, in 2015 and 2014, the impact of other income and launches of new products, the net profit would have increased 17% totalling 26.2 million euros.

Gross profit increased 2% in 2015, to 149.9 million euros, reflecting a decrease of the gross margin of 0.5 percentage points down to 61.0% in 2015 versus 61.5% in 2014. However, if we exclude the impact of the "other income" item (grants), the gross margin would have been increased up to 60.5% in 2015 compared to 60.3% in 2014. The reduction of the cost of Bemiparin raw material had a positive impact in the margin of the year 2015.

The expenses in research and development increased 37% to a total of 16.5 million euros in 2015 mainly as a result of the development of the study PRISMA-2, a phase II study in several USA centres to evaluate the safety and the pharmacokinetic profile of Risperidone-ISM® and



the performance of activities of development for the formulation of phase III study of Risperidone ISM® and of phase I of Letrozole-ISM®.

General, sales and administration costs increased 4% in 2015, compared to the previous year, up to 101.7 million euros, due to the launches of new products such as Hirobriz®, Ulunar®, Volutsa® and Orvatez®. Likewise, the increase of these expenses reflected the investment effort of ROVI in human capital to target pneumologists and primary care, main target of products like Hirobriz® and Ulunar®. Excluding the impact of these new product launches, general, sales and administration costs would have been increased in 2% in 2015, to 98.4 million euros.

Depreciation and amortization expenses were increased in a 12% in 2015 compared to the previous year, to a total of 10.0 million euros, as a result of the new purchases of fixed assets made in the last twelve months.

Sales outside Spain decreased in 3% totalling 82.8 million euros in 2015, compared to the same period of the previous year. The sales outside Spain represented 34% of the operating income in 2015 versus 36% in 2014.

The line other income (grants) was reduced 65% to reach one million euros in 2015 compared to 2.9 million euros in 2014.

GENERAL, SALES AND ADMINISTRATION COSTS INCREASED 4% DUE TO THE LAUNCHES OF NEW PRODUCTS"



### **Consolidated Balance**

ASSETS	2015	2014
NON-CURRENT ASSETS		
Property, plant and equipment	81,803	73,593
Intangible assets	18,881	17,206
Deferred assets	8,871	8,280
Available-for-sale financial assets	70	71
Financial receivables	139	137
	109,764	99,287
CURRENT ASSETS		
Inventories	63,859	67,567
Trade and other receivables	57,028	63,678
Current income tax assets	3,945	4,117
Cash and cash equivalents	29,251	26,671
	154,083	162,033
Total assets	263,847	261,320
EQUITY	2015	2014
CAPITAL AND RESERVES ATTRIBUTABLE TO SHAREHOLDERS OF THE COMPANY		
Share capital	3,000	3,000
Legal reserve	600	600
Treasury shares	-8,112	-2,813
Retained earnings and voluntary reserves	149,490	133,569
Profit for the period	19,809	24,116
Reserve for available-for-sale assets	-2	-2
Total equity	164,785	158,470
LIABILITIES	2015	2014
NON-CURRENT LIABILITIES		
	32,631	32,032
Deferred income tax liabilities	1,344	1,818
Non-current deferred revenues	5,861	6,883
Non current defence revenues	39,836	40,733
CURRENT LIABILITIES		
Trade and other payables	45,742	55,018
Financial debt	10,147	4,274
Current deferred revenues	840	798
Provisions for other liabilities and changes	2,497	2,027
To not on other nubling of und ondingeo	<u> </u>	62,117
Total liabilities	99,062	102,850
Total equity and liabilities	263,847	261,320



Thousand euros

### **Consolidated Income Statement**

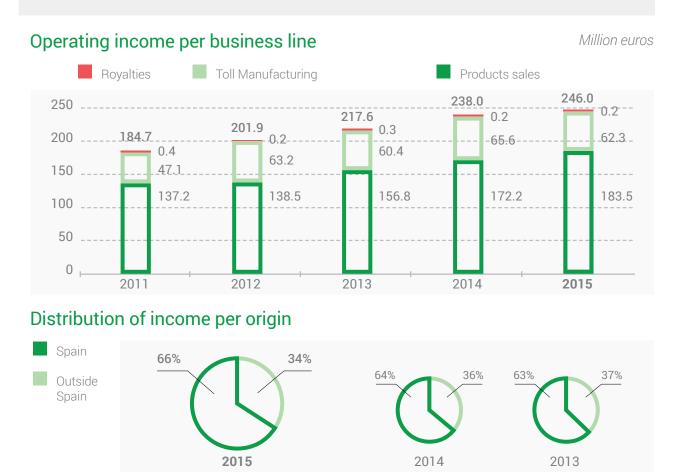
Thousand euros

	2015	2014	Variation (%)
Revenue	246,009	238,047	3.3%
Allocation of grants relating to non-financial assets and others	1,013	2,855	-64.5%
Total revenue	247,022	240,902	2.5%
Cost of sales	-97,075	-94,578	2.6%
Gross profit	<b>149,947</b>	<b>146,324</b>	<b>2.5%</b>
%	61.0%	61.5%	0.0pp
R&D expenses	-16,451	-11,978	37.3%
Selling, general and administrative expenses	-101,679	-97,770	<u>4.0%</u>
<b>EBITDA</b>	<b>31,817</b>	<b>36,576</b>	<b>-13.0%</b>
%	12.9%	15.4%	-0.2pp
Depreciation, amortisation and impairment charges	-9,975	-8,884	12.3%
<b>EBIT</b>	<b>21,842</b>	<b>27,692</b>	-21.1%
%	8.9%	11.6%	-0.2pp
Finance Income	837	545	53.6%
Finance costs	-1,781	-2,603	-31.6%
Finance costs-net	<b>-944</b>	<b>-2,058</b>	<b>-54.1%</b>
Profit before income tax	<b>20,898</b>	<b>25,634</b>	<b>-18.5%</b>
Income tax	-1,089	-1,518	-28.3%
Effective tax	5.2%	5.9%	-0.1pp
<b>Profit for the period</b>	<b>19,809</b>	<b>24,116</b>	<b>-17.9%</b>



