

I TEGRATED REPORT

2018



Researching to grow for health.



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FINANCIAL AND **NON-FINANCIAL FIGURES**



FINANCIAL FIGURES

RESULTS

Millions of euros	2018	2017	2016	2015	2014	2013
Revenue	304.8	277.4	266.7	247.0	240.9	218.9
EBITDA	29.5	29.9	39.3	31.8	36.6	32.4
EBIT	17.5	18.4	28.3	21.8	27.7	25.5
Net profit	17.9	17.2	26.1	19.8	24.1	23.0
Capex*	26.4	19.9	18.1	19.9	25.1	24.7
Financial debt	34.2	43.2	33.8	42.8	36.3	31.0
Net financial debt	-62.8	1.1	-9.0	12.1	8.3	-5.8



(*)Include acquisitions and capitalization of development expenses.



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FINANCIAL STRUCTURE

	2018	2017	2016	2015	2014	2013
Net debt/EBITDA	-2.13x	0.04x	-0.23x	0.38x	0.23x	-0.18x
Net debt/Equity	-0.22x	0.01x	-0.05x	0.07x	0.05x	-0.04x





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STOCK MARKET

	2018	2017
Number of shares	56,068,965	50,000,000
Year-end closing price	17.45 euros	15.65 euros
Capitalisation at 31/12	978,403,439 euros	782,500,000 euros
Total dividend	9,150,000 euros	9,025,000 euros
Dividend paid per share	0.1207 euros	0.1830 euros
Pay-out (as % of consolidated net profit)	35%	35%
Profit per share	0.32 euros	0.34 euros
PER	54.53	46.03







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NON-FINANCIAL FIGURES



HUMAN RESOURCES

1,224 33 558 / 666	1,191
	41
558 / 666	
	527/664
1,209	1,182
6	4
2	2
6	2
1	1
24,057	28,215
2.7%	2.9%
0.52%	1.10%
2.09%	1.84%
	1,209 6 2 2 6 1 1 24,057 2.7% 0.52%





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ENVIRONMENT

	2018	2017	Variation
CO2 emissions (tonnes)	9,434	8,957	1%
Hazardous waste generation (tonnes)	1,424	1,079	23%
Non-hazardous waste generation (tonnes)	2,084	1,948	6,7%
kWh electricity consumed	18,940,410	19,313,337	-2%
kWh natural gas consumed	22,740,242	24,103,226	-6%
Vehicle fuel consumed (litres)	520,841	469,620	11%
Water consumed (m3)	142,742	156,021	-7%
m3 of water / million units produced	0.46	0.76	-39%

COMMUNITY



	2018	2017	2016	2015
Economic value generated (million euros)	304.8	277.4	270.8	247.0
Value distributed (million euros)				
Shareholders	4.5	6.0	9.1	7.0
Suppliers	172.7	154.7	153.5	137.0
Society	-1.2	0.3	1.8	1.1
R&D	32.4	28.3	17.5	16.5
Employees	70.2	64.0	60.5	61.8
Providers of capital	0.8	0.9	0.5	0.9
Amortization and depreciation	12.0	11.5	11.0	10.0
Reserves (retained value)	13.4	11.8	17.0	12.8



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GROUP PROFILE

ROVI is fully-integrated Spanish pharmaceutical group engaged in the research, development, manufacturing and marketing of small molecules and biological specialties. Its operations encompass the marketing of both its own and licensed products and the provision of services to other companies, such as production, filling and packaging, with three large pillars of growth:

- Pharmaceutical specialties: with a diversified portfolio of its own and licensed products protected by patents. The LMWH Division, which represented 40% of group sales in 2018, should be highlighted.
- Toll manufacturing of prefilled syringes and oral forms.
- Sound, low-risk R&D policy.

CORPORATE INFORMATION

Name:	Laboratorios Farmacéuticos Rovi, S.A.
Address:	Julián Camarillo, 35. 28037 Madrid. Spain
Telephone:	0034 91 375 62 30
Website:	www.rovi.es
Share capital:	3,364,137.90 euros
Number of shares:	56,068,965
Par value:	0.06€ share
Activity:	Manufacturing and marketing of pharmaceutical products and toll manufacturing services.
Markets:	The ROVI group has direct presence in Spain, Portugal, Germany, France, the United Kingdom, Italy and Poland and is listed on the Barcelona, Bilbao, Valencia and Madrid Stock Exchanges





PLANTS AND CENTERS

CORPORATE NAM	ADDRESS	ΑCTIVITY
Laboratorios Farmacéuticos ROVI, S.A.	Madrid, C/Julián Camarillo, 35	A
Pan Química Farmacéutica, S.A.	Madrid, C/Rufino González, 50	A
Gineladius, S.L.	Madrid, C/Rufino González, 50	B
Rovi Contract Manufacturing, S.L.	Madrid, C/Julián Camarillo, 35	A
Bemipharma Manufacturing, S.L.	Madrid, C/Julián Camarillo, 35	A
Bertex Pharma GmbH	Inselstr.17. 14129 Berlin (Germany)	C
Frosst Ibérica, S.A.	Alcalá de Henares, Avenida Complutense, 140 Madrid (Spain)	
Rovi Biotech, Ltda	La Paz (Bolivia)	
Rovi Biotech Limited	Davis House, 4th floor, Suite 425, Robert Street. CRO 1QQQ Croydon (United Kingdom)	
Rovi Biotech, S.R.L.	Viale Achille Papa, 30. 20149 Milan (Italy)	A
Rovi GmbH	Rudolf-Diesel-Ring, 6. 83607 Holzkirchen (Germany)	A
Rovi S.A.S.	Rue du Drac, 24. 38180 Seyssins (France)	A
Rovi Biotech sp. z o.o. or Rovi Biotech spółka z o.o	Mokotów, ul. Rzymowskiego 53, 02-697 Warsaw, Poland	

(A) Manufacturing, marketing and sale of pharmaceutical, healthcare and medicinal products.

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

(C) Development, distribution and trading of pharmaceutical products related to microparticle technology.





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LETTER FROM THE CHAIRMAN

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Our 2018 dividend, together with the rise of the share price on the stock markets, will bring a good result for our shareholders

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Dear shareholders,

Healthcare and scientific knowledge are two of the ratios that show the social well-being of a country.

Specifically, Spanish healthcare is one of the best in the world. It provides us with the benefit of being the country with the second-longest life expectancy and medicines are an important part of this achievement. Healthcare is an asset for the citizen and is universal. Healthcare services are not related to people's financial resources. In our European environment, Spain is the only country where prior payment is not necessary in order to receive the services.

Once again this year, I would like to thank you for trusting and investing in Rovi and I would like to confirm to all of you that attention to our shareholders is the greatest priority for the management team and chairman.

I will now describe the key events and figures of 2018.

In 2018, for a further year, we obtained excellent results. EBITDA, after deduction of R&D and non-

recurring expenses, rose by 8% in the year.

The year's result was achieved through work managed by a great management team. I would like to highlight this team as one of the company's assets.

In companies, Transparent, Efficient, Disciplined and Professional Management and Administration are, without any doubt, the bases of the balance required to obtain profits and value-added, thus ensuring stable wages, social security contributions and retirement for all the employees.

Congratulations to our Employees, Management, Chief Executive Officer and Board of Directors. With these people, Rovi is in the ascendant.

During the year, we increased our capital by 88 million euros, bringing in new shareholders, increasing the free float and providing equity for our research, to the detriment of already-existing shareholders, whom I thank for their consent. It is preferable to have a more solvent company, as this gives us strength, solidity and credibility.





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The pharmaceutical industry is synonymous with R&D. Our raison d'être is to provide treatments for unmet medical needs Well-managed companies in which a majority of the capital is family owned tend to think more of long-term profits than short-term gain, although never neglecting the annual dividend.

Rovi is a family company. Our 2018 dividend, together with the rise of the share price on the stock markets, will bring a good result for our shareholders.

In 2018, as will be the case in forthcoming years, we invested huge sums for a company of our size. The year's Research & Development expenses were 32.4 million euros, 15% up on the preceding year.

Warren Buffet, in his letters to shareholders of 1989 and 1990, used the term "institutional imperative" to describe the tendency of many executives to imitate the practices of their peers in other companies, in either the same sector or a different one, without paying much attention to whether they are really rational and make strategic sense or not. Warren Buffet highlighed the importance of avoiding this type of company that follows the institutional imperative, as well as the importance of having a good management team when investing in other companies.

The pharmaceutical industry is synonymous with R&D. Our raison d'être is to provide treatments for unmet medical needs. I can assure you that, without long-term research, we would cease to exist. The risk is to create value-added and Rovi has shown evidence of its research with promising results.

Hibor was, in its day, one of the most significant products in terms of results and the same is now true of the enoxaparin biosimilar, which has begun in a way that heralds success.





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With these strands, we have created our internationalisation, with our own representation in Europe.

Shareholders, we sell in more than 56 countries, with direct presence in Europe and our manufacturing operations in Spain.

This is Rovi's value-added: exports. We contribute to our country's balance of trade and hope that the Spanish government will recognise companies that are constantly helping to prevent the deficit that does so much damage to the GDP.

We are European citizens and companies like Rovi need Europe for their trading framework and legal certainty.

This trust in Europe, world healthcare under expansion, human resources like the ones we have, efficient professional management and the financial resources to undertake research provide us with a safe path to follow and thus ensure that the Rovi share remains a safe investment.

Thank you for your attention.

Juan López-Belmonte López

Chairman



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CONSOLIDATION PERIMETER FOR FINANCIAL AND NON-FINANCIAL INFORMATION AND PROCESS FOR PREPARING THE REPORT

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This Annual Report includes relevant information on ROVI in relation to financial and strategic aspects and ESG (environment, social and governance) in 2018. The previous report was drawn up in June 2018 and included information on the 2017 calendar year. The information provided in this document relates to the company as a whole, except where a different perimeter is specified. There have been no significant changes in the coverage or material issues and has been no restatement of information.

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) Sustainability Reporting Guidelines, 2016 version.

This Annual Report also contains information with 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 described or implied in said forecast-based information.

The information contained in this document represents ROVI's prospects and forecasts at the date of this Report. 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 wishes to expressly state that it is under no obligation to do so. These forecastbased statements should not be relied upon as representing ROVI's prospects or forecasts at any date subsequent to the date hereof.

In 2018, the external firm that reviewed the 2018 Statement of Non-Financial Information was KPMG Auditores S.L. Said document, presented with the Management Report, has been the basis for the information on sustainability matters contained herein.

Any queries regarding this Report may be sent to:





KEY LETTER FROM THE CHAIRMAN

ABOUT THIS REPORT

MATERIALITY ANALYSIS

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In order to determine which issues are most important to ROVI and its different stakeholders in the course of its activity, a materiality analysis was carried out in 2017 with the assistance of the consultancy firm PwC. The work consisted of an external diagnosis -in which analyses were made of four companies in the same sector, 15 reference studies and information appearing in the general, financial and industry-related media- and an internal diagnosis -with a self-evaluation of the group's performance and six interviews with members of the management team-. Thus, 20 material issues were identified and are discussed in this report, grouped into eight categories:



GOOD GOVERNANCE AND ETHICAL CONDUCT

- 1. Responsible governance
- 2. Ethics and compliance
- 3. Risks and crisis management

TRANSPARENCY AND DIALOGUE

- 4. Information transparency
- 5. Dialogue and relations with stakeholders

PRODUCT QUALITY AND SAFETY

- 6. Product quality
- 7. Pharmacovigilance and product safety

ENVIRONMENT

- 8. Circular economy
- 9. Atmospheric emissions
- 10. Climate change
- 11. Drug pollution

RELATIONS WITH CUSTOMERS, PATIENTS AND HEALTH PROFESSIONALS

12. Attention to and relations with customers, patients and health professionals



- 13. Safety and well-being
- 14. Training and development
- 15. Attracting and retaining talent
- 16. Internal dialogue and communication

SUPPLY CHAIN

17. Responsibility in the supply chain

HEALTH AND WELL-BEING OF SOCIETY

- 18. Access to medicines
- 19. Research and development

20.Contribution to the social and economic progress of the communities in which ROVI operates





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MATERIALITY GRAPH

The following materiality graph shows the degree of influence of these matters on ROVI's long-term objectives. This influence has a dual axis: the influence on business success and the importance for stakeholders.





BUSINESS MODEL

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ROVI IS A LEADING PHARMACEUTICAL SPECIALTY COMPANY ENGAGED IN THE RESEARCH, DEVELOPMENT, MANUFACTURING AND MARKETING OF SMALL MOLECULES AND BIOLOGICAL SPECIALTIES.





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IDENTITY AND COMMITMENT

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ROVI's mission, vision and values are the guidelines that govern all the decisions made in relation to both business development and the professional performance of its workers, guiding the group's business strategy:





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MANAGEMENT OF CSR AT LABORATORIOS ROVI



Corporate social responsibility (CSR) is a crucial part of ROVI's identity. It is incorporated into its business strategy, since it is a key factor for the company's long-term sustainability and the key tool to reinforce the relationship and trust between ROVI and its stakeholders.

ROVI globally, and all the companies that form part of the group individually, are aware that the products they provide contribute to improving people's health and, thus, it is sought to respond to specific social demands, while, at the same time, taking care with the impact and footprint on society and the environment.

