



2016

ANNUAL  
REPORT



# CONTENTS



ANNUAL FINANCIAL  
STATEMENTS



ANNUAL CORPORATE  
GOVERNANCE REPORT

## 4 Key figures

5 Financial and non-financial figures  
10 Group profile

## 14 Letter from the Chairman

## 18 About this Report

## 20 Business model

21 Identity and commitment  
29 Business units

## 44 Strategy

45 Market environment  
48 Strategic and financial priorities  
50 CSR Strategic Plan

## 52 Corporate governance

53 Corporate governance model  
54 Corporate governance bodies  
67 Ethics framework  
68 Risk management

## 72 2016 reporting period

73 Results  
86 Customers  
89 Human resources  
98 Suppliers  
101 Society and public authorities  
105 Environment



# KEY FIGURES

**5** Financial and non-financial figures

**10** Group profile

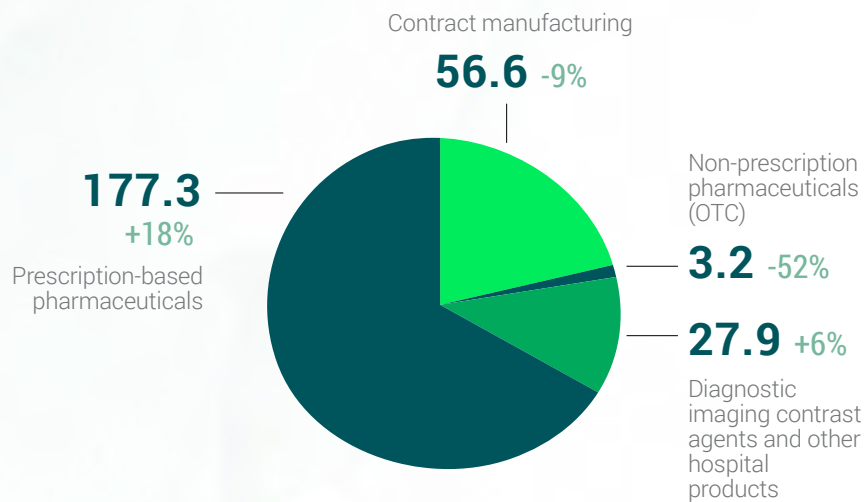
# Financial and non-financial figures

## Financial figures

Million euros

	2016	2015	2014
Results			
<i>Sales</i>	266.7	247.0	240.9
<i>EBITDA</i>	39.3	31.8	36.6
<i>EBIT</i>	28.3	21.8	27.7
<i>Net profit</i>	26.1	19.8	24.1
<i>Capex</i>	18.1	19.9	25.1
<i>Financial debt</i>	33.8	42.8	36.3
<i>Net financial debt</i>	9.0	12.1	8.3

## Sales by activity



**Key figures**

Letter from the Chairman  
 About this Report  
 Business model  
 Strategy  
 Corporate governance  
 2016 reporting period

	<i>(million euros)</i>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Financial structure	<i>Net debt/EBITDA</i>	<i>0.23</i>	<i>0.38</i>	<i>0.23</i>
	<i>Net debt/Equity</i>	<i>0.05</i>	<i>0.07</i>	<i>0.05</i>

	<b>2016</b>
Stock market information	
<i>Number of shares</i>	<i>50,000,000</i>
<i>Year-end closing price</i>	<i>12.33 euros</i>
<i>Capitalization at 31/12</i>	<i>616,500,000 euros</i>
<i>Total dividend</i>	<i>6,853,000 euros</i>
<i>Dividend per share paid in 2016 against 2015 profit</i>	<i>0.1390 euros</i>
<i>Proposed dividend per share against 2016 profit</i>	<i>0.1830 euros</i>
<i>Pay-out (as % of consolidated net profit)</i>	<i>35%</i>
<i>Profit per share</i>	<i>0.52</i>
<i>PER</i>	<i>23.6</i>

**Key figures**

Letter from the Chairman  
 About this Report  
 Business model  
 Strategy  
 Corporate governance  
 2016 reporting period

## Non-financial figures

### Human Resources

	2016	2015	2014
<i>Average number of employees</i>	1,126	1,102	1,082
<i>Net jobs created</i>	24	20	112
<i>Diversity (men / women)</i>	508 / 618	495 / 607	480 / 602
<i>By location</i>			
<i>Madrid</i>	860	835	809
<i>Granada</i>	54	54	54
<i>Alcalá de Henares</i>	212	213	219
<i>Hours of training</i>	636,059	9,000	85,330
<i>Turnover</i>	2.8%	2.9%	2.5%
<i>Accident rate</i>	1.3%	2.9%	1.6%
<i>Absenteeism rate</i>	2.9%	3.4%	2.0%

## Environment

	2016	2015	2014
<i>CO<sub>2</sub> emissions (tonnes)</i>	9,926.38	8,219.76	5,123.88
<i>Hazardous waste generation (tonnes)</i>	641.68	519.06	838.22
<i>Non-hazardous waste generation (tonnes)</i>	2,168.99	852.58	817.52
<i>Electricity consumed (kWh)</i>	17,846,340	16,659,473	17,668,424
<i>Natural gas consumed (kWh)</i>	23,187,891	20,778,025	4,221,476
<i>Vehicle fuel consumed (litres)</i>	454,705	394,677	417,055



**Key figures**

Letter from the Chairman  
 About this Report  
 Business model  
 Strategy  
 Corporate governance  
 2016 reporting period

## Community

	2016	2015	2014
<b><i>Economic value generated (million euros)</i></b>	270.8	247.0	240.9
<b><i>Value distributed (million euros)</i></b>			
<i>Shareholders</i>	9.1	7.0	8.5
<i>Suppliers</i>	153.5	137.0	134.3
<i>Company</i>	1.8	1.1	1.5
<i>R&amp;D</i>	17.5	16.5	12.0
<i>Employees</i>	60.5	61.8	58.1
<i>Providers of capital</i>	0.5	0.9	2.1
<i>Amortization and depreciation</i>	11.0	10.0	8.9
<i>Reserves (retained value)</i>	17.0	12.8	15.6



## Key figures

Letter from the Chairman  
About this Report  
Business model  
Strategy  
Corporate governance  
2016 reporting period

# Group profile

*ROVI is a specialized pharmaceutical company engaged in the research, development, manufacturing and marketing of pharmaceutical products. Its operations encompass the marketing of both its own and licensed products and the provision of services, such as production, filling, packaging and running clinical trials, to other companies.*

On its own product portfolio, special attention should be drawn to Bemiparin, which is currently distributed in more than 55 countries through strategic alliances and has become one of the leading therapeutic propositions for the prevention and treatment of venous thromboembolism.

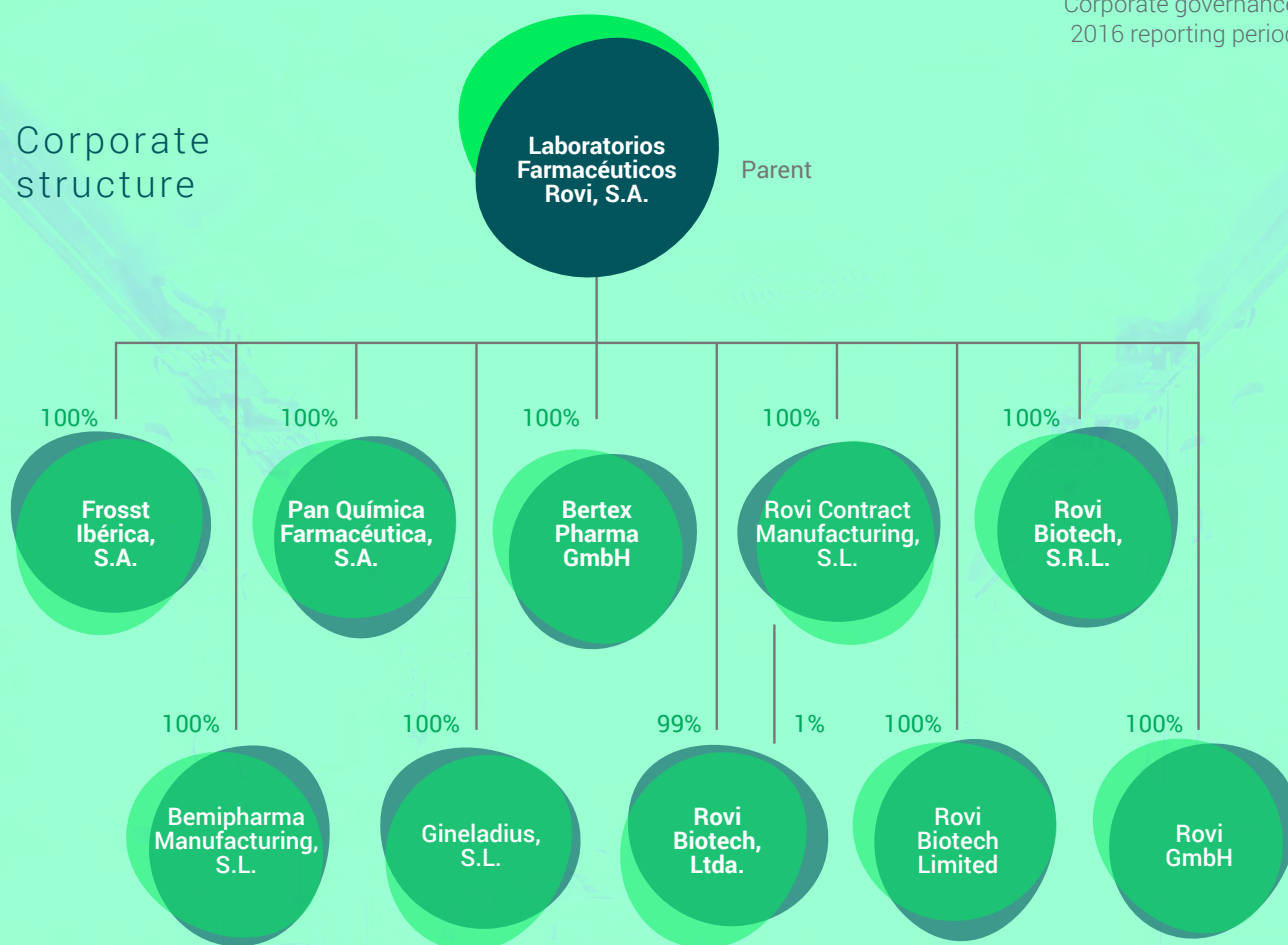
In addition, the Company provides a wide range of services to other companies, ranging from product manufacturing, filling, packaging and distribution to running clinical trials.

## Corporate information

<i>Name:</i>	<i>Laboratorios Farmacéuticos Rovi, S.A.</i>
<i>Address:</i>	<i>Julián Camarillo, 35 28037 Madrid. Spain</i>
<i>Telephone:</i>	<i>0034 91 375 62 30</i>
<i>Website:</i>	<i>www.rovi.es</i>
<i>Share capital:</i>	<i>3,000,000.00 euros</i>
<i>Number of shares:</i>	<i>50,000,000</i>
<i>Par value:</i>	<i>€0.06 share</i>
<i>Activity:</i>	<i>Manufacturing and marketing of pharmaceutical products and contract manufacturing services.</i>
<i>Markets:</i>	<i>The ROVI Group has direct presence in Spain and Portugal and is listed on the Barcelona, Bilbao, Valencia and Madrid Stock Exchanges.</i>

**Key figures**

Letter from the Chairman  
About this Report  
Business model  
Strategy  
Corporate governance  
2016 reporting period

Corporate  
structure

Corporate name	Address	Activity
Pan Química Farmacéutica, S.A.	Madrid, C/Rufino González, 50 (Spain)	
Gineladius, S.L.	Madrid, C/Rufino González, 50 (Spain)	
Rovi Contract Manufacturing, S.L.	Madrid, C/Julián Camarillo, 35 (Spain)	
Bemipharma Manufacturing, S.L.	Madrid, C/Julián Camarillo, 35 (Spain)	
Bertex Pharma GmbH	Inselstr.17. 14129 Berlin (Germany)	
Frosst Ibérica, S.A.	Alcalá de Henares, Avenida Complutense, 140, Madrid (Spain)	
Rovi Biotech, Ltda.	La Paz (Bolivia)	
Rovi Biotech Limited	10-18 Union Street, London (United Kingdom)	
Rovi Biotech, S.R.L.	Via Monte Rosa 91, Milan (Italy)	
Rovi GmbH	Ruhlandstr. 5, Bad Tölz (Germany)	

Manufacturing, marketing and sale of pharmaceutical, health and medicinal products

Import, export, purchase, sale, distribution and marketing of articles related to comprehensive women's healthcare

Development, distribution and trading of pharmaceutical products related to microparticle technology

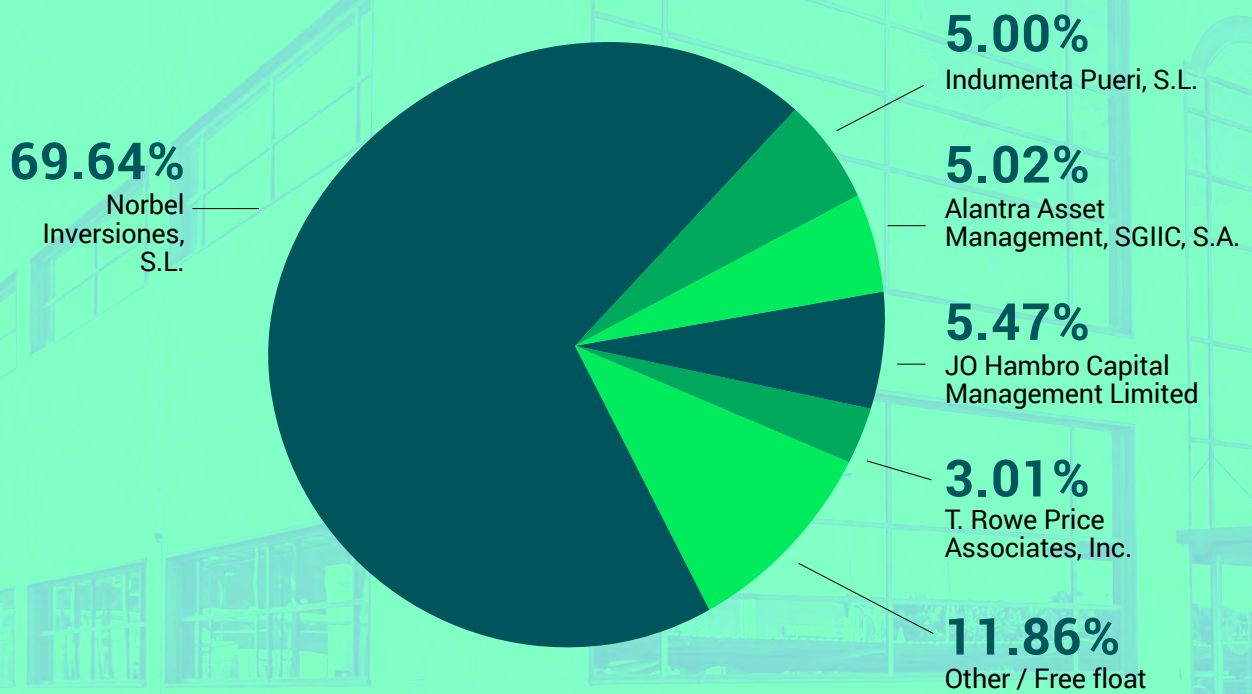




### Key figures

Letter from the Chairman  
About this Report  
Business model  
Strategy  
Corporate governance  
2016 reporting period

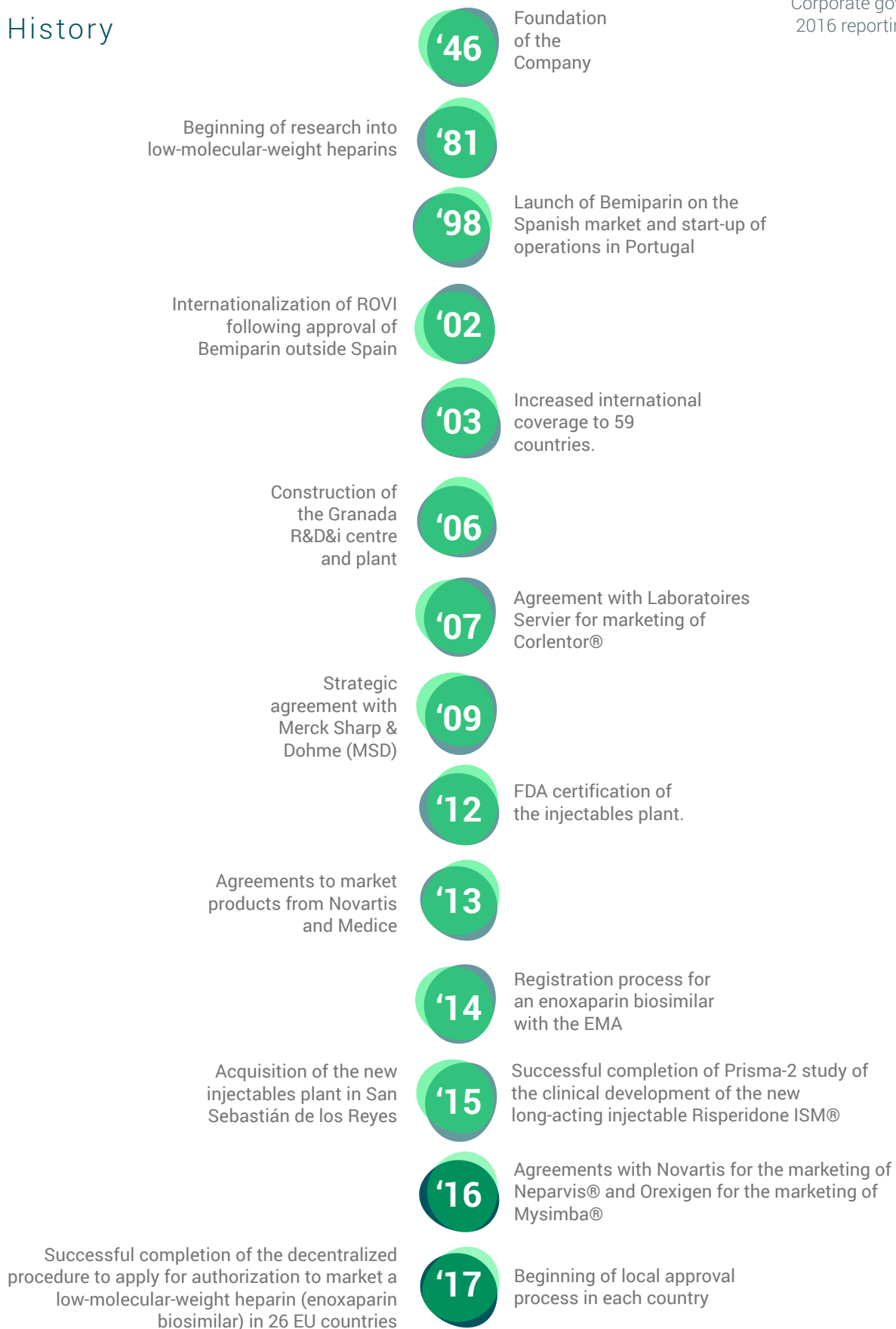
## Shareholders



**Key figures**

Letter from the Chairman  
 About this Report  
 Business model  
 Strategy  
 Corporate governance  
 2016 reporting period

## History





**Letter from  
the Chairman**

## *The strength of our prescription-based pharmaceutical business has, once again, been the Group's driving force*

Dear shareholders,

For a further year, I have the satisfaction of addressing you to take stock of ROVI's business evolution in 2016. The information that we provide forms part of the commitment to transparency and good corporate government that we have assumed with both our shareholders and the Company's other stakeholders.

Like the preceding one, this report presents, in an integrated manner, transparent and relevant information on the Company's activity in 2016 in both financial and non-financial aspects. We feel that a global view of the business and the management of its impact on the environment allows both the Company's development and the progress in its sustainability strategy to be properly assessed at the same time.

As a result of our solid business model and the stable position that ROVI enjoys in a complex market with high entry barriers in the different Autonomous Regions of Spain, our operating revenue grew by 8% in 2016. The strength of our prescription-based pharmaceutical business has, once again, been the Group's driving force and sales increased by 18% in the period, amply surpassing the behaviour of the pharmaceutical market.

This has led to outstanding results, with net profit growing by 32% in comparison to 2015 and totalling 26.1 million euros, and EBITDA of 39.3 million euros, i.e. 24% higher.

### **Solid track record in a complex market**

The pharmaceutical market in Spain continues to be complex and, if we have already had to tackle a complicated situation in previous years, a new adjustment of 550 million euros is forecast in the pharmaceutical expenditure

planned for 2017 –according to the Budget Plan sent by the Spanish government to the European Commission<sup>1</sup>–, while the QuintilesIMS forecasts<sup>2</sup> for the sector indicate a 1%-4% growth rate to 2021. Even with these prospects, we expect the growth rate of ROVI's operating income to be between 1% and 5% for 2017.

However, according to the same consulting firm, the innovative product market in Spain grew by 4% in 2016 and, not only is ROVI prepared for this future growth factor, but it is in a superb position, given the solidity of its product portfolio.

This is why we are confident we will continue to increase our business as a result of, among other factors, our benchmark product Bemiparin, which continues to contribute to strengthening our growth. Specifically, in 2016, Bemiparin sales rose by 9% in the domestic market and 1% outside Spain, attaining total sales of 79.7 million euros.

Furthermore, ROVI has sound product projects with excellent expectations for forthcoming years, such as the reinforcement of the cardiovascular franchise through the launch of Neparvis®, a Novartis product with a high strategic value, and Orexigen's Mysimba®, a new pharmacological alternative to treat obesity, in Spain. Marketing of both these products commenced at the beginning of 2017 and we expect them to be of key importance for the Company's short- and medium-term results.

These are the latest products to be included on a solid and diversified portfolio, on which other products, including Hirobriz® Breezhaler® and Ulunar® Breezhaler®, increased sales by 64% in 2016, totalling 12.2 million

<sup>1</sup> [http://www.mineco.gob.es/stfls/mineco/comun/pdf/161017\\_plan\\_presupuestario.pdf](http://www.mineco.gob.es/stfls/mineco/comun/pdf/161017_plan_presupuestario.pdf)

<sup>2</sup> Outlook for Global Medicines through 2021. Report by the QuintilesIMS Institute.



***Bemiparin sales rose by 9% in the domestic market and 1% outside Spain, attaining total sales of 79.7 million euros***

euros. Volutsa®, of Astellas Pharma, doubled its sales in the urology sector, which rose to 6.9 million euros. We can also highlight the reinforcement of the hypercholesterolemia franchise, with Orvatez®, of Merck Sharp and Dohme (MSD), which, together with Vytorin® and Absorcol®, grew by 38%, totalling 33.5 million euros.

These recent launches cover our needs in the face of growing demand and we expect them to provide us with an opportunity for sustained and profitable future growth.

Additionally, the agreement with MSD will allow us to launch four more products over the next two years, which will contribute to the Company sustained long-term growth, since it will extend the average life of our product portfolio by several years.