### SALES GROWTH

Operating revenue increased by 3%, to 246.0 million euros in 2015, mainly as a result of the strength of the pharmaceutical specialties business, where sales increased 7%. Total income increased 3% to 247.0 million euros in 2015, more than doubling the total revenue of the year 2007, when ROVI was started its IPO.





### SALES OF PRODUCTS

The sales of prescription-based pharmaceutical products grew 7% reaching 150.5 million euros in 2015.

Sales of Bemiparin, the low molecular weight heparin (LMWH) of ROVI, had a positive performance in Spain in 2015, with a rise of 5% to 50.4 million euros. International sales remained stable in 24.7 million euros, due mainly to the launch of the product in China and Brazil in the last quarter, where the sales reached 0.9 million euros, recovering the deceleration of the sales of first nine months of 2015. The total sales of Bemiparin increased 3% in 2015, reaching 75.1 million euros.

### SALES OF BEMIPARIN HAD A POSITIVE PERFORMANCE IN SPAIN, WITH A RISE OF 5%"





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Sales of Vytorin®, Orvatez® and Absorcol®, the first of the five licences of MSD indicated as adjunctive therapy to diet in patients with hipercholestoremia, grew 14% in 2015, reaching 24.3 million euros.

Sales of Hirobriz® Breezhaler® and Ulunar® Breezhaler®, both bronchodilators by inhalation of Novartis aimed at patients with respiratory difficulties due to a lung disease called Chronic Obstructive Pulmonary Disease (COPD) that ROVI started to market in Spain in the last quarter of 2014, increased by 3.6 times reaching 7.5 million euros in 2015.

Sales of Volutsa®, a prescription product of the company Astellas Pharma indicated for the treatment of moderate to severe storage and voiding symptoms associated to benign prostatic hyperplasia, that ROVI distributes in Spain since February 2015, reached 3.2 million euros in 2015.

Sales of Medicebran® and Medikinet®, prescription products of the company Medice indicated for the treatment of the ADHD (Attention Deficit Hiperactivity Disorder) in children and teenagers, that ROVI distributes, on exclusivity basis, since December 2013, decreased 1% in 2015, totalling 7.4 million euros.

Sales of Corlentor®, a prescription product for chronic stable angina pectoris and chronic heart failure of the company Laboratories Servier, were reduced a 3% in 2015, reaching 13.4 million euros.

Sales of Exxiv®, a selective COX-2 inhibitor of MSD, decreased 14% in 2015 down to 5.9 million euros, mainly due to the market downturn of the COX-2.

Sales of Thymanax®, an innovative antidepressant of Laboratories Servier, that ROVI distributes in Spain under a co-marketing agreement since March 2010, decreased 28% in 2015 totalling 7.4 million euros.

According to IMS, the market of innovative products in Spain decreased a 0.9% in 2015 compared to the previous year. However, the sales of pharmaceutical products with prescription of ROVI increased 7% in 2015, outperforming the market in 7.9 percentage points.

Also, it is expected an annual rise of 0.6% of pharmaceutical expenditure in 2016, according to Farmaindustria<sup>9</sup>. Furthermore, the IMS Health<sup>10</sup> forecast for the pharmaceutical expenditure in Spain points to an annual growth rate of between 1.3% and 1.6% for the period 2016-2019. Despite the difficult situation the pharmaceutical industry is going through, ROVI expects to grow at higher rates than the forecast for the growth of pharmaceutical expenditure.

The sales of imaging contrast media agents for imaging diagnosis and other hospital products increased 7% in 2015, to 26.3 million euros.

The sales of over the counter products (OTC) and others decreased 5% to 6.7 million euros in 2015 compared to the previous year.



http://www.farmaindustria.es/web/documento/indicadores-basicos-del-sectorla-industria-farmaceutica-espanola-y-sumercado-en-cifras/.

<sup>10.</sup> IMS Health, Market Prognosis. September 2015.

#### **Toll Manufacturing**

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Toll Manufacturing sales decreased by 5% in 2015, totalling 62.3 million euros. The positive evolution of the injectable plant, whose revenue increased by 10% to 31.4 million euros in 2015, partially offset the 6.1 million euros revenue decline in the Frosst Ibérica plant, that reached 30.9 million euros in 2015, mainly as a result of a lower production for Merck Sharp & Dohme (MSD).

### **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 31st of December of 2015, ROVI had a total debt of 42.8 million euros. Debt with public administration, at 0% interest rate, represented at the time 34% of the total debt.

Bank borrowings increased in 7.6 million euros. In 2015, ROVI refinanced its bank debt with better financial conditions; banks debt increased in 10 million euros with type of interests applicable to the existing debt from 0.70% to 1%.

Financial expenses decreased 32% in 2015, compared with 2014, due to the accounting in 2014 of the interests linked to the return of loan granted by the Ministry of Health, Social Services and Equality for the development of the vaccine project in 2009. Also, the financial costs include the implicit interests accounted for refundable advances granted by the Public Administration at zero interest.