CSR impregnates all ROVI's activity and structure, from strategic and governance decisions to management tasks and day-to-day activity. Decisions on sustainability and CSR are made by the Management Committee and, finally, the Board of Directors.

In this area, in 2018, ROVI focused on reinforcing its commitment to ethical management and transparency. To do this, a number of documents were updated, such as the Code of Ethics, the Anti-Bribery and Anti-Corruption Policy and the Code of Ethics for Suppliers, in order to furnish the organisation with a framework for action that is kept updated and ensures a day-to-day activity that is carried on ethically, honestly, morally, legally and in accordance with the principles and values that define the company.

Objectives of the CSR policy and support tools

ROVI is aware that its economic development must go hand-in-hand with ethical conduct -socially, in the labour area, environmentally and in terms of respect for human rights-. This is channelled through a number of policies for action in which the commitment to business ethics materialises, as well as the manual for action applicable to any member of ROVI's workforce in their relations with stakeholders:



All these aspects have a series of common principles for action, which are the backbone of ROVI's day-today management and furnish it with consistency.



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ROVI is aware that its economic development must go hand-in-hand with ethical conduct



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ROVI'S GENERAL PRINCIPLES FOR ACTION

Eegality

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

쥦 Human rights

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.

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.



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Honesty

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

Communication

Foment 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, ROVI contributes to harmonising 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.

Oontribution to society

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.**

Environment

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 to and mitigating climate change, in accordance with the group's Environmental Policy.



Commitment to transparency as a way to transmit confidence and credibility to 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 nonfinancial 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.



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IDENTIFICATION OF AND RELATIONSHIP WITH STAKEHOLDERS

ROVI considers CSR to be a commitment acquired with society, given the importance of its work for the well-being of society and the improvement in the quality of life of patients and the assistance they receive, promoting human health through the innovation, manufacture, marketing and distribution of medicines and other healthcare products. In this respect, the company has identified six groups -and the goals it seeks in relation to each one of themthat, directly or indirectly, contribute to the proper performance of its activities and with whom it has a number of communication channels:



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The company has identified six groups that contribute to the proper performance of its activities





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SUPPLIERS

CHANNELS

A voluntary document called "CSR Commitment" is sent to all the group's suppliers and subcontractors. This document requests certifications or urges them to adopt good practices.

On-site audits which check that:

- Suppliers operate in accordance with national and local regulations.
- There are no significant breaches of workplace safety rules.
- No practices infringing workers' rights exist.

Confidential communication mechanisms to report irregularities considered illegal or a breach of ROVI's Code of Ethics for Suppliers.

GOAL

To allow them to find in ROVI a partner for mutual benefit.





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BUSINESS UNITS

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







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In 2018, the ROVI group faced the challenge of strengthening its international presence as a result of the launch of the enoxaparin biosimilar, principally through its recently-created subsidiaries. Having a sound strategy and clear pillars of growth furnishes the company with a defensive profile that has allowed it to increase its profits each year. In 2018, this reached double-digit figures, with a growth rate of 10%.

GROWTH PILLARS

Benchmark company for LMWH	>	Revenue 2018 121.5 Mn€ 2010-18 CAGR ': 14% Represented 40% of total revenue and 42% of growth in 2018	OPERATING INCOME 2018: 303.2 Mn :
Leading Spanish pharmaceutical specialty company	>	Revenue 2018 127.1 Mn€ 2010-18 CAGR ': 6%	2010-18 CAGR ¹ : 8
Toll manufacturing of prefilled syringes and solid oral forms	>	Revenue 2018 54.6 Mn€ 2010-18 CAGR ': 5%	
Sound R&D&i and extensive portfolio of products under development	>	More than 500patents	



(1) CAGR: Compound annual growth rate.

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COMPETITIVE **ADVANTAGES**

ROVI's nature, principles and commitment to the activity it carries on have allowed it to obtain a series of competitive advantages that have positioned it as one of the main leaders in its market niche, in a sector which, moreover, has high entry barriers.






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ROVI operates with a lowrisk strategy, concentrating on diseases with extensive medical requirements





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INTERNATIONAL PRESENCE

Although it had commenced in previous years, 2018 was the year in which ROVI's international expansion played a leading role. The company has created its own subsidiaries in France, Germany, Italy, United Kingdom and Poland and, through them, is or will be marketing its enoxaparin biosimilar, among other products (such as Falithrom®, in Germany and Polaramine®, in France).

This expansion continues to be one of the strategic goals, in both organizational and marketing terms, mainly through distribution of the enoxaparin biosimilar, which was launched in Germany in 2017 and, in 2018, began to be marketed in the United Kingdom, Italy, Spain, France, Austria, Latvia and Estonia. It is expected to be extended to 26 EU Member States and, likewise, to other areas (North Africa, Middle East, Asia and South America) over the next few years through various distribution agreements signed last year.



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- Turkmenistan
- Uzbekistan



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Pharmaceutical specialties

ROVI has a diversified portfolio comprising over 40 of its own and licensed products, most of which are subject to growing demand and which are virtually unaffected by the reference pricing system in Spain. They are grouped into nine therapeutic areas and are indicated for either the treatment of different complaints or diagnosis.

ROVI's growth engines are Bemiparin, the distribution licence agreements (Neparvis®, Volutsa®, Orvatez® and Ulunar®), the enoxaparin biosimilar, the existing pharmaceutical specialty product portfolio, new product distribution licences and new customers in the toll manufacturing area.



ROVI aspires to become a world leader in lowmolecular-weight heparins (LMWHs). To achieve this, it has two products from its own research: Hibor® and an enoxaparin biosimilar. The low-molecularweight heparin division accounted for 40% of total group sales in 2018.

Hibor®

Hibor (Bemiparin) is a low-molecular-weight heparin (fast-acting anticoagulant) used to prevent and treat venous thromboembolic disease (VTD) in both surgical and medical patients, and for the acute longterm 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, which may grow, progress and fragment. In the event of fragmentation, some of the fragments may reach the lung and cause pulmonary embolism. In Spain alone, it is estimated that close to 65,000 cases of deep vein thrombosis occur every year, as well as a further 25,000 cases of pulmonary embolism (data extrapolated from Thromb Haemost 2000, 2001 and 2005).

Over recent years, Bemiparin has become one of the main treatments for this disease worldwide, having expanded its presence to 56 countries as the result of a strategic alliance network. Currently, Bemiparin is ROVI's principal product and accounts for 30% of the group's operating revenue.

Enoxaparin Biosimilar

ROVI began marketing its enoxaparin biosimilar (low-molecular-weight heparin) in Spain under the trademark "Enoxaparina ROVI". With this launch, ROVI expanded its presence in Europe, which had commenced in 2017 with the marketing of the product in Germany and been extended to the United





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Kingdom and Italy in the first half of 2018 and to Austria, Estonia, France and Latvia in the second half, in addition to Spain. Furthermore, also in 2018, ROVI signed an agreement with Biogaran SAS, the leading French pharmaceutical company in generics and biosimilars and a subsidiary of Laboratorios Servier, to market its enoxaparin biosimilar in France on a semiexclusive basis.

ROVI's enoxaparin sodium biosimilar is an anticoagulant that belongs to the low-molecularweight heparin group. It is used to treat and prevent deep vein thrombosis and pulmonary embolism.

As of 31 December, 2018, ROVI had obtained authorisation to market its enoxaparin biosimilar in all the European countries except Greece and Luxembourg from the competent national authorities. The enoxaparin market totals more than 900 million euros in Europe (according to estimates based on the 2018 sales reported by Sanofi-Aventis), approximately 75% of which are concentrated in Germany, France, Spain, United Kingdom, Portugal and Poland (QuintilesIMS-2015 figures), countries in which ROVI hopes to market its product directly through its subsidiaries. Outside Europe, ROVI signed agreements to distribute the producer in 64 countries, the most outstanding being those signed with Hikma Pharmaceuticals PLC and with Sandoz; the first for 17 MENA (Middle East and North Africa: Saudi Arabia, Jordan, Algiers, Egypt, Tunisia, Sudan, Syria, Yemen, Iraq, Oman, United Arab Emirates, Kuwait, Qatar, Bahrain, Libya, Palestine and Lebanon) and the second for 14 countries / regions (Australia, New Zealand, Philippines, Hong Kong, Singapore, Vietnam, Malaysia, Canada, South Africa, Brazil, Colombia, Argentina, Mexico and Central America).

ROVI manufactures and packages its enoxaparin biosimilar in Spain thanks to its four production plants, in which it invested 17.2 million euros between 2014 and 2016 in order to increase capacity and prepare for this new production milestone. Enoxaparin sales totalled 30.2 million euros in 2018.

With the enoxaparin biosimilar, ROVI aspires to become one of the main European -and, in the medium- and long-term, world players in a global market of more than 1.5 billion euros where there are only two other biosimilars, due to the competitive edge provided by the vertical integration of processes in the group.



The following are the products marketed under licensing agreements that make the greatest contribution to the group's EBITDA:

Neparvis®

ROVI began to market Neparvis® (sacubitril/valsartan) of Novartis in December 2016. This product is indicated in adult patients for treatment of symptomatic chronic heart failure with reduced ejection (the proportion of blood leaving the heart) fraction.

Hirobriz® Breezhaler® y Ulunar® Breezhaler®

In the last quarter of 2014, ROVI commenced the marketing of Breezhaler (indacterol maleate) and Ulumar Breezhaler (indacaterol maleate and glycopyrronium bromide) in Spain. Both these 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 the two products under licence from Novartis.





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Volutsa®

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

Vytorin®, Orvatez® y Absorcol®

Vytorin® (ezetimibe and simvastatin), Orvatez® (ezetimibe y atorvastatin) and Absorcol® (ezetimibe) are products used as adjunctive therapy to diet in patients with hypercholesterolemia and are the first of the five MSD marketing licences granted to ROVI.

In the second quarter of 2018, the patent for the active substance ezetimibe expired and, therefore, the price of Absorcol® dropped. Likewise, generic medicines formulated with ezetimibe and simvastatin have recently started to be marketed and, therefore, the price of Vytorin® has been lowered in order to maintain its competitivity.

Medikinet® y Medicebran®

Medikinet (methylphenidate hydrochloride with modified release) and Medicebran (methylphenidate hydrochloride with immediate release) are prescription products 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.



In the first quarter of 2019, ROVI announced the acquisition of two products, Falithrom® and Polaramine®. These purchases are within the framework of its operating leverage strategy for its international subsidiaries.

Falithrom®

In January 2019, ROVI announced the purchase of Falithrom®, which had belonged to Hexal AG, a company belonging to the Sandoz Division of Novartis, in order to distribute it directly in Germany. Under this agreement, Falithrom® will be marketed directly in Germany by ROVI, once the administrative procedures to authorise the transfer of the marketing authorisation have been completed with the German Federal Institute of Medicines and Medical Devices (BfArM).

This product is used for the prevention and treatment of thromboembolic disease, including venous thrombosis and pulmonary embolism, as well as the prevention of ischemic strokes in patients with atrial fibrillation.

Polaramine® y Polaracrem TM

ROVI has reached an agreement with a subsidiary of Merck Sharp and Dohme ("MSD") whereby it acquires certain rights for MSD's dexchlorpheniramine maleate product line, allowing it to distribute this product directly in Spain in its different pharmaceutical forms (tablets, syrup and ampoules, marketed under the trademark POLARAMINE®, and cream, marketed under the trademark POLARACREM[™]) and in France in its injectable form (ampoules).

This product line belongs a group of medicines known as antihistamines. They are indicated for the symptomatic treatment of seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis, allergic cutaneous manifestations of urticaria or angioedema; and reactions to blood or plasma. It is also indicated, together with adrenalin or other appropriate measures, for treatment of anaphylactic reactions after the acute manifestations have been controlled. These products often relieve cutaneous manifestations such as allergic eczema, atopic and contact dermatitis, insect bites, dermographisms and drug reactions.



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4 Diagnostic imaging contrast agents and other hospital products

Tetridar®

In April 2019, ROVI informed about the agreement reached with Teva Pharmaceutical Industries Ltd. to market this medicine in Spain (expected to commence in the third quarter of 2019) for the treatment of osteoporosis in adults. This agreement will last for five years and may be extended for a further five years.

Osteoporosis is a disease that weakens bones and makes them fragile. This disease is especially frequent in post-menopausal women, but may also affect men. In addition, osteoporosis often occurs in patients treated with corticosteroids. According the data of the specialised healthcare management consultant lqvia, in the twelve months up to February 2019 (MAT February 2019), sales of the original teriparatide molecule in Spain totalled 69.2 million euros. 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 approximately 10% of the company's revenue, comprises a broad product portfolio, including those marketed under licence from Bracco: lomeron® and lopamiro® (for computed tomography and intervention), Multihance® y Prohance® (for magnetic resonance imaging), Sonovue® (for ultrasounds), and Bracco Injeenering: EmpowerCTA+®, EmpowerMR® and CT Exprès (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®).





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The company has positioned itself strategically to take advantage of the trend among many pharmaceutical companies to outsource their manufacturing processes

Toll manufacturing

ROVI is one of the main companies in the toll manufacturing business in the sector and among the world leaders in prefilled syringe production. It 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, together with the San Sebastián de los Reyes plant, have allowed an increase in the injectables production lines and are approved by the European and/or United States regulators –the European Medicines Agency (EMA) and the Food and Drug Administration (FDA), respectively–.