In addition, we cannot ignore the decrease in the sales of our contract manufacturing business. This drop is mainly due to lower production for MSD since 31 March, 2015, when the initial contract with this company expired. During 2016, we worked intensively to acquire new customers, in order to take advantage of the capacity of our Frosst Ibérica plant, as may be seen from the agreement signed with Merus Labs to manufacture Sintrom® as from the third quarter of 2016 onwards. This is already helping to strengthen this business line and will continue to do so.

**The “core” of ROVI’s business: R&D&i**

Likewise, we are confident of the potential of our current R&D projects, in which we are making a significant investment effort, since we trust they will be our growth engine in the future. We are excited about the potential of ISM® technology. In particular, we hope to commence the phase II clinical trial for Risperidone ISM® in the second quarter of 2017 and to develop a new phase I study for another candidate, Letrozol ISM®, an a long-acting injectable aromatase inhibitor for treating hormone-dependent breast cancer.

Furthermore, we are especially satisfied with the successful completion of the decentralized procedure for registration of an enoxaparin biosimilar in Europe, which will be one of our pillars for immediate development. We have now obtained the approval of the European authorities and, if all runs according to schedule, we will have national authorization from the 26 European countries in which ROVI hopes to market the product before the end of the year.

**Shareholder remuneration against excellent results**

Although we cannot say that the behaviour of the ROVI share was optimal in 2016, ROVI’s business showed a sound statement of financial position and the capacity to finance its organic growth. The operating leverage provided by the latest product launches allows ROVI’s attractive prospects to be maintained as a profitable long-term investment and, in view of the results obtained, the dividend for the period has been increased by 32% to 0.1830 euros per share, representing a pay-out to group shareholders of approximately 35% of the 2016 net consolidated profit.

Ten years have passed since our initial public offering and many shareholders have remained with us since then. I thank them for their loyalty. It is true that those who have invested in ROVI have made significant capital gains, since the behaviour of our share has shown it to be one of the



most stable, safe and profitable securities, especially at a time when there is a low return on money.

### **Decided commitment to Corporate Social Responsibility and sustainability**

Another of ROVI's pillars over the more than 70 years of its existence has been its belief in the value of supporting research, education and the environment, cultivating a responsible relationship with all the groups with which it has connections, including employees, shareholders, suppliers and the rest of society.

In this respect, in 2016, we doubled the amount assigned to environmental expenses, where the greatest increase took place in investments in environmental improvements at our facilities, which tripled in comparison with 2015.

### **Looking forward**

A sound business model that is profitable even in the worst environment, leading-edge research activity that materializes in innovative products and high sales prospects in new market niches, and a professional team committed to the highest quality standards are ROVI's guarantees for the future.

Regarding forthcoming months and years, the group has significant growth prospects as a result of the launch of new licensed products in markets where the Company is already a benchmark, the announcement of new contracts in our contract manufacturing division, thus recovering from the lower pace in 2016, and the culmination of various R&D&i projects, which will result in leading-edge products with high probabilities of success.

Our country, Spain, has a higher growth rate than the European average and it is growing within the framework of the European Union.

Our four plants are located in Spain. ROVI is an example of reliability in the training of its employees and managers and we do not seek low-cost alternatives elsewhere.

Our R&D centre is likewise located in Granada. I would like to highlight the good work carried out by the R&D team. Research, improvement and the contribution of value-added to our product portfolio represent our survival and the future of our share on the stock markets.

Let me tell you about our very talented employees: we have them and they have created a reality, not simply a hope for the future. In research, results are necessary and ROVI has them now and will continue to have them in the future.

It only remains to thank all those involved in this magnificent company. The shareholders, for the trust they place in us, ROVI's Management Committee, and each and every one of the Company's professionals, since these are the people who are really responsible for the group's successes and its prestige as a benchmark in the pharmaceutical market, both in Spain and elsewhere.

Juan López-Belmonte López

Chairman



**ABOUT  
THIS REPORT**



Any queries regarding  
this Report may be sent to:

This Annual Report includes relevant information on ROVI in relation to financial and strategic aspects and ESG (environment, social and governance) in 2016. The previous report was drawn up in 2016 and included information on the 2015 calendar year. The information provided in this document relates to the Company as a whole, except where specified otherwise.

The structure of the information contained herein follows the Integrated International Reporting Council (IIRC) framework [IR] and, for non-financial aspects, the Global Reporting Initiative (GRI) G4 Sustainability Reporting Guidelines.

This Annual Report also contains information based on forecasts for the future. Information of this nature implies known and unknown risks, uncertainties and other factors that may mean that ROVI's results, profitability or actual achievements, or its industrial results, differ materially from the results, profitability or future achievements set out or implied in such forecast-based information.

The information contained in this document represents ROVI's prospects and forecasts at the date hereof. ROVI wishes to make it clear that future events and developments may lead to changes in these prospects and forecasts. Notwithstanding, although ROVI may choose to update this information with new forecasts at some point in the future, it expressly wishes to state that it is under no obligation to do so. These forecasts should not be relied upon as representing ROVI's prospects or forecasts at any date subsequent to the date hereof.

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### **Materiality analysis**

This 2016 Annual Report discusses issues that are material to the Company, either because they reflect significant economic, environmental and/or social effects of the organization, or because they affect stakeholders. ROVI is working on a materiality study to define and classify material issues and confirm them with the stakeholders. The results of this study will be available in the 2017 Annual Report.



# BUSINESS MODEL

21 Identity and  
commitment

29 Business  
units

# Identity and commitment

## Mission, vision and values

### Mission

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

### Vision

ROVI aspires to be recognized as a benchmark for research and the manufacture of products to improve health.

### Values

- |  |   |
|--|---|
| <b>01</b> We are the Company's main asset.                               | <b>06</b> We make our customers' concerns our own and share their successes.        |
| <b>02</b> We feel changes to be real opportunities for development.      | <b>07</b> Our diversity in training, experience and points of view makes us better. |
| <b>03</b> It is important to feel that we learn something new every day. | <b>08</b> We are committed to innovative drugs as a growth engine.                  |
| <b>04</b> We like to assume responsibilities from start to finish.       | <b>09</b> We demand strict ethical standards of ourselves and our partners.         |
| <b>05</b> We know we have to win the patients' trust day by day.         | <b>10</b> Our final success depends on the effort of all of us.                     |

## CSR Management at Laboratorios ROVI

Corporate social responsibility (CSR) is a crucial part of ROVI's identity and is incorporated into the Company's business strategy to ensure its long-term sustainability and reinforce the confidence of our stakeholders.

CSR is a commitment that ROVI has acquired with society, given the importance of the Company's work and products in improving human health and quality of life. Therefore, over recent years, the Company has carried on intensive activity to support research and foment the prevention and knowledge of certain diseases.

ROVI's commitment to ethical management and transparency is reflected in the new General Corporate Social Responsibility Policy approved by the Board of Directors in 2015 and updated at the Board Meeting held on April 20, 2017. Additionally, ROVI is currently reviewing its CSR strategy and is committed to approving its CSR Strategic Plan 2017-2020 in 2017.

### CSR policy objectives and support tools

All the companies that belong to the ROVI Group are aware of the health improvements their products provide and would like to meet certain social demands in relation to the impact of their activities on society and the environment.

Therefore, ROVI's economic development must be compatible with its conduct in relation to ethics, society, the workplace, the environment and respect for human rights.

Knowing these values, making them known to others and implementing them express the Group's commitment in relation to business ethics and corporate social responsibility and provide guidance for the actions of ROVI's Board of Directors and other governing bodies in their relations with stakeholders.

The support tools that have been developed are:

**THE CORPORATE SOCIAL RESPONSIBILITY POLICY**

**THE INTEGRATED MANAGEMENT POLICY**

**THE CODE OF ETHICS**

**THE ANNUAL CORPORATE SOCIAL RESPONSIBILITY REPORT**

When these tools are put into practice, they should:

- Favour attainment of the Group's strategic objectives.
- Improve the Group's competitiveness by implementing management practices based on innovation, equal opportunities, productivity, profitability and sustainability.
- Manage risks and opportunities derived from the changing environment responsibly, maximizing the positive impacts of the Group's activities in the different territories where it operates and minimizing any adverse impacts as far as possible.

- Promote a culture of ethical conduct and increase business transparency, in order to generate credibility and confidence among stakeholders, including society as a whole.
  - Promote trust relationships and value creation for all stakeholders, providing all of them with a balanced and integrating response.
- As a result, in order to pursue these objectives appropriately, the following general principles for action have been put in place.

*ROVI's commitment to ethical management and transparency is reflected in the new General CSR Policy, updated on April 20, 2017*



## General principles for action



### *Compliance with legal regulations*

*Compliance with legal regulations in the places where ROVI companies are located.*



### *Support the principles of the United Nations Global Compact*

*Support the principles of the United Nations Global Compact by adopting and transmitting them, as well as those of other international instruments, especially in the areas of human rights, workplace practices, the environment and anti-corruption.*



### *Follow the guidelines of the Code of Ethics*

*Follow the guidelines of the Code of Ethics, which includes the Company's commitment to the principles of business ethics and transparency in all its spheres of action and regulates responsible conduct on the part of all Group professionals in the course of their work.*





### Promote free market practices

Promote free market practices, rejecting any kind of illegal or fraudulent practice and implementing effective mechanisms to prevent, monitor and penalize irregularities.



### Conservation and promotion of the environment

ROVI carries on its activity with the firm commitment of contributing to sustainability from an environmental standpoint. This commitment materializes by integrating the environment into the different business areas, conserving biodiversity, preventing pollution, managing resources efficiently and adapting and mitigating climate change, in accordance with the Group's Environmental Policy.



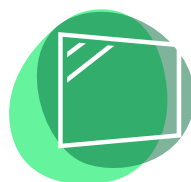
### Tax responsibility

The taxes ROVI pays in the places where it operates are the main contribution that Group companies make to sustaining public funds and, therefore, are one of its contributions to society.



### Improvement of communication and dialogue channels

Improvement of communication and dialogue channels, as well as promoting the Group's relations with shareholders, investors, employees, customers, suppliers and, in general, all its stakeholders. Thus, the Group contributes to harmonizing business values and social expectations by adapting, as far as possible, the Group's policies and strategies to the interests, concerns and needs of stakeholders, using all the communication tools available, including direct contact and the Group's corporate website.



### Commitment to transparency

Commitment to transparency as a way to transmit confidence and credibility among stakeholders. This will entail:

- a. Providing stakeholders with relevant and accurate information, complying with any legal public information requirements that may exist.
- b. Preparing and publishing financial and non-financial information, using, in the latter case, an internationally-accepted methodology and submitting the information to the appropriate internal and external review processes that guarantee the reliability of the information and encourage continuing improvement.

## Identification of and relations with stakeholders

Awareness of stakeholder expectations forms part of ROVI's CSR strategy. Therefore, the Company strives to maintain smooth and constant dialogue to detect and respond to their interests, thus ensuring the business's long-term viability.

The Company has identified six groups that contribute, either directly or indirectly, to good business results and, in this respect, ROVI has the following objectives:

### Stakeholders



## *Awareness of stakeholder expectations forms part of ROVI's CSR strategy*

### Communication channels

The Company has put a number of communication and consultation channels in place in order to find out the needs of its stakeholders and respond to their expectations.

#### **Employees**

Employees may use the suggestion boxes that can be found throughout the facilities and are intended to facilitate anonymous communications concerning improvements.

Furthermore, ROVI has a mechanism that allows its employees to notify any irregularity that could be deemed illegal, criminal or a breach of the principles of ROVI's Code of Ethics confidentially and, if seen fit, anonymously.

This mechanism seeks to improve the monitoring and control measures that all listed companies must have in place to prevent activities that are criminal or illegal or that breach its internal ethics principles.

#### **Suppliers**

ROVI periodically sends, on a voluntary basis, a document called "CSR Commitment" to all the Group's suppliers and subcontractors. This document requests certifications or urges them to adopt good practices.

Likewise, on-site audits are performed to check that suppliers operate in accordance with national and local regulations, that there are no significant breaches of workplace safety rules and that no practices infringing workers' rights exist.

#### **Shareholders**

Since the Company was first listed on the stock markets, it has reported regularly on all its activities and keeps its "Policy for Communication with Shareholders, Institutional Investors and Proxy Advisors" updated, ensuring that it is applied.

ROVI considers responding to queries and requests made by shareholders and investors to be a priority, in order to keep them updated on the Group's activities. As an example of this commitment to transparency, the Company has made a number of direct communication channels available to shareholders and investors, such as the e-mail address [ir@rovi.es](mailto:ir@rovi.es), and information may be requested through the corporate website. Additionally, shareholders have the possibility of receiving ROVI's financial information automatically through an e-mail alert system.

Furthermore, regular, prompt and relevant information on the Company is provided, such as presentations, legal documents on economic and financial aspects and corporate governance documents, which may be consulted on the corporate website: [www.rovi.es](http://www.rovi.es).

#### **Customers**

There is a query channel for information requests from both international partners, through an exclusive portal ([www.bemimed.com](http://www.bemimed.com)), and direct customers, patients and professionals. In the event of a complaint, the Company commences investigations immediately in order to identify the cause and prevent any repetition.



*The Company has carried on intensive activity to support research and foment the prevention and knowledge of certain diseases*

## Society and environment

ROVI's commitment to society and environmental protection is firm and constant and forms part of its day-to-day activities.

The Company's environmental policy is based on commitments to continuous improvement, legal compliance and additional voluntary requirements. In relation to environmental queries, ROVI has a corporate procedure (SOPc813 "Communication, Participation and Consultation") through which it manages

communications (queries, complaints, etc.) related to the environment and occupational health and safety. On the corporate website ([www.rovi.es](http://www.rovi.es)), the quality, environmental and occupational health and safety certifications held by Group companies are available to the public.

Furthermore, ROVI uses part of its resources to promote medical research. Over recent years, the Company has carried on intensive activity to support research and foment the prevention and knowledge of certain diseases.

## Business units

ROVI is a leading pharmaceutical company engaged in the research, development, manufacturing and marketing of pharmaceuticals. It has three principle pillars of growth:



### *Pharmaceutical specialties.*

*With a diversified portfolio of both its own and licensed innovative products, protected by patents.*



### *Contract manufacturing of prefilled syringes and oral solid forms.*

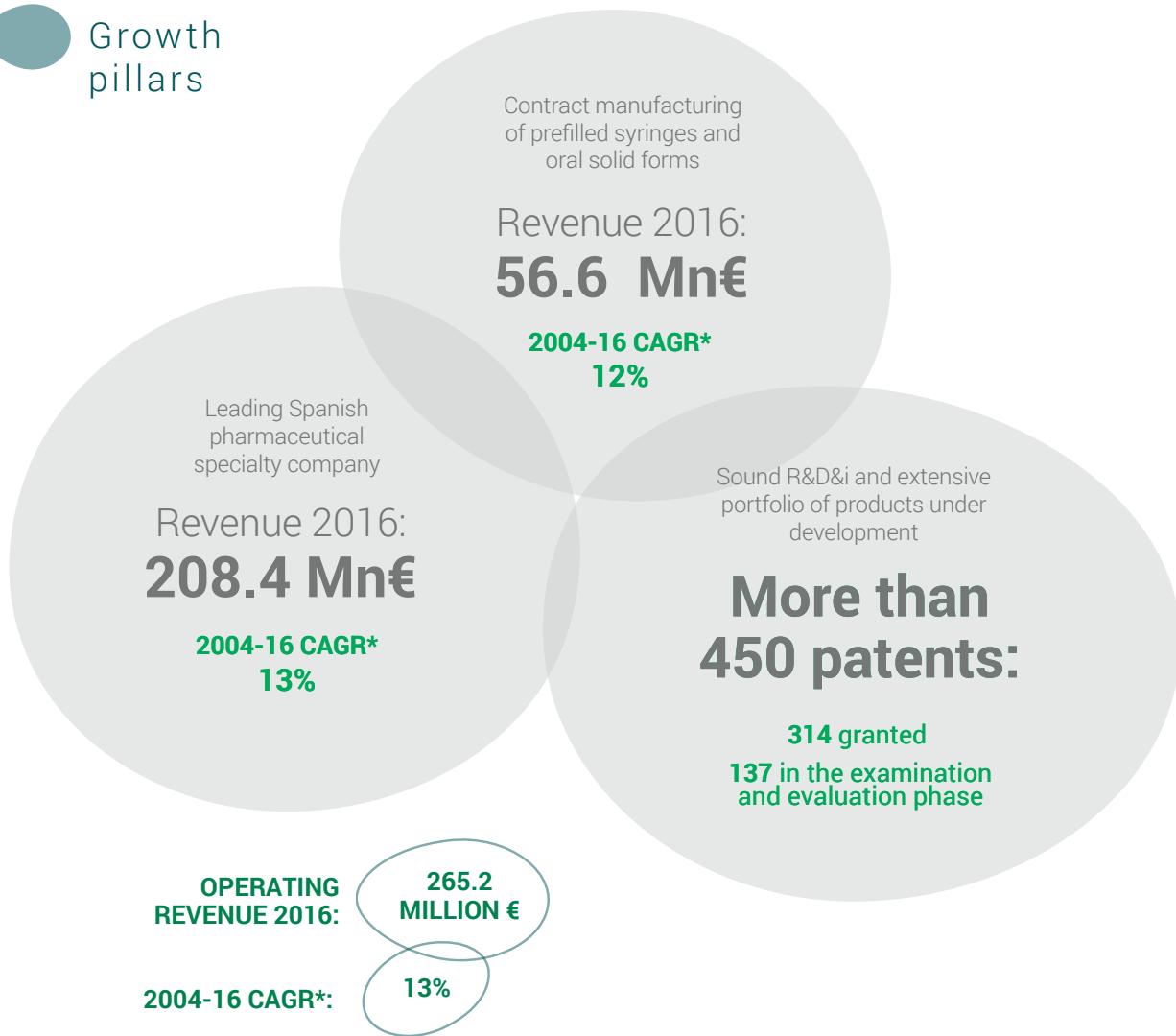


### *A sound, low-risk R&D policy.*



The growth of these pillars provides ROVI with a defensive profile that has allowed it to increase profits over recent years, in spite of the difficult environment that exists in the sector, hampered by the cuts in public pharmaceutical spending.

**Growth pillars**



(\*) CAGR: Compound Annual Growth Rate.

## Competitive advantages

ROVI enjoys a series of competitive advantages that have allowed it to position itself as one of the main leaders in its market niche, in a sector which, moreover, has high entry barriers.



### Unique knowledge of LMWH

ROVI has been engaged in the study and development of drugs based on heparin, a fast-acting anticoagulant, for more than 70 years and, since 1981, of its fractioned derivatives, low-molecular-weight heparins (LMWH). This has allowed ROVI's product Bemiparin to become one of the main therapeutic propositions for the prevention and treatment of venous thromboembolic disease in more than 55 countries.



### Infrastructure with operating advantages

ROVI is one of the main companies in the contract manufacturing business in the sector, among the world leaders in prefilled syringe production and has one of the largest European plants for manufacturing oral solid forms, exporting to more than 40 countries.

Its production plants in Madrid and Alcalá de Henares are approved by the European and United States regulators –the European Medicines Agency (EMA) and the Food and Drug Administration (FDA)- and, in 2016, the injectables production capacity was increased by the plant acquired in 2015 in San Sebastián de los Reyes, likewise approved by the EMA.



### Diversified portfolio protected by patents

The Company has a product portfolio (of both its own and licensed products) for which there is growing demand and which is not affected by the reference pricing system in Spain. It covers nine therapeutic areas:

- Cardiovascular
- Osteoarticular – women's health
- Anaesthesia – pain relief
- Diagnostic imaging contrast agents
- Central nervous system
- Urology
- Endocrinology
- Respiratory system
- Primary healthcare

It also has an OTC product line (no prescription required) and more than 20 products that have been launched since 2005, with the target of adding a further four by 2019 under licence from MSD.



*Low-risk innovation*

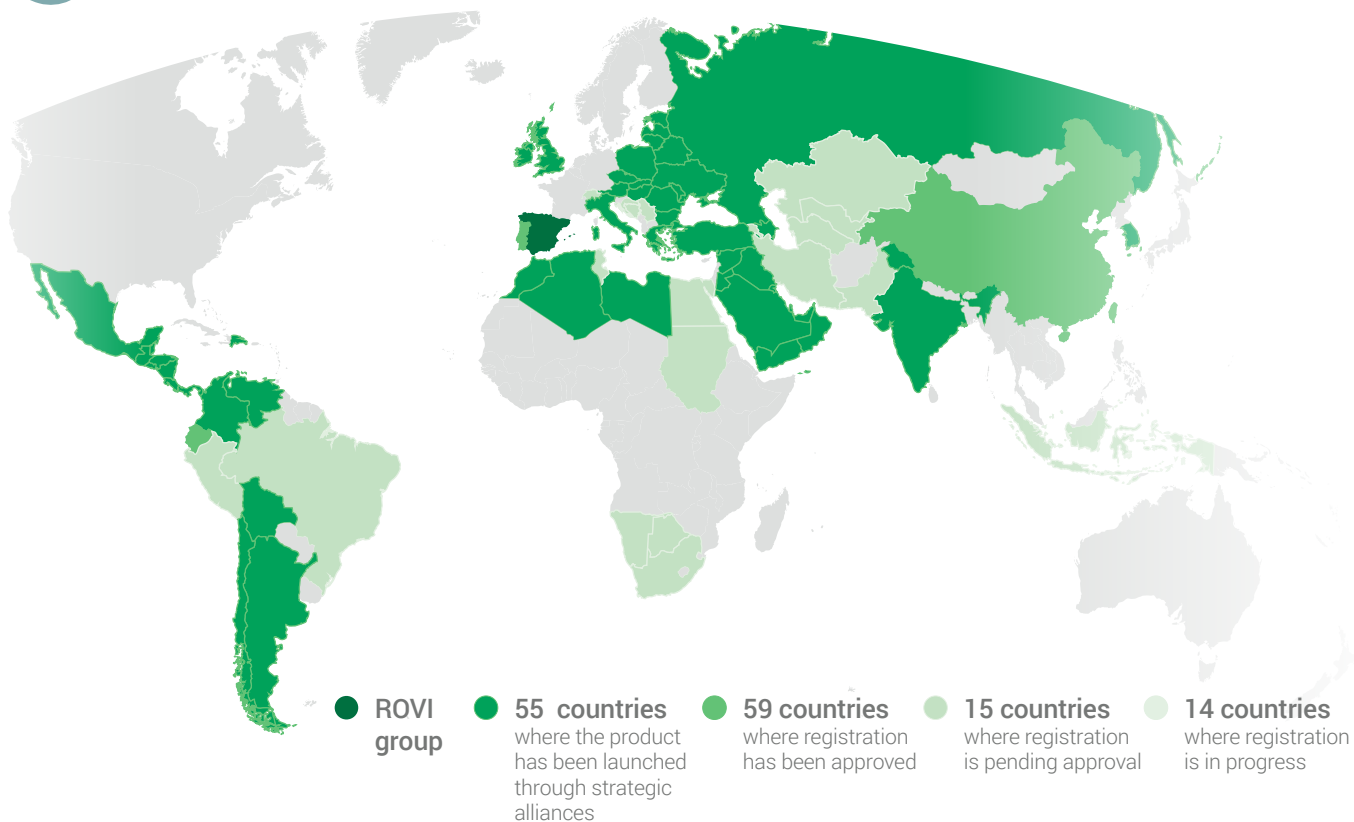
*ROVI allocates a substantial part of its revenue to research. Even so, the Company operates with a low-risk strategy, concentrating on diseases with broad medical requirements and establishing international strategic alliances to address the more expensive clinical programs.*



*International expansion*

*ROVI strives to increase its international presence by entering new markets. However, it never abandons its risk-minimization policy. ROVI's star product, Bemiparin, is registered in 60 countries, as a result of strategic alliances with international partners.*

Global presence of Bemiparin







## Pharmaceutical specialties

ROVI has a diversified portfolio comprising around thirty of its own and licensed products. This portfolio has a defensive profile, since it has been practically unaffected by reference pricing in Spain.