The item financial income increased 54% in 2015 respect to the previous year, as a result of higher returns obtained in financial investments, arising from exchange rate operations.

Free cash flow increased reaching 10.3 million euros in 2015 versus -1.6 million euros from the previous year mainly due to: (i) the decrease of 5.2 million euros in the acquisition and sales of fixed assets; (ii) the redution of 6.7 million euros in the item "Trade and other receivables"



in 2015, compared to an increase of 7.8 million euros in 2014; and (iii) the reduction of 3.7 million euros in the item "inventories", versus the increase of 8.8 million euros in 2014. These positive impacts were partially offset with the reduction in 9.3 million euros of the item "Trade and other payables" in 2015, compared to the increase of 11.5 million euros in 2014.

As of 31st of December of 2015, ROVI had a gross cash position of 30.7 million euros, versus 28.0 million euros as of 31st of December 2014, and a net debt of 12.1 million euros, compared to 8.3 million euros as of 31st of December 2014.

**30.7** MILLION EUROS

Gross cash position

ANNUAL REPORT 2015

### **INVESTMENTS**

ROVI has invested 19.9 million euros in assets in 2015, compared to the 25.1 million euros in 2014. From this investment should be highlighted the following:



The rest of investments made in 2015 correspond mainly to the acquisition of assets of the plant in San Sebastián de los Reyes.



### Consolidated Statement of Cash Flow

CASH FLOW FROM OPERATING ACTIVITIES 2015 2014 20.898 25.634 Profit before income tax ADJUSTMENTS FOR NON-MONETARY TRANSACTIONS: 9,975 8,884 Amortisation -837 -545 Interest income -2,013 2,865 Impairment losses 1,781 2,603 Interest expenses 470 -344 Net changes on provisions -638 -2.268 Grant for non-financial fixed assets and income from distribution licences **CHANGES IN WORKING CAPITAL:** 6,508 -7,746 Trade and other receivables 5,041 -11,229 Inventories -9.276 11.533 Trade and other payables **OTHER COLLECTION AND PAYMENTS:** Proceeds for distribution licences 110 210 -645 -2,658 Interest paid -1,982 -3,937 Income tax cash flow Net cash flow generated (used) from operating activities 29,392 23,002 CASH FLOW FOR INVESTMENT ACTIVITIES 2015 2014 -3,657 -4,201 Purchases of intangible assets -16,244 -20,853 Purchases of property, plant and equipment 41 38 Proceeds from sale of property, plant and equipment 16,201 Proceeds from avaible-for-sale financial assets -170 Contracting current bank deposits 365 776 Interest received Net cash flow generated (used) in investing activities -19,254 -8,450 CASH FLOW FROM FINANCING ACTIVITIES 2014 2015 Repayments of financial debt -5,671 -18,907 11,607 21,636 Proceeds from financial debt -6,546 -3,345 Purchase of treasury shares -8,346 -8,042 **Dividends** paid 1,398 1,376 Reissue of treasury shares Net cash flow generated (used) in financing activities -7,558 -7.282 Net variation in cash and cash equivalents 2,580 7,270 Cash and cash equivalents at the beginning of the period 26,671 19,401 Cash and cash equivalents at the end of the period 29,251 26,671



ANNUAL REPORT 2015

Thousand euros

### EVOLUTION OF THE MAIN R&D PROJECTS

### **Trade information**

### **Risperidona ISM®**

ROVI has successfully completed the trial of Riperidone ISM® PRISMA-2 and the final positive results were presented on March 2016 in the 24° European Congress of Psychiatry<sup>11</sup>.

#### Letrozol ISM®

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ROVI is building a new plant that will produce new products with the ISM® technology for high strength active principles, as in the case of Letrozole. After completing regulatory non-clinical studies with Letrozole ISM®, this product will start into clinical development. This new manufacturing plant will produce medication for the first study in humans with Letrozole ISM®, expected to start in the second half of 2016.

### **Biosimilar of enoxaparin**

Last 9th of February of 2015, after completing the validation phase, was started the evaluation process in Europe to obtain the marketing authorization by ROVI of a low molecular weight heparin, biosimilar of enoxaparin. The evaluation process is on progress as per the established schedule. ROVI's share has shown a good performance during 2015. The share price closed at 14.44 euros as of the 31st of December of 2015, representing more than 4 euros above the closing price in 2014. This variation has resulted in an increase in the shares revaluation of 40.2%.

The Board of Directors of ROVI will propose, to be approved in the Annual General Meeting, the payment of a dividend of 0.1390 euros per share payable, on the application of the results of 2015. This dividend proposal would involve the distribution of approximately 35% of consolidated net profit of year 2015.



Anta L, Llaudó J, Ayani I, Gorostidi B, Monreal M, Martínez-González J, Ochoa L, Gutierro I. Pharmacokinetics, Safety, And Tolerability Of Four 28 Days Cycle Intramuscular Injections For Risperidone-Ism 75 Mg In Patients With Schizophrenia: A Phase-2 Randomized Study (PRISMA-2). European Psychiatry.2016; 33S: S285. [24th European Congress of Psychiatry, Madrid (Spain)].

### Stock market information

Total number of shares	50,000,000
Listing price at closing	14.44 euros
Capitalization at 31/12	722,000,000 euros
Total dividend	6,950,000 euros
Dividend per share paid in 2015 on 2014 earnings	0.1690 euros
Dividend per share proposed on 2015 earnings	0.1390 euros
Pay out (as % of consolidated net profit)	35%
Earnings per share	0.40 euros
PER	36.1
Revaluation in 2015	40.2%



# Customers, patients and professionals

ROVI aims at the satisfaction of the needs and expectations of its customers, whether through the offering of "on-demand" services in its contract manufacturing area, as through a portfolio of products whose ultimate goal is improving the quality of people's lives.