The company has positioned itself strategically to take advantage of the trend among many pharmaceutical companies to outsource their manufacturing processes and makes good 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, including prefilled syringes, vials, suppositories, tablets, coated tablets, hard capsules and sachets.

ROVI's profile is unique in this market, due to the unification of all the services within the same company, from the development of a project until the final product release, including preliminary clinical trials, stability studies and physical, chemical and microbiological analyses, with the resulting saving of time and money for the customers. Thus, it provides a personalised service depending on the needs of each customer.

The contracts signed with its customers usually have an average term of between 3 and 5 years, which helps to generate a considerable stable flow of revenue. Furthermore, the long regulatory process that a pharmaceutical company has to undergo to change its manufacturer makes the toll manufacturing business model generate "lifelong customers", as long as the service provided is optimal in meeting the customers' needs.

Toll manufacturing is divided into:



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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 this market, since entry barriers are high, given the biological nature of the medicines manufactured and the aseptic conditions (handling of the product in sterile, microbiologically-controlled rooms) in which the prefilled syringes are filled.

The company has a plant specialised in 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. These syringes and vials are filled in aseptic conditions in sterile rooms and there is also terminal sterilisation if the product so requires. Additionally, there is the possibility of placing safety devices in the syringes. The annual capacity for vials is 60 million, while it is 150 million for suppositories. The plant has been approved by the European and United States regulators. It has also been approved by the authorities of Korea, Brazil and the Gulf States and holds the certifications ISO9001, ISO14001 and OSHAS.

Over recent years, ROVI has increased its production capacity subsequent to agreements such as the one signed with Crucell Spain in 2015, which led to the acquisition of the assets of the injectables manufacturing plant located in San Sebastián de los Reyes, with the primary purpose of allowing the ROVI Group's production lines for injectables (different to those that Crucell had been manufacturing) to be expanded in the future. In 2016, it was approved by the European health authorities and began to operate in 2017.



ROVI has a plant for solid forms that has a long tradition in the manufacture of pharmaceutical products and uses the most advanced technology for the manufacture of oral forms (tablets, coated tablets, hard capsules and sachets). The plant, with 83,000 square metres, has an annual global 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.



The company offers a wide range of services for the performance of clinical trials, manufacture and filling, labelling, packaging and logistics, always applying the strictest quality standards. The machinery used is the same as is used for an industrial-sized batch and, therefore, the latest European regulations on clinical trials are met. Since ROVI works to both United States and European quality standards, it also provides costcompetitive technical, with a flexible and reliable model.





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Research, development and innovation (R&D&i)

The company allocates a large part of its revenue to research, in order to remain in vanguard in terms of both products and manufacturing and development systems. ROVI operates with a low-risk strategy, concentrating on chronic diseases with extensive medical requirements and setting up international strategic alliances to undertake the most arduous clinical programmes.

Commitment to research and technology

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Factors like research, development and technological innovation are strategic elements in order to compete in the current market and, at the same time, are used by ROVI to differentiate itself from the other companies in the sector. For this reason, ROVI has made a strategic bet on the protection of R&D&I results, thanks to the patent system and the business secret protection system. This firm bet has materialised in a portfolio of more than 500 patents, 408 of which have been granted, while 98 are in the examination and evaluation phase.

In this area, furthermore, the investment made in R&D in 2018 is significant, mainly related to development of the ISM® technological platform, which led expenses to increase by 15% in comparison to the preceding year, totalling 32.4 million euros in 2018 (in comparison with the 28.3 million euros of 2017 and the 17.5 million euros of 2016). The factors that caused this increase in the expense were principally the development of the Phase III trial of Risperidone ISM® and the execution of the Phase I trial of Letrozole ISM®.

In addition, ROVI coordinates all its research activity from Spain, distributing it over the Madrid and Granada centres, with three R&D&I centres and two pilot plants for the manufacture of injectable medicines on which research is in progress. Furthermore, ROVI is present in the creation and leadership of large strategic national research consortia, so much so that, since 2006, it has been a partner in the activities of different consortia within the CENIT programme, the Nanofarma Consortium (2006), the Melius Consortium (2007) and the CeyeC Consortium (2009) and, since 2011, has been actively leading research consortia, such as the SNC_Integra Consortium, the ADELIS Consortium (2013) and the BIOMAP Consortium (2015), all of which fall within the framework of the FEDER-Innterconecta Programme for Andalusia, co-financed by European Union Structural Funds.

At the same time, it also holds agreements with several public and private entities in order to combine efforts and reinforce scientific, technological and educational activities, as well as spreading knowledge, in Spain.





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In this respect, it continuously co-operates with the University of Granada in research activities and the training of scientific personnel through projects within the framework of the incentives awarded by the Technological Corporation of Andalusia.

Furthermore, the company receives the support of the Ministry of Economy, Industry and Competitiveness for its research and development work through the Torres Quevedo Programme. This program promotes the recruitment of doctors to carry out industrial research and experimental development programs as well as prior viability studies, in order to favour the professional careers of the developers, stimulate private-sector demand for personnel who are sufficiently qualified to undertake R&D plans and projects, and help consolidate technological companies.

As a result of the financing received, the company's personnel has been reinforced by the recruitment of two doctors to carry out R&D&i activities within the framework of the following projects:

• Technological clinical research platform for the development of medicines (ISM®, In Situ Microparticles). Ref.: PTQ-15-07720.

- Evaluation of the efficacy of Risperidone ISM® in adult patients with acute exacerbation of schizophrenia, Ref.: PTQ-15-07457.
- Validation of processes involved in the new ISM technological platform developed by Laboratorios Farmacéuticos Rovi. Ref.: PTQ-16-08424

At the same time, the company receives support from important bodies, such as the Industrial Technological Development Centre and the Technological Corporation of Andalusia in its development activities, having received funding in 2018 for its main line of research, the development of new controlled-release systems based on ISM® technology, through the following projects:

- IDI-20160109 "Evaluation of the efficacy of Risperidone ISM® in adult patients with acute exacerbation of schizophrenia (2015 -2019).
- IDI-20170024 "Definition of the design space by applying the QbD methodology for ISM® formulations" (2017-2019). Project led from the Granada R&D Centre, co-funded with FEDER Funds.
- IDI-20180128 "Study of comparative bioavailability in steady state of Risperidone ISM® vs. oral risperidone" (2017-2019).
- IDI-20170717 "Phase I clinical trial, with single increasing doses of letrozole using a prolonged-release injectable system" (2017-2019).
- P16-872 "Study, design and development of the immediate packaging for the development of products with new release technology" (2015-2018).







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Areas of research

ROVI's portfolio of products in the research and development phase is numerous. However, it concentrates primarily on three areas: sophisticated drug release technologies, glycomics and polymeric multilayer systems for urethral catheters. The most significant R&D milestones in recent years relate, firstly, to the development of heparin-based products and other glycosaminoglycans and, secondly, to the development of new controlled drug release systems, based on the patented ISM® technology.



ISM® technology and long-acting injectables

Long-acting injectables (LAIs) are becoming the drugrelease system of choice for the care of some complaints, such as schizophrenia, replacing oral medication on a significant scale as a result of the improvement in patient adherence to treatment, ensuring that the prescribed dose is received. In this respect, ISM® is a technological drug-release platform patented by ROVI, based on the formation of biodegradable matrices after administration of a carrier liquid, once it has been injected into the patient's organism. This is why, in the world of LAIs, ISM® is an optimal alternative for the treatment of chronic diseases with unmet medical needs.

In the case of formulations based on ISM® technology, the product is presented in a kit with two syringes, one of which contains the polymer and active substance in solid form, while the other contains the liquid required for reconstitution, allowing it to be reconstituted just before it is administered to the patient. The medicine then precipitates in the muscle after it has been injected into it, giving rise to formation of a solid or semi-solid implant by spreading the carrier through the patient's own corporal fluids. This design increases the stability of the composition considerably, avoiding the need for it to be stored in a cool place and allowing clinically significant release profiles to be obtained from the first day after the injection. Furthermore, it attains clinical levels that are maintained over time and can be reproduced

after intramuscular administration, meaning that the treatment does not require any oral supplement or the establishment of initial guidelines.

A distinguishing feature of ISM® technology is that it is the exclusive property of ROVI and is protected by patents until at least 2033 and it has the advantage of significantly improving the clinical use of drugs that are currently administered orally or by prolonged-action parenteral formulations.

The first two product developments using this technology, which are also candidates to be licensed to third parties, are Risperidone ISM® (registered with the trademark Doria®)and Letrozole ISM®, both of which will become revolutionary treatments because of, firstly, their doses and, secondly, the improvement in the quality of the treatment and the life of patients with schizophrenia and breast cancer, respectively. In the section summarising the events of 2018 (page 94), further details are given of their characteristics, benefits and commercial prospects, as well as the status of the different studies that are being performed to obtain the approval of the health authorities in a number of countries.

Both projects represent a significant economic effort for the company, which is supported by the granting of public funds from the Industrial Technological Development Centre (CDTI).





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As a result of its effort and investment in this area, ROVI has developed its enoxaparin biosimilar



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 GAGs 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 specialisation and knowledge attained in this area allows the expansion of alternative applications, indications and action mechanisms for heparin-derived products and other glycosaminoglycans, based on both anticoagulant and non-anticoagulant activity, to be considered.

As a result of its effort and investment in this area, ROVI has developed its enoxaparin biosimilar (a lowmolecular-weight heparin with an antithrombotic effect), marketing of which commenced in 2017 and which, in 2018, had become one of the company's pillars of growth for forthcoming years, as described in the section on products and expended in the summary of 2018 (page 85).



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 using antibiotics.

During 2018, ROVI continued with the preclinical development of its multilayer technology, which uses polymeric materials to form a bioerodible 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.



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PRODUCTION PLANTS AND R&D CENTRES

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





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ROVI is among the world leaders in prefilled syringe production



(2 Employees shared between the two ISM® manufacturing plants)



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STRATEGIC AND FINANCIAL PRIORITIES



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MARKET ENVIRONMENT

The pharmaceutical market's prospects for forthcoming years could not be better. IQVIA (formerly IMSQuintiles), in its report "The Global Use of Medicine in 2019 and Outlook to 2023", forecasts that, in the next five years, the global pharmaceutical market can be expected to surpass 1.5 trillion dollars – the amount recorded in 2018 being 1.2 trillion dollars –. This represents growth of between 3% and 6%.

By geographical area, U.S.A. is expected to continue to be one of the drivers of pharmaceutical expenditure, with spending that may reach 600,000 million dollars, driven by factors such as the inclusion of new products and brand pricing, which are, nevertheless, offset by patent expiries and a lower cost of generics.

In Europe, the cost containment measures, such as the Reference Pricing Order (RPO) of 27 November, 2018 in Spain, as well as the lower growth in new products due to the promotion of generics, mean that the forecasts are for slower growth, between 1% and 4%, in comparison with the average 4.7% growth rate of recent years.

Asia shows two sides of the same coin. For example, in Japan, where 86,000 dollars were reached in 2018, a decrease of between 3% and 0% is expected for 2023, due to exchange rates and the continuing use of generic medicines. China reached 137,000 million dollars in 2018 and is expected to rise to between 140 and 170 thousand million dollars by 2023, although its growth is likely to decelerate by between 3% and 6%.

Developed markets will see how their dynamics are driven by the launch of new products and losses of

exclusivity. An average of 54 launches of new active substances (NAS) per year is expected and two thirds of them will be specialty products, representing close to 50% of pharmaceutical spending by 2023.

IQVIA evaluates losses of exclusivities at around 121,000 million between 2019 and 2023, the U.S.A. coming off worst with 80% of this loss, close to 85,000 million dollars Furthermore, the competition of biosimilars in the market is forecast to be almost three times higher than at present.

Net growth in medicine prices in 2018 was lower than that of the general economy. This is expected to continue for the next five years. The higher prices are partly due to the change in new medicines to treat smaller populations, 30% and 45% of the new active substances expected in the next five years being oncological medicines and orphan medicines, respectively.

Evolution and prospects of the pharmaceutical market in Spain

The pharmaceutical market shows aggregated growth of 1.9% in value and 0.8% in units over the last 12 months, according to the figures of the latest IQVIA report "Evolución del Mercado de la farmacia Española", published in February 2019. In 2018, the market showed higher growth than in 2017, especially in volume, where the negative trend was reversed.

Antithrombotic agents and antidiabetics continue to be the categories making the greatest contribution to the positive growth of the medicine market. Since 2015, the market penetration of generics has



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Since 2014, the market penetration of generics has remained stable, with a share of 40% in units remained stable, with a share of 40% in units. In terms of value, this percentage drops to 21% and shows higher growth than the brands in both units and value, a change in trend that was more marked in 2018 because of the two Reference Pricing Orders, at the end of each year, approved by the Spanish government, which constitute the main regulatory stumbling block for the sector.

The application of Reference Pricing Order SCB/1244/2018 of 27 November, 2018 will have a similar impact to the 2017 Order – according to the latest IQVIA analysis –. Taking the volume of units sold from November 2017 to October 2018 as a reference, after the entry into force of the lower prices in accordance with the current homogenous groups, the annual value of the reimbursement segment would be reduced by 66 million euros per year, which would be added to the 77 million euros resulting from applying the new prices for the last 12 months to the market in said period.