The most important products in terms of their contribution to the Group's EBITDA are described below:

### **Hibor®** (bemiparin)

Low-molecular-weight heparin (fast-acting anticoagulant) used to prevent and treat venous thromboembolic disease (VTD), in both surgical and medical patents, and for the acute long-term treatment of patients who have suffered VTD. VTD is a serious and potentially fatal process, the main characteristic of which is the formation of a fibrin clot, thrombosis, inside the veins of the deep vein system, with the consequences that may result from the evolution of the venous thrombus, including growth, progression and fragmentation. In the event of fragmentation, some of the fragments may reach the lung and cause pulmonary embolism.

Over recent years, Bemiparin has become one of the main treatments for this disease worldwide, having expanded its presence to more than 55 countries as the result of a strategic alliance network. At present, Bemiparin is ROVI's principal product and accounts for 30% of the Group's operating revenue.

### **Absorcol®, Vytorin® and Orvatez®** (ezetimibe) / (ezetimibe and simvastatin) / (ezetimibe and atorvastatin)

These are used as adjunctive therapy to diet in patients with hypercholesterolemia. They represent the first of five licences from MSD and ROVI has been distributing them in Spain under a co-marketing agreement since January 2011, in the case of Absorcol and Vytorin, and since June 2015, in the case of Orvatez.

### **Hirobriz® Breezhaler® and Ulunar®** **Breezhaler®** (indacaterol maleate) / (indacaterol maleate and glycopyrronium bromide)

Marketed by ROVI since the end of 2014, both the active substances are long-acting bronchodilators, indicated for the maintenance treatment of Chronic Obstructive Pulmonary Diseases (COPD) in adult patients and administered by inhalations through the Breezhaler device. ROVI markets both products under a licence from Novartis.

### **Volutsa®** (solifenacin succinate and tamsulosin hydrochloride)

This Astella Pharma product has been marketed by ROVI since 2015 and is indicated for the treatment of moderate to severe storage systems symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign hyperplasia (BPH) in men who are not responding adequately to monotherapy treatment.

**Medikinet® and Medicebran®**  
(*methylphenidate hydrochloride with modified release*)

Prescription medicines that are indicated for treatment of ADHD (Attention Deficit Hyperactivity Disorder) in children and adolescents. Both products are from the company Medice and ROVI has been distributing them on an exclusive basis in Spain since December 2013.

**Corlantor®**  
(*ivabradine*)

A prescription product for chronic stable angina pectoris and chronic heart failure that ROVI has been marketing under a licence from Laboratorios Servier since 2007.

**Exxiv®**  
(*etoricoxib*)

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 to acute gouty arthritis, as well as the moderate short-term pain associated to dental surgery. It is a Merck Sharp & Dohme research product that has been marketed in Spain by ROVI since 2008.

**Thymanax®**  
(*agomelatine*)

A medicine indicated for the treatment of major depression episodes in adults. It is a Laboratorios Servier research product that ROVI has been distributing in Spain under a co-marketing agreement since March 2010.

**Diagnostic imaging contrast agents and other hospital products**

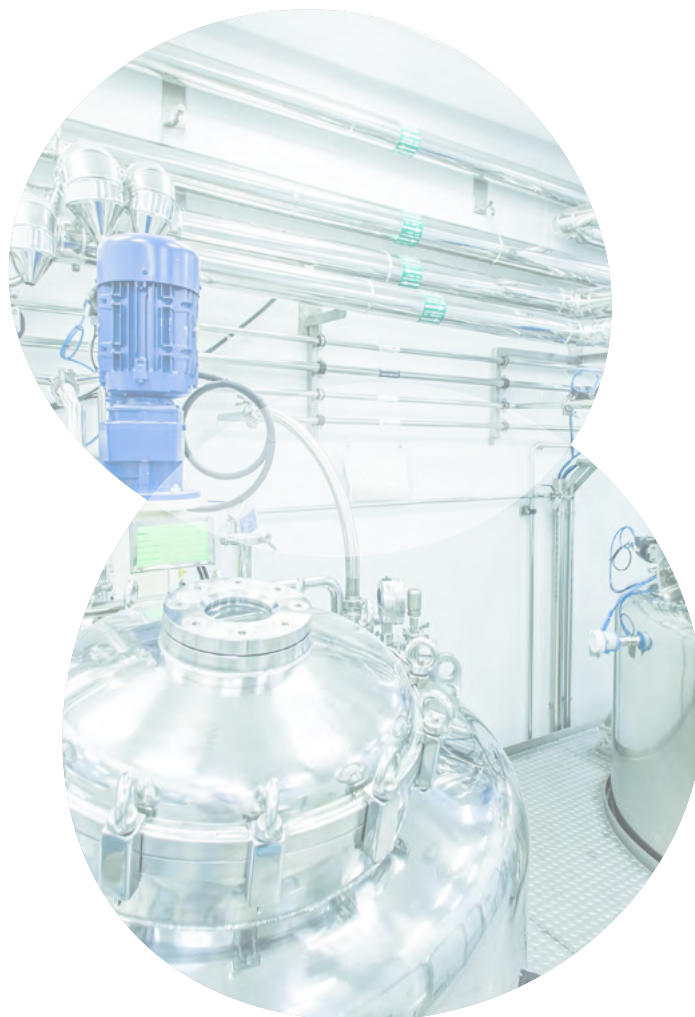
ROVI is one of the market leaders in the marketing of contrast agents, hospital products for imaging diagnosis (computed tomography, magnetic resonance imaging, ultrasound scan, etc.). This area, which accounts for more than 10% of the Company's revenue, comprises a broad product portfolio, including those marketed under licence from Bracco (Iomeron® and Iopamiro® (for computed tomography and intervention), Multihance® y Prohance® (for magnetic resonance imaging), Sonovue® (for

ultrasounds), and Bracco Injeenering: EmpowerCTA+®, EmpowerMR® and CT Expres (contrast injection systems and compatible disposable material).

The hospital product portfolio is completed by healthcare products for care and maintenance of intravenous catheters: Fibrilin® and Fibrilin Salino®.

**OTC products**

ROVI also has business line for the distribution of OTC pharmaceuticals (products for which no prescription is required). In March 2016, ROVI and Enervit announced that they were setting up a joint venture for the distribution of nutritional and other non-pharmacological products in Spain and Portugal.



## New products 2016

Through different agreements, in 2016 ROVI became the distributor of the following products, which will provide impetus to its business in 2017:

### **Neparvis®**

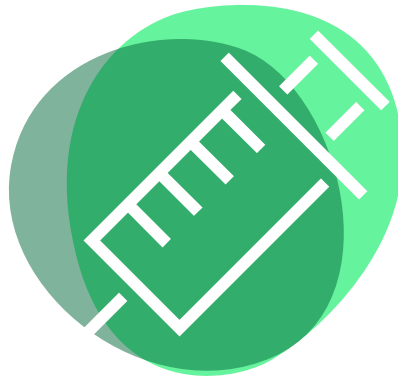
At the end of 2016, ROVI signed an agreement with Novartis Farmacéutica S.A. for the marketing of Neparvis® (sacubitril/valsartan), which corresponds to Entresto® of Novartis, in Spain. ROVI began to market the product in December 2016 and will be responsible for promoting and distributing it in Spanish territory for the next ten years.

Neparvis® is indicated in adult patients for treatment of symptomatic chronic heart failure with reduced ejection (the proportion of blood leaving the heart) fraction. According to IMS Health, in the twelve months ending September 2016 (annual average rate September 2016), the heart failure with reduced ejection market (where Neparvis® is included) represents consumption of approximately 2 million units of ACE (angiotensin-converting-enzyme) inhibitors and approximately 280,000 patients suffer from this disease annually.

### **Mysimba®**

As the result of an agreement signed in August 2016 with Orexigen Therapeutics Ireland Ltd. (Orexigen), a biopharmaceutical company focusing on obesity treatment, ROVI will be responsible, on an exclusive basis, for the distribution of Mysimba®, a medicine approved by the European Medicines Agency for weight management in obese or overweight adults, when one or more weight-related complications exist (for example, type 2 diabetes, dyslipidaemia or controlled hypertension). Obesity and its associated complications are an important health problem in Spain, where approximately 53% of adults are overweight or obese, according to the latest National Health Institute statistics.

Marketing of this product began in the first quarter of 2017 and will continue for an initial term of five years, which may be renewed for a further five years.



## Contract manufacturing

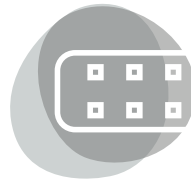
ROVI has successfully positioned itself to take advantage of the growing trend among pharmaceutical companies to outsource their manufacturing processes. Thus, the Company makes use of the high manufacturing capacity available at its facilities by providing the whole range of manufacturing services for injectables, suppositories and oral solid forms.

The Company, through its three production plants, two of which are used for injectables (ROVI Contract Manufacturing in Madrid and the San Sebastián de los Reyes plant), while the other specializes in oral forms (Frosst Ibérica), provides manufacturing services to other companies for a wide range of pharmaceutical forms, including prefilled syringes, vials, suppositories, tablets, hard capsules and sachets.

ROVI unifies all services within the same company, from the development of a project until the final release of the product, including preliminary clinical trials, stability studies and physical, chemical and microbiological analyses, with the resulting savings of time and money for the customers. Thus, it provides a personalized service depending on the needs of each customer.

The contracts signed with the customers for whom ROVI manufactures usually have an average term of between 3 and 5 years, which contributes to considerable revenue stability. Furthermore, the long regulatory process that a pharmaceutical company has to undergo to change its manufacturer makes contract manufacturing a “lifetime customer” business model, as long as the service provided is optimal in meeting the customer’s needs.

Contract manufacturing is divided into:



### Injectables

ROVI is currently one of the leading prefilled syringe manufacturers in Europe in terms of the number of units manufactured (filled) per year, with a total annual production capacity of 270 million units.

There are very few competitors in the contract manufacturing of prefilled syringes worldwide, since entry barriers in this business are high, given the biological nature of the medicines and the aseptic conditions in which they must be manufactured. At ROVI, the filling process takes place in sterile microbiologically-controlled rooms and, if the product so requires, there is also a terminal sterilization. Likewise, there is the additional possibility of placing safety devices in the syringes.

The Company has a plant specialized in the filling and packaging of parenteral solutions in prefilled SCF syringes of from 0.5ml to 20ml (filled from 0.2ml to 20ml) and in vials of from 2ml to 10ml. The plant is approved by the European and United States regulators. It has also been approved by the regulators of Korea and Brazil and those of the Gulf States. It likewise holds the ISO 9001, ISO 14001 and OSHAS certifications

The contract manufacturing business was reinforced in 2015 by the acquisition of the plant located in San Sebastián de los Reyes after the agreement with Crucell Spain, S.A. This has allowed the production lines for injectables (other than those that Crucell had been manufacturing) to be expanded and has assured the production capacity required to carry out the Company's future strategic plans for international expansion. During 2016, the plant was approved by the European health authorities.



### Oral solid forms

ROVI has a plant for oral solid forms that has a long tradition in the manufacture of pharmaceutical products and uses the most advanced technology for the manufacture of solid oral forms (tablets, coated tablets, hard capsules and sachets).

The plant, with 83,000 square metres, has a global annual capacity of 3,000 million tablets, 300 million hard capsules and 30 million sachets using different

production lines. Furthermore it has storage capacity for 9.000 pallets.

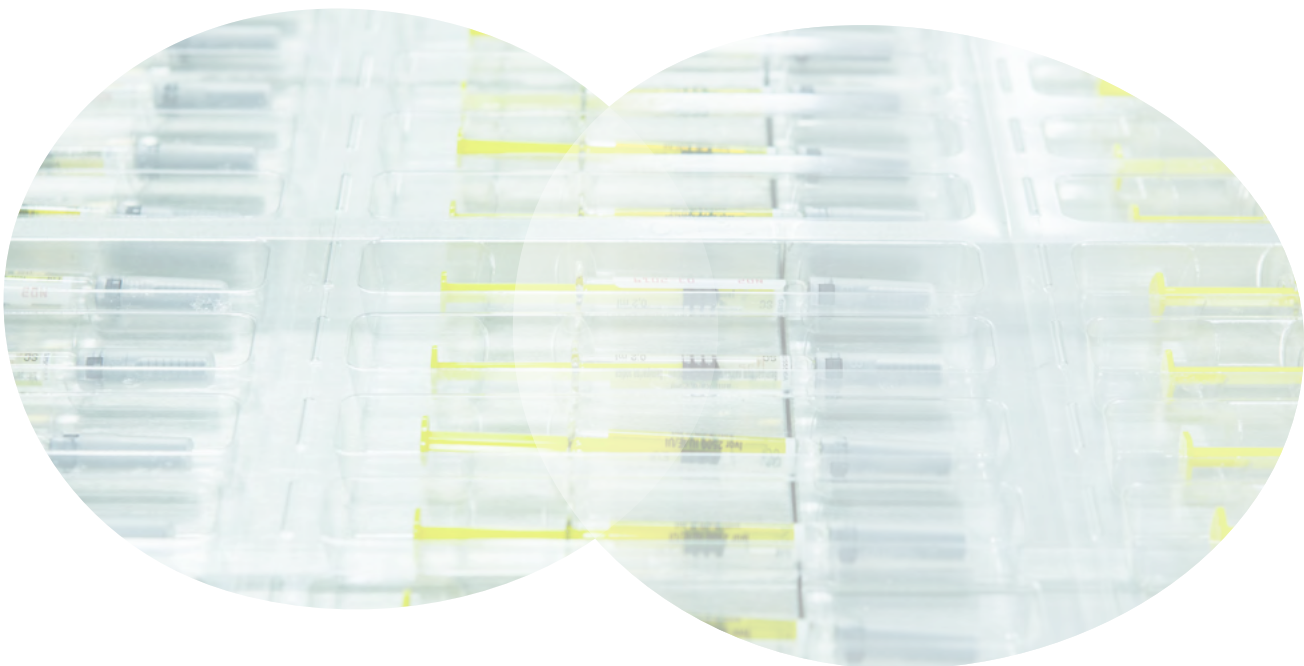
In order to supply all markets, this plant is approved by the European and United States authorities. It has also been approved by the Japanese, Mexican, Brazilian, Kenyan and Belarusian authorities and those of the Gulf States.



### Clinical trials

Since it works under both United States and European quality standards, ROVI offers technical support that is cost-competitive, flexible and reliable.

The Company can provide a wide range of services for clinical trials, product preparation and filling, labelling, packaging and logistics, always applying the strictest quality standards. The machinery used is the same as for an industrial-scale batch and, therefore, it complies with the latest European regulations on clinical trials.





trial of Letrozol ISM®. This slight increase was mainly due to the delay in commencing the phase III trial of Risperidone ISM® as a result of a number of meetings with the FDA and the EMA in order to obtain scientific advice on the design of the phase III clinical trial. As a consequence of these investments, at present, approximately 50% of the revenue of the pharmaceutical specialties area comes from ROVI's own products.

ROVI has three R&D&i centres and two pilot plants for the manufacture of injectable medicines on which research is in progress and is present in the creation of large national strategic research consortia in the CENIT program: the Nanofarma Consortium (2006), the Melius Consortium (2007) and the CeyeC Consortium (2009). It has been actively leading other research consortia, including the SNC\_Integra Consortium (2011), the ADELIS Consortium (2013) and, since 2015, the BIOMAP Consortium, within the framework of the FEDER-Innterconecta Program for Andalusia, cofinanced by European Union Structural Funds.

At the same time, ROVI keenly supports academic research and holds agreements with different universities to combine efforts and reinforce scientific, technological and educational activities, as well as spreading knowledge, in Spain. At present, it is cooperating with the University of Granada in research activities and the training of scientific personnel (through different projects co-financed by the Andalusian Technological Corporation, CTA), with the Biomedical Research Centre of the CSIC (Spanish National Research Council) and the University of La Rioja (UNIR).



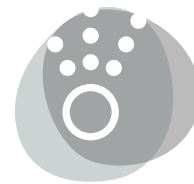
Subvencionado por el CDTI



## ROVI has three R&D&i centres and two pilot plants for the manufacture of injectable medicines

### Research areas

Current research developments are addressed primarily at three areas: drug release technologies, glycomics and multi-layer technologies for urethral catheters.



#### DRUG RELEASE TECHNOLOGIES

Drug administration has a direct effect on its efficacy, since it affects factors such as concentration and absorption by the organism. Research in this field allows factors like active substance degradation to be minimized, the prevention of side effects and an increase in bio-availability (the drug's capacity to act with the appropriate dose).

ROVI has developed a leading-edge research line in the field of extended release using ISM® technology. In this way, the product is reconstituted just before administration into a fluid that precipitates inside the muscle after it has been injected, leading to the formation of solid/semi-solid implants by diffusion of the solvent in the body fluids.

ISM technology is intended to overcome most of the difficulties of extended-release oral or parenteral formulations

**In 2016, ROVI made significant progress in developing the first candidate of its leading-edge drug-release technology, ISM®**



and has certain advantages, such as being easier to administer, highly-efficient encapsulation, greater stability of the active substance and better control of the initial release of the drug, among others.

In 2016, ROVI made significant progress in developing the first candidate of its leading-edge drug-release technology, ISM® for the extended release of risperidone, a second-generation antipsychotic medicine, the use of which is consolidated for the treatment of schizophrenia.

In November, 2016, the results of the phase I trial "PRISMA-1" were published in the medical journal International Clinical Psychopharmacology and showed that Risperidone ISM® was safe and well tolerated, providing an extended release of risperidone over the four-week period covered by the dose, without the need to include oral supplements, reaching therapeutic levels in plasma as from the first day<sup>3</sup>.

Likewise, the phase II clinical trial of Risperidone ISM®, "PRISMA-2", concluded successfully and the final

(3) Llaudó J, et al. Phase I, open-label, randomized, parallel study to evaluate the pharmacokinetics, safety, and tolerability of one intramuscular injection of risperidone ISM at different dose strengths in patients with schizophrenia or schizoaffective disorder (PRISMA-1). Int Clin Psychopharmacol. 2016;31(6):323-31.



favourable results were presented on 13 March, 2016 at the 24th European Congress of Psychiatry<sup>4</sup>. The PRISMA-2 is an open parallel phase II clinical trial carried out at four United States centres. The main objective of this trial was to assess the safety and pharmacokinetic profile of multiple intramuscular doses of Risperidone ISM® in 67 patients with stable schizophrenia. The PRISMA-2 study also showed that Risperidone ISM® reaches therapeutic levels in plasma as from the first few hours after the drug is administered, without the need for any oral risperidone supplement, and provides extended release over the four-week period covered by the dose, with multiple intramuscular injections, irrespective of the part of the body where it is injected (gluteus or deltoid).

The United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have reviewed the results of the PRISMA-2, together with the data from previous studies, and the proposed phase III program. Subsequently, they discussed them at an end of phase II meeting, in the case of the FDA, and a scientific advisory meeting, in the case of the EMA. Furthermore, the FDA made a more in-depth evaluation of the study protocol for the phase III "PRISMA 3" clinical trial, through a Special Protocol Assessment. Subsequently, in December 2016, the applications for approval of the clinical trial commenced. The recruitment of patients for the "PRISMA 3" clinical trial for approval of Risperidone ISM® in the United States and Europe is forecast to begin in the second quarter of 2017.

In addition, in the same research area, in October 2016, ROVI requested a preliminary meeting with the FDA for a new medicine which is being researched (pre-IND), in order to obtain advice on the clinical development of Letrozol ISM®, a long-acting injectable aromatase inhibitor to treat hormone-dependent breast cancer. The Company filed an application for an investigational new drug (IND) with a view to commencing the first phase I clinical trial in the second half of 2017.



## GLYCOMICS

Glycomics is the study and profiling of the sugars that compose a cell, including the glycosaminoglycans (GAG), which, in addition to their role in regulating blood coagulation, are involved in processes like cell growth, immune response and inflammation. To carry out these functions, the GAG interact with numerous proteins. Glycomics studies provide very valuable information in this respect, since they allow the receptors that take part in the interaction with each type of GAG to be determined.

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

As a result of its effort and investment in this area, ROVI has developed an enoxaparin biosimilar (a low-molecular-weight heparin with an antithrombotic effect), for which it applied to the European health authorities for marketing authorization in 2014. In 2015, the evaluation process to obtain marketing authorization for a low-molecular-weight heparin (enoxaparin biosimilar) commenced in Europe. In 2016, it continued to progress according to the calendar fixed previously and, in March 2017, the decentralized procedure for registration of medicines in twenty-six European Union countries was completed successfully.

Now, the national phase of the registration process has commenced and will conclude, foreseeably, with the granting of the marketing authorization by the respective competent national authorities for each individual country. It is estimated that the national phase will take between three and ten months.

(4) 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). 24th European Congress of Psychiatry, March 13, 2016, Madrid (Spain) [<http://epa-abstracts-2016.elsevier.cc/#289/z>]



## MULTILAYER TECHNOLOGIES FOR URETHRAL CATHETERS

One of the most important aspects in the use of stents and urethral catheters is the high prevalence of bacteria that, in some cases, may lead to the appearance of clinical symptoms and complications, including severe sepsis and death. At present, the incidence of urinary tract infection is still very high, as biofilm formation makes it difficult to eradicate microorganisms with antibiotics.

During 2016, ROVI continued with the preclinical development of its multilayer technology, which uses polymeric materials to form a bioerosionable system that depends on the bacterial metabolism. It provides significant advantages over the current state of the art, decreasing bacterial adhesion, facilitating biofilm elimination, reducing the appearance of encrustations and, to a large extent, preventing catheter blockage.

ROVI now has a portfolio of 14 international patent applications in this area, but the development of this line of research provides the possibility of increasing the portfolio of both the Company's patents and its commercial products in the medical device area in a way that is both innovative and competitive, since this technology is intended as a platform for future development.

*In March 2017, the decentralized procedure for registration of medicines in twenty-six European Union countries was completed successfully*



## Production plants and R&D centres

ROVI has three research and development centres and four manufacturing plants for its own products and services to others. The work performed at these facilities is crucial to the Group's business.