The company has placed customers, patients, and professional as the main focus of its daily activity, with the conviction that by reaching a high degree of satisfaction and creating long term solid trust relationships, the growth objectives set by the group can be reached. ROVI is committed to guarantee the confidentiality of customers' data and not to disclose information to third parties.

The group considers essential to establish long lasting relationships based on proximity, a constant service based attitude and in trust.

## QUALITY IN MANAGEMENT AND PRODUCTION

Ensure the quality, safety and effectiveness of the products that the company places in the market, is the main objective of ROVI and of all the people that form part of the company. To do this, all the companies of the group have established procedures describing the controls performed in all the phases of the process, from research and development of products, reception of raw materials, packaging materials, production, storage and distribution to our customers.

The standards set meet completely with the internal demands of the company, but also with the external demands established by regulating bodies on the different products that form our portfolio.

In order to assess compliance with these procedures, internal audits are performed periodically in all the facilities of the group. There are yearly reviews in which the main points of improvement in our organization are analysed by the Management.

On the other side, the quality audits by external organizations evidence the commitment to continuous improvement and the maintenance of high quality standards.

In addition, and according to the frequency established in the legislation applicable to the products, all the companies of the group are inspected by the Health Authorities, both Spanish and of the countries where our products are exported.

### TREATMENT OF QUERIES

The company has available since 2008 of an exclusive *web site for international partners* (www.bemimed.com), aimed to strengthen business relationships and to create a bi-directional communication channel. Likewise, since 2009, ROVI has available a website for health professionals.



This has allowed the positioning of Bemiparin in a digital and interactive environment, making use of the new technologies to promote the exchange of promotional and scientific information of molecule, with the private network for partners, and to disseminate the latest developments in the fight against the venous thromboembolic disease and the use of Bemiparin with the scientific community.

In addition, in each of the companies of the group there are trained professionals to attend the main queries that could rise both in direct customers and to patients and professionals.

### TREATMENT OF COMPLAINTS

In all those cases in which a complaint is issued, an investigation is conducted to identify the root cause of the same. This investigation could involve several departments, or even our suppliers and our subcontractors. The analysis of these causes has as main purpose the adoption of measures to avoid recurrence of the same.

The efficacy of these actions is analyzed yearly, in the system review by ROVI's Management.

### TREATMENT OF ADVERSE REACTIONS

An adverse reaction is an unexpected or dangerous reaction to a drug, unwanted and harmful and that occurs when applying a dose in the human for prophylaxis, diagnosis or treatment of diseases, or for the restoration, correction or modification of physiological functions.

ROVI, as manufacturer and distributor of drugs, is committed to the safety of the patients that are administered its medicines. For that, the company has established the appropriate



THE QUALITY AUDITS BY EXTERNAL ORGANIZATIONS EVIDENCE THE COMMITMENT TO CONTINUOUS IMPROVEMENT" controls so that the medicines have the best balance riskbenefit. Furthermore, ROVI has implemented a pharmacovigilance system that allows detecting possible adverse reactions of its medicaments and health products.

ROVI has enabled the email *farmacovigilancia@rovi.es* for the notification of adverse reactions.

### **REINFORCE CONFIDENCE**

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.

### SUPPORT TO PATIENTS AND PROFESSIONALS

ROVI's *web page* (www.rovi.es) has enabled a section for patients where addresses useful advice and health campaigns:

#### Advices

Physical exercise and osteoporosis. Several exercises are described to contribute to the increase and maintenance of bone mass, key factor in the prevention of osteoporosis, and also increase muscle strength, coordination and balance.

#### **Health campaigns**

ROVI has joined the active promotion that the Ministry of Health, Social Services and Equality through several campaigns along the year:

- AIDS prevention
- There is a way out for the gender based violence.
- Early detection of cancer
- European Antibiotic Awareness Day.



# Employees

Employees are for ROVI a basic pillar in the development of the Company. Thus, offers possibilities of professional development and training in the company, social benefits, reconciliation measures, and a working environment in which health and safety are key aspects in the Human Resources management.

A good example of this is the commitment of the company with job creation. This commitment can be evidenced by the fact that, at the end of 2015, ROVI almost reached 1,100 employees, being a staff of highly qualified, young and dynamic professionals, based on equal opportunities. Personnel are one of the main pillars of its structure.

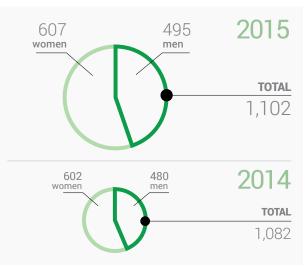
ROVI works to achieve the best collaborators for its projects. For this, the company focuses in an adapted loyalty policy. It also considers that the best flagships of the brand are their employees and promotes a constant, participative and open communication.

### MAIN MILESTONES

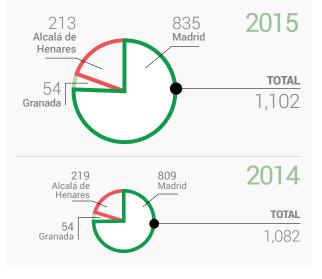
During 2015, ROVI has received the support of the Ministry of Economy and Finance for its work in Research and Development through the program EMPLEA. This program is intended, from one side, to encourage quality job creation promoting the development of R&D&I activities in companies, and from the other side, to achieve a collective of University Graduates specially trained to manage these types of activities, providing them with the necessary training.