The impact of the Reference Pricing Order in 2018 represents a variation of -1.3% in the market segment subject to reference pricing, 92% of which is concentrated in non-generic products. The impact of the price decreases, both current and those expected in the future, on the total of the brands subject to reference pricing is 100 million euros (3.3%). According to IQVIA, the actual decrease will be greater and will depend on the penetration of the new generics.



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STRATEGIC AND FINANCIAL PRIORITIES

ROVI forecasts that the growth rate of its operating revenue for 2019 will be close to 20%, mainly driven by the pharmaceutical specialties business and supported by toll manufacturing.

PHARMACEUTICAL SPECIALTIES: CONSTANT GROWTH ENGINE

The group trusts that it will continue to grow thanks to, among other things, its benchmark product, Bemiparin, which showed growth of 15% in the domestic market in 2018. At the same time, the enoxaparin biosimilar will drive growth in forthcoming years. Said product had been approved in 24 EU countries as of 31 December, 2018 and approval in Greece and Luxembourg is expected in 2019. Likewise, ROVI has distribution agreements for this product in 64 countries, among which those with Hikma Pharmaceuticals, which holds exclusive rights for 17 countries in the Middle East and North Africa, and Sandoz, for another 14 countries/regions, may be highlighted.

In addition, the enoxaparin market continues to represent a growth opportunity for ROVI, since the size of the European market is around 900 million dollars. The group continues to market this product in Germany, United Kingdom, Italy, Spain and France, five of the main markets in Europe, and began to market it in Austria, Latvia and Estonia in the last quarter of 2018, with good sales expectations. Likewise, in Spain, there are good prospects for the next few years thanks to the opportunities provided by products such as:

- Nevarpis®, a product with a high strategic value that provides support to the company's cardiovascular franchise;
- Hirobriz® Breezhaler® and Ulunar® Breezhaler®, in the respiratory niche, also belonging to Novartis;
- Volutsa®, of Astellas Pharma, with which ROVI entered the urology market;
- Orvatez®, of Merck Sharp and Dohme, which helped to strengthen the hypercholesterolemia market.

These products will help the company to perform well over forthcoming years, since they meet needs for which there is growing demand and provide an opportunity for sustained and profitable growth in the future.

In 2018, ROVI's internationalisation was promoted or consolidated and it now has subsidiaries in Germany, United Kingdom, France, Italy and Poland. Thus, the group aspires to become one of the leading companies in the world in the low-molecular-weight heparin field.



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TOLL MANUFACTURING

As has been the case over recent years, ROVI is keeping its focus on taking advantage of the strengths inherent to its business model, not only to acquire new customers, but also to make good use of the capacity of its injectables and oral forms plants for the manufacture of its own products. This business has many synergies with the pharmaceutical specialty area, since its main products, Hibor® and the enoxaparin biosimilar, are prefilled syringes and are manufactured at the injectables plants.

ROVI hopes to continue to develop operating synergies and extend the scope of its value-added services with its current customers and potential new ones.

Through the toll manufacturing business, ROVI provides prefilled syringes and the manufacture of oral forms to leading companies all over the world. The company has a customer-oriented business model with high value-added services and unique capacities that represent a high entry barrier for the competition.

The focus on long-term contracts provides a tremendously stable base for this business line, whereby ROVI produces drugs that are distributed in more than 40 countries and has a sound track record in regulatory compliance in different geographical areas, shown by the GMP and FDA certifications held by its plants.

R&D&I, PROJECTS FOR TOMORROW

ROVI has total confidence in the potential of its current R&D&i project portfolio, where it is making a significant investment effort, since it is expected to be the company's growth engine in the future. Principally, ROVI's confidence is placed in the potential of ISM® technology, which belongs exclusively to ROVI and for the which the Phase III Prisma-3 study has been completed. Information on the main favourable results of this study has already been published.

Furthermore, it is planned to file an NDA (New Drug Application) –a USA registration application– with the FDA (Food and Drug Administration in the second half of 2019.

Likewise, a Phase I study is underway for another candidate, Letrozole, showing the clear bet on ISM® technology. ROVI is currently undergoing a transformational growth process and the capital increase carried out recently has reinforced this new growth phase.

The versatility of ISM® technology, developed by ROVI, has huge potential for licensing. The development of this technology concentrates on improving the way is which compounds that have already been approved, with an appropriate risk-benefit balance, are administered and the dosage thereof.

At the same time a strategy has been implemented to protect our patented technology and the new pharmaceutical and biotechnological technologies by seeking patent protection for all aspects associated with the development of the main technologies (including the active compounds, procedures for obtaining them, methods of administration, new therapeutic uses and administration kits, new analysis methods and innovative pharmaceutical formulations). Finally, ROVI's extensive manufacturing capacity, with multiple FDA and GMP approvals, provides strong support to our research and development initiatives.



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ISM® TECHNOLOGY: THE FUTURE OF ROVI'S **PRODUCTS AND** LICENCES

ROVI's ISM® technology is an innovative drugrelease platform, developed internally and patented, that allows the sustained release of compounds administered by injection. The following key aspects contribute to the success of ISM® technology:

- · Highly-efficient medicine retention
- Excellent stability of active substance
- High level of control and predictability of the initial release of the medicine
- · Avoids the need to store in a cool place
- Flexible dose frequency of between one and six months

• Protected by patents until at least 2033

ROVI's ISM® technology has been developed in order to overcome the disadvantages of the existing prolonged-release systems by providing injectable formulations that furnish greater simplicity, efficacy and stability. There is great potential for extensive applicability of ISM® technology to new chronic therapeutic areas, including psychiatry and oncology. Its vertical integration and experience in the manufacture of prefilled syringes places ROVI in a leading position in the market.

In this respect, ROVI has prepared a research financing plan for its ISM® technology platform until 2021, which

HIGHLIGHTS OF THE ISM® PLATFORM





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it hopes to fund through a combination of funds obtained as a result of the capital increase conducted in 2018, the group's internal cash flow generation and its debt capacity.

ROVI has made significant progress in the development of the first candidate of its leadingedge drug-release technology, registered under the trademark DORIA®. This first candidate guarantees prolonged release of risperidone, a second-generation antipsychotic medicine the use of which is consolidated for the treatment of schizophrenia. After successfully completing the programme for Phases I and II of Doria®, ROVI commenced the pivotal Phase III trial, PRISMA-3, with the recruitment of the first patient in May 2017. An update of the project was published with details of the design and the cost of Phase III, together with a presentation given to analysts in October, 2017. In March 2019, ROVI published the principal favourable results of the DORIA® Phase III study, which show that primary and secondary efficacy variables have been achieved for patients with acute exacerbation of schizophrenia. Consequently, ROVI plans to file an NDA (New Drug Application) -an application that is filed with the FDA (Food and Drug Administration) in the United States- in the second half of 2019.

Long-acting injectables (LAIs) are becoming the benchmark for the care of schizophrenia, rather than the oral treatment, and, with Doria®, ROVI hopes to occupy a prominent position in schizophrenia treatment with LAIs in the United States and Europe, with an estimated total value of 4,200 million dollars in 2021 –3,300 million dollars in the United States and 930 million dollars in the five main markets in Europe– (source: IQVIA).

In addition, in November 2017, the clinical development with Letrozole commenced. This is the first long-acting aromatase inhibitor for the treatment of hormonedependent breast cancer and ROVI's second ISM® technology-based candidate. During 2018, the first Phase I clinical trial was carried out, the LISA-1³ study. This is an open-label, single-dose, dose-increasing study to evaluate the pharmacokinetic profile, safety and tolerability of intramuscular injections of Letrozole ISM®, with different concentrations, in healthy postmenopausal women.



(3) Evaluation of IM Letrozole ISM® Pharmacokinetics, Safety, and Tolerability in Healthy Post-menopausal Women (LISA-1). Clinicaltrials.gov#NCT03401320 [https://clinicaltrials.gov/ct2/show/NCT03401320].



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CSR STRATEGIC PLAN

ROVI is a Spanish specialised pharmaceutical group, which is fully integrated and engaged in the research, development, manufacturing and marketing of small molecules and biological specialties. Its activity encompasses the marketing of its own and licensed products and the provision of services, such as production, filling and packaging, to other companies.

Aware of the health improvements provided by their products, all the ROVI companies wish to respond to certain social demands in relation to the impacts of their activities on society and the environment. For this reason, the group has put in place action policies that express ROVI's commitment to business ethics and corporate social responsibility and provide guidance for the Board of Directors and other group bodies in their relations with stakeholders.

In this respect, these policies can be seen in aspects such as the Annual CSR Report, the Integrated Management Policy or the Code of Ethics, which are considered tools to attain the following goals defined in the group's General CSR Policy (approved in 2016 and revised in April 2017).

To attain these CSR goals, the ROVI group has adopted the following general principles for action, which also appear in the General CSR Policy (see page 28).

CSR GOALS



Favour attainment of the group's strategic objectives.

Ι

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, maximising the positive impacts of the group's activities in the different territories where it operates and minimising 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.

S III

Promote trust relationships

and value creation for all stakeholders, providing all of them with a balanced and integrating response.



CORPORATE GOVERNANCE

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CORPORATE GOVERNANCE MODEL



ROVI's corporate governance model helps to promote honest conduct on the part of the company

Laboratorios Farmacéuticos ROVI, S.A. (the "Company" or "ROVI") takes the current good corporate governance framework in Spain very much into account, at the same time as it keeps up to date on international good governance criteria and principles and the most recent initiatives related to good corporate governance practices. In particular, ROVI's internal regulations are adapted to the Good Governance Code of Listed Companies approved by the National Securities Market Commission (CNMV) in February 2015 (the Good Governance Code). This model helps to promote honest conduct on the part of the company, which helps to maintain the confidence generated among stakeholders and ensure that the interests of all the shareholders are defended.

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 General Shareholders' Meeting and the Regulations of the Board of Directors, which are available to be consulted on the company's website (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 established 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 company's results and financial situation. 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, including, in the consolidated version, a statement of non-financial information and diversity with the contents set out in Law 11/2018 of 28 December, whereby the Code of Commerce, the revised text of the Capital Companies Act approved by Royal Legislative Decree 1/2010 of 2 July, and Law 22/2015 of 20 July on Account Auditing were amended in relation to non-financial information and diversity. The statement of non-financial information has been reviewed by KPMG Asesores, S.L. as an independent service provider, as required by the applicable legislation. This documentation is available on the corporate website (www.rovi.es).

In addition to the governing bodies mentioned above, ROVI has a Management Committee responsible for the company's day-to-day management and formed by 13 managers, headed by the CEO.



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CORPORATE GOVERNANCE 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.

Meetings that are not considered ordinary general meetings are considered extraordinary general meetings.

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 they hold at least one share and that it is registered in their name in the relevant account entry register five days before the date the general meeting is held.

Additionally, in order to attend a general meeting, each shareholder must have an attendance card, i.e. the certificate issued by the entity responsible for the relevant account entry register or the document which legally proves their status as a shareholder.

2018 GENERAL SHAREHOLDERS' MEETING

The most recent Ordinary General Shareholders' Meeting of Laboratorios Farmacéuticos Rovi, S.A. was held in Madrid on 29 May on the first call, with a total of 46,563,544 shares (34,840,934 present and 11,722,610 represented) in attendance, representing 93.13% of the share capital (69.68% present and 23.45% represented).

Among the resolutions adopted by the Meeting were: (i) approval of the individual and consolidated annual accounts, (ii) the proposed application of the individual profit for the reporting period ended 31 December, 2017, specifically, payment of a fixed gross dividend of 0.1207 euros per share entitled to receive it, (iii) approval of the management and performance of the Board of Directors in 2017, (iv) the maximum annual remuneration of the members of the Board of Directors, in their capacity as such, for 2018, and (v) approval of the Long-Term Incentive Plan (2019-2021) whereby the executive directors receive company shares.



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The Ordinary General Shareholders' Meeting was held in Madrid on 29 May with a quorum of 93.13% of the share capital



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BOARD OF DIRECTORS

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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 seven members: three executive directors, one proprietary director and three independent directors. The independent directors 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 focuses its activities on

The Board of Directors met on 11 occasions and the percentage attendance was 100% of total votes 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.

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 decisionmaking power within the company without being submitted to counterweights and controls and that no shareholder is treated more favourably than others.

Its specific responsibilities are set out in article 5 of the Regulations of the Board of Directors and include, specifically, those of preparing the strategic plan and management objectives and approving the 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 2018, the Board of Directors met on 11 occasions and its chairman was present at all the meetings. The percentage attendance (including proxies granted with precise voting instructions) was 100% of total votes.

The Board of Directors carried out the evaluation of its own performance in 2018 on the basis of a report drawn up for this purpose by the Nomination and Remuneration Commission, in accordance with article 5.7 of the Regulations of the Board of Directors. No significant changes in its internal organisation or the procedures applicable to its activities derived from this evaluation. In 2018, in order to comply with Recommendation 36 of the Good Governance Code of Listed Companies, the





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BOARD OF DIRECTORS

	POSITION	TYPE OF DIRECTOR	NOMINATION AND REMUNERATION COMMISSION	AUDIT COMMITTEE
- Mr Juan López-Belmonte López	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
Mr José Fernando de Almansa Moreno-Barreda	Director	Independent	Member	Member
Mr Enrique Castellón Leal	Coordinating Director	Independent	Member	Chairman
Mr Gabriel Núñez Fernández	Non-Director Secretary		Secretary	Secretary
Mr Ignacio Zarzalejos Toledano	Deputy Non- Director Secretary		Deputy Secretary	Deputy Secretary

annual evaluation of the performance of the Board of Directors in 2017 was performed with the support of an external advisor, PricewaterhouseCoopers Auditores, S.L., in order to furnish the report with a more objective and independent vision. This evaluation reflected the efficiency and proper operation of the ROVI's Board of Directors and did not give rise to significant changes in its internal organisation or the procedures applicable to its activities.