### ROVI CONTRACT MANUFACTURING

#### Madrid

 378


 syringes : 150 million  
 suppositories : 150 million



### BEMIPARIN PRODUCTION PLANT

#### Granada

 54


 syringes : 240 million

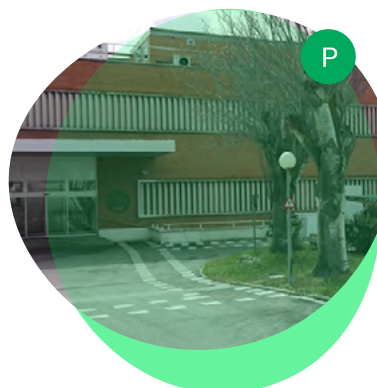


### FROSST IBÉRICA

#### Alcalá de Henares

 212


 tablets : 3.000 million  
 hard capsules : 300 million  
 sachets : 30 million



### INJECTABLES PLANT

#### San Sebastián de los Reyes

 16

 syringes : 120 million  
 vials : 60 million



 groninger

# STRATEGY

**45** Market environment

**48** Strategic and financial priorities

**50** CSR Strategic Plan

## Market environment

The Spanish economy had made significant progress at the end of 2016, reflected in growth of 3.2% in the GDP, the highest rise since the onset of the crisis in 2007. The strength may be mainly attributed to both a rise in private consumption and business investment.

However, this economic growth had very little effect on the pharmaceutical sector, where the effects of the efforts to contain the deficit are still being felt. The accumulated 12-month public pharmaceutical expenditure at the end of December in Spain showed 4% growth, but remained 28% lower than its all-time high in 2010. The increase in pharmaceutical spending in 2016 was due to a 2.2% increase in the number of prescriptions and a rise of 1.7% in the average expenditure per prescription.

### Growth rate of pharmaceutical market

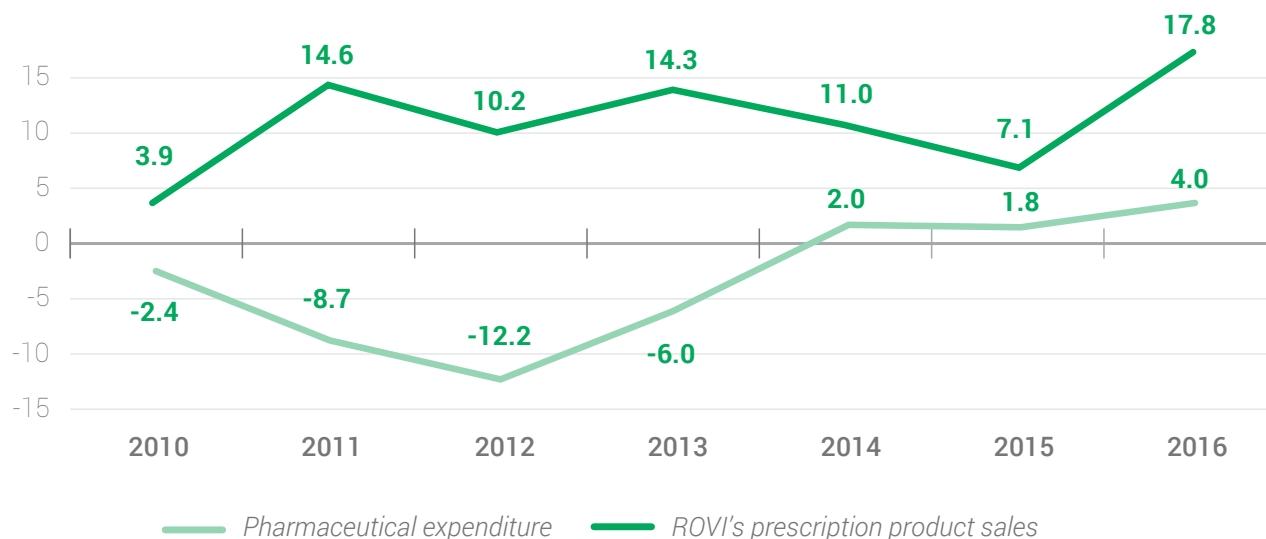
PERCENTAGE



SOURCE: FARMAINDUSTRIA

## ROVI's sales growth vs pharmaceutical expenditure growth

PERCENTAGE



SOURCE: FARMAINDUSTRIA AND ROVI

Data provided by QuintilesIMS indicate that the innovative product market in Spain rose by 4% in 2016 in comparison with the preceding year. Notwithstanding, sales of ROVI's prescription-based pharmaceuticals increased by 18%, 14 percentage points above the market increase.

In addition, a new adjustment of 550 million euros to pharmaceutical expenditure is expected for 2017, according to the Budget Plan sent by the Spanish government to the European Commission<sup>5</sup>. Likewise, QuintilesIMS<sup>6</sup> forecasts a 1%-4% growth rate for pharmaceutical spending in Spain to 2021. In spite of the difficult situation that the pharmaceutical industry is undergoing, ROVI expects to grow by higher percentages than those estimated for the increase in pharmaceutical spending.

According to the December 2016 data of QuintilesIMS, in the classification of laboratories, ROVI is in 23rd place, in terms of value, and was the company showing the highest growth among the first 23 companies in 2016.

**Sales of ROVI's prescription-based pharmaceuticals increased by 18%, 14 percentage points above the market increase**

(5) [http://www.mineco.gob.es/stfls/mineco/comun/pdf/161017\\_plan\\_presupuestario.pdf](http://www.mineco.gob.es/stfls/mineco/comun/pdf/161017_plan_presupuestario.pdf)

(6) Outlook for Global Medicines through 2021. Report by the QuintilesIMS Institute.

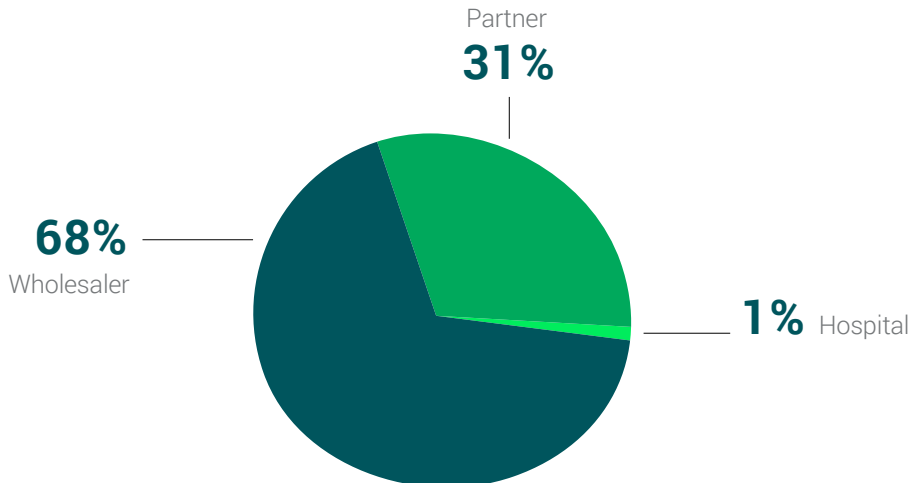
## Bemiparin market

Bemiparin, a low-molecular-weight heparin researched by ROVI itself, is registered in 60 countries and present in more than 55 markets all over the world. Its main market is Spain, which accounts for 69% of all product sales. Outside Spain, ROVI markets Bemiparin through international partners. Sales of the product outside Spain were 24.9 million euros in 2016, 1% up on 2015, representing 31% of the sales of the product and 9% of Group sales.

In 2016, international sales were affected by currency devaluations in emerging countries, which are ROVI's principal markets. Although the international partners assume the exchange-rate risk, since ROVI invoices in euros, the currency crisis in these countries affected Bemiparin sales. Even with this exchange-rate risk, international sales of this drug are still driven by the growth in the market for both low-molecular-weight heparins and the product itself in key countries, such as Turkey, Greece, the Czech Republic, Algeria, the MENA (Middle East and North Africa) countries, Morocco, the Baltic states and Austria, which account for 77% of international sales of the product.

### Principal customers Bemiparin ROVI

PERCENTAGE



Finally, the new launches in 2016 in Argentina and the Philippines, two important emerging countries in which the low-molecular-weight heparin market has yet to be developed, helped to consolidate Bemiparin sales outside Spain.



# Strategic and financial priorities

ROVI forecasts a low- to mid-single digit growth rate in its operating revenue in 2017, in spite of a new 550 million-euro adjustment to pharmaceutical spending expected for the coming year, according to the Budget Plan sent by the Spanish government to the European Commission<sup>7</sup>, and the QuintilesIMS<sup>8</sup> forecast for pharmaceutical expenditure in Spain, which indicates a 1%-4% growth rate to 2021.

## Pharmaceutical specialties

ROVI expects its growth engine to continue to be Bemiparin, supported by the existing pharmaceutical specialties portfolio, the latest distribution licence agreements (Neparvis®, Volutsa®, Orvatez®, Ulunar® and Mysimba®) and the new customers in the contract manufacturing area.

As a consequence of the successes in this market and the development of new products resulting from ROVI's R&D&i work, the pharmaceutical specialties marketed in Spain are expected to continue to contribute high strategic value over forthcoming years, where Bemiparin will remain as one of the long-term growth engines and, primarily, one of the Company's internationalization objectives.

ROVI has been maintaining its effort to share the benefits of this product with doctors and patients all over the world since 2001, when it decided to market Bemiparin internationally. Since then, the product's presence has been expanded to cover more than 55 countries.

Additionally, the agreement with MSD will allow ROVI to launch four more products over the next two years, which will contribute to the Company's sustained long-term growth. All these new product launches allow the average life of the product portfolio to be extended for several years.

## Contract manufacturing

In 2017 and in the medium term, ROVI will strive to strengthen its operations by acquiring new customers. This will allow the potential of its three contract manufacturing plants to be maximized and optimized.

(7) [http://www.mineco.gob.es/stfls/mineco/comun/pdf/161017\\_plan\\_presupuestario.pdf](http://www.mineco.gob.es/stfls/mineco/comun/pdf/161017_plan_presupuestario.pdf)  
(8) Outlook for Global Medicines through 2021. Report by the QuintilesIMS Institute.



***In 2017 and in the medium term, ROVI will strive to strengthen its operations by acquiring new customers***

The Madrid injectables plant and the solid forms plant in Alcalá de Henares are approved by the United States FDA and the European health authorities, have significant production capacities and provide a service based on excellence. One of the results of the effort to foster customer loyalty in this segment has been the renegotiation of the contract with MSD, extending the formulation and packaging services for the medicines Maxalt® y Maxalt-MLT® until March 2020. In September 2016, ROVI began manufacturing Sintrom® for Merus Labs. In 2017, ROVI expects the manufacture of this new product to partially offset the lower volumes manufactured for MSD after expiry of the initial contract in March 2015.

Regarding the San Sebastián de los Reyes plant, which concentrates on the production of injectables and was acquired from the company Crucell in 2015, ROVI expects to begin to manufacture its own product Bemiparin on a routine basis in September 2017.

## R&D&i

The essence of ROVI's success stems from its investigation work and R&D&i, which leads to the development of new products and technologies that are likely to guarantee the long-term future of the Company and its business lines.

In this respect, ROVI continues to bet on ISM® technology, a drug release system belonging to the Company, the objective of which is to improve patient adherence to treatment. As may be seen in detail in the relevant sections of this Annual Report, this has allowed the development of new products, such as Risperidone ISM® and Letrozol ISM®. A preliminary meeting with the FDA in the United States has already been requested for the latter, in order to obtain advice on the product's clinical trial. The Company hopes to commence the first phase I clinical trial in the second half of 2017.

At the same time, in December 2016, the applications for approval of the phase III "PRISMA 3" clinical trial for the long-acting injectable Risperidone ISM® were initiated. Recruitment of patients for the "PRISMA 3" clinical trial for the approval of Risperidone ISM® in the United States and Europe is forecast to begin in the second quarter of 2017.

Another project that shows the importance of research to ROVI as a key strategic factor for the future is, in the glycomics area, the development of an enoxaparin biosimilar. The decentralized procedure for registration of this drug in twenty-six European Union countries has concluded successfully. The national processes to obtain the relevant marketing authorizations have been initiated and ROVI hopes to start marketing it in the last quarter of 2017.



# CSR Strategic Plan

In ROVI's business strategy, corporate social responsibility (CSR) is crucial to ensuring the Company's long-term sustainability and reinforcing the confidence of the different stakeholders related to the Company. With this objective in mind, ROVI plans to implement its 2017-2020 CSR Plan, for which it is currently preparing the following activities:

- Internal and external CSR diagnosis to identify the Company's positioning in CSR.
- Materiality analysis, in order to identify the key issues for attaining ROVI's long-term objectives and, therefore, for its sustainability.
- Design of a CSR plan that identifies ROVI's main strategic lines in CSR, as well as the actions to be implemented in the period 2017-2020.

We highlight the fact that the content of the 2017-2020 CSR Plan will be structured and based on the seven core issues of the international standard ISO



*In 2017, ROVI plans to implement its 2017-2020 CSR Plan*

26000, which provides a global comprehension of what social responsibility is and what organizations should do in order to operate in a socially responsible way.

The seven core issues of ISO are:



*Organizational  
governance.*



*Human  
rights.*



*Labour  
practices.*



*The  
Environment.*



*Fair operating  
practices.*



*Consumer issues, which, for  
ROVI, refer to customers,  
patients and professionals.*



*Community  
involvement and  
development.*



# CORPORATE GOVERNANCE

**53** Corporate  
governance model

**54** Governing  
bodies

**67** Compensation  
Policy

**68** Ethics  
Framework

## Corporate governance model

The corporate governance of Laboratorios ROVI includes current national and international recommendations and, in particular, its internal regulations apply the Good Governance Code of Listed Companies approved by the National Securities Market Commission (CNMV) in February 2015 (the Good Governance Code). This model guarantees ethical behaviour on the part of the Company, allowing the trust created among interest groups to be preserved and the defence of the interests of all our shareholders to be assured.

ROVI's main governing bodies are the General Shareholders' Meeting and the Board of Directors. The powers and operation of each of these is regulated in the Company's Bylaws, the Regulations of the Board of Directors and the Regulations of the General Shareholders' Meeting which are available to be consulted on the Company's website ([www.rovi.es](http://www.rovi.es)).

The Board of Directors is ROVI's highest management body and is responsible for defining corporate strategy and monitoring and controlling that Management meets the objectives fixed and respects the Company's corporate purpose and interests. Good governance requires stakeholders to have access to relevant information, in relation to both governance rules and practice and the results attained. Therefore, each year, ROVI presents an Annual Corporate Governance Report and Annual Director Compensation Report. Furthermore, it submits regular information on the Company's most significant results to the CNMV and draws up a Management Report that accompanies the Annual Financial Statements. This documentation is available on the corporate website ([www.rovi.es](http://www.rovi.es)).

In addition to governing bodies described above, ROVI has a Management Committee, which handles the Company's day-to-day management and is formed by 14 members of management, led by the CEO.



*ROVI's corporate  
governance model  
guarantees ethical  
behaviour on the part  
of  
the Company*





# Governing bodies

## General Shareholders' Meeting

The General Shareholders' Meeting is the Company's highest decision-making and control body for the matters within its competence. It meets at least once a year at the Ordinary General Meeting, held within the first six months of each year to, if appropriate, approve the corporate management and the annual financial statements for the preceding year and adopt a decision on the application of the profit, although it is likewise competent to deliberate and decide on any other item on the Agenda.

Extraordinary General Meetings are those not included in the preceding paragraph.

### Unlimited right to attend

All shareholders, irrespective of the number of shares they hold, are entitled to attend both ordinary and extraordinary general meetings, provided the shares are registered in their name in the relevant account entry register five days before the date the general meeting is held.

## General Shareholders' Meeting 2016

On 31 May, 2016, ROVI held an Ordinary General Shareholders' Meeting. Shareholders holding a total of 47,300,526 shares were either present or represented (36,103,492 present and 11,197,034 represented), corresponding to 94.601% of the share capital (72.207% present and 22.394% represented).

The resolutions passed by the Meeting included:

- Approval of the individual annual financial statements of ROVI and the consolidated annual financial statements of the Company and its subsidiaries, as well as the Company's individual management report and the consolidated management report of the Company and its subsidiaries, all of which were for the reporting period ended 31 December, 2015.
- Approval of the proposed application of the individual profit for the reporting period ended 31 December, 2015, specifically payment of a fixed gross dividend of 0.1390 euros per share with the right to receive it.
- Approval of the management and performance of the Board of Directors in the reporting period ended 31 December, 2015.
- Approval of the amendment of the Company's Bylaws in the terms of the directors' report drawn up in this respect.

**On May 31, 2016,  
 the Ordinary General  
 Shareholders Meeting was  
 held with a quorum of 94.6%  
 of the share capital**



- Approval of the amendment of the Regulations of the General Shareholders' Meeting in the terms of the directors' report drawn up in this respect.
- Approval of the maximum annual compensation of the members of the Board of Directors in their capacity as such for 2016.
- Approval of the director compensation policy for the period 2016-2019.
- Approval of the Long-term Incentive Scheme (2016-2018), consisting of awarding company shares to the Company's executive directors.
- Approval of the re-appointment of the account auditors for the Company and its group for 2016.
- Delegation of powers to formalize and register the resolutions passed by the General Shareholders' Meeting and carry out the mandatory filing of the annual financial statements.
- Approval, on a consultative basis, of the Company's Annual Director Compensation Report.



## Board of Directors

The Board of Directors is the Company's highest decision-making, supervision and control body, except in matters reserved to the General Shareholders' Meeting. It is currently formed by three executive directors, one proprietary director and three independent directors of recognized prestige. All of them were appointed on the basis of their merits, irrespective of gender. According to the Bylaws, the Board

of Directors must be formed by no less than five and no more than 15 members, pursuant to corporate governance recommendations.

As the highest decision-making body, it delegates ordinary business management to the management team and concentrates its activities on general supervisory duties. This implies determining ROVI's policies, controlling management, evaluating the performance of the managers and, in general, adopting the most important decisions for the running of the Company, as well as liaising with shareholders.

### Board of Directors

	Position	Type of director	Nomination and Compensation Commission	Audit Committee
<b>Mr. Juan López-Belmonte López</b>	Chairman	Proprietary		
Mr. Juan López-Belmonte Encina	Chief Executive Officer	Executive		
Mr. Iván López-Belmonte Encina	First Deputy Chairman	Executive		
Mr. Javier López-Belmonte Encina	Second Deputy Chairman	Executive		
Mr. Miguel Corsini Freese	Director	Independent	Chairman	Member & Secretary
Mr. José Fernando de Almansa Moreno-Barreda	Director	Independent	Member	Member
Mr. Enrique Castellón Leal	Coordinating Director	Independent	Member & Secretary	Chairman
Mr. Gabriel Núñez Fernández	Non-director Secretary			



In the course of its duties, it strives to ensure that regulatory requirements and the Company's social and ethical duties are met. Likewise, it ensures that no one person or small group exercises decision-making power within the Company without being submitted to counterweights and controls and that no shareholder is treated more favourably than others.

Its responsibilities are set out in article 5 of the Regulations of the Board of Directors and include, specifically, those of preparing the strategic plan, management objectives and annual budget. Likewise, it defines the structure of the company group, establishes the investment and financing policy and approves the dividend, treasury share, corporate governance and social responsibility policies. It also establishes the risk control and management policy, including tax risks, as well as regularly monitoring the internal information and control systems and determining the Company's tax strategy.

In 2016, the Board of Directors held eight meetings, two of which took place using the written procedure without the physical presence of the members. All the meetings were chaired by the Chairman. The percentage attendance was 100% of total votes.

The Board of Directors carried out a self-evaluation of its activities on the basis of a report drawn up by the Nomination and Compensation Commission, in accordance with article 5.7 of the Regulations of the Board of Director. Said evaluation has not led to significant changes in internal organization or in the procedures applicable to the Board's activities.

In accordance with article 8.3 of the Regulations of the Board of Directors, the Coordinating Director, Mr. Enrique Castellón Leal, is entitled to request a Board meeting be called or that new items be included on the agenda of a Board meeting that has already been called, as well as to coordinate and meet with the non-executive directors and, if applicable, organize the periodic evaluation of the Chairman of the Board. Likewise, he is authorized to chair Board meetings in the absence of the Chairman and Deputy Chairmen; voice the concerns of non-executive directors; maintain contacts with investors and shareholders in order to hear their points of view and form an opinion on their concerns, in particular in relation to the Company's corporate governance; and coordinate the plan of succession of the Chairman.



***The Board of Directors held  
eight meetings and the  
percentage attendance was  
100% of total votes***

## Director profiles



***Mr. Juan López-Belmonte López***

Chairman of ROVI for the last 22 years, he graduated in Economic and Business Sciences from the Universidad Complutense de Madrid in 1969. In addition to Chairman of the Board of Directors of ROVI, he is also President of the Madrid Chamber of Commerce, a member of the Plenary Session of the Spanish Chamber of Commerce and a member of the governing body of the IFEMA (Madrid Trade Fair Institute). He is a shareholder of Norbel Inversiones, S.L. (ROVI's controlling shareholder).



***Mr. Juan López-Belmonte Encina***

Chief Executive Officer since October 2007, he has been working for the Company since 1994 and was appointed General Manager in 2001. He graduated in Economic and Business Sciences from CEU San Pablo, Madrid, specializing in Auditing, in 1993. He began his professional career working in important international pharmaceutical companies, such as Nielsen Group in Spain, Tyco Group in the United States, and Boots Pharmaceuticals in the United Kingdom, in different pharmaceutical areas. He is a Vice-president of the Board of Governors and Executive Board of Farmaindustria and Chairman of the R&D&I Commission of the CEOE (Spanish Confederation of Business Organizations). He is a shareholder of Norbel Inversiones, S.L. (ROVI's controlling shareholder).



***Mr. Javier López-Belmonte Encina***

Chief Financial Officer since 2001 and Second Deputy Chairman of ROVI's Board of Directors, he graduated in Economic and Business Sciences from Colegio Universitario de Estudios Financieros (CUNEF), Madrid, specializing in Financing, in 1998. He began his professional career in the banking sector in 1998, working for Argentaria, S.A. in the United Kingdom as an analyst and in the pharmaceutical sector with Medeva Pharma. He joined ROVI in 2000. He is a member of the Board of Governors and Vice-president

of the Executive Committee of the CEIM (Madrid Business Confederation). Likewise, he is Chairman of the Health and Social Affairs Commission of the CEIM and a member of the Board of Directors of Avalmadrid, representing the Madrid Business Confederation-CEOE. He is also a member of the Social Council of the Universidad Autónoma de Madrid and a shareholder of Norbel Inversiones, S.L. (ROVI's controlling shareholder).



**Mr. Iván López-Belmonte Encina**

Corporate Development Manager since 2007, Assistant General Manager since 2001 and First Deputy Chairman of ROVI's Board of Directors, he graduated in Economic and Business sciences from Universidad Complutense de Madrid, specializing in Auditing, in 1994. He began his professional career in Germany, working in pharmaceutical sector companies such as Amersham and Hexal AG. He has been working for the Company since 1994. He is a shareholder of Norbel Inversiones, S.L. (ROVI's controlling shareholder).