### Average staff of ROVI



### Staff by location



### Staff by production plant

		2015			2014	
	PERMANENT	TEMPORARY	TOTAL	PERMANENT	TEMPORARY	TOTAL
Lab. Fcos. Rovi	385	52	437	389	54	443
Panquimica	77	2	79	31	2	33
Rovi Contract	261	107	368	229	150	379
Frosst Ibérica	180	33	213	192	27	219
Bemipharma	5	0	5	8	0	8
Total	908	194	1,102	849	233	1,082

Thanks to the funding received, ROVI has reinforced company's personnel through the recruitment of a licence qualified technologist for the performance of the R&D&I activity for the position of "Coordinator of phase III International trial for patients with schizophrenia".

### EQUAL OPPORTUNITIES

The right to equal treatment and non-discrimination and the principle of equal opportunities for men and women are essential to build a just society, socially and economically developed.

In this regard, ROVI has a clear positioning: 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.

### EVALUATION AND RETRIBUTION

Equal opportunities both internal and external, is a hallmark of ROVI. At the same time, to maintain its competitiveness, participates in different compensation studies of the pharmaceutical sector in order to attract and retain talent.

The remuneration policy is in line with the objectives of the company and takes into account two aspects: quality and efficiency. To involve employees in the progress of the business, part of the salary is variable and is associated to the achievement of personnel objectives.



### **Social Benefits**

All employees, regardless of their type of contract or employment, enjoy the same social benefits. Although there are no new benefits along 2015, the existing ones have been maintained:

### **Reconciling working and family life**

Gender Equality Act raises to the category of rights the different instruments for reconciliation of work and family life of workers to promote a balanced assumption of family responsibilities, avoiding any discrimination. The regulation of specific rights for reconciliation is established in the Workers' Statute for every person working in the private sector.

Collective agreements can, within their scope, extend these rights and sometimes required to be included in collective agreements.

ROVI's commitment to employees is a key to the success of the company. The reconciliation of working 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.

### **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.

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.

During 2015, almost 9,000 hours of training have been delivered, what represents approximately 8.2 hours of training per employee. The courses include training for middle management in leadership, teams' management, risks prevention as well as training in ROVI's products.

WOMEN

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People with reduced shift or making use of any option to reconcile working and family life



∕IEN ╋ **32**TOTAL



### CHEMICAL INDUSTRY WAGE AGREEMENT

ROVI's group is adhered to the Chemical Industry Wage Agreement. During 2015, was signed the XVII agreement and the company complies and implements some improvements respect to the same. 100% of employees are covered by this agreement or the one applicable to each working area (offices, sales, etc.).

ROVI keeps an appropriate understanding with workers representatives. In particular, ROVI has four trade union representatives.

#### **COMMUNICATION CHANNELS**

ROVI, aware of the importance of encouraging a flow of constant communication with its staff, has started, in 2015, a complaints channel that can be used by any employee of the company in case of detecting any breach of Code of Ethics.

In addition, ROVI has a specific confidential reporting channel for financial and accounting irregularities that could be detected.

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.



During the year 2015, in line with the philosophy of continuous improvement, several improvement opportunities have been implemented, affecting areas such as production, maintenance, laboratories, etc. This culture for identification of improvements is performed in workshops with the employees in all plants.

ROVI has encouraged among its collaborators different projects and activities linked to the CSR strategy of the company, as part of its activities of communication towards employees.

### HEALTH AND SAFETY AT WORK

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.

To achieve the knowledge and the involvement of its employees, ROVI has its own Prevention Service, responsible for performing actions like the promotion of a healthy life style, prevention of accidents and diseases or the communication through education and training campaigns. ROVI HAS ITS OWN PREVENTION SERVICE, RESPONSIBLE FOR PERFORMING HEALTH AND SAFETY AT WORK ACTIONS"



### **Education and training campaigns**

### "Healthy Company" project.

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During 2015, have been implemented several guidelines to make ROVI a "Healthy Company". In this area the following actions have been performed:

- Healthy breakfast.- Since April it has been implemented the "fruit day", in which two days a month employees can enjoy seasonal fruit in the different canteens of ROVI's companies.
- **Healthy vending**.- In the canteens have been installed healthy vending machines (salads, fruit, yogurt...) and machines dispensing natural orange juice.
- **Sport practices**.- The Safety and Environment department has reached agreements with different sports centres (i.e. gyms, riding centres), near the facilities of ROVI, to get competitive prices, that encourage our staff to practice sport.

 Companies' race. - Last December was held in Madrid the Companies Race. Several groups of employees took part on it in representation of ROVI.

#### Accidents prevention.

Different procedures have been developed to follow up and improve safety performance and health, to monitor the following aspects:

- Safety inspections of equipments and facilities, as well as working sites.
- Investigation of accidents.



During the year 2015, 0.9 million euros were invested in preventive actions for personnel health and safety, aiming to reduce at group level accident rate and improve the communication system in case of an accident due to a worker fainting in the case of performing the activity alone.