In accordance with article 8.3 of the Regulations of the Board of Directors, the Lead Director, Mr Enrique Castellón Leal, is entitled to request a Board meeting be called or that new items by 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, organise the periodic evaluation of the Chairman of the Board. Likewise, he is authorised 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 chairman succession planning.





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DIRECTOR PROFILES

Mr Juan López-Belmonte López

Mr. López-Belmonte López graduated in Economic and Business Sciences from Universidad Complutense de Madrid in 1969 and is an insurance actuary. He is the Chairman of ROVI and a shareholder of Norbel Inversiones, S.L., of which he holds 20% (this company is, in turn, ROVI's controlling shareholder). He was Chairman of the Madrid Chamber of Commerce from March 2016 to April 2018. Likewise, he has been chairman of Asociación para el Autocuidado de la Salud (ANEFP) and Deputy Chairman of Farmaindustria. He was appointed as a director of the company on 27 July, 2007 when ROVI was first listed on the securities markets and re-elected by the General Meeting in 2012 and 2017. Currently, Mr López-Belmonte is Chairman and a member of the Board of Directors of Norbel Inversiones, S.L., Norbepa Inversiones, S.L., Lobel y Losa Development, S.L., Inversiones Borbollón, S.L. and Alentia Biotech, S.L.

Mr Juan López-Belmonte Encina

Mr Juan. López-Belmonte Encina graduated in Economic and Business Sciences, specialising in Auditing, from CEU San Pablo, Madrid in 1993. He joined ROVI in 1994 and was appointed General Manager in October 2001. Since October 2007, he has been the company's Chief Executive Officer, having been re-elected to this position by the General Meeting in 2012 and 2017. He is the Deputy Chairman of the Governing Council and Management Board of Farmaindustria. Likewise, he was Chairman of the R&D&i Committee of the CEOE (Spanish Confederation of Business Organisations) from March 2015 until the end of 2018. He began his professional career working in different professional areas of important international pharmaceutical companies in the United States and United Kingdom. Currently, Mr López-Belmonte Encina is likewise a shareholder of Norbel Inversiones, S.L. (ROVI's controlling shareholder).

Mr Iván López-Belmonte Encina

Mr Iván López-Belmonte Encina graduated in Economic and Business Sciences, specialising in Auditing, from CEU San Pablo, Madrid in 1994. He joined ROVI in 1995 and has been Corporate Development Manager since September 2007. He is First Deputy Chairman of the Board of Directors of ROVI, having initially been appointed a director of the company on 27 July, 2007 when ROVI was first listed on the securities markets and re-elected by the General Meeting in 2012 and 2017. He began his professional career in Germany, working in companies like Amersham, engaged in nuclear medicine, and Hexal AG, specialised in generics. Currently, Mr López-Belmonte Encina is likewise a shareholder of Norbel Inversiones, S.L. (ROVI's controlling shareholder).

Mr Javier López-Belmonte Encina

Mr Javier. López-Belmonte Encina graduated in Economic and Business Sciences from Colegio Universitario de Estudios Financieros (CUNEF), Madrid, specialising in Financing, in 1998. He obtained a joint Executive MBA from the University of Brown and the Instituto de Empresa in Madrid in 2017. He joined ROVI in 2000 and has been Chief Financial Officer since 2001. He is the Second Deputy Chairman of ROVI's Board of Directors, having initially been appointed a director of the company on 27 July, 2007 when ROVI was first listed on the securities markets and re-elected by the General Meeting in 2012 and 2017. He is a member of the Management Board of CEIM. Likewise, he is a member of the Social Council of the Universidad Autónoma de Madrid representing CEIM. 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, also in the United Kingdom. Currently, Mr López-Belmonte Encina is likewise a shareholder of Norbel Inversiones, S.L. (ROVI's controlling shareholder).





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Mr Miguel Corsini Freese

Mr Corsini is an independent external director of ROVI. 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 Meetings held in 2014 and 2018. Mr Corsini Freese holds a degree in Law and is an expert in Labour Law. For many years, his professional career was linked to RENFE, the Board of Directors of which he chaired between 1996 and 2004. He was also President of IUR (International Union of Railways) from 1998 until 2000. Mr Corsini Freese is also currently Chairman of the Board of Directors of Cetren and a member of the Board of AZVI, S.A.

Mr José Fernando de Almansa Moreno-Barreda

Mr Almansa is an independent external independent director of ROVI. He was appointed as an independent director on 9 June, 2015 for the Bylaw-stipulated term of four years. Mr Almansa holds a degree in law from the University of Deusto (Bilbao). He joined the Diplomatic Service on 2 December, 1974. Between 1976 and 1992 he held different positions: Secretary of the Spanish Embassy in Brussels, Cultural Attaché at the Spanish Embassy in Mexico, Chief Director of the Coordination Section of the Subdirectorate-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 in Brussels, Minister-Counsellor of the Spanish Embassy in the Soviet Union, Secretary General of the National Commission for the Fifth Centenary of the Discovery of America 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.

Mr Enrique Castellón Leal

Mr Castellón is an independent external director of ROVI. He was appointed as an independent director on 24 October, 2007 and re-elected by the General Meeting in 2012 and 2017. He graduated in Medicine and Surgery from the Universidad Complutense de Madrid and in Economic and Business Sciences from the Universidad Autónoma de Madrid. Likewise, he holds a Master in Public Health and a Master in Health Policy and Management from the University of Harvard. He has been a physician with the Internal Medicine Service at Hospital Clínico San Carlos in Madrid, a Social Security Medical Inspector, General Manager of the Galician Health Service and Undersecretary at the Ministry of Health and Consumption. Likewise, he regularly advises several foundations engaged in research and development in the health science area and carries on consulting activities for Castellón Abogados. He has worked as a consultant in health projects funded by the Inter-American Development Bank (World Bank Group) and is a founding shareholder of Cross Road Biotech SCR y de Cross Road Biotech Inversiones Biotecnológicas SGEIC, SA. Currently, Mr Castellón Leal is Chairman of the Board of Directors of Cross Road Biotech, SCR; a director Owl Genomics, S.L.; a director Biocross, S.L.; Chairman of Cross Road Biotech Inversiones Biotecnológicas SGEIC, S.A.; a director of Atlas Molecular Pharma, S.L.; Chairman of Health In Code S.L.; Chairman of Venter Pharma, S.L. and Deputy Chairman of Additum Blockchain, S.L.



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The composition of the Committee favours diversity of knowledge, experience and gender

BOARD COMMITTEES

In order to comply with the applicable legislation and enhance its efficiency in performing its duties, the Board of Directors has created two Board committees: (i) the Nomination and Remuneration Commission, and (ii) the Audit Committee.

Nomination and Remuneration 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 reelected 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; assess 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; prepare and review the criteria that should be followed regarding the composition of the company's management team; and strive to ensure that the compensation policy established by the Commission is observed and is transparent. In 2018, it met on six 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; ensures the independence of the statutory auditors; and strives to ensure the independence and efficacy of the internal audit service. It meets on a quarterly basis to review the financial information which the company, as a listed company, must publish regularly. In 2018, the Committee held eight meetings. Therefore, its meetings were sufficiently frequent to allow it to carry out its duties correctly.





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MANAGEMENT COMMITTEE

The Management Committee has 13 members who represent ROVI's main organisational 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.



Ms Mercedes Benítez del Castillo Sánchez. Legal Department Manager.



Mr Ibón Gutierro Adúriz. Pre-clinical Research Manager.



Mr Iván López-Belmonte Encina. Corporate Development Manager.



Mr Pedro Carretero Trillo. Hospital Network Manager.



Mr Fernando Martínez Garijo. Sales Effectiveness Manager.



Mr Francisco Javier Ángulo García. Human Resources Manager.



Mr Miguel Ángel Castillo San Román. International & Business Development Manager.



Mr Miguel Ángel Ortega Sánchez. Industrial Manager.



Ms Beatriz Ávila Alcalde. Sales Manager Line B.



Mr Pablo Domínguez Jorge. Financial-Administrative Manager.



Ms M. ^a 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.



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Incorporation of CSR into management ROVI considers Corporate Social Responsibility (CSR) to be a commitment acquired with society, given the

to be a commitment acquired with society, given the importance of its work and products in enhancing people's health and quality of life. This commitment has resulted in intensive activity on the part of ROVI over the last few years to support research and foment the prevention and knowledge of certain diseases.

Likewise, ROVI's commitment to ethical management and transparency is reflected in the development of its internal regulations.

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.

In addition, both the Audit Committee, according to article 13 of the Regulations of the Board and article 10.d) of the Regulations of the Audit Committee, and the Nomination and Remuneration Commission (NRC), according to article 14.2 of the Regulations of the Board, are 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.

In 2018, subsequent to a favourable report from the Nomination and Compensation Commission, the Board of Directors examined and approved the Corporate Social Responsibility Report for 2017, which had been prepared in accordance with Recommendation 55 of the Good Governance Code. This report is published on ROVI's website in accordance with Recommendation 6 of the Good Governance Code.

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REMUNERATION POLICY

In compliance with article 14 of the Regulations of the company's Board of Directors, which incorporates the provisions of article 529 quindecies, 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 remuneration policy for the company's directors and senior management in 2018, 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 remuneration policy for the period 2016-2019, in accordance with article 529 novodecies of the Capital Companies Act.

In addition, ROVI's General Shareholders' Meeting held on 29 May, 2018 decided to fix a maximum global relation for the members of the Board of Directors in their capacity as such of 616.3 thousand euros for 2018. The General Meeting delegated the distribution of this sum to the Board of Directors, taking account of the functions and responsibilities attributed to each director, whether or not they are members of Board committees and any other

objective circumstances that the Board deems relevant.

Consequently, the Board of Directors distributed among its members a sum of 510,000 euros of the maximum amount of 616,300 euros approved by the General Meeting as fixed annual remuneration for Board members in their capacity as such in 2018. The sum was allocated taking account of the duties and responsibilities attributed to each director and whether or not he was a member of Board committees and the foregoing was carried out in accordance with a prior proposal from the Nomination and Remuneration Commission.

Likewise, the Board decided to distribute fixed global annual remuneration of 792,000 euros among the executive directors as remuneration for their executive and senior management duties, in accordance with the terms and conditions agreed between the executive directors and the company in their contracts, taking account of the duties and responsibilities of each director, on the basis of the proposal submitted by the Nomination and Remuneration Commission.

Regarding the variable incentive for the executive directors, the Board distributed 383,000 euros at





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The remuneration policy does not foresee that the independent directors receive variable remuneration

the proposal of the Nomination and Remuneration Commission, taking account of the company's results for 2018 and the targets fixed for each director.

Likewise, these sums were allocated to the executive directors applying criteria based on parameters such as the evolution of the ROVI group's operating revenue in accordance with the budgeted targets set out in the Business Plan and meeting the strategic goals determined in said Plan and the targets fixed for each director, as well as the investment operations performed and the consequences of strategic alliances during the year, which may have helped the company to strengthen its bases for present and future growth, plus the criteria fixed in the Director Remuneration Policy approved by ROVI's General Shareholders' Meeting of 31 May, 2016, which the company prepared with the advice of Landwell-PricewaterhouseCoopers Tax & Legal Services, S.L. Furthermore, when fixing the annual variable remuneration of the executive directors for 2018, individual non-financial targets related to social and environmental parameters and compliance with Codes of Ethics and Good Practices applicable to the company and its group were taken into account.

Moreover, at the end of 2018, the Long-Term Incentive

Plan for the period 2016-2018, which is limited solely to ROVI's executive directors, concluded. The criteria for fixing this long-term incentive plan took the following parameters into account:

- a) the increase in the quoted value of ROVI's shares; and
- b) the evolution of the ROVI group's business results, for which parameters such as EBITDA, margin or revenue were used.

In this respect, the Nomination and Remuneration Commission was responsible for assessing the degree to which targets had been met during the three years covered by the plan and for putting the proposal to settle the long-term incentive plan 2016-2018 to the Board of Directors. The proposal was approved by the Board and the amounts are shown in Section C of the Annual Director Remuneration Report drawn up by the Board of Directors, which is available on the corporate website (www.rovi.es) and the website of the CNMV (www.cnmv.es).

Finally, with regard to ROVI's workforce, which, at 31 December, 2018, consisted of 1,224 employees, it received gross global annual remuneration of around 70.18 million euros in 2018.


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ETHICS FRAMEWORK

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ROVI has a Code of Conduct (the "Code of Ethics"), the latest version of which was approved by the Board of Directors on 19 February, 2019, which is the basis of the ethics principles of the company and its group. This Code is applicable to all employees, to whom it has been communicated, and has the fundamental objective of providing a framework of guidelines and recommendations that transmit the good practices of ROVI's employees in their day-to-day work to its stakeholders (employees, shareholders, suppliers, customers, patients, professionals, public authorities and society in general), while, at the same time, it provides guidance for making everyday decisions. ROVI considers this Code of Ethics to be an opportunity to put values that identify it as a company into practice, such as mutual respect, the quest for innovation or the competitiveness that results from scientific excellence.