**Mr. Miguel Corsini Freese**

One of ROVI's external independent directors, he was appointed as a director of ROVI by co-option on 12 November, 2008 and ratified and re-elected by the General Shareholders' Meeting held on 17 June, 2009. He was further re-elected for the Bylaw-stipulated term of office by the General Meeting held on 12 June, 2014. Mr. Miguel Corsini was Chairman of the Board of Directors of RENFE for several years and President of IUR (International Union of Railways) from 1998 to 2000. He is currently a member of the Executive Commission of Confederación Empresarial de Madrid (CEIM) (Madrid Business Confederation) and a member of the Plenary Session of the Madrid Chamber of Commerce. He has also been the treasurer of the same Chamber of Commerce and, in October 2007, was appointed First Vicepresident. Likewise, Mr. Corsini is the President of Cetren and sits on the Boards of Directors of several companies, such as Azvi and Legalitas.



**Mr. Enrique Castellón Leal**

One of ROVI's external independent directors, he was appointed as a director of ROVI on 24 October, 2007 and re-elected for a five-year term at the General Meeting held on 13 June, 2012. He is a regular participant in several foundations engaged in promoting Research & Development in health sciences; carries on consulting activities with Castellón Abogados; and has worked as a health project consultant on several Inter-American Development Bank projects (World Bank Group). He has been a physician with the Internal Medicine Service at Hospital Clínico San Carlos, Madrid, a Social Security Medical Inspector, General Manager of the Galician Health Service, Deputy Head of the Health Department of the Madrid Autonomous Region and Undersecretary at the Ministry of Health and Consumption. He is a founding shareholder and Chairman of the Board of Directors of Cross Road Biotech FCR, Chairman of Cross Road Biotech Inversiones Biotecnológicas, SGEGR, S.A., Health in Code S.L. and Venter Pharma S.L., and is a member of the Board of Directors of Atlas Molecular Pharma S.L., Owl Genomics, S.L. and Biocross, S.L.



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

One of ROVI's external independent directors, he was appointed to the Board on 9 June, 2015 for the Bylaw-stipulated term of four years. Mr. Almansa is a diplomat. He has been Secretary of the Spanish Embassy in Brussels, Cultural Attaché at the Spanish Embassy in Mexico, Chief Director of the Coordination Section of the Subdirector-General for Eastern Europe, Director of Atlantic Affairs at the Directorate-General of Foreign Policy for Europe and Atlantic Affairs, Political Counsellor to the Permanent Representative of Spain on the North Atlantic Council, Minister-Counsellor of the Spanish Embassy in the Soviet Union, Secretary General of the National Commission for the Fifth Centenary of the Discovery of American and Subdirector General for Eastern Europe, reporting to the Directorate-General of Foreign Policy for Europe. Likewise, from 1993 to 2002, he was appointed Privy Councillor to HRH King Juan Carlos I. Currently, he is a member of the Board of Directors of the company Telefónica Móviles México, S.A. de C.V.



## Committees

In order to enhance its efficiency in performing its duties, the Board of Directors organizes its work through two committees: the Nomination and Compensation Commission and the Audit Committee.

### NOMINATION AND COMPENSATION COMMISSION.

It is formed by three directors, all of whom are independent. They were appointed on the basis of their knowledge, skills and experience in relation to the tasks they are required to perform. The Chairman is also an independent director and must be replaced every four years, although he can be re-elected when one year has elapsed since he left the position. The Commission's main role is to report on and submit proposals on the appointment and dismissal of directors and senior management to the Board of Directors, assessing the skills, knowledge and experience necessary on the Board, as well as the time and dedication required from Board members for the proper fulfilment of their duties; preparing and reviewing the criteria that should be followed regarding the composition of the Company's management team; and striving to ensure that the compensation policy established by the Commission is observed and remains transparent. In 2016, it met on four occasions, which was sufficient to allow it to carry out its duties correctly.

### AUDIT COMMITTEE.

It is formed by three Board members, all of whom are independent, appointed on the basis of their knowledge and experience in accounting, auditing or risk management, as well as their knowledge, skills and experience in relation to the Committee's other duties. The Chairman is also an independent director, likewise appointed on the basis of his knowledge and experience in accounting, auditing or both, and must be replaced every four years, although he can be re-elected when one year has elapsed since he left the position. Among other duties, the Committee supervises the process of preparing the financial reporting on the Company and the Group, ensuring it is complete; regularly reviews the information and internal control systems and risk management policy; and strives to ensure the independence and efficacy of the auditors. It meets on a quarterly basis to review the financial information which the Company, as a listed company, must publish regularly. In 2016, the Committee held six meetings, one of which was held using the written procedure without the physical presence of the members. Therefore, its meetings were sufficiently frequent to allow it to carry out its duties correctly.

## Management Committee

Since 15 February, 2017, the Management Committee has been formed by 14 members who represent ROVI's main organizational areas. The Management Committee, led by the CEO, Mr. Juan López-Belmonte Encina, is the body to which the Board of Directors delegates the day-to-day running of the Company.

The composition of the Management Committee is as follows:

- Mr. Juan López-Belmonte Encina. Chief Executive Officer.
- Mr. Javier López-Belmonte Encina. Chief Financial Officer.
- Mr. Iván López-Belmonte Encina. Corporate Development Manager.
- Mr. Francisco Javier Ángulo García. Human Resources Manager.
- Ms. Beatriz Ávila Alcalde. Sales Manager, Line B.
- Ms. Mercedes Benítez del Castillo Sánchez. Legal Department Manager.
- Mr. Pedro Carretero Trillo. Hospital Network Manager.
- Mr. Miguel Ángel Castillo Román. International & Business Development Manager.
- Mr. Pablo Domínguez Jorge. Financial-Administrative Manager.
- Mr. Ibón Gutierrez Adúriz. Research and Development Manager.
- Mr. Fernando Martínez Garijo. Sales Effectiveness Manager.
- Ms. Maite Muñoz Pineda. Sales Manager, Lines C & D.
- Mr. Miguel Ángel Ortega Sánchez. Industrial Manager.
- Ms. M<sup>a</sup> Rosario Perucha Pérez. Marketing Manager.

This Committee reflects ROVI's commitment to promoting a policy of equal opportunities for men and women, avoiding discrimination in wages, training, promotion opportunities or any other area.

The composition of the Committee favours diversity of knowledge, experience and gender, with women accounting for close to 30% of the total members.

- 62
1. Mr. Francisco Javier Ángulo García. Human Resources Manager.
  2. Ms. Mercedes Benítez del Castillo Sánchez. Legal Department Manager.
  3. Mr. Fernando Martínez Garijo. Sales Effectiveness Manager.
  4. Ms. Maite Muñoz Pineda. Sales Manager, Lines C & D.
  5. Ms. M<sup>a</sup> Rosario Perucha Pérez. Marketing Manager.
  6. Mr. Ibón Gutierro Adúriz. Research and Development Manager.
  7. Mr. Iván López-Belmonte Encina. Corporate Development Manager.
  8. Mr. Juan López-Belmonte Encina. Chief Executive Officer.



9. Mr. Miguel Ángel Ortega Sánchez. Industrial Manager.  
10. Ms. Beatriz Ávila Alcalde. Sales Manager, Line B.  
11. Mr. Miguel Ángel Castillo Román. International & Business Development Manager.  
12. Mr. Pedro Carretero Trillo. Hospital Network Manager.  
13. Mr. Javier López-Belmonte Encina. Chief Financial Officer.  
14. Mr. Pablo Domínguez Jorge. Financial-Administrative Manager.



## Incorporation of CSR into ROVI's management

ROVI incorporates CSR into its governance, management and day-to-day operations. CSR decisions are made by the Board of Directors and, in particular, the Board is responsible for approving the Company's Corporate Social Responsibility Policy, in accordance with article 5.3 of the Regulations of the Board of Directors.

According to article 13 of the Regulations of the Board, the Audit Committee is responsible for reviewing the CSR Policy, ensuring that it is orientated towards value creation, and for monitoring corporate social responsibility strategies and assessing the degree of compliance therewith.

Likewise, the Nomination and Compensation Commission is the body responsible for reviewing the Company's CSR Policy, ensuring that it is orientated towards value creation.

In 2016, subsequent to a favourable report from the Nomination and Compensation Commission, the Board of Directors examined and approved the Corporate Social Responsibility Report for 2015, which had been prepared in accordance with Recommendation 55 of the Good Governance Code.

This Report is published on ROVI's website, thus complying with Recommendation 6 of the Good Governance Code.

*CSR decisions are made by the Board of Directors*





## Compensation Policy

In compliance with article 14 of the Regulations of the Company's Board of Directors, which incorporates the provisions of article 529 quidecies, of Royal Legislative Decree 1/2010 of 2 July, whereby the revised text of the Capital Companies Act was approved (the "Capital Companies Act"), the Nomination and Compensation Commission prepared a compensation policy for the Company's directors and senior management in 2016, which was submitted to the Board of Directors for approval.

Likewise, ROVI's General Shareholders' Meeting held on 31 May, 2016 approved, at the proposal of the Board of Directors, with a prior favourable report from the Nomination and Compensation Commission, the director compensation policy for 2016 and the three following years (2016-2019), in accordance with article 529 novodecies of the Capital Companies Act.

In order to prepare said director compensation policy, the Company received advice from Landwell-PricewaterhouseCoopers Tax & Legal Services, S.L.

According to article 45 of the Company's Bylaws, the members of the Board of Directors are entitled to be compensated, in their capacity as such, by a fixed annual sum in cash, the maximum global amount of which for the entire Board will be determined by the General Shareholders' Meeting. The Board will distribute the compensation decided by the General Meeting among its members, taking into account the duties and responsibilities attributed to each director, whether or not they sit on Board committees and any other objective circumstances that the Board of Directors deems relevant.

Additionally, irrespective of the compensation mentioned above, although likewise within the framework of the compensation policy, provision is made for the possibility that the General Shareholders' Meeting may establish director compensation systems linked to the share price, or systems that entail awarding shares or share options.

### *The General Shareholders' Meeting approved the director compensation policy for 2016 and the three following years*

According to article 24 of the Regulations of the Board of Directors, compensation through the award of Company shares may also be considered for compensating non-executive directors, when this is subject to the shares being held by the director in question until he/she leaves the Board, unless he/she needs to dispose of them to settle costs related to their acquisition.

Insofar as concerns the weight of variable compensation items in respect of fixed items, the Company's compensation policy has been and is for the executive directors' fixed compensation to represent a significant proportion of their total compensation.

The executive directors will receive an annual bonus in relation to the targets fixed for each year, which may total up to 50% of the fixed global compensation received by the executive directors overall as members of senior management (this percentage may be raised to 60% in the event that the targets are surpassed), depending on attainment of the objectives fixed for the Group and for each director at the beginning of the period.

The Company's director compensation policy does not provide for any variable compensation being paid to external directors.

In 2016, the Board of Directors distributed 510 thousand euros among its members, out of the maximum sum of 600 thousand euros approved by the General Meeting as the fixed annual compensation of Board members for 2016



## **The Board distributed 382 thousand euros as variable compensation**

for performing their duties and responsibilities as directors. It was allocated on the basis of the duties and responsibilities assigned to each director and whether or not he sat on any Board Committees and the distribution was proposed by the Nomination and Compensation Commission.

Likewise, the Board agreed to distribute global fixed annual compensation of 850 thousand euros among the executive directors as remuneration for their executive and senior management duties, in accordance with the terms of their contracts as executives and the terms and conditions agreed with the Company, taking the duties and responsibilities performed by each director into account and likewise based on the proposal submitted by the Nomination and Compensation Commission. Once the relevant adjustments had been made in accordance with the conditions of their contracts, the executive directors received an actual total amount of 771 thousand euros as global fixed remuneration.

At the proposal of the Nomination and Compensation Commission, the Board distributed 382 thousand euros as variable compensation, taking the following three objectives assigned to each executive director for 2016 into account:

- a. *A quantitative financial objective at ROVI Group level, which, for the three executives, consisted of the ROVI Group's obtaining the operating revenue fixed in the 2016 Budget.*
- b. *A second quantitative financial objective, at departmental level, which, for the three executives, considered the results obtained by the different management areas for which each one of the executives is responsible.*

- c. *A third objective, fixed individually and qualitative in nature, consisting of the development and, if appropriate, execution of projects considered strategic for the ROVI Group in which the executive directors were involved.*

The Annual Director Compensation Report drawn up by the Board of Directors is available on the Company's website ([www.rovi.es](http://www.rovi.es)) and at the CNMV ([www.cnmv.es](http://www.cnmv.es)).

ROVI's payroll, which consisted of 1,150 employees at 31 December, 2016, received gross global annual compensation of around 60 million euros in 2016.

# Ethics Framework

In order to reaffirm the values and principles which are the basis for ROVI's activities, the Group has a Code of Ethics, approved by the Board of Directors, the objective of which is for all interactions with shareholders and with society in general to be governed by ethics and good practices. This Code of Ethics is mandatory for all employees and serves as a guide when they are carrying out their duties or in the event of conflicts of interest.

According to the Code, the Company undertakes to apply the highest standards of ethics and transparency in its communications, information records and reports regarding both financial matters and its products and activities. This entails the obligation for the accounting, financial statements, books, records and accounts of both the Group and the individual companies to be prepared in compliance with legal requirements and for current accounting principles to be applied correctly, in order to provide an accurate picture of their business activities and financial situation.

The Code of Ethics establishes a complaints channel that may be used by any Company employee in the event that they detect breaches of the Code of Ethics. Additionally, the Company has a specific confidential complaints channel that allows any financial and/or accounting irregularities to be notified.

According to the Code, the Code of Ethics Monitoring Commission is responsible for analyzing breaches of the Code and proposing corrective actions and penalties and will submit an annual report on the actions taken during the year to the CEO. The Audit Committee will strive to ensure the independence of the auditors, in order to guarantee the accuracy of the public information issued by the Company.

***The Code of Ethics establishes a complaints channel that may be used by any Company employee***

The Group also endeavours to monitor and control the Good Governance Code recommendations. Thus, the Company has mechanisms to avoid forms of conduct that are damaging to its shareholders and stakeholders, such as the concentration of power, lack of transparency or lack of auditor independence.

Likewise, the Company has an anti-bribery and anti-corruption policy that applies to all ROVI's employees and agents. It defines and describes the actions to be taken in cases of: bribery, political contributions, charity contributions and sponsorship, facilitation payments, gifts, hospitality and expenses, and accounting control.

ROVI is committed to actively supporting the Universal Declaration of Human Rights and requires its employees to comply with the principles thereof in the course of the Group's day-to-day activity. The Company combats practices contrary to human dignity and strives to prevent workplace discrimination.

No breaches of the Code of Ethics were detected in 2016.

# Risk Management

ROVI has a Risk Management and Control System that allows any possible contingency that could prevent the attainment of corporate objectives to be identified, classified, assessed and provided with a response.

The objectives of this system, which is supervised by the Audit Commission, are to promote attainment of the proposed objectives, avoid adverse impacts derived from the materialization of risks, preserve the Company's image and reputation, ensure continuity in the analysis and detection of possible threats, obtain reliable accounting information and reinforce confidence in the Company's compliance with the applicable rules.

ROVI follows a risk management and control model based on three lines of defence:

- The first line of defence is formed by the Group's different operating areas, which, in the course of their day-to-day operations, must identify, classify, assess and monitor the risks, in accordance with the risk level accepted by ROVI.
- The second line of defence comprises the risk control and management service. This service is responsible for the implementation of the risk control and management system, cooperating in initially establishing it and, once it is in place, contributing to its enhancement, monitoring its performance and coordinating its development.
- The third line of defence is Internal Audit, which supervises the internal control and risk management systems by auditing both the first and second lines of defence.

## Responsibility for risk control, monitoring and management

According to the Risk Management and Control Policy, which includes the general risk management principles applied in Rovi, the bodies involved in this management are:

### 1. AUDIT COMMISSION

This is the body responsible for reviewing and supervising the Company's internal control and risk management mechanisms, as well as their efficacy, so that the main risks can be appropriately identified, managed and made known.

### 2. MANAGEMENT COMMITTEE

The Management Committee identifies, classifies, assesses and monitors the risks, taking the categories of risk and acceptable risk levels fixed by the Audit Committee into account, and applies the measures that are in place to mitigate the impact in the event that any risks materialize.

### 3. HEAD OF RISK MANAGEMENT AND CONTROL SYSTEMS

Duties include the task of implementing the System, cooperating in initially establishing it and, once it is in place, contributing to its enhancement, monitoring its performance and coordinating its development. Likewise, he/she reports periodically to the Audit Committee on the correct operation of the System and/or, if applicable, any risks that may have materialized.

## Risk Control and Management Process

The steps that ROVI follows in risk management are as follows:

**1 Fixing the risk level.** The Audit Committee establishes a risk classification in accordance with the possible economic impact, considering the probability of occurrence and a valuation of the losses that a risk could cause if it materialized.

**2 Identification.** The different areas of ROVI proceed to identify the risks that could affect attainment of the Company's objectives. Once they have been identified, risks are classified as follows:

- Strategic risks: those that affect high-level objectives, directly related to ROVI's strategic plan.
- Operational risks: those that affect objectives related to the efficiency and efficacy of the operations, including objectives concerning performance and profitability.
- Reporting risks: they affect objectives concerning the reliability of the information provided both internally and externally.
- Compliance risks: those that affect compliance with the applicable rules and legislation.

**3 Assessment.** Each one of the risks identified is assessed in accordance with the probability of occurrence and impact. The assessment obtained will determine the position of each risk on the corporate risk map.

**4 Determination of the response to a risk.** Measures are adopted to tackle any possible contingencies as efficiently and economically as possible, minimizing exposure. At the same time, mechanisms and procedures must be put in place to allow management to supervise the implementation of actions to neutralize any risk detected and control their effectiveness.

**5 Risk management monitoring.** All the departments have both periodic and continuous information systems capable of duly capturing any changes that have either already taken place or will be taking place in the future that might prevent attainment of objectives under the forecast conditions, as well as the viability, efficiency, efficacy and sufficiency of the responses established for the different risks.

**6 Reporting to the Audit Committee.** The Audit Committee is informed on at least the following aspects of risk management with a minimum frequency of every six months:

- Whether the Risk Control and Management System is operating efficiently or not, taking possible changing conditions, both internal and external, into account.
- Whether Risk Management incidents are detected and solved swiftly.
- Whether the Map has been duly updated with the applicable changes (changes in the risks considered, any applicable new risks, etc.).
- Whether any of the risks included in the Catalogue or any other risk materialized in the preceding period.

## Risk Map

The main risks to which the Company considers it is exposed in respect of meeting its business objectives and which, among others, form part of the risks included in the Corporate Risk Map are:

### Risk Map

#### Strategic risks

Changes in the market rules and regulations aimed to contain pharmaceutical expenditure (price control, reference pricing, promotion of the use of generic drugs, co-payment, purchase platforms).

End of the contractual relationship with customers who represent a significant part of its sales or renewal under terms that are less favourable than the current ones.

Changes in the supply conditions for raw materials and other packaging materials necessary for the manufacture of its products.

#### Operational risk

Short-term delay in payment from the public authorities.

#### Compliance risk

Tax risk inherent to companies of the size and complexity of ROVI.

ROVI is permanently vigilant and alert to the risks that may have an adverse effect on its business activities, applying the appropriate principles and mechanisms to manage them and constantly developing contingency plans able to mitigate or offset their impact. Among them, we can highlight the fact that the Company has an internal saving plan, which concentrates on improving efficiency, likewise continuing with its objective of opening up new markets as a result of its international expansion plan and working incessantly to maintain broad and diversified product and customer portfolios.

Furthermore, the Company implements strict credit control and effective cash management that ensures that sufficient working capital is generated and maintained to enable it to carry out its day-to-day operations. The Company has an exhaustive tax risk control system, with external tax advisors that review both the preparation and filing of the different taxes and tax decision-making.

## Risks materialized in 2016

In 2016, ROVI had to face changes in prescription criteria and the pricing system established by the competent authorities, as well as other pharmaceutical expenditure containment measures.

The pharmaceutical expenditure containment measures that have been affecting the pharmaceutical sector over recent years through Royal Decree-Laws 4 and 8/2010, 9/2011 and 16/2012 and, in particular, Royal Decree 177/2014 of 21 March, which regulated the reference pricing system and homogenous drug groups in the National Health System and certain information systems concerning medicine and health product financing and prices, as well as the successive Ministerial Orders that updated the reference pricing system for medicines in the National Health System, have been causing a significant decrease in public expenditure on pharmaceuticals in Spain since 2010.

The entry into force of Order SSI/2160/2015 of 14 October, which updated the reference pricing system for medicines in the National Health System, and Order SSI/1305/2016 of July 27, which updated the reference pricing system for medicines in the National Health System in 2016, have not

***ROVI is persevering with a saving plan that has concentrated on enhancing the efficiency of its operating processes***

had a material impact for ROVI, since the number of Group products affected has been very low and, furthermore, they had already been affected by previous Royal Decrees.

Although, basically, the impact of these latest measures has been minimal for ROVI because its product portfolio is new, the Company continues to work to maintain a well-diversified product portfolio in which the boost provided by innovative and competitive products offsets and surpasses the deceleration of those most affected by the governmental and regional measures to contain pharmaceutical expenditure. Additionally, ROVI is persevering with an internal saving plan that has concentrated principally on enhancing the efficiency of its internal and external operating processes.



# PERIOD 2016

**73** Results  
for the period

**86** Customers

**89** Human resources

**98** Suppliers

**101** Society and  
public authorities

**105** Environment



# Results for the period

## 2016

### April

ROVI leads the BIOMAP consortium, created to drive forward the multivariate design of assays in order to develop biopharmaceuticals with the pharmaceutical industry's highest criteria of quality, safety and efficacy.

### November

Agreement for the marketing of Nevarpis®, a Novartis medicine indicated for symptomatic chronic heart failure with reduced ejection (the proportion of blood leaving the heart) fraction, in Spain.

## 2017

## Highlights

### March

Creation of the joint venture Enervit Nutrition, S.L., held by ROVI and the Italian company Enervit, S.p.A., to distribute and market dietetic, food and nutritional products, as well as other non-pharmacological products, in Spain and Portugal.

### August

Signature of an agreement with Orexigen Therapeutics Ireland Ltd. to market Mysimba®, a medicine used to control weight in patients suffering from obesity and its complications (for example, type 2 diabetes, dyslipidemia or controlled hypertension).

### March

Successful completion of the procedure to apply for marketing authorization for the enoxaparin biosimilar in 26 European Union countries.

## Financial results

ROVI continues to grow year after year, in spite of the unfavourable market environment in which it is operating. As a result of the strength of the pharmaceutical specialties business, operating revenue increased by 8% to 265.2 million euros in 2016. The prescription-based pharmaceutical business was especially prominent in the year, with sales increasing by 18%, well above the market average. Total revenue was 266.7 million euros, more than double the total revenue in 2007, when ROVI was first listed on the stock markets.