Likewise, in the plants and subsidiaries of the group have been implemented measures as awareness-raising actions in terms of health and safety, investments in machinery and infrastructure or the implementation of industrial hygiene programs. Also, some improvement suggestions, made by the personnel, relative to working conditions have been implemented. **G** DURING 2015, 0.9 MILLION EUROS WERE INVESTED IN PREVENTIVE ACTIONS FOR PERSONNEL HEALTH AND SAFETY"

### Work safety

	2015	2014
% of workers represented in Health and Safety at Work Commitee	100%	100%
Accident rate = (accidents nº/ workers nº)*100	2.9%	1.6%
Investment in Health and Safety at Work (million euros)	0.9	1.9



THE COMPANY HAS TWO MECHANISMS TO ENSURE AND PROMOTE THE ADOPTION OF GOOD SOCIAL CORPORATIVE PRACTICES IN ITS SUPPLY CHAIN"

### 100

# Suppliers

ROVI considers Suppliers as a group of strategic interest for our activities, and with this is mind has established some specific acting principles for its field of activity, according, in any case, with the company's principles and values. With this, it is intended to reinforce sustainability and competitive advantages of its value chain, encouraging the suppliers to follow equal opportunities policies and to express its commitment with basic principles of ethic and professional conduct.

The group tries to involve all its suppliers and subcontractors to adopt good practices in terms of corporate social responsibility, so that, like ROVI, regulate their 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

ROVI is aware of the importance of suppliers for its business, therefore, does its best to comply with its commitments of selection criteria and information transparency.

ROVI sends periodically to suppliers and subcontractors of the group a document entitled "commitment with CSR", in which is requested certifications such as SA-8000 or



request them to adopt good practices. Currently, more than 55% of these companies have signed this CSR commitment, although the objective is that all suppliers adhere 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 noncompliance 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.

### **AUDITS**

Environmental audits at ROVI aim to quantify achievements and the environmental position of the company. By doing so, the Company develops a similar function to financial audits. The report of an environmental audit includes a description of the performance and the environmental situation reached, and aim to identify pending requirements to maintain or improve the indicators of such performances and achievements.

During the year 2015, ROVI has performed 3 audits to suppliers in which has been evaluated compliance with environmental regulation. Likewise, ROVI has verified that, at group level, 61% of suppliers and subcontractors have ISO 14001 certification or EMAS.

### SUPPLIER'S CONTROL

ROVI has stipulated a series of manuals for standardized procedures for every supplier of product purchase in

which are established some guidelines as responsibilities precautions and instructions.

The manuals of procedures the company has available are the following:

- Initial assessment and follow up of manufacturers and subcontractors of health products;
- · Distribution of other health products;
- Contracts and monitoring of manufacturers and logistics operators;
- Import and distribution of the locator and extractor of lice and nits; and
- Evaluation and monitoring of transport companies.

Regarding large services suppliers, ROVI controls monthly the preparation of orders, the level of service as well as incidences or complaints that may arise.

# POLICY AND FLOW OF PAYMENTS TO SUPPLIERS

ROVI has, since 2013, an overall company policy for payments to suppliers that has the objective to establish a frame of relationships with suppliers and third party creditors, as well as ensuring the maximum effectiveness accounting the invoices and policy of payments, and also a greater homogeneity in the negotiations.

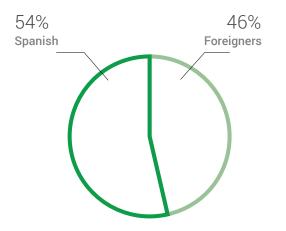
Each department of ROVI, if they need to hire a service to a new supplier must make sure that they do it according to the terms stipulated by the company and is responsible



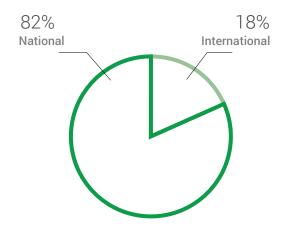
to chose raw materials, products, and services following the criteria that follow: best price, quality, environmental support, social responsibility and legal compliance, to get the best economic results, quality and service for company benefit. The policy of payments also establishes the conditions to negotiate discounts, payments in advance and other type of contractual conditions. The average period of ROVI for payments to suppliers in the year 2015 was 55 days.

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# Suppliers by geography purchases in euros ratio



# Number of Suppliers by Country

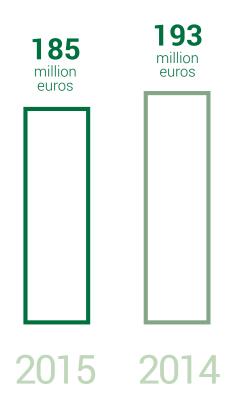


Approximately 2,100 suppliers



The number of suppliers in 2015 increased to 2,100 approximately, that represents an increase of 300 suppliers compared to the circa 1,800 of 2014.

# Average volume of orders







# Environment and society

### **Environmental objectives:**

### Environment

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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 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 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.



improvements in waste management, to allow recycling better, if possible.



During the year 2015, 340,884 euros were destined to environmental expenses, with the objective of improving dangerous waste management and reduce power, water and gas consumption. The main part was destined to the management of waste produced (237,720 euros), followed by the treatment of emissions into atmosphere (7,560 euros).

Additionally, the Environment Department performed investments to improve the facilities for a total amount of 95,604 euros. The main actions performed were:

#### In Alcalá de Henares plant:

- Flash recovery system.
- Energy efficient improvement cooling towers.

#### In Granada plant:

- Study of a VOC abatement system.
- Study of corrective measures for noise.

#### In Madrid plant:

- Phase 1 separating system OCS-INVES (line F4).
- Volume control G1 and G2.

GE 340,884 EUROS WERE DESTINED TO ENVIRONMENTAL EXPENSES, WITH THE OBJECTIVE OF IMPROVING DANGEROUS WASTE MANAGEMENT AND REDUCE CONSUMPTIONS"



### WASTE MANAGEMENT

Waste generation is inherent to the activity of ROVI. For this reason, and as part of the commitment to the prevention of pollution, processes related with waste are aimed to be minimized in the production process and a correct waste management, to facilitate its use and evaluate its use when possible.