The Code of Ethics is formally signed by all workers when they join the workforce of any ROVI group company.

ROVI's Code of Ethics includes a specific section on financial integrity and protection of its assets, whereby it undertakes to apply the highest standards of ethics and transparency in its communications, information records and reports concerning its products and activities. This entails the obligation that, when preparing the accounting for the financial statements, books, records and accounts, ROVI will meet legal requirements and will properly apply current accounting principles, in order to provide an accurate picture of its business activities and the group's financial situation.

Additionally, ROVI has an Anti-Bribery and Anti-Corruption Policy, the latest version of which was approved by the Board of Directors on 19 February, The company has mechanisms to prevent behaviour that is damaging to shareholders and stakeholders

2018. This Policy develops one of the principles of the Code of Ethics, which is to reject any practice that includes bribery or corruption. The Anti-Bribery and Anti-Corruption Policy, also applicable to all ROVI's employees, states that detailed books, records and accounts that accurately show the group's assets and transactions must be kept and that an appropriate system of internal control over financing reporting must be in place.

The body responsible for ensuring compliance with the Code of Ethics is the Compliance Function, to which this responsibility was assigned in the charter approved by the Audit Committee on 25 July, 2017. This permanent, internal, collegial body reports directly to the Audit Committee and is considered an advisory body to said Committee on compliance matters. The Compliance Department is the area responsible for performing day-to-day compliance coordination activities, providing support to the Compliance Committee and reporting to it on relevant matters.

In 2018, ROVI personnel received training in the Code of Ethics, imparted by the Compliance area. Said



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training had two main gaols:

- To reinforce the idea that all the employees and members of governing bodies of ROVI are subject to the Code and that it is binding on them; and
- To provide training on all the principles for action contained in the Code of Ethics, with their possible applications and interpretations.

Additionally, the Compliance Committee approved the "Code of Ethics for Suppliers" on 7 November, 2017. The main objective of this Code is to ensure that ROVI's suppliers and other components of the value chain not only respect current legislation, but also the values of the ROVI's corporate governance system, the principles set out in its Corporate Social Responsibility Policy and other internal rules of ROVI. This Code was implemented during 2018 by some of the departments who deal with suppliers.

ROVI has "Regulations of the Ethics Channel for Employees and Suppliers", the latest update of which was approved by the Audit Committee on 7 November, 2017. These establish that the managing body of ROVI's ethics channels is the Ethics Channel Management Committee, which is likewise responsible for ensuring that all reports submitted through this channel receive attention and are managed appropriately, confidentially and in full. Said body is responsible for analysing cases of non-

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compliance and proposing corrective measures. The possible sanctions derived from non-compliance are the responsibility of the Human Resources Department.

ROVI employees may communicate with the Ethics Channel at the e-mail address <u>canaletico@rovi.es</u> or by physical mail.

Likewise, ROVI has a specific Ethics Channel for suppliers, partners, external collaborators, etc. that allows them to report any irregularity or breach of the ROVI group's Code of Ethics for Suppliers they may detect to the organisation. Various mechanisms have been put in place to enable suppliers to communicate with ROVI's Ethics Channel for Suppliers, among which the e-mail address <u>canaleticoproveedores@</u> <u>rovi.es</u> is included, as well as a physical mailbox at ROVI's offices.

ROVI undertakes to actively support the Universal Declaration of Human Rights and requires its employees to comply with said principles in their dayto-day activity in the group. The company combats practices contrary to human dignity and workplace discrimination. The group also endeavours to carry out appropriate monitoring and control of the Good Governance Code recommendations. Thus, the company has mechanisms to prevent behaviour that is damaging to shareholders and stakeholders, such as the concentration of power, lack of transparency or lack of auditor independence. ROVI also strives to monitor and control the recommendations of the Unified Code of Good Governance for Listed Companies appropriately and, on 7 November, 2017, the Audit Committee approved the Regulations of the Audit Committee, in line with the recommendations of the CNMV's Technical Guide 3/2017 on Audit Committees.

Finally, ROVI has Internal Regulations on Conduct in the Securities Markets, the latest version of which was approved by the Board of Directors on 25 July, 2017. The purpose of these Regulations is to adjust the actions of the company, its governing bodies and other persons subject to the rules on conduct to the legislation related to the securities markets.

No irregularities related to the financial reporting were received in 2018.



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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 materialisation 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:

1	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.
2	The second line of defence comprises the risk control and management function. This function 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.
3	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.



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



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Responsibility for risk control. monitoring and management

According to the company's Regulations of the Board of Directors, a full Board meeting is responsible for approving the Risk Management and Control Policy, including tax risks, as well as the regular monitoring of the internal reporting and control systems. Exercising this responsibility, in May 2016, the Risk Management and Control Policy, which includes ROVI's general risk management principles, was approved. According to this Policy, the bodies involved in said management are:

Audit Committee

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.

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 in place to mitigate the impact in the event that any risks materialise.

Head of Risk Management and Control System

Has 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 materialised.



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RISK CONTROL AND MANAGEMENT PROCESS



The steps that ROVI follows in risk management are 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 performance- and profitability-related targets.
- 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.

- 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 materialised in the preceding period.





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Control and management systems in relation to the process of issuing financial information (SCIIF – ICFR)

The ICFR system (SCIIF) is aimed to obtain reasonable certainty as to the reliability of the financial information. The bodies responsible are:







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RISK MAP

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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:



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RISKS MATERIALISED IN 2018

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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, more recently, 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 (Royal Decree 177/2014), 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 pharmaceutical expenditure in Spain since 2010.

The new reference pricing Order approved in 2018, which includes a drop in the prices of several of the company's products, has not had a significant impact on the group, since the same products had already been affected by previous Ministerial Orders.

Since the deficit control measures of both the State and the Autonomous Regions are continually affecting the pharmaceutical sector, the company still cannot rule out the approval of new changes to the legislation that may have a significant impact on the development plans of the pharmaceutical industry in general and may specifically affect attainment of the company's corporate objectives. The company, which is fully aware of this, regularly draws up contingency plans in order to try to reduce the impact of any new measures to a minimum.

The company has applied the oversight and control systems and response plans described in section E6 to the risk mentioned in this section and considers them to have operated properly in forecasting and detecting the occurrence of these risks and minimising their impact.

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104 Human resources

> 118 suppliers

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RESULTS FOR THE PERIOD

ROVI's prescription pharmaceuticals sales rose by 18% in 2018

ROVI is continuing to grow and, specifically in 2018, its operating revenue rose by 10% to 303.2 million euros, mainly due to the pharmaceutical specialties business, which increased by 16%. Bemiparin, the group's flagship product, continued to be the principal growth engine, with a 15% increase in the Spanish market.

According to the consultant IQVIA, the innovative products market in Spain grew by 2% in 2018 in comparison with 2017. Notwithstanding, ROVI's prescription pharmaceuticals rose by 18% in 2018, outperforming the market by 16 percentage points.

As a member of Farmaindustria, the Spanish pharmaceutical industry association, ROVI is subject to the co-operation agreement signed between this association and the Spanish government in 2016 and renewed in December 2017. According to the agreement, in the event that public spending on medicines (excluding generics and biosimilars) exceeds the actual growth rate of the GDP of the Spanish economy, the pharmaceutical industry must reimburse the government for the difference with monetary payments. In 2018, the public spending growth rate exceeded the growth rate of the GDP, meaning that the companies subject to the agreement must make the applicable reimbursement. Thus, the sale recognised by ROVI were 3.5 million euros lower than the actual sales.

However, 2018 was also the year in which ROVI's international strategy was consolidated and sales outside Spain show this, with growth of 25% to 99.4 million euros. 27.1 million euros related to sales of the international offices, principally due to sales of the enoxaparin biosimilar. Sales outside Spain accounted for 33% of operating revenue in 2018, in comparison with 29% in 2017.

Total revenue likewise rose by 10%, totalling 304.8 million euros in 2018. Gross profit rose by 5%, to 176.2 million euros, in 2018, reflecting a decrease of 2.6 percentage points in the gross margin, which dropped to 58.1% in 2018, in comparison with 60.7% in 2017. This fall in the gross margin was mainly due to:

- The sales reduction in the injectables division, which had added higher margins in 2017.
- The increase in sales of the enoxaparin biosimilar, which contributed lower margins in 2018, after the product had been launched in seven new markets.
- The 3.5 million-euro sales reduction in relation to the agreement signed between Farmaindustria and the Spanish government.
- The increase in raw material prices for lowmolecular-weight heparins which, in 2018, were 30% up on the 2017 prices. ROVI expects this rising trend in raw material prices to continue during 2019.

EBITDA dropped by 1% to 29.5 million euros in 2018, showing a decrease of 1.1 percentage points in the EBITDA margin to 9.7% in 2018, in comparison with 10.9% in 2017. EBIT fell by 5% to 17.5 million euros in 2018, showing a decrease of 0.9 percentage points to 5.8%, in comparison with the 6.7% margin of 2017.





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EBITDA "without R&D", calculated by excluding R&D expenses in 2018 and 2017 and the impact of non-recurring expenses in 2018, grew by 8%, from 58.2 million euros in 2017 to 63.0 million euros in 2018, reflecting a drop in the EBITDA margin of 0.3 percentage points, to 20.8%, in 2018. The equivalent EBIT rose by 9%, from 46.7 million euros in 2017 to 51.0 million euros in 2018, reflecting a decrease of 0.1 percentage points in the EBIT margin in 2018 to 16.8%.

In addition, if the same amount of R&D expenses as recorded in 2017 is maintained in 2018 and the impact of non-recurring expenses, for a value of 1.1 million euros, is excluded, EBITDA would have risen by 16% to 34.7 million euros, with the EBITDA margin showing an increase of 0.6 percentage points to 11.5% in 2018, from 10.9% in 2017. EBIT would have risen by 23% to 22.7 million euros, with an increase of 0.8 percentage points in the EBIT margin to 7.5% in 2018, up from 6.7% in 2017.

The aforementioned non-recurring expenses were linked to a substantial change to Frosst Ibérica employees working conditions, mainly related to the removal of the catering service, for which the employees were compensated with a sum similar to the costs that ROVI would have incurred in the following five-year period.

Low-molecular-weight heparins, with increasing weight as a pharmaceutical specialty business driver

The strength of ROVI's pharmaceutical specialty business is still the group's growth engine, with sales that rose by 16%, while total revenue was 304.5 million euros, 10% up on 2017.

Once again, the sales of the Low-Molecular-Weight Heparin (LMWH) Division led the prescription-based pharmaceutical sales, which grew by 18% in 2018 to 216.8 million euros. Specifically, sales of LMWH (enoxaparin biosimilar and bemiparin) rose by 42% and totalled 121.5 million euros, accounting for 40% of operating income in 2018, in comparison with the 31% of 2017.

Sales of the enoxaparin biosimilar in particular reached 30.2 million euros in 2018, the first full year of sales, during which marketing of this product also commenced in the United Kingdom, Italy, Spain, France, Austria, Latvia and Estonia. Bemiparin sales rose by 9% to 91.3 million euros. Sales under the trade mark Hibor in Spain increased by 15% to 67.4 million euros, while there was a 5% drop in international sales to 23.8 million euros.

> Sales of the enoxaparin biosimilar reached 30.2 million euros



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ENOXAPARIN BIOSIMILAR: ROVI'S PRESENT AND FUTURF

As of 31 December, 2018, all the European Union countries where ROVI had applied for approval of the national registration of the enoxaparin biosimilar had approved said registration, except for Greece and Luxembourg.

In April 2018, ROVI signed an agreement with Hikma Pharmaceuticals PLC, a listed multinational pharmaceutical group (LSE:HIK), for the exclusive distribution and marketing of its enoxaparin biosimilar in 17 MENA (Middle East and North Africa) countries: Saudi Arabia, Jordan, Algeria, Egypt, Tunisia, Sudan, Syria, Yemen, Iraq, Oman, United Arab Emirates, Kuwait, Qatar, Bahrain, Libya, Palestine and Lebanon.

Likewise, in June 2018, ROVI announced signature of an agreement with Sandoz, a division of Novartis AG and one of the world leaders in generic and biosimilar medicines, for the distribution and marketing of its enoxaparin biosimilar in 14 countries/regions (Australia, New Zealand, Philippines, Hong Kong, Singapore, Vietnam, Malaysia, Canada, South Africa, Brazil, Colombia, Argentina, Mexico and Central America). Under this agreement, ROVI grants Sandoz an exclusive licence to market the product in three of these countries, Hong Kong, Singapore and Vietnam.

In September 2018, ROVI announced that it had signed an agreement with Biogaran SAS, the leading French pharmaceutical company in generics and biosimilars and a subsidiary of Laboratorios Servier, to market its enoxaparin biosimilar in France on a semi-exclusive basis.

In addition to the European countries mentioned, as of December 2018, ROVI had signed marketing agreements for its enoxaparin biosimilar in 64 countries.