### In 2016, ROVI attained the highest EBITDA and net profit of its history

EBITDA increased by 24% in comparison with 2015, totalling 39.3 million euros, with the EBITDA margin rising from 12.9% in 2015 to 14.8% in 2016, an increase of 1.9 percentage points. This was mainly due to the positive impact of non-recurrent revenue of 4 million euros recognized as a consequence of the creation of a joint venture by ROVI and Enervit for the distribution of nutritional products in Spain and Portugal. Notwithstanding, excluding the effect of this non-recurrent revenue, the EBITDA would have risen by 11% to 35.3 million euros, showing an increase of 0.4 percentage points in the EBITDA margin, which would have risen to 13.3% in 2016.

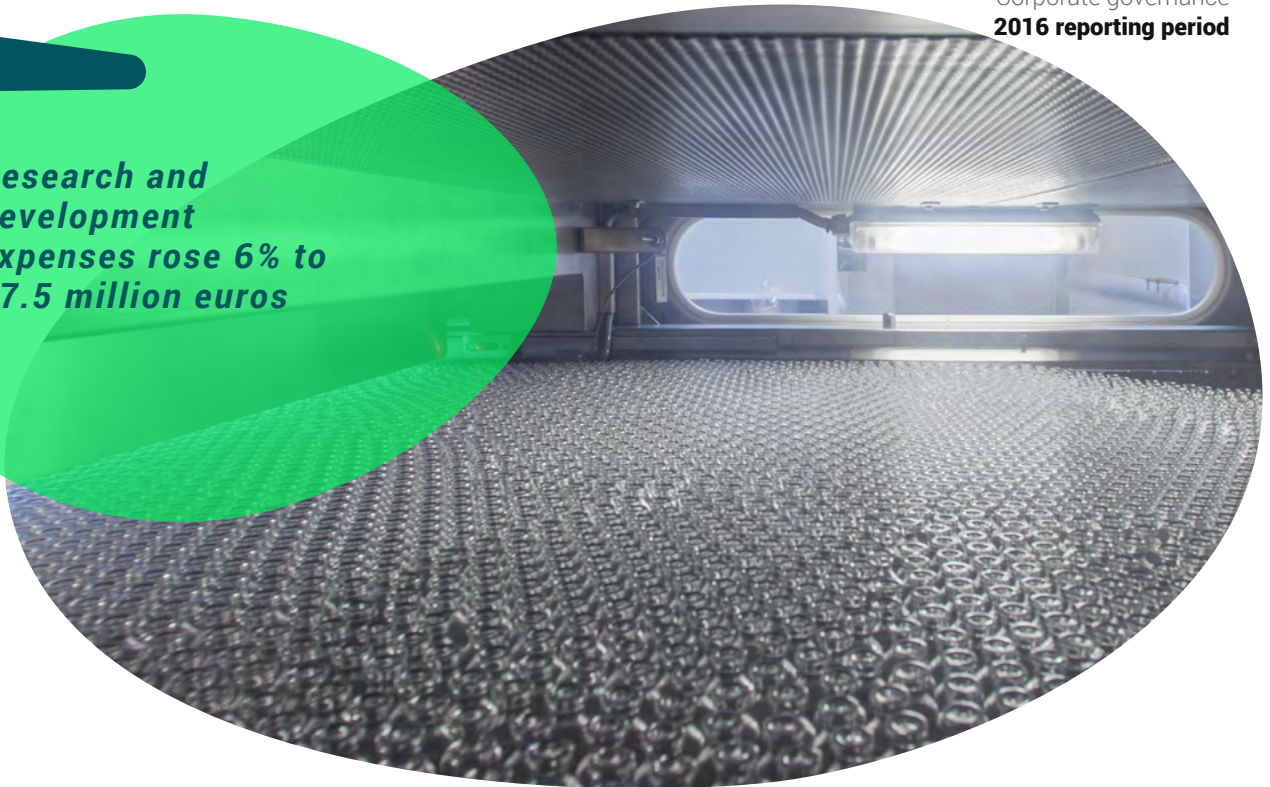


## Results

MILLIONS OF EUROS

	2016	2015	2014
<i>Sales</i>	266.7	247.0	240.9
<i>EBITDA</i>	39.3	31.8	36.6
<i>EBIT</i>	28.3	21.8	27.7
<i>Net profit</i>	26.1	19.8	24.1
<i>Investment</i>	18.1	19.9	25.1
<i>Financial debt</i>	33.8	42.8	36.3
<i>Net financial debt</i>	9.0	12.1	8.3

**Research and  
development  
expenses rose 6% to  
17.5 million euros**



EBIT rose by 30% in comparison with the preceding year, totalling 28.3 million euros in 2016 and showing an increase of 1.8 percentage points in the EBIT margin, up from 8.9% in 2015 to 10.7% in 2016. Once again, this was affected favourably by the aforementioned non-recurrent revenue, excluding which it would have increased by 11% to 24.3 million euros, with a rise of 0.3 percentage points in the EBIT margin, which would have risen to 9.2% in 2016.

Net profit rose to 26.1 million euros in 2016, an increase of 32% on the preceding year. Excluding the profit on the joint venture between ROVI and Enervit, net profit also showed a high growth rate and would have increased by 13% to 22.3 million euros.

Sales expenses, overheads and administration expenses were 101.9 million euros in 2016, which was similar to the 2015 figure in spite of the increase in sales, principally due to the launch of products such as Hirobriz®, Ulunar®, Volutsa® and Orvatez® in 2015, which involved expenses of 3.3 million euros, and strict cost control on the part of ROVI, which was maintained in 2016.

Depreciation and amortization expenses increased by 11% in 2016 in comparison with the preceding year and totalled 11.0 million euros, as a result of the new property, plant and equipment and intangible assets purchases made in the last twelve months.

Finally, research and development expenses (R&D&i) rose 6% to 17.5 million euros in 2016, as a result of the preparation of the phase III trial for Risperidone ISM® and formulation development activities for the phase III trial of Risperidone ISM® and the phase I trial of Letrozol ISM®. The slight increase was mainly due to a delay in commencing the phase III trial of Risperidone ISM® as a consequence of the various meetings held with the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA) in order to obtain scientific advice on the design of the phase III clinical study.

ROVI expects growth to continue in 2017, even though a new adjustment of 550 million euros in pharmaceutical spending is forecast for the year, according to the Budget Plan sent by the Spanish government to the European Commission<sup>9</sup>, and the QuintilesIMS<sup>10</sup> forecast which indicates a 1%-4% growth rate to 2021.

(9) [http://www.mineco.gob.es/stfls/mineco/comun/pdf/161017\\_plan\\_presupuestario.pdf](http://www.mineco.gob.es/stfls/mineco/comun/pdf/161017_plan_presupuestario.pdf)

(10) Outlook for Global Medicines through 2021. Report by the QuintilesIMS Institute.



Key figures  
Letter from the Chairman  
About this Report  
Business model  
Strategy  
Corporate governance  
**2016 reporting period**

76

## Consolidated statement of financial position

THOUSANDS OF EUROS

<b>ASSETS</b>	<b>31 December, 2016</b>	<b>31 December, 2015</b>
<b>NON-CURRENT ASSETS</b>		
Property, plant and equipment	82,822	81,803
Intangible assets	24,872	18,881
Investment in joint venture	2,571	-
Deferred tax assets	10,252	8,871
Available-for-sale financial assets	70	70
Financial receivables	189	139
<b>Total non-current assets</b>	<b>120,776</b>	<b>109,764</b>
<b>CURRENT ASSETS</b>		
Inventories	67,386	63,859
Trade and other receivables	53,842	57,028
Current tax assets	4,466	3,945
Cash and cash equivalents	41,378	29,251
<b>Total current assets</b>	<b>167,072</b>	<b>154,083</b>
<b>TOTAL ASSETS</b>	<b>287,848</b>	<b>263,847</b>
<b>EQUITY</b>		
<b>CAPITAL AND RESERVES ATTRIBUTABLE TO COMPANY SHAREHOLDERS</b>		
Share capital	3,000	3,000
Legal reserve	600	600
Treasury shares	(8,701)	(8,112)
Retained earnings and voluntary reserves	162,421	149,490
Profit for the period	26,089	19,809
Reserve for available-for-sale assets	(3)	(2)
<b>Total equity</b>	<b>183,406</b>	<b>164,785</b>
<b>LIABILITIES</b>		
<b>NON-CURRENT LIABILITIES</b>		
Financial debt	20,828	32,631
Deferred tax assets	1,640	1,344
Deferred revenue	5,532	5,861
<b>Total non-current liabilities</b>	<b>28,000</b>	<b>39,836</b>
<b>CURRENT LIABILITIES</b>		
Trade and other payables	59,852	45,742
Financial debt	12,966	10,147
Deferred revenue	746	840
Provisions for other liabilities and charges	2,878	2,497
<b>Total current liabilities</b>	<b>76,442</b>	<b>59,226</b>
<b>TOTAL LIABILITIES</b>	<b>104,442</b>	<b>99,062</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>287,848</b>	<b>263,847</b>



## Consolidated income statement

THOUSANDS OF EUROS

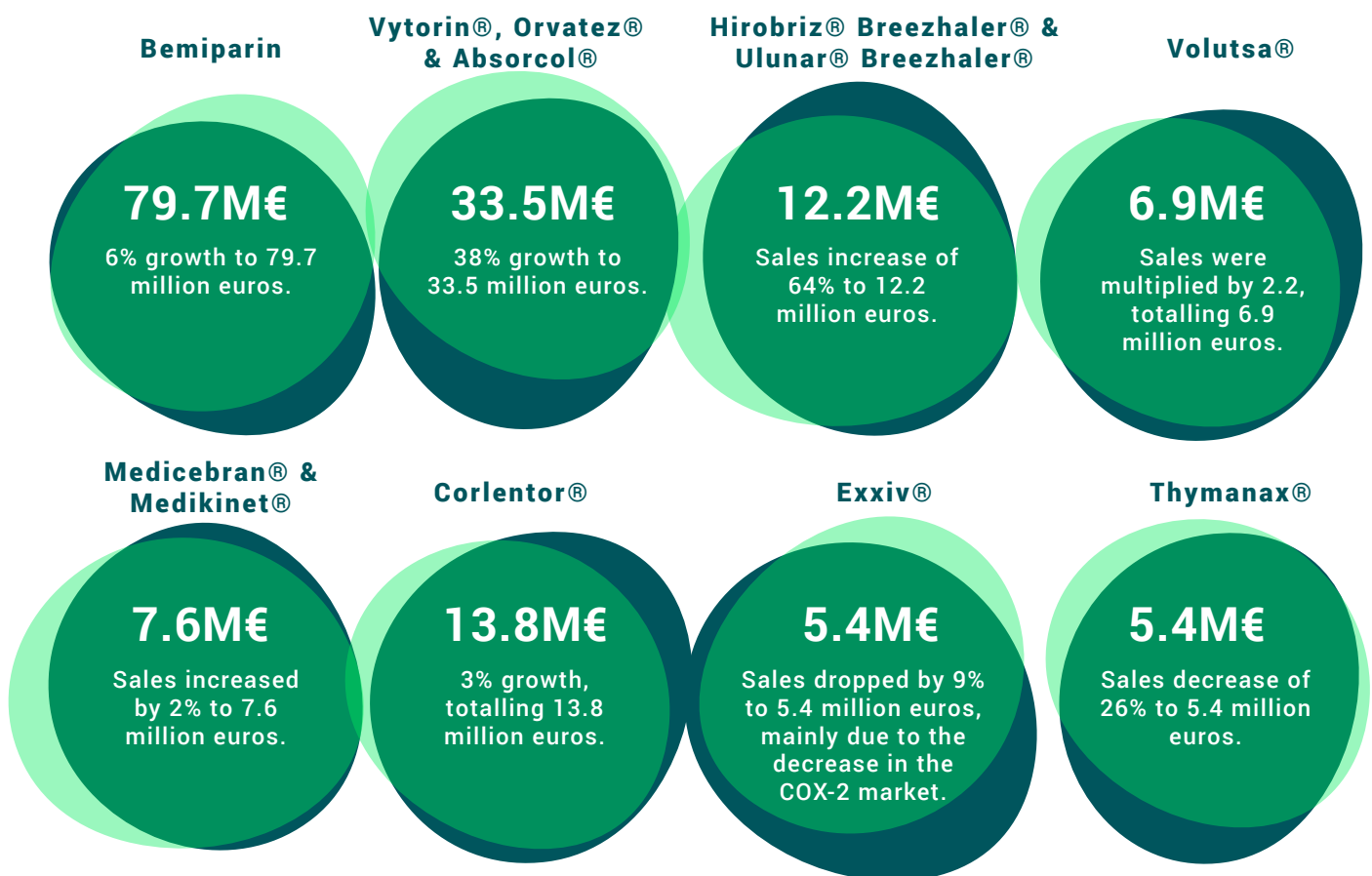
	<i>Period ended 31 December</i>	<b>2016</b>	<b>2015</b>
Revenue		265,166	246,009
Cost of sales		(112,024)	(97,075)
Employee benefit expenses		(60,465)	(61,769)
Other operating expenses		(58,916)	(56,361)
Depreciation, amortization and impairment		(11,023)	(9,975)
Recognition of government grants on non-financial assets and other		1,565	1,013
Other income		3,997	-
<b>OPERATING PROFIT</b>		<b>28,300</b>	<b>21,842</b>
Finance income		426	837
Finance costs		(915)	(1,781)
<b>FINANCE COSTS - NET</b>		<b>(489)</b>	<b>(944)</b>
Share in profit from joint ventures		71	-
<b>PROFIT BEFORE TAX</b>		<b>27,882</b>	<b>20,898</b>
Income tax		(1,793)	(1,089)
<b>PROFIT FOR THE PERIOD</b>		<b>26,089</b>	<b>19,809</b>

## Bemiparin, once again, the leader in ROVI's business growth

Sales of prescription-based pharmaceuticals grew by 18% to 177.3 million euros in 2016. Sales of Bemiparin, ROVI's low-molecular-weight heparin (LMWH) performed very positively in 2016, with growth of 6% to 79.7 million euros. Sales in Spain (Hibor®) rose by 9% to 54.7 million euros and international sales showed a 1% increase to 24.9 million euros in 2016, mainly due to the launching of the product in two new countries –Argentina and the Philippines- in 2016.

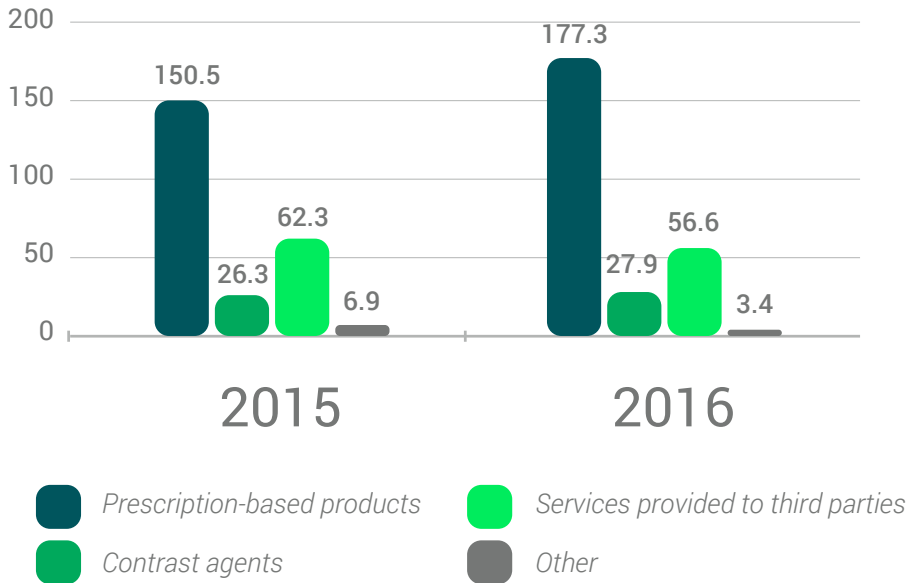
ROVI's sales outside Spain decreased by 8% in comparison with the preceding year, dropping to 76.4 million euros. They accounted for 29% of operating income in 2016, in comparison with 34% in 2015. This was mainly a result of the deceleration in the contract manufacturing business, sales of which are essentially aimed at international markets.

### Sales by product in 2016



## Operating income by business area

MILLION EUROS



### Deceleration in contract manufacturing business

Contract manufacturing sales dropped by 9% in 2016, falling to 56.6 million euros, mainly due to a decrease of 5.1 million euros in the revenue from the Frosst Ibérica plant, which was 25.8 million euros in 2016, as a consequence of lower production for MSD after expiry of the initial contract with said company on 31 March, 2015. Furthermore, revenue from the injectables plant fell by 0.6 million euros.

### Growth in diagnostic imaging contrast agents and other hospital products

Sales of diagnostic imaging contrast agents and other hospital products rose by 6% in 2016, totalling 27.9 million euros, while sales of non-prescription pharmaceuticals (OTC) and others dropped to 3.2 million euros, a decrease of 52% on the preceding year. Attention should be drawn to the fact that, in 2016, OTC sales only included those of

### Sales of diagnostic imaging contrast agents and other hospital products rose by 6%

the first quarter for the EnerZona product, as a result of the joint venture created by ROVI and Enervit at the end of the year for the distribution of nutritional products in Spain and Portugal.

Finally, the other revenue caption (grants) showed a 54% increase to 1.6 million euros in 2016, rising from 1 million euros in 2015.

## Breakdown by type of debt

THOUSANDS OF EUROS

	2016	2015
<i>Banks borrowings</i>	20,931	28,179
<i>Debt with government entities</i>	12,863	14,599
<b>Total</b>	<b>33,794</b>	<b>42,778</b>

## Analysis of the financial position

Regarding capital management, ROVI remains true to its objective of having low leverage. This makes it easier for the Group to obtain external funding to undertake new investments, if necessary.

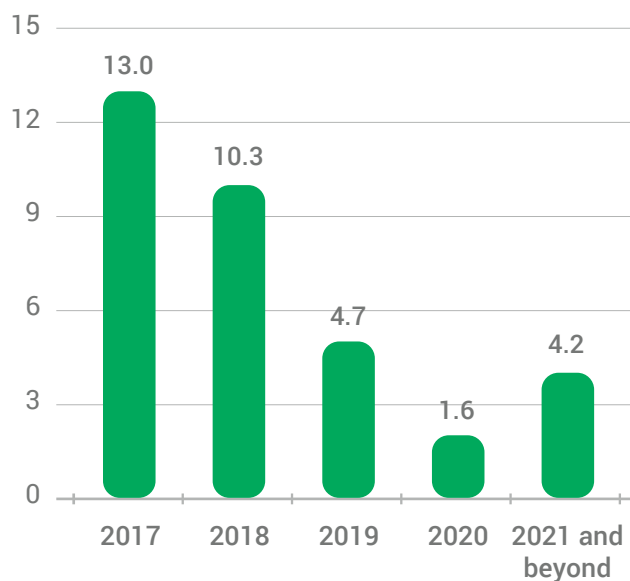
At 31 December, 2016, ROVI had total debt of 33.8 million euros. Debt with government entities, at a 0% interest rate, represented 38% of this figure at said date. The total debt owing to ROVI by the Social Security and public authorities was 6.0 million euros, 4.9 million euros of which related to Spain and 1.1 million euros to Portugal.

The increase in working capital in 2016 was mainly due to an increase of 14.1 million euros in the "Trade and other payables" caption and a decrease of 3.2 million euros in the "Trade and other receivables" caption. Inventories increased by 3.5 million euros as a result of the higher levels of stock of sodium heparin in 2016 and cash rose by 12.1 million euros in comparison to the preceding year.

ROVI had a gross cash position of 42.8 million euros at the end of 2016, in comparison with 30.7 million euros at 31 December, 2015, with a net cash position of 9.0 million euros (available-for-sale financial assets, plus cash and cash equivalents, less current and non-current financial debt), in comparison with net debt of 12.1 million euros in 2015. The finance income item decreased by 49% in 2016 in comparison with 2015, when non-recurrent gains were obtained on financial exchange rate investments. Finance costs likewise decreased by 49% in 2016 in comparison with 2015.

## Debt calendar

MILLION EUROS





## Consolidated statement of cash flows

THOUSANDS OF EUROS

	<i>Period ended 31 December</i>	<b>2016</b>	<b>2015</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Profit before income tax		27,882	20,898
<b>ADJUSTMENTS FOR NON-MONETARY TRANSACTIONS:</b>			
Amortization, depreciation and impairment		11,023	9,975
Interest income		(426)	(837)
Impairment losses		1,864	(2,013)
Interest expense		915	1,781
Net changes in provisions		381	470
Grant on non-financial assets and income from distribution licences		(1,847)	(638)
Loss on creation of joint venture		(4,068)	-
<b>CHANGES IN WORKING CAPITAL</b>			
Trade and other receivables		4,131	6,508
Inventories		(4,940)	5,041
Trade and other payables		13,505	(9,276)
<b>OTHER COLLECTIONS AND PAYMENTS:</b>			
Proceeds from distribution licences		505	110
Interest paid		-	(645)
Income tax cash flow		(3,399)	(1,982)
<b>Net cash generated (used) in operating activities</b>		<b>45,526</b>	<b>29,392</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Purchases of intangible assets		(8,396)	(3,657)
Purchases of property, plant and equipment		(9,680)	(16,244)
Proceeds from sales of property, plant and equipment		43	41
Contracting current bank deposits		-	(170)
Investment in joint venture		(3)	-
Sale of investments in joint ventures		1,000	-
Interest received		738	776
<b>Net cash generated (used) in investing activities</b>		<b>(16,298)</b>	<b>(19,254)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Repayments of financial debt		(10,274)	(5,671)
Proceeds from financial debt		797	11,607
Interest paid		(230)	-
Purchase of treasury shares		(987)	(6,546)
Reissue of treasury shares		446	1,398
Dividends paid		(6,853)	(8,346)
<b>Net cash generated (used) in financing activities</b>		<b>(17,101)</b>	<b>(7,558)</b>
<b>Net (decrease)/increase in cash and cash equivalents</b>		<b>12,127</b>	<b>2,580</b>
<b>Cash and cash equivalents at beginning of the period</b>		<b>29,251</b>	<b>26,671</b>
<b>Cash and cash equivalents at end of the period</b>		<b>41,378</b>	<b>29,251</b>



## Investments

ROVI invested 18.1 million euros in fixed assets in 2016, in comparison with the 19.9 million euros of 2015. The following investments may be highlighted:

- 2.6 million euros were invested in the injectables plant, in comparison with the 4.3 million euros invested in 2015.
- 0.6 million euros were invested in the Granada plant, in comparison with the 1.5 million euros of 2015.
- 2.6 million euros were invested in the Alcalá de Henares plant (Frosst Ibérica), in comparison with 3.7 million euros in 2015.
- 3.2 million euros were applied to investments in the San Sebastián de los Reyes plant in 2016, in comparison with the 6.1 million euros invested in 2015 in acquiring the assets of said plant.
- 9.1 million euros related to investment in maintenance and other (which includes the investment related to the new product distribution agreements), in comparison with 4.3 million euros invested in 2015.

## Evolution of the R&D projects

### Risperidone ISM®

In 2016, ROVI made significant progress with the first candidate of its leading-edge drug-release technology, ISM®. In November, 2016, the results of the phase I trial "PRISMA-1" were published in the medical journal *International Clinical Psychopharmacology* and showed that Risperidone ISM® was safe and well tolerated, providing an extended release of risperidone over a four-week period, without the need to include oral supplements, reaching therapeutic levels in plasma as from the first day<sup>11</sup>.