### Waste management

	2015	2014	VAR
Tonnes of hazardous waste generated	519.06	838.22	-38%
Tonnes of non hazardous waste generated	852.58	817.52	4%
TOTAL	1,371.64	1,655.74	-17%



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### POWER CONSUMPTION

During the year 2015, the consumption of energy has been reduced in all the sources we use in our activities, evidencing the efficacy of awareness, raised among employees, and of the reduction measures implemented. The variation, per type, is as follows:

- Electric power consumption, in the group, has undergone a reduction of 6.8% compared to the values of year 2014, demonstrating that reduction schemes have been effective.
- Natural gas consumption, in those facilities that have this alternative available, has suffered decrease of 0.29%
- Fuel consumption has suffered a reduction of 5.37%.

Power consumption		
	2015	2014
kWh of electric power consumed	16,659,472	17,668,424
kWh of natural gas consumed	20,778,025	4,221,476
Litres of fuel vehicles	394,677	417,055
Reduction of electric power per unit manufactured	33.78%	-
Reduction of natural gas consumption per unit manufactured	8.58%	-



### NATURAL RESOURCES CONSUMPTION

During the year 2015, water consumption in our facilities has been 142,918 m<sup>3</sup> what means a 23% more than in the previous year. This increase, although is significant, has its origin in the increase of production.

#### ATMOSPHERIC EMISSIONS

In ROVI, and as contribution to the fight against climate change, we not only take into account the electric power consumption, but also we measure the emissions of  $CO_2$  from the consumption of natural gas and diesel, derived from electricity and vehicles, as well as other substances that act destroying the ozone layer.

# Natural resources consumption

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In order to reduce the effect of the emissions to the atmosphere of our centres, we have made an investment of more than 7,500 euros in active carbon. Furthermore, among the investments made, we have conducted a study of a new VOC abatement system in the Granada plant.

	2015			
m³ of water / million units manufactured	1.72	Atmospheric emissions		
			2015	2014
		Tonnes of CO <sub>2</sub> emitted*	8,219.76	5,123.88
		Reduction of tonnes of CO <sub>2</sub> emitted*	+ 64% (*)	-

(\*) During this year 2015 we haven't reduced the tonnes of  $CO_2$  calculated as those have been considered in the consumption of natural gas.



# ENVIRONMENTAL MANAGEMENT IN THE SUPPLY CHAIN

In 2015, 3 audits have been made to suppliers in which have been evaluated its compliance with environmental regulations. Likewise, it has been verified that, at a group level, 61% of suppliers and subcontractors have certification ISO 14001 or EMAS.

### TREATMENT OF ENQUIRIES

ROVI has established a procedure that describes the methodology followed for the treatment of queries related to the company's environmental behaviour. In this sense, during the year 2015 we have answered a total of 13 environmental consultations, mainly related to the system followed by ROVI for hazardous waste management.

### ACTIVE INVOLVEMENT

The companies that are part of ROVI group participate in several environmental protection organization, the main ones are:

- SIGRE
- ECOEMBES
- ECOLEC Foundation

### **OBJECTIVES FOR 2016**

For the current period, ROVI has set the following environmental objectives:

ISO

Implementation and certification of the environmental management systems, based in the standard ISO 14.001:2015.



In the Madrid plant is expected a reduction of 1%, respect to the figures of 2015, of the quantity of waste generated from expired products that have not come out to the sales channel.



In the Granada plant is planned the implementation and certification of a power management system based on the standard ISO 50.001:2011.



Also in Granada, is expected a reduction of 10% of paper consumption (measured in kg) compared to the figure of 2015.



The objective of the facilities at Alcalá de Henares is increasing the good environmental practices in the different areas.





#### MAIN EVENTS

World Environment Day.- On the occasion of the World Environment Day, celebrated on the 5th of June, the Safety and Environment Department prepared an awareness campaign under the slogan: "The value of each drop". In this campaign, besides giving a small commemorative gift, all personnel received an information pack aiming to raise awareness about the need of reducing resources.

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### 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. In 2015, the company donated more than 665,000 euros to institutions (mainly foundations and medical research associations) for this purposes.

### COMMITMENT WITH RESEARCH

In this context, it has launched an International Grants Award for Biomedical Research on Bemiparin, a low molecular weight heparin, indicated in the prophylaxis 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 55 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 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).

### COMMITMENT WITH TRAINING

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

### Commitment with social projects



### Spanish Paralympic Team.

During this year 2015, ROVI has become the sponsor of the Spanish Paralympics Team.



### Foundations "También" and "Deporte y Desafío".

As part of the support of ROVI to promote healthy practices in society, in 2015 the Management Team has approved the sponsor of training activities and support for social health activities for professionals (trainers, physiotherapists...) that collaborate with foundations "También" and "Deporte y Desafío". These are two non-profit private institutions, whose main purpose is the social integration of people with disabilities through sport. The collaboration of ROVI is aimed to the performance of skiing activities.

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 11th and 12th of April, 2015 in the slopes of Sierra Nevada.

During the year 2016, the company will continue this collaboration.



### Spanish Red Cross.

ROVI continues collaborating with Red Cross – Granada –, in particular this year with the sponsorship of the Flag Day, where all the funds raised during the day were destined to the Program of Attention to Asylum Seekers and Refugees.