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TABLE OF RESULTS

Millions of euros	2018	2017	2016	2015	2014	2013
Sales	304.8	277.4	266.7	247.0	240.9	218.9
EBITDA	29.5	29.9	39.3	31.8	36.6	32.4
EBIT	17.5	18.4	28.3	21.8	27.7	25.5
Net profit	17.9	17.2	26.1	19.8	24.1	23.0
Сарех	26.4	19.9	18.1	19.9	25.1	24.7
Financial debt	34.2	43.2	33.8	42.8	36.3	31.0
Net financial debt	-62.8	1.1	-9.0	12.1	8.3	-5.8







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SALES BY PRODUCT

Millions of euros and Percentaje



The products Corlentor® and Thymanax®, the 2017 sales of which were 2.5 million euros and 3.9 million euros, respectively, were not marketed in 2018. Furthermore, in the second half of 2018, the patent on the active substance ezetimibe expired and, therefore, the price of Absorcol® was reduced. Likewise, marketing of generic medicines formulated with ezetimibe and simvastatine commenced recently and, therefore, the price of Vytorin® was lowered to maintain its competitiveness. Finally, the sale decrease in Exxiv® was mainly due to a drop in the COX-2 market.

At the beginning of 2019, Falithrom® joined the company's product portfolio. This medicine is used for the prevention and treatment of thromboembolic disease. including venous thrombosis and pulmonary embolism, as well as the prevention of ischemic strokes in patients with atrial fibrillation. ROVI paid 9 million euros to Hexal AG -a company belonging to the Sandoz Division of Novartis- for Falithrom®, a product that, in Germany alone, obtained sales of 3.5 million euros in 2018 and will be marketed there directly by ROVI once the administrative procedures to authorise the transfer of the marketing authorisation have been completed with the German Federal Institute of Medicines and Medical Devices (BfArM).

In addition to this launch, an agreement was signed with Merck Sharp and Dohme (MSD) in early 2019 to acquire certain rights for the dexchlorpheniramine maleate product line. This allows ROVI to distribute this product directly in Spain in all pharmaceutical forms (tablets, syrup and ampoules, marketed under the trade mark Polaramine®, and cream, marketed under the trademark Polaracrem®, and in France in its injectable form (ampoules).

According the MSD, this product line obtained sales of around 6.3 million dollars in Spain and France in 2017 and belongs to the antihistamine group of medicines. They are indicated for the symptomatic treatment of seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis, allergic cutaneous manifestations of urticaria or angioedema; and reactions to blood or plasma. They are also indicated, together with adrenalin or other appropriate measures, for treatment of anaphylactic reactions after the acute manifestations have been controlled. These products often relieve cutaneous manifestations such as allergic eczema, atopic and contact dermatitis, insect bites, dermographisms and drug reactions.





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Finally, ROVI reached an agreement with Teva Pharmaceutical Industries Ltd. to market Tetridar in Spain from the third quarter of 2019. Sales of teriparatide, the active principle of this medicine indicated for the treatment of osteoporosis in adults, totalled 69.2 million euros in the twelve months up to February 2019 (MAT February 2019). business in comparison with 2017, when the volumes manufactured for some customers were exceptionally high. Frosst Ibérica fell by 1% in comparison with the preceding period, with sales of 25.9 million euros.

Contrast agents, other hospital products, OTC products an others

Diagnostic imaging contrast agents and other hospital products rose by 4% in 2018 in comparison with the preceding year, totalling 29.7 million euros.

Non-prescription pharmaceuticals ("OTC") and others fell by 17% in 2018, to 2.2 million euros.

Toll manufacturing, less activity in a stable market

Toll manufacturing activities decreased by 11% in 2018 in comparison with 2017, totalling 54.6 million euros. This was mainly due to the drop in the injectables

SALES BREAKDOWN

	2018	2017	VAR.(%)
Revenue	303,203	275,649	10,0%
Sales of goods	248,628	214,550	15,9%
PRESCRIPTION-BASED PHARMACEUTICALS	216,783	183,407	18,2%
LMWH	121,508	85,341	42,4%
Enoxaparin biosimilar (Enoxaparin Becat)	30,246	1,486	n.a.
Hibor	91,262	83,855	8.8%
Sales in Spain	67,441	58,775	14.7%
Sales abroad	23,820	25,081	-5.0%
Neparvis	13,557	4,697	2.9x
Ulunar & Hirobriz	15,279	14,298	6.9%
Volutsa	11,221	9,000	24.7%
Vytorin & Absorcol & Orvatez	36,050	39,423	-8.6%
Medikinet & Medicebran	7,381	7,529	-2.0%
Exxiv	2,336	3,591	-34.9%
Other products	27,703	34,206	-19.0%
Discounts to National Health System	-18,252	-14,679	24.3%
Contrast agents and other hospital products	29,688	28,541	4.0%
Non-prescription pharmaceuticals ("OTC") and other	2,157	2,603	-17.1 %
Services provided	54,575	61,099	-10.7%



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SOUND FINANCIAL SITUATION

ROVI remains firm in its commitment to maintain low leverage in capital management. As of 31 December, 2018, ROVI had total debt of 34.2 million euros.

Debt with government entities, at a 0% interest rate, accounted for 34% of total debt at said date. As of 31 December, 2018, the total debt from the Social Security and public authorities in ROVI's favour was 7.3 million euros, 4.6 million euros of which related to Spain, 1.1 million euros to Portugal and 1.6 million euros to Italy.

As of 31 December 2018, bank borrowings had decreased by 8.2 million euros due to debt repayment. In December 2017, ROVI announced the European Investment Bank (EIB) had granted it a loan to support its investments in Research, Development and Innovation. The loan is for 45 million euros. ROVI may draw down this amount during a period of 24 months as from signature of the contract and the loan will mature in 2029. The loan provides for a three-year grace period and financial conditions (i.e. applicable interest rates, repayment periods, etc.) favourable to ROVI. As of 31 December 2018, ROVI had drawn down 5 million euros against this credit line.

Also in 2018, ROVI increased its equity by 88 million euros. The net transaction-related expenses were 3.9 million euros, meaning that the net capital increase was 84.1 million euros.

The purpose of the funds obtained from the capital increase was to partially fund the Phase III clinical trials of Risperidone ISM® and other expenses related to Risperidone ISM® until it was, if approved, marketed; to fund, fully or partially, the Phase I clinical trials of Letrozole ISM®; to support the current marketing of the enoxaparin biosimilar Becat®;





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and any other general corporate needs, possibly including acquisitions. To date, ROVI has used 22.5 million euros of these funds to acquire Falithrom® and Polaramine®, among other uses.

As a result of the capital increase carried out in October 2018, as of 31 December, 2018, ROVI had a gross cash position of 97.0 million euros, in comparison with the 18.9 million euros at 30 September, 2018 and the 42.1 million euros at 31 December, 2017, and net cash of 62.8 million euros (variable-income securities, plus deposits, plus cash and cash equivalents, less current and non-current financial debt), in comparison with net debt of 20.6 million euros as of 30 September, 2018 and net debt of 1.1 million euros as of 31 December, 2017.

The increase in working capital in 2018 was mainly due to:

- A 19.4-million-euro increase in inventories, principally as a result of higher levels of heparin stock in 2018;
- A 10.4-million-euro increase in the "Trade and other receivables" caption;
- An increase of 15.2 million euros in the "Trade and other payables" caption in 2018, partly due to the inclusion of 3.5 million euros in said period in accordance with the new IFRS 15, which, as of 31 December, 2017, had been recognised under the capitation "Provisions for other liabilities and expenses"; and
- A cash increase of 54.8 million euros in 2018, as a result of the capital increase carried out in October 2018.

TABLE OF DEBT

	2018	2017	2016	2015	2014	2013
Net debt/EBITDA	-2.13x	0.04x	-0.23x	0.38x	0.23x	-0.18x
Net debt/Equity	-0.22x	0.01x	-0.05x	0.07x	0.05x	-0.04x

ROVI ended the year with a gross cash position of 97.0 million euros





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CONSOLIDATED INCOME STATEMENT

Thousands of euros	2018	2017	VAR. (%)
	707.007		10.00/
Net revenue	303,203	275,649	10.0%
Recognition of grants on non-financial fixed assets and other	1,587	1,773	-10.5%
Total operating revenue	304,790	277,422	9.9%
Cost of sales	-128,612	-110,192	16.7%
Gross margin	176,178	167,230	5.4%
%	58.1%	60.7%	-2.6pp
 R&D expenses	-32,376	-28,251	14.6%
Sales, overhead and administrative expenses	-113,206	-108,491	4.3%
Other expenses	-1,094	0	n.a.
Share in profit/(loss) of joint ventures	24	-567	-104.2%
EBITDA	29,526	29,921	-1.3%
%	9.7%	10.9%	-1.1pp
Amortisation or depreciation	-12,044	-11,479	4.9%
EBIT	17,482	18,442	-5.2%
%	5.8%	6.7%	-0.9pp
Finance income	16	93	-82.8%
Finance costs	-712	-1,013	-29.7%
Impairment and gain/(loss) on measurement of financial instruments	-23	_	n.a.
Exchange rate differences	-83	-	n.a.
Net finance costs	-802	-920	-12.8%
Profit before tax	16,680	17,522	-4.8 %
Income tax	1,215	-281	n.a.
Effective rate	-7.3%	1.6%	-8.9pp
Profit for the period	17,895	17,241	3.8%





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BUSINESS STRATEGY CORPORATE MODEL GOVERNANCE

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CONSOLIDATED STATEMENT OF FINANCIAL POSITION

Thousands of euros	31-DIC-18	31-DIC-17
ASSETS		
Non-current assets		
Property, plant & equipment	95,837	89,056
Intangible assets	34,650	27,078
Investment in joint venture	2,038	2,054
Deferred tax assets	16,036	11,893
Variable-income securities	70	69
Trade and other receivables	65	65
	148,696	130,215
Current assets		
Inventories	94,861	75,492
Trade and other receivables	60,180	49,747
Current tax assets	3,414	2,228
Financial derivatives	17	
Prepaid expenses	21	
Cash and cash equivalents	95,511	40,700
	254,004	168,167
Total assets	402,700	298,382
Capital and reserves attributable to company shareholders	3 36 /	3000
Share capital	3,364	3,000
Share premium	87,636	-
Legal reserve	600	600
Treasury shares	-8,812	-8,407
Retained earnings and voluntary reserves	186,792	179,255
Profit for the period	17,895	17,241
Other reserves	-3	-2
Total equity	287,472	191,687
LIABILITIES		
Non-current liabilities		
Financial debt	16,589	27,029
Deferred tax liabilities	1,243	1,438
Contractual liabilities	6,263	-
Deferred revenue	3,621	5,005
	27,716	33,472
Current liabilities		
Financial debt	17,635	16,208
Trade and other payables	68,165	52,942
Contractual obligations	1,159	-
Deferred revenue		565
	553	
Provisions for other liabilities and expenses	-	3,508
Provisions for other liabilities and expenses Total liabilities	553 - 87,512 115,228	



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2018 INVESTMENTS

ROVI invested 26.4 million euros in fixed assets in 2018, in comparison with the 19.9 million euros of 2017. The following investments may be highlighted:

• 3.8 million euros

Were invested in the injectables plant, in comparison with the 2.9 million euros invested in 2017;

• 2.8 million euros

Were applied to investments in the San Sebastián de Los Reyes plant in 2018, in comparison with the 4.8 million euros invested in 2017;

• 3.0 million euros

Were invested in the Granada plant, in comparison with the 1.6 million euros invested in 2017;

• 5.5 million euros

Were invested in the Alcalá de Henares (Frosst Ibérica) plant, in comparison with 3.8 million euros invested in 2017;

• 2.3 million euros

Were invested in maintenance and other, in line with the investment made in 2017.

• In 2018, ROVI invested **9.0 million euros** in the acquisition of Falithrom®.

Likewise, the company recorded an investment of **4.5 million euros** in the enoxaparin biosimilar in 2017.

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EVOLUTION OF THE MAIN R&D PROJECTS: DORIA® AND LETROZOL®

DORIA®: FIRST LEADER IN ISM® TECHNOLOGY

The main candidate to lead ROVI's ISM® platform is Doria®, a risperidone LAI patented by ROVI. If approved, Doria® is well positioned to become the LAI treatment of choice for those patients for whom risperidone is the drug of choice and, therefore, to capture an important part of an attractive market, in which approximately 20.1% of schizophrenia patients in the USA and EU are treated with oral risperidone, according to IMS Midas in 2017. LAIs are increasingly becoming the standard treatment for schizophrenia and have numerous cost-related advantages over oral anti-psychotics.







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Doria® is based on ISM® technology and uses the risperidone molecule, which has been demonstrating its efficiency and clinical safety for years. The unique pharmacological profile of Doria® has shown therapeutic levels in plasma two hours after the injection, with a single monthly dose and no need for other injections or oral supplements.

After successfully concluding the clinical research programme in Phases I and II, the Phase III clinical trials were performed, intended to show a swift reduction in the PANSS score (positive and negative syndrome score) in schizophrenic patients with an acute exacerbation of their disorder. ROVI commenced the pivotal Phase III trial, "PRISMA-3" with the recruitment of the first patient in May 2017. An update of the project with details of the design and cost of Phase III was published together with a presentation given to analysts in October 2017.