At the same time, the phase II clinical trial of Risperidone ISM®, "PRISMA-2", concluded successfully last year. On 13 March, 2016, the final results were presented at the 24th European Psychiatry Congress<sup>12</sup>. The main objective of this trial was to assess the safety and pharmacokinetic profile of multiple intramuscular doses of Risperidone ISM® in 67 patients with stable schizophrenia. The results of the "PRISMA-2" were reviewed by the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA). This allowed the applications for approval of the clinical trial to be initiated in December 2016 and recruitment of patients for the "PRISMA-3" clinical trial for approval of Risperidone ISM® in the United States and Europe to commence in the second quarter of 2017.

### Letrozol ISM®

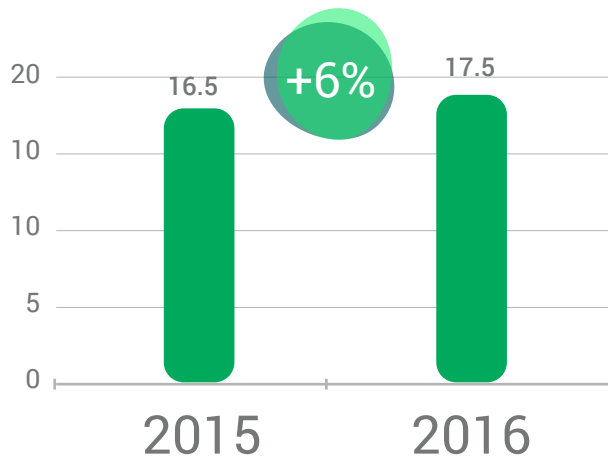
In the last quarter of 2016, a request made to the FDA for a preliminary meeting to obtain advice on the clinical development of this new medicine, an extended-action injectable aromatase inhibitor to treat hormone-dependent breast cancer, a complaint which is currently a matter of great concern to society.

(11) Llaudó J, et al. Phase I, open-label, randomized, parallel study to evaluate the pharmacokinetics, safety, and tolerability of one intramuscular injection of risperidone ISM at different dose strengths in patients with schizophrenia or schizoaffective disorder (PRISMA-1). *Int Clin Psychopharmacol.* 2016;31(6):323-31.

(12) 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). 24th European Congress of Psychiatry, March 13, 2016, Madrid (Spain) [<http://epa-abstracts-2016.elsevier.cc/#289/z>]

## R&D expenses

MILLION EUROS



### *Enoxaparin biosimilar*

The evaluation process of an enoxaparin biosimilar progressed as planned in 2016 and, in March 2017, ROVI successfully completed the decentralized procedure for registration of this drug in 26 European Union countries. At present, ROVI has initiated the national phase of the registration process, which is expected to conclude with the granting of marketing authorizations by the competent national authorities in each country. It is estimated that the national phase will take between three and ten months.

ROVI is expected to put this new product on the market at the end of the year, with high expectations of success and sales.

***ROVI is expected to put its enoxaparin biosimilar on the market at the end of the year***



## Stock market information

ROVI's share showed an irregular performance in 2016. It started the year at 14.15 euros per share and closed it at 12.33 euros. During the year, it reached a high of 15.22 euros and a low of 11.02 euros per share.

Although 2016 ended with a drop in the quoted price, prospects for 2017 are much more optimistic. In the first few months of the year up to March, the value of the ROVI share grew by more than 18%, supported by the announcement made on 7 March concerning the successful completion of the decentralized registration procedure for a low-molecular-weight heparin (enoxaparin biosimilar) in 26 European Union countries.

The good results have allowed ROVI to propose a dividend of 0.1830 euros per share, charged to the 2016 profit, to the General Shareholders' Meeting. This represents an increase of 32% on the dividend charged to the 2015 profit (0.1390 euros per share).

## Stock market information

2016

Number of shares	50,000,000
Year-end closing price	12.33 euros
Capitalization at 31/12	616,500,000 euros
Total dividend	6,853,000 euros
Dividend per share paid in 2016 and charged to the 2015 profit	0.1390 euros
Proposed dividend per share charged to the 2016 profit	0.1830 euros
Pay-out (as a % of net consolidated profit)	35%
Profit per share	0.52
PER	23.6

## Share price performance in 2016

EUROS



The Company regularly reports publicly on all its activities, as it states in its "Policy for Communication with Shareholders, Institutional Investors and Proxy Advisors".

## Investor relations activity

At the same time, ROVI is active throughout the year in meetings, forums and events with investors. In 2016, ROVI held 8 roadshows, participated in 11 events with investors and received 10 visits to its facilities from investors, which meant that more than 150 investors received attention.

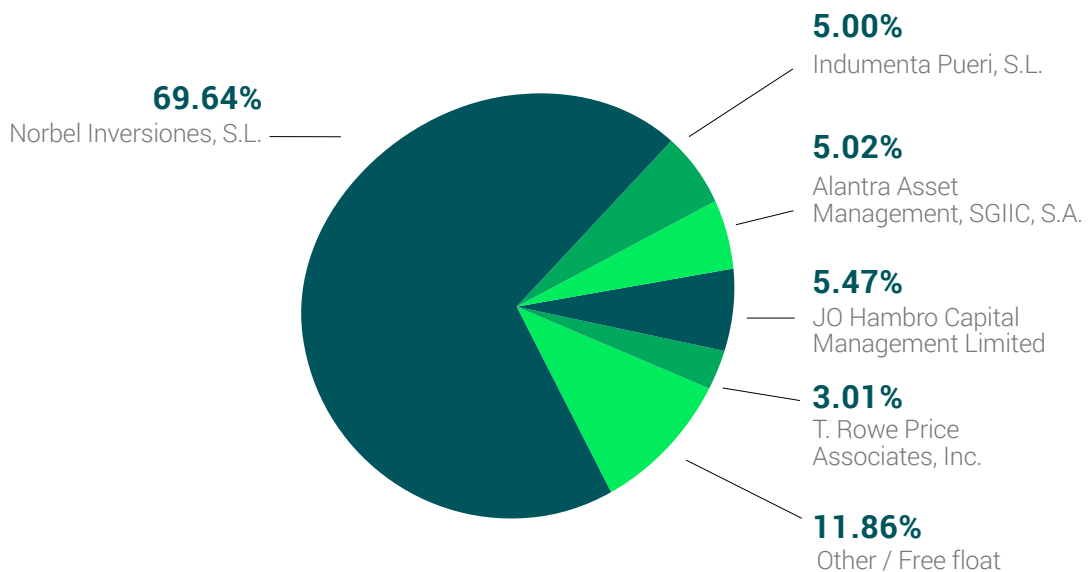
## Capital structure

The Company's main shareholder is Norbel Inversiones (69.64%), a company that encompasses the holding of the López-Belmonte family, which founded the Company. Norbel Inversiones is the only shareholder represented on the Board of Directors. In second place is JO Hambro Capital management (5.47%), a funds manager headquartered in London. Alantra, formerly Nmás1, is the third shareholder, with 5.02%, and is a collective investment institution management company headquartered in Madrid that exercises the voting rights of QMC II Iberian Capital Fund and QMC II Iberian. Fourth is Indumenta Pueri (5.00%), the holding company of the Domínguez family. The other significant shareholder is T. Rowe Price Associates (3.01%), a United States fund management company.

There were important shareholder movements in 2016. In the first half of the year, JO Hambro Capital Management Limited became a significant shareholder of ROVI, attaining a holding of 5.47% in the Company's capital.

## Shareholder composition (at 31 December, 2016)

PERCENTAGE



# Customers

For ROVI, the ultimate purpose of all its work is to meet the needs and expectations of its customers, which it considers to include both the companies to which it is related in its facet as a contract manufacturer and the health professionals to whom it offers the best treatment options, not forgetting the patients who can benefit from the latest advances and best medicines to treat their complaints.

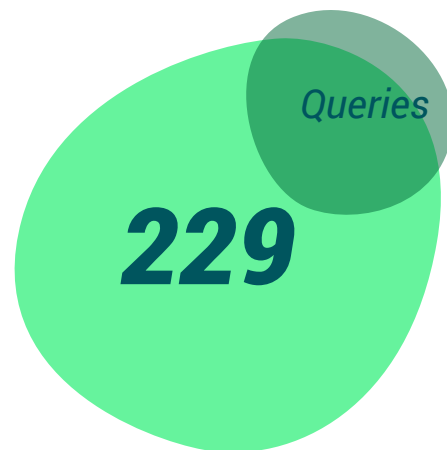
The Company places customers, patients and professionals at the centre of its activities and is committed to the idea that a high degree of satisfaction can only be attained by establishing solid long-term trust relationships. This is also the key to achieving the growth objectives set by the Group.

## Communication and transparency

The Group feels it essential to establish lasting commercial relationships based on proximity, a permanent positive service attitude and trust. All of this begins with total transparency and openness through the consultation channels put in place for information requests, both from international partners, through an exclusive portal created in 2008, [www.bemimed.com](http://www.bemimed.com), and from direct customers, patients and professionals.

Likewise, since 2009, ROVI has had an exclusive portal for health professionals and, in each one of the Group companies, there are health professionals trained to handle the principal queries that may be submitted by direct customers, patients and professionals. Through this portal, a total of 229 queries were received in 2015, divided between therapeutic queries (160) and those related to product quality.

At the same time, ROVI participates actively in industry-specialized forums, such as AEFI, PMFARMA and Asinfarma, in order to strengthen relations with health professionals, answer their queries and capture talent.



## Immediate response to complaints

This is the medium through which complaints may also be received. The Company immediately initiates an investigation process to identify the cause and prevent any repetition. The investigation may involve several departments and include suppliers, subcontractors or both. The efficacy of these actions is analyzed annually in system review conducted by ROVI Management.

The following complaints were handled in 2016:

### Complaints

	<b>2016</b>
<i>MANUFACTURING</i>	
<i>Quality-related complaints</i>	327
<i>Complaint/million units put on the market</i>	0.0023
<i>DISTRIBUTION</i>	
<i>Quality-related complaints</i>	125
<i>Complaint/million units put on the market</i>	6.90
<b>TOTAL Complaints/million units</b>	<b>0.0031</b>

## Cooperation with and remuneration of health professionals

The combined work of the pharmaceutical industry and health professionals has played a vital role in the research and development of medicines that save lives and the use of these medicines in clinical practice. This consolidated, highly-regulated relationship is based on a common objective: the enhancement of the quality of life of patients through advances in their treatment and care.

ROVI, as part of the pharmaceutical industry, works closely with the medical profession in widely-differing activities, shaping the future of clinical research, designing and executing clinical trials, sharing the best clinical practices, working on the awareness of different pathologies, ranging from prevention to diagnosis and treatment, as well as patient support programs.

Sharing knowledge is the core of the relationship between the industry and the scientific community. The medical professional provides the industry with valuable information in areas of medical needs that are not covered, potential therapeutic solutions and the everyday use of treatments in clinics. This helps the industry to design the way in which it develops and provides new medicines to improve the results in patients. In exchange, the industry provides them with the opportunity to optimize the therapeutic environment.

It is, therefore, fully appropriate for health professionals to be remunerated adequately for the knowledge and services they contribute to the pharmaceutical industry. This compensation is highly regulated and, since June 2016, both ROVI and the rest of the pharmaceutical industry have begun to publish the payments made to health professionals on the Internet, in order to increase the transparency of this relationship, which is already highly regulated. This is intended to strengthen the bases for future cooperation, guaranteeing that patients in Europe continue to benefit from the combined work of the industry and the health professionals.

## Constant vigilance of adverse reactions

ROVI maintains the highest commitment in the event of any unintended adverse reaction to a medicine when it is administered in the normal doses for a human being for the prophylaxis, diagnosis or treatment of diseases, or to restore, correct or modify physiological functions.

The Company, aware that, as a medicine manufacturer and distributor, it is also the guarantor of the safety of the patients to whom its medicines are administered, has exhaustive controls in place to ensure that its products maintain an optimal balance between benefit and risk.

In this respect, it has a pharmacovigilance system for the early detection of any possible adverse reactions to its medicines and healthcare products and an e-mail address, [farmacovigilancia@rovi.es](mailto:farmacovigilancia@rovi.es), where anyone can notify any incident of this nature.

In accordance with the guidelines, a total of 1,000 adverse reactions were recorded in 2016.

## Support to patients and professionals

Furthermore, ROVI has contributed to the active promotion organized by the Ministry of Health, Social Services and Equality through multiple campaigns during the year:

- World AIDS Day.
- Gender violence has a way out.
- European Vaccination Week.
- European Antibiotics Awareness Day.
- Protect Yourself against 'Flu; Vaccinate Yourself.

Also through ROVI's own website, health professionals may access a complete medical and pharmaceutical information service. Moreover, for some of the Company's products, specific pages have been prepared, where professionals may obtain further information.





## Human resources

ROVI's employees are the basic pillar in the Company's development and structure. The Group offers a wide range of professional development possibilities to its human team, at the same time as it ensures that their training needs are met, in order to maintain an optimal performance in their work.

A good example of this is the Company's commitment to job creation. This commitment may be seen from the fact that, at the end of 2016, ROVI had 1,150 employees, a young and dynamic workforce of highly-qualified professionals, based on equal opportunities.

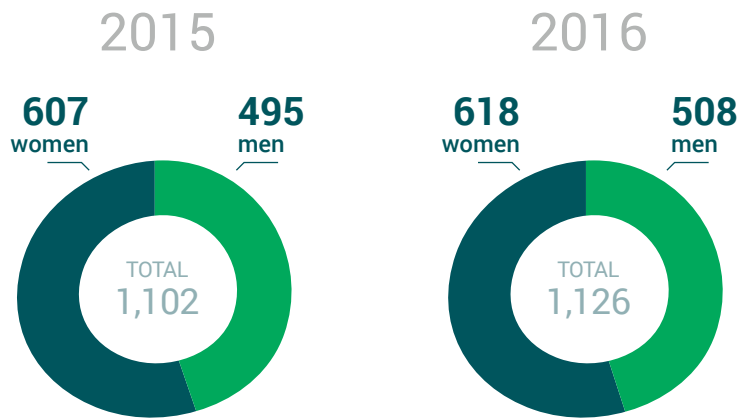
At the same time, ROVI likewise ensures that employee benefit programs are revised and renewed, in addition to implementing the necessary work-life balance measures and guaranteeing a workplace environment with the highest standards of safety and health.

Likewise, ROVI follows a meticulous human resources policy with its employees, constantly seeking the best talent and the best people to collaborate on each one of its projects. It makes use of elements like an adapted loyalty policy and considers that its brand's best standard-bearers are its employees, promoting constant, open and participative communication with and amongst them.

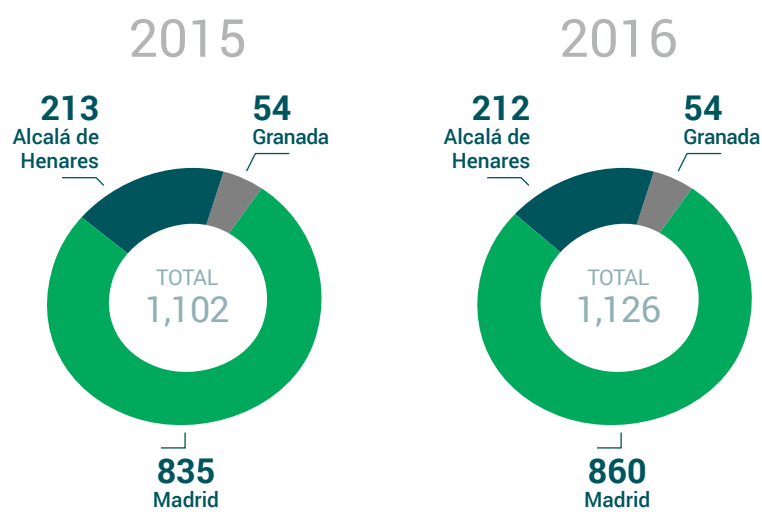
***ROVI had a young and dynamic workforce of highly-qualified professionals***



ROVI's average headcount by gender



ROVI's average headcount by location



ROVI's headcount by plant and contract type

	2016			2015		
	Permanent	Temporary	Total	Permanent	Temporary	Total
<i>Lab. Fcos. Rovi</i>	363	52	415	385	52	437
<i>Panquímica</i>	103	2	105	77	2	79
<i>Rovi Contract</i>	275	119	394	261	107	368
<i>Frosst Ibérica</i>	179	33	212	180	33	213
<i>Bemipharma</i>	-	-	-	5	-	5
<b>Total</b>	<b>920</b>	<b>206</b>	<b>1,126</b>	<b>908</b>	<b>194</b>	<b>1,102</b>

## Persons with disabilities

(31/12/2016)

ROVI	7
ROCM	4
FROSST	4
<b>GROUP TOTAL</b>	<b>15</b>

Average  
employee turnover

**2.8**%

## Average employee turnover

PERCENTAGE

$[(\text{Employees joining} - \text{Employees leaving}) / \text{total employees}] * 100$

	Women	Men
35 years and under	3.64	2.34
From 36 to 45 years	1.21	1.56
From 46 to 55 years	0.43	0.78
Over 55 years	0.09	0.35

## Diversity in ROVI Group employees (as of 31 December 2016)

	Men	Women	Total
Executive directors	3	-	3
Management	18	7	25
Administration	45	133	178
Sales	153	140	293
Production and plants	236	246	482
Research	59	110	169
<b>TOTAL</b>	<b>514</b>	<b>636</b>	<b>1,150</b>

## Principal 2016 milestones

As in previous years, in 2016, ROVI continued to receive support from the Ministry of Economics and Competiveness for its Research and Development activities through the EMPLEA and Torres Quevedo programs. This initiative addresses both job creation and the performance of R&D&i activities in companies, in order to provide real professional development and practical training opportunities to university graduates and keep the best talent in Spain.

## Equal opportunities

Equal opportunity is one of ROVI's hallmarks, both internally and externally, and the Company ensures that none of its employees suffer discrimination on the grounds of gender, ideology or any other factor. In this respect, it has careful monitoring systems to ensure that there is no preferential treatment or discrimination when hiring employees or rewarding merit.

The Group's compensation policy is aligned only with the Company's objectives and observes two aspects: quality and efficiency. This is why, in order to involve employees and reward their contribution to the business's evolution, part of the salary is variable and is associated to the attainment of personal objectives for each professional and global Group objectives.

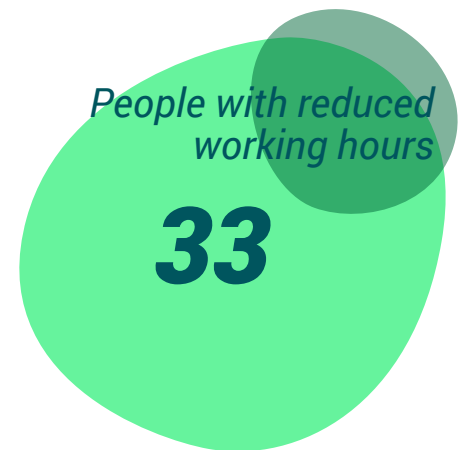
## Welfare benefits

All ROVI employees, with no distinction between types of contract or jobs, have the same welfare benefits. Although the sum assigned did not increase in 2016, the benefits the Company offered were maintained, including:

### Work-life balance measures

ROVI's commitment to its employees is a key factor in the Company's success and a satisfactory work-life balance is part of this concern, since the wellbeing and health of the workers has a direct effect on value creation in the Company.

Therefore, the Company has different mechanisms, such as flexible working hours, which help to improve the employees' quality of life and have been in operation in the Company since 2012.



### Work-life balance

	Men	Women	TOTAL
<i>People with reduced working hours or who use any other options to reconcile their personal and professional lives</i>	2	31	<b>33</b>

### Professional training

Continuing education is crucial to ROVI's long-term growth. From both its central Human Resources Department and the departments in each one of its subsidiaries, the Company decidedly promotes employee training.

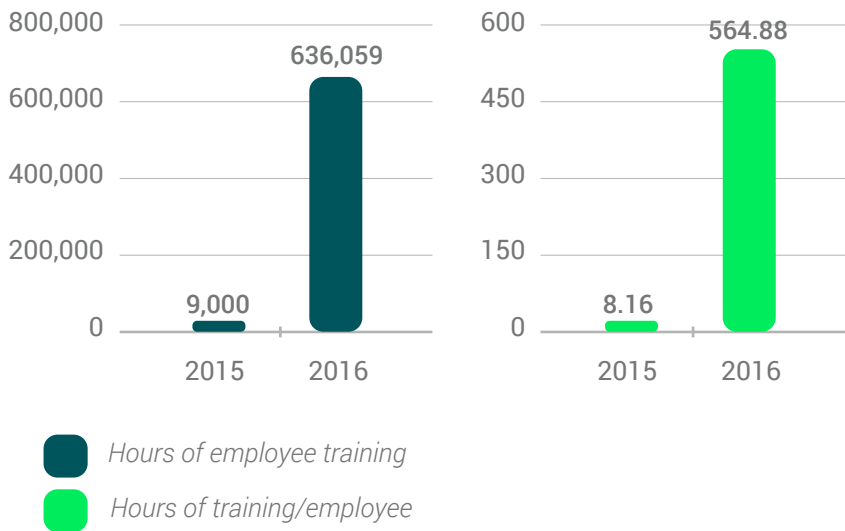
Thus, the Group foments and offers courses that provide the necessary skills for each work position, as well as specific training related to ROVI products and their quality. All this takes place in an open work environment, in which equal opportunities are guaranteed and both professional and personal development in different disciplines are encouraged.

During 2016, there was a considerable increase in the number of hours of training imparted. 636,059 hours were given, equivalent to 564.88 hours per employee. This growth was due principally to the increase in the number of employees, since all employees joining the Company receive education and training in the responsibilities they will be assuming. The second reason for the increase was the improvements in processes and procedures, which involved

## Training

HOURS

**100% of the employees are covered  
 by the XVII Chemical Industrial  
 Collective Labour Agreement**



additional training. Among the subjects imparted were leadership training for middle management, team management, risk prevention and training in ROVI products.

### Smooth relations and communication with workers' representatives

ROVI has an adequate relationship with the workers' representatives. Specifically, ROVI Contract Manufacturing has four trade union representatives.

The ROVI Group adheres to the XVII Chemical Industrial Collective Labour Agreement, the latest text and update of which has been in force since 2015. 100% of the employees are covered by this Agreement or the agreements applicable in each specific work area (offices, sales, etc.). The Company not only complies with the Agreement, but also implements certain improvements on it.

## Communication channels

ROVI is aware that it is even more important to maintain a constant, bidirectional flow of communication with its own human team.

Among the mechanisms the Company offers to its employees is the complaints channel, which, in the event of detecting any infringement of ROVI's Code of Ethics, may be used by any professional in the Company. Furthermore, it has a specific confidential complaints channel for any financial or accounting irregularities detected.

Likewise, ROVI has suggestion boxes at all its offices. In this respect, at some of its plants, the Company organizes workshops at which human resources personnel study and analyze each one of the proposals, so that, among all of us, we can improve the workplace environment. Furthermore, various communications have been issued by the Human Resources Department in order to keep all our employees informed on the most important issues that may be of interest to them.