### "Proyecto Hombre".

One more year ROVI has collaborated with "Proyecto Hombre"- Granada, in the development of programmes for the treatment of addictions and social reinsertion of drug addicts.



### **FISCAL POLICY**

The sustainability of the processes followed by ROVI demands an unwavering commitment of contribution to the economic and social development of the different markets in which we operate. This commitment is materialized in the tax sector mainly through the compliance with all tax obligations and the payment of all taxes, fees and tariffs that are accrued as a result of its business activities, according to the local and international legislation applicable.

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All the operations of ROVI are developed under a responsible and ethical prism in all aspects, including the fiscal one. For this reason, ROVI's fiscal policy ensures that the compliance of all tax obligations is carried out through ethical and responsible practices, according to the acting criteria established by the group. Also, ROVI does not use corporate structures or any other type in order to conceal, disguise or reduce the transparency of its activities to the tax authorities or to any other interested party.

### CONTRIBUTION TO LOCAL DEVELOPMENT

The activity of research, development and manufacturing of pharmaceutical products of ROVI is entirely developed in Spain. In this sense, the involvement of the company with innovation in the national territory has been reflected in its figures:

- The investment in R&D increased 37% in 2015, totalling 16.5 million euros.
- Acquisition of fixed assets, mainly aimed at their manufacturing plants in Madrid, Alcalá de Henares, San Sebastián de los Reyes and Granada, reached the figure of 19.9 million euros in 2015.

In this sense, ROVI has evidenced its commitment to local industrial structure with the acquisition of the injectable plant in San Sebastian de los Reyes, Madrid, in 2015.

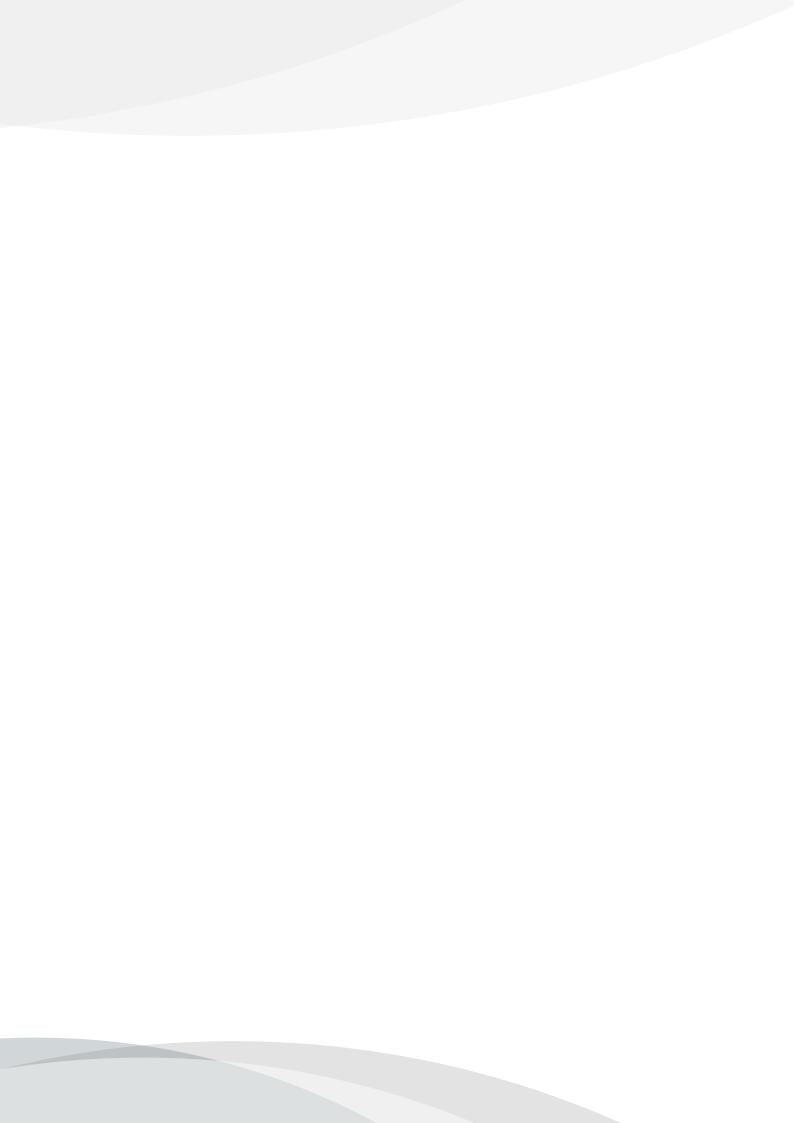
The work of ROVI has also an impact in the generation of local employment. Despite the economic crisis suffered in Europe in the last decade, ROVI has maintained a constant job creation in its work centres in Spain. In fact, the staff of ROVI as of 31st of December of 2015, with a total of 1,098 employees, exceed in more than double the personnel that had when started its IPO in 2007, incorporating more than 500 people from the 1st of April of 2010. A good example with the commitment with local and quality employment is the plant of Granada that counts with a high percentage of personnel with higher education, almost 70%, as the work performed in these premises requires a high professional qualification workforce.



### Economic value generated and distributed

	2015	2014	2013
Economic value generated (million euros)	247.0	240.9	220.3
Value distributed (million euros)			
Shareholders	7.0	8.5	8.1
Suppliers	137.0	134.3	121.8
Society	1.1	1.5	1.2
R&D	16.5	12.0	10.5
Employees	61.8	58.1	55.6
Capital suppliers	0.9	2.1	1.2
Amortizations and depreciations	10.0	8.9	6.9
Reserves (retained value)	12.8	15.6	15.0





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