The PRISMA-3 study is a randomised, multicentric, double-masked, placebo-controlled clinical trial to evaluate the efficacy and safety of monthly intramuscular injections of the product registered under the trademark DORIA® in patients with acute exacerbation of schizophrenia⁴. In May 2018, it was announced that an independent data supervisory committee had reviewed the provisional results of the Phase III trial and recommended continuing with the clinical trial without the need to increase the number of patients. In September 2018, the recruitment of patients for the double-blind part (the main part) of the study was completed and, in December 2018, all the patients completed said part.

In March 2019, ROVI published the main favourable results of the Phase III study of Doria®, which showed that the primary and secondary variables that are the key to efficacy in patients with acute exacerbation of schizophrenia had been achieved. Consequently, ROVI plans to file an NDA (New Drug Application) –an application that is filed with the FDA (Food and Drug Administration) in the United States– in the second half of 2019.

If approved, Doria® will be well positioned to enter into the attractive market, with prospects of heavy growth, of schizophrenia treatment. Schizophrenia is a chronic and progressive disorder and it is necessary to adhere strictly to treatment plans to avoid relapses. It affects 21 million people all over the world according to the epidemiological data of the Kantar Health Epi Database.

(4) Study to Evaluate the Efficacy and Safety of Risperidone In Situ Microparticles® (ISM®) in Patients With Acute Schizophrenia (PRISMA-3). Clinicaltrials.gov#NCT03160521 [https://clinicaltrials.gov/show/NCT03160521].





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It is a large and growing market in terms of both units and value, with a high rate of treatment changes. In the United States and Europe, there are around 3 million patients (Source: IQVIA) diagnosed with a schizophrenic disorder. These disorders cannot be cured but there are treatments that control the symptoms efficiently. These treatments use second-generation anti-psychotics (SGA), which have a predictable efficacy and safety profile. From among them, risperidone is one of the most widelyused active substances. With Doria®, ROVI is trying to occupy a prominent position in the markets for schizophrenia treatment with LAIs in the United States and Europe, with a total value of 4,200 million dollars (3,300 million dollars in the United States and 900 million dollars in the five main markets in Europe (source: IQVIA).

According to this consultancy firm, the injectables market for schizophrenia in the USA grew at a CAGR of 34.3% between 2011 and 2017. The second largest LAI market for schizophrenia was Europe, with the five major European countries growing at a CAGR of 15.1% from 2011 to 2017, reaching a value of 1,000 million dollars. The penetration of LAIs remains low, with market shares of 12.5%, in terms of units, in the United States and 20.7% in Europe, according to Datamonitor.

LETROZOLE ISM®, INNOVATION IN THE FIELD OF BREAST CANCER TREATMENT

In November 2017, the clinical development of Phase I, the LISA-1 study, with Letrozole ISM® commended. This is the first long-acting aromatase inhibitor for the treatment of hormone-dependent breast cancer and ROVI's second ISM® technology-based candidate. This is an open-label, single-dose, dose-increasing study to evaluate the pharmacokinetic profile, safety and tolerability of intramuscular injections of Letrozole ISM®, with different concentrations, in healthy post-menopausal women.

ROVI is firmly convinced that medicines directed at hormone receptors provide a unique opportunity to take advantage of its ISM® platform. According to Datamonitor, the hormone-receptor positive (HR+) breast cancer market in the United States, Japan, the United Kingdom, Germany, France and Italy combined will grow by 16.7% between 2015 and 2024. Letrozole ISM® is designed to treat hormonedependent breast cancer with the aromatase inhibitor letrozole, which blocks oestrogen production in postmenopausal women.

ROVI's objective with Letrozol ISM® is to obtain a longacting injectable formulation of letrozole (six months or more), which avoids the daily dose and is included in the breast cancer maintenance treatment for this group of patients. It is the first injectable on this type that is being developed and has a number of potential advantages, such as improving the patients' quality of life, decreasing the social and health costs and improving the rate of patient adherence to treatment.

Letrozole is a key active substance for treating hormone-positive receptor breast cancer. Is one of the third-generation aromatase inhibitors (AI), together with anastrozole and exemestane, active substances that detain oestrogen production in postmenopausal women. Currently, the dosage of the Als is daily oral administration for a period of at least five years and, therefore, non-adherence and even early abandonment of the treatment are frequent, which may affect the survival results.





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This represents an opportunity for Letrozole ISM®, since it could improve the treatment and gain market share. Furthermore, lower but more sustained doses are under study. These, compared with those of the oral treatment, could reduce adverse secondary effects, such as loss of bone mass and dyslipidemia, due to lower exposure to the drug. If this enhanced

safety profile is demonstrated in the clinical trials, it has the potential to make a positive impact on treatment adherence.

SECURITIES MARKET INFORMATION

The ROVI share ended 2018 with a value of 17.45 euros per share. It's lowest point was a value of 14.80 euros per share and its peak in the period was 18.15 euros. During the year, it accumulated growth of 12%, an especially promising figure when compared with the 15% fall in the IBEX-35 in the same period. However, apart from the share price, the really important aspect of ROVI's

securities market performance in 2018 was its capital increase, after which it had 56,068,965 ordinary shares with a par value of 0.06 euros per share. All these shares belong to the same class and have the same voting and economic rights. They are listed on the Madrid, Barcelona, Bilbao and Valencia Stock Markets through the Securities Market Interconnection System.

EVOLUTION OF THE SHARE

- ROVI.MC 16.20

(Euros)

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								۷W		15.0
FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	——————————————————————————————————————



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ROVI always remained a sound and safe share, outperforming the market average

Based on the closing price at the 2018 year end. ROVI's capitalisation at 31 December was 978,403,439 euros, in comparison with the 782,500,000 euros as of the same date in 2017.

ROVI's capital increase was announced in a relevant event (register No. 270159) dated 4 October, 2018 and was charged to cash contributions by means of the issuance of new ordinary shares with a par value of 0.06 euros each, under the authorisation provided by the General Shareholders' Meeting (the "Initial Offering Shares" and the "Capital Increase"), which could be increased by additional new ordinary shares representing up to 10% of the Initial Offering Shares issued (the "Option Shares" and, together with the "Initial Offering Shares", the "Offering Shares") to cover any excess shares that might be placed in relation to the offering of the Initial Offering Shares or short positions derived from stabilisation operations.

In spite of having a complicated year, ROVI always remained a sound and safe share, outperforming the market average at almost all times. Particularly after the capital increase, ROVI rose considerably, while other indexes, like the aforementioned or the BME (Bolsa y Mercados de España) average, showed a downward trend. This was reflected in 12% growth at the end of the year, while both the BME and the IBEX-35 accumulated negative results, -6% and -15%, respectively, in 2018.

EVOLUTION OF THE SHARE IN COMPARISON WITH THE CONTINUOUS MARKET AND IBEX-35

(Percentage)







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ROVI's good business results allowed the General Shareholders' meeting to approve payment of a dividend of 1.1207 euros per share entitled to receive it, charged to the 2017 profit.

2018	2017
56,068,965	50,000,000
17.45 euros	15.65 euros
978,403,439 euros	782,500,000 euros
9,150,000 euros	9,025,000 euros
0.1207 euros	0,1830 euros
35%	35%
0.32 euros	0.34 euros
54.53	46.03
	56,068,965 17.45 euros 978,403,439 euros 9,150,000 euros 0.1207 euros 35% 0.32 euros

With the marketing phase of enoxaparin biosimilar fully underway in Europe and the good development prospects for products like Doria® for the immediate future, ROVI has begun 2019 with constant growth in its share value, which reached a historical high of 19.40 euros per share in the first quarter. Shareholders owning significant direct or indirect interests of more than 3% in the share capital of Laboratorios Farmacéuticos Rovi, S.A. of which the company is aware, according to the information in the official records of the National Securities Market Commission as of 31 March, 2019, are the following:

SIGNIFICANT SHAREHOLDERS (AS OF 31 MARCH, 2019)

PERCENTAGE OF VOTING RIGHTS	DIRECT	INDIRECT	TOTAL
Norbel Inversiones, S.L.	62.102%	_	62.102%
Indumenta Pueri, S.L.	-	5.057%	5.057%
Alantra Asset Management, SGIIC, S.A.	-	4.821%	4.821%
T. Rowe Price As-sociates, Inc	-	3.390%	3.390%
JO Hambro Capital Management Limited	-	4.787%	4.787%
Wellington Management Group, LLP	-	4.980%	4.980%
TOTAL	62.102%	2.035%	85.137%





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Significant shareholders hold 85.137% of ROVI's capital. In October 2018, the increase in equity led to the dilution of the majority shareholders, Norbel Inversiones, S.L., whose interest dropped from 69.640% to 62.102%. All the significant shareholders, except JO Hambro Capital Management, subscribed to the capital increase.

Attention should be drawn to the inclusion of Wellington Management Group as a significant shareholder. It subscribed to the capital increase with an interest of 3,013% and, between then and 31 March, 2019, increased its position by 1.967 percentage points, to 4,980%.

The company Norbel Inversiones, S.L. holds 62.102% of the shares of Laboratorios Farmacéuticos Rovi, S.A. Norbel Inversiones, S.L. is owned by Mr Juan López-Belmonte López (20.000%) and Messrs Juan, Iván and Javier López-Belmonte Encina (26.667% each). Therefore, Mr Juan López-Belmonte's interest in ROVI at the end of 2018 was 12.420%, while those of Messrs Juan, Iván and Javier López-Belmonte Encina were 15.561% each at the end of 2018.

The composition and characteristics of the rest of the shareholders with significant interests are as follows:

- Indumenta Pueri, S.L. is the asset management company of the Domínguez family, which owns the children's fashion company Mayoral in Malaga.
- Alantra Asset Management SGICC, S.A. is a collective investment institution management company headquartered in Madrid.
- JO Hambro Capital Management Limited is a collective investment institution management company headquartered in the United Kingdom.
- TRowe Price Associates, Inc Limited is a collective investment institution management company headquartered in the United States.
- Wellington Management Group LLP is a collective investment institution management company headquartered in the United States.

Through its "Policy for Communication with Shareholders, Institutional Investors and Proxy Advisors", which is constantly updated and applied, ROVI maintains regular, smooth communication on all its activities. In this respect, it has several channels for contact with investors, such as the e-mail address for direct queries (ir@rovi.es) or the form on its website: www.rovi.es/contact.

ROVI offers all its shareholders the possibility of receiving the company's financial information automatically through an e-mail alert system and regular, prompt and relevant information on the company, such as presentations and legal documents on economic and financial aspects and corporate governance, may be consulted on the group's website.

Investor relations activity

Finally, in 2018, ROVI continued with its intensive investor relations activity, which materialised in 12 road shows, the participation in 9 events with investors and 23 visits to investors and teleconferencing calls. This, in total represented attention to more than 215 investors.

Analysts' coverage

At 31 December, 2018, ROVI was being covered by 14 analysts. In 2018, two new analysts began to cover ROVI, Jefferies and Renta4, while another two, Banco Santander and Kepler Cheuvreux, resumed coverage. The consensus of the analysts was a buy recommendation for ROVI with an average target price of 18.53 euros, 6% higher than the closing price of the share at 31 December, 2018, which was 17.45 euros.



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CUSTOMERS, PATIENTS AND PROFESSIONALS

ROVI has a triple commitment with customers, patients and professionals. They are the centre of its day-to-day activity and it wants to achieve a high degree of satisfaction with them, creating solid and long-lasting relationships of trust by offering "a la carte" services as a toll manufacturer, placing the best treatment options in the hands of professionals and, at the same time, offering patients the possibility of benefiting from the latest advances and best medicines for treatment of their complaints.

In both its toll manufacturing activity and the distribution of products, whether they be manufactured at its plants or marketed under license, ROVI plays all its capacity at the disposal of other laboratories to outsource their manufacturing processes, with a wide range of pharmaceutical forms, including prefilled syringes, vials, suppositories, tablets, hard capsules and sachets.

ROVI's own products are, likewise, distributed to subsidiaries and international partners, pharmaceutical wholesalers, pharmacies and hospitals all over Spain. And, finally, ROVI has been working as a marketing partner for medicines and medical devices of other companies for many years.

The group is aware that these groups are the basis of the company's business and, therefore, focuses on providing a service based on quality and experience. They are the centre of the company's day-to-day activity and, with them, it wishes to reach a high degree of satisfaction by creating solid and longlasting relationships of trust.

COMMITMENTS

To bet on innovative pharmaceuticals as a growth engine for ROVI.

To pay special attention to protecting the health and safety of our customers and patients throughout the life cycle of our products through strict compliance with the applicable legislation.



To observe due confidentiality in data processing.

- To manage and solve their queries and complaints in the shortest time possible.
- To monitor customer experience via surveys that measure their satisfaction and other means and systems that allow permanent active listening to the customer in all those processes and operations in which the latter relates to the company.
- To operate appropriate and efficient communication channels, using the most suitable means for this purpose.
- To observe and comply with the rules that regulate communication and marketing activities and assume the voluntary codes that endow such actions with transparency and veracity.



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To ensure smooth dialogue with all them, ROVI has had a channel in place for more than ten years for information requests from both international partners – who have an exclusive portal, <u>www.bemimed.com</u> – and direct customers, patients and professionals.

The Bemimed portal is where complaints may also be received. When this occurs, the company immediately opens enquiries in order to identify the cause and prevent any repetition. These enquiries may involve several departments or even suppliers