Within the framework of ROVI's philosophy of continuing improvement, various channels have been opened up over recent years to detect opportunities for improvement in all areas (production, maintenance, laboratories, etc.). This is also carried out through workshops and meetings with employees at all the plants, since the Group considers that these are the people with the closest view of areas for improvement and the specific options for developing each one of them.

As part of the communication activities for employees, ROVI has promoted, among its participants, the different projects and activities related to the CSR strategy of the company.



***Various channels have been opened up over recent years to detect opportunities for improvement in all areas***

## Occupational health and safety

Employee health is one of ROVI's priorities and, in 2016, this concern was rewarded by the accident insurance company FREMAP, in collaboration with the CEIM (Madrid Business Confederation), which acknowledged the Company's work in relation to the decrease in workplace accidents and preventive excellence. The honourable mention given to Laboratorios ROVI is the result of the work and effort of the excellent human team that forms the Company, committed to the health and safety of all its workers, which is a fundamental value for the whole Group.

ROVI is firmly convinced that all accidents are avoidable and, therefore, at the same time as it strives to have facilities with the highest safety standards, it foments a workplace risk prevention culture common to all employees, based on the idea that the right attitude is crucial in safety matters.

During 2016, 321,112 euros were invested in preventive measures in relation to employee health and safety, in order to reduce the accident rate at Group level and enhance communications in the event that an accident were to occur because a worker working alone had passed out, in addition to the specific objectives established for each plant.

In this respect, a total of 10 objectives related to occupational health and safety have been established. At the date of this Report, none of them is running behind schedule. Two of them have been implemented, two are in the evaluation phase and the remainder are under implementation.



## Employee health

	2016	2015
<i>% of workers represented on Occupational Health &amp; Safety Committees</i>	100%	100%
<i>Accident rate (%) = (No. accidents / No. workers)*100</i>	1.3%	2.9%
<i>Occupational health &amp; safety investment (million euros)</i>	0.3	0.9



## ***Different Health & Safety Committees are in place, where all ROVI employees are represented***

These objectives include the following:

- Adoption of measures to comply with the limits on the number of accidents, with or without absence from work, approved at Group level.
- Implementation of a computer system for management of the employees' occupational health & safety documentation: the design of the application has already been approved and, at present, the application is in the development phase.
- Measures intended to attain category 2 protection (according to the Nauman methodology) at production sites. To do this, work procedures have been implemented and a HEPA vacuum cleaner has been acquired.
- Reduction of the risk of falls to a different level in plant maintenance operations and for production workers.
- Acquisition of a reagent dosing system that allows the amount used to be optimized before adding the exact amount of reagent necessary, eliminating the operation of transferring the content of the bottle to the beaker.
- Modification of fire alarm systems.
- Improvements to production tank stability.

The Group has a Prevention Service responsible for carrying out actions like the promotion of healthy lifestyle habits, accident and disease prevention and communication through education and training campaigns in order to share the best practices and know-how and involve the employees. Furthermore, different Health & Safety Committees are in place, where all ROVI employees are represented.

Their duties include monitoring and enhancing the health and safety performance of all the plants, through both preventive procedures and safety inspections of equipment, facilities and workplaces, and being proactive in meticulous investigations of accidents.



*In 2016, ROVI awarded the Occupational Health and Safety Prizes in which Group employees were encouraged to submit ideas related to Occupational Health and Safety*



### **Actions to promote Occupational Health and Safety**

In 2016, ROVI awarded the Occupational Health and Safety Prizes. With the slogan "Have you got a brilliant idea?", a competition was held in which Group employees were encouraged to submit ideas related to Occupational Health and Safety. The employees were asked to submit simple, economical ideas that would be easy to implement at all Group facilities and that were intended to improve safety and reduce accidents in the industrial area.

Furthermore, since 2015, continuing in 2016, the success of the Healthy Company project may be highlighted. The objective of this project is to encourage ROVI employees to adopt the best eating and exercise habits. It includes activities such as:

- Healthy breakfast - "Fruit day" has been introduced. Two days a month, employees may enjoy seasonal fruits, free of charge, in the canteens of ROVI companies.
- Healthy vending - Vending machines that provide healthy food (salads, fruit, yogurts) have been installed in the canteens, as well as machines that prepare natural orange juice.
- Sports - The Safety and Environment Department has reached agreements with various sports centres (e.g. gymnasiums, equestrian centre) close to ROVI's facilities to obtain competitive prices that encourage its professionals to practice sports.
- Companies' Race - ROVI invites its employees to take part in the Companies' Race, which is also a way of encouraging the human team to practice sport together.

# Suppliers



## CSR in the supply chain

The Group makes its best efforts to comply with its commitments, where selection criteria and information transparency prevail, and is aware of the important role that suppliers play in its business in this respect.

The Company has two mechanisms to try to guarantee and encourage the adoption of good social responsibility practices in its supply chain:

- It periodically sends a voluntary document entitled “Commitment to CSR” to all Group suppliers and subcontractors, where it requests certifications such as SA-8000 or urges them to adopt good business practices. At present, more than 55% of the companies have signed this social responsibility commitment. ROVI’s target is for all its suppliers to adhere to this initiative.
- On-site audits, in which it checks that suppliers operate in accordance with national and local regulations, that there are no significant non-compliances in respect of occupational safety and that there are no practices that infringe the workers’ rights. Among other aspects, the auditors ensure that a safe work environment is provided, environmental legislation is observed and the employees do not suffer abuse or discrimination.

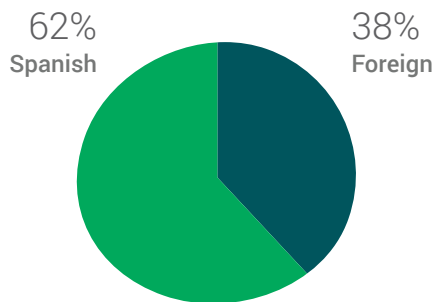
Suppliers are a group of strategic interest in relation to ROVI’s R&D&i activities. For this reason, it has put in place a series of specific action principles aligned with the Company’s principles and values and intended to reinforce the sustainability and competitive advantage of the value chain.

In the same way as the Company maintains a constant focus on equal opportunities, occupational safety and care of the environment, it invites all its suppliers to guarantee these factors and declare their commitment to basic principles of ethics and professional conduct.

Therefore, at the same time as ROVI develops them internally, it tries to involve suppliers and subcontractors in the adoption of the best corporate social responsibility practices to regulate their activities in accordance with the standards included in the certifications SA-8000, SGE-21 or similar.

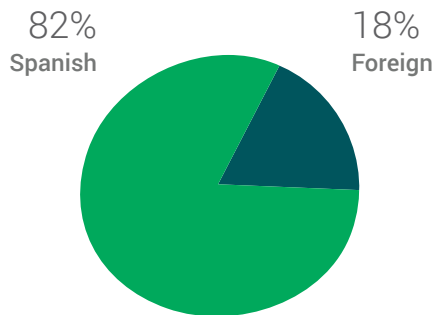
## Suppliers by geography purchases in euros ratio

PERCENTAGE



## Number of suppliers by geographical area

PERCENTAGE



## Environmental care

ROVI did not perform any environmental audits on its suppliers during the year. However, at Group level, ROVI has found that more than 50% of its suppliers and subcontractors are certified under ISO 14001 or EMAS.

ROVI is progressing in the implementation of a system to quantify the environmental achievements and positions of the organization and its suppliers. The environmental audit report measures and describes the performance level and the environmental situation attained, thus aspiring to define outstanding needs to maintain or enhance the indicators of said performance and achievements.

## Control of suppliers

ROVI has a series of standard procedure manuals in which guidelines regarding responsibilities, precautions and instructions are set out. The Company periodically controls the preparation of orders, the service level and any incidents or complaints that may arise.

## Supplier payment policy and flow

Since 2013, the Group has had a supplier payment policy in place to establish a framework for relations with suppliers and creditors that is common to the whole company. This guarantees full efficiency in accounting for invoices, an appropriate payment policy and greater consistency in negotiations.

When needing to contract a service with a new supplier, each of ROVI's departments must ensure that the contracting is carried out in the terms stipulated by the Company and is responsible for choosing the raw materials, goods and services applying the criteria of best price, quality, support to the environment, social responsibility and legal compliance, obtaining the best

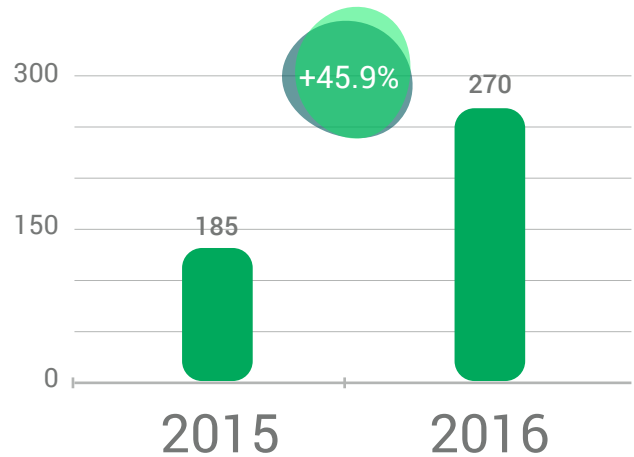


100

**ROVI's average supplier payment period in 2016 was 53 days**

**Order volume (invoices accounted for)**

MILLION EUROS



results in economic terms and in quality and service for the Company's benefit. The payment policy also establishes the conditions under which agreements may be reached on discounts, advance payments and other kinds of contractual conditions.

ROVI's average supplier payment period in 2016 was 53 days and the volume of orders (invoices accounted for) totalled 270 million euros, with a total of 1,749 suppliers in the year.

# Society and public authorities

## Society

ROVI is aware of the social impact of its activity on different levels of society. For this reason, apart from its commercial activity, the Group is permanently involved in providing support to medical research, committed to higher education in Spain, and acts responsibly both in respect of its tax obligations and in its role as an employer and economic agent in its immediate environment.

### Commitment to research

In addition to offering high-quality products intended to improve patients' health, ROVI considers it of key importance to support and foster medical progress at all levels. Therefore, it assigns part of its resources to this purpose and, in 2016, carried on intensive activity to promote research and the prevention and knowledge of certain diseases by making various donations, mainly to medical and research foundations and associations.

In this respect, the Company continues to sponsor the International Grants Competition for Biomedical Research into Bemiparin, a low-molecular-weight heparin indicated for the prophylaxis and treatment of venous thromboembolic disease. This competition promotes original independent research to expand scientific knowledge of this antithrombotic drug, which has a unique pharmacological profile.

In addition, ROVI holds cooperation agreements with different universities and training centres in order to support and combine efforts to increase scientific, technological and training activities and the sharing of knowledge. These centres include the University of Granada, through the SNC\_Integra and ADELIS projects within the framework

of the FEDER-Interconnecta program, as well as the Biomedical Research Centre of the CSIC and the University of La Rioja (UNIR).

### Commitment to training

Also through a cooperation agreement with around twenty universities and educational centres, ROVI offers a training program to provide opportunities for entering the labour market in a professional work environment, so that highly-qualified students can improve their skills, knowledge and experience. In 2016, 41 people were included in this program.

### Contribution to local development

The research, development and manufacture of ROVI's pharmaceutical are carried on entirely in Spain. The Company is, therefore, fully involved with innovation in national territory and this involvement may be seen in figures such as:

- For a further year in 2016, R&D investment rose to 17.5 million euros, in comparison with 16.5 million euros in 2015.
- The acquisition of property, plant and equipment and intangible assets, used mainly at its manufacturing plants in Madrid, Alcalá de Henares, San Sebastián de los Reyes and Granada, totalled 18.1 million euros in 2016.

ROVI's work also has an impact on local job creation and, in spite of the employment situation in Spain, over the last few years, ROVI has constantly created employment at its work centres in this country. In fact, there were almost 1,150 employees at 31 December, 2016, once again surpassing the previous year's figure and adding more than 500 people

since 1 April, 2010. A good example of the commitment to high-quality local employment is the Granada plant, which has a high percentage of employees (almost 70%) with a university degree, given that the work carried on at these facilities requires highly-qualified personnel.



## Economic value generated and distributed

	2016	2015	2014
<b>Economic value generated (million euros)</b>	270.8	247.0	240.9
<b>Value distributed (million euros)</b>			
Shareholders	9.1	7.0	8.5
Suppliers	153.5	137.0	134.3
Society	1.8	1.1	1.5
R&D	17.5	16.5	12.0
Employees	60.5	61.8	58.1
Capital providers	0.5	0.9	2.1
Amortization & depreciation	11.0	10.0	8.9
Reserves (retained value)	17.0	12.8	15.6

## Commitment to social projects

At both corporate level and through initiatives taken by its employees, ROVI helps and supports various charities and social integration projects for different groups.

In 2016, a new project was initiated to allow ROVI to grow in terms of commitment and solidarity, when the first Corporate Volunteering program commenced, moved by the desire to contribute to a fairer society. ROVI's idea is to offer all employees the opportunity to play an important role in the change and cooperate as volunteers in social action projects organized with the Foundation. Thus, ROVI volunteers cooperated in the following activities:

- Adaptive skiing weekend campus in Sierra Nevada (5 and 6 March).
- XI Santiveri Trophy Sierra Nevada (9 and 10 April).

Among the new projects in which ROVI became involved and began to cooperate in 2006 were:

- Fundación Recover: Hospital for Africa: founded in Spain in 2006 by a group of professionals related to the health industry to take action to improve health in developing countries.
- Fundación Manantial: its purpose is to integrate people with severe mental disorders. ROVI cooperates with this foundation in several ways, since it is also certified for the secondary reconditioning of the Company's products.

Other projects in which both the Group and its employees continued to cooperate in 2016 were:

- Spanish Paralympic Team: ROVI has been cooperating with the Spanish Paralympic Team since 2015.
- Spanish Red Cross: ROVI continues to support the Red Cross in Granada by sponsoring different events, such as Flag Day, where the funds collected during the day are used for the Asylum Seeker and Refugee Support Program.
- Proyecto Hombre: for a further year, ROVI cooperated with Proyecto Hombre in Granada in programs for addiction treatment and the social reinsertion of drug addicts.

***In 2016, the first Corporate Volunteering program was initiated***



## ***ROVI's tax policy ensures compliance with all tax obligations through ethical and responsible practices***

### **Tax policy**

The sustainability of the processes followed by ROVI requires an undeniable commitment to contribute to the economic and social development of the markets in which it operates. In the tax sphere, this commitment materializes principally by meeting all tax payment obligations for all taxes, levies and duties that accrue from trading operations, in accordance with the applicable local and national regulations.

All ROVI's operations are carried on from an ethical and responsible perspective in all aspects, including the tax aspect. Therefore, ROVI's tax policy ensures compliance with all tax obligations through ethical and responsible practices, in accordance with the criteria established by the Group. Likewise, ROVI does not use corporate or any other type of structures in order to conceal, mask or reduce the transparency of its activities vis-à-vis the tax authorities or any other interested party.

In this respect, the effective tax rate in 2016 was 6.4%, in comparison with 5.2% in the preceding year. This favourable effective tax rate is the result of the deduction of existing research and development expenses and the capitalization of negative tax bases of the company Frosst Ibérica, S.A. At 31 December, 2016, Frosst Ibérica's negative tax bases were 36.7 million euros, 1.6 million euros of which were offset against the corporate income for 2016.

On 3 December, 2016, the Official State Gazette published Royal Decree-Law 3/2016, which approved tax measures intended to consolidate public finances and other urgent social measures. These measures came into force on the

same day. These tax measures will have an adverse effect on the ROVI Group's income statement and the amount of tax payable. Notwithstanding, ROVI expects the effective tax rate to maintain from high single digit to low double digit over the next few years.

Among the tax measures that will affect corporate income tax, the following may be highlighted:

- The offsetting of negative tax bases from preceding years is limited to 25%.
- The R&D tax credit scheme remains unchanged.

## **Public authorities**

As a provider of high-quality active substances, medicines, healthcare products, food supplements and cosmetics, ROVI has a constant ongoing relationship with the health agencies. The Group actively strives to ensure that all their requirements are met in all its activities -industrial development, the manufacture and supply of products, the supply of units for clinical trials-, which are always carried on in an environment of strict compliance with all the legal and regulatory requirements that apply to them, as well as the authorizations granted by the authorities.



# Environment

ROVI has a firm and constant commitment to environmental protection, which forms part of its day-to-day activity. The Group's environmental policy is based on continuing improvement commitments, legal compliance and compliance with additional voluntary requirements.

In this respect, a total of 14 environmental objectives were approved in 2016. At the time of writing, 3 of them had been attained. A further two were in the evaluation phase and the deadline for the remaining seven had not yet been reached, since they were two-year objectives that were not intended to be met within the calendar year.

The measures approved are principally intended to improve waste management. They included the following:

- Improvements to manufacturing waste separation, providing the plants with more containers to facilitate on-site separation.
- Improvements to waste separation at the Analytical Development Laboratory.
- Planting vegetation around the perimeter of the Granada plant to improve the visual impact, as well as trees in the grounds.
- Preparing the Environmental Management System and adapting it to the requirements of the standard ISO 14001-2015.
- Reduction of the amount of waste generated by expired products that have not entered the sales channel, in comparison with the amount generated in previous years.



## ROVI's environmental waste management system

ROVI's principal tool to ensure that environmental aspects are correctly managed is the environmental waste management system, based on the criteria established in international standard ISO 14001-2004 and the Eco-Management and Audit Scheme (EMAS) rules. These certifications recognize the quality of the system and demonstrate that ROVI's commitment to the environment goes beyond the requirements of current national legislation.

At all ROVI's production facilities, production management that respects the environment is sought. This means a constant effort to reduce energy consumption and manage waste more efficiently.

In 2016, ROVI spent 680,026.23 euros on environmental expenses, with the objective of improving waste management and reducing energy, water and gas consumption. Almost all these expenses came from waste management (355,308.79 euros) and the treatment of emissions of air pollutants (7,560 euros).

The Environmental Department made a number of investments to improve the facilities for a global amount of 317,157.44 euros. The main actions undertaken were aimed to improve condensate return and change fans.

## Waste management

Waste generation is inherent to ROVI's activity and, precisely for this reason, treating and reducing it is a crucial part of the Company's commitment to preventing pollution. The processes related to waste treatment are mainly intended to minimize waste in production processes and, when it has been produced, manage it correctly to foment its recovery and recycling wherever possible.



### Waste management

	2016	2015	VAR (%)
<i>Tonnes of hazardous waste generated</i>	641.68	519.06	24%
<i>Tonnes of non-hazardous waste generated</i>	2,168.99	852.58	154%
<b>TOTAL</b>	<b>2,810.67</b>	<b>1,371.64</b>	<b>105%</b>
<i>Tonnes hazardous waste / million units</i>	0.005	0.006	-27%
<i>Tonnes non-hazardous waste / million units</i>	0.015	0.010	50%
<b>TONNES WASTE / MILLION UNITS</b>	<b>0.020</b>	<b>0.016</b>	<b>25%</b>

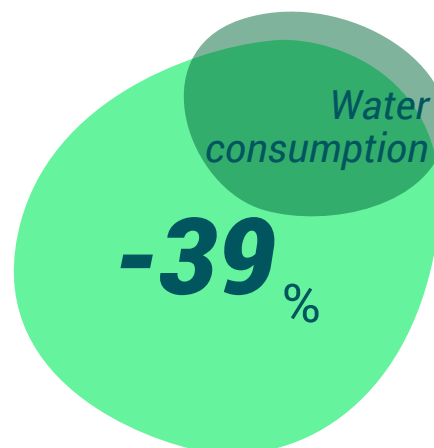
## Energy consumption

In 2016, energy consumption underwent various increases at all the facilities in general. The start-up of new facilities in San Sebastián de los Reyes and the inclusion of figures from the new subsidiaries contributed, without any doubt, to this increase:

- The Group's global electricity consumption rose by 7.1% in 2016. This evident increase originated from the production increase.
- Natural gas consumption increased by 11.6% at the facilities that use this source of energy.
- Fuel consumption rose by 15.2%.

## Energy consumption

	2016	2015	VAR (%)
<i>kWh of electricity consumed</i>	17,846,340	16,659,473	7.1%
<i>kWh of natural gas consumed</i>	23,187,891	20,778,025	11.6%
<i>Litres of vehicle fuels</i>	454,705	394,677	15.2%



## Natural resource consumption

Water consumption at ROVI's facilities in 2016 was 0.87 m<sup>3</sup> per million units produced, representing a significant reduction on 2015. This was achieved due to a decided bet on awareness measures, implemented by the Group at all its plants and companies.

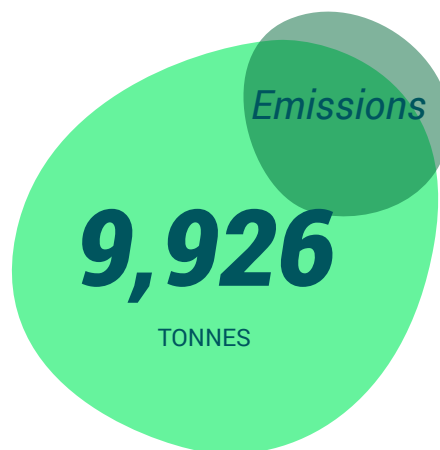
## Water consumption

	2016	2015	VAR (%)
<i>m<sup>3</sup> of water / million units produced</i>	0.87	1.43	-39%

(\*) There is a minor discrepancy between the value stated in the 2015 Report and that included here. This is because invoices were recorded in two companies at the same time.

## Emissions of air pollutants

In addition to seeking a constant reduction in energy consumption, ROVI is also committed to reducing its carbon footprint and controlling CO<sub>2</sub> emissions from the consumption of natural gas and diesel oil and emissions derived from electricity and motor vehicles, as well as other substances that act to destroy the ozone layer.



### Emissions of air pollutants

	2016	2015
<i>Tonnes of CO<sub>2</sub> emitted</i>	9,926.38	8,219.76
<i>Variation in tonnes of CO<sub>2</sub> emitted</i>	21%	64%
<i>Tonnes CO<sub>2</sub> / million units</i>	0.07	0.10
<i>Variation tonnes CO<sub>2</sub> / million units</i>	-30%	---

In order to decrease the effects of pollutant emissions from lights, investment of more than 7,500 euros was made in activated carbon at the Granada plant.

## Waste management in the supply chain

ROVI feels it important to transmit the environmental commitment that the Group itself has acquired to its suppliers and subcontractors. Therefore, it periodically sends them an environmental commitment document and requests copies of any certifications held by their environmental management systems. Details of these actions may be found in the "Suppliers" section above.

## Handling queries

ROVI has a procedure that describes the system followed to handle queries on the Company's environmental conduct. In this respect, a total of 15 environmental queries were answered, mainly related to ROVI's hazardous waste management system.



***A total of 15 environmental queries were answered in 2016***

## Active participation in environmental protection

The companies that form ROVI take part in a number of environmental protection organizations, such as:

- SIGRE
- ECOEMBES
- Fundación ECOLEC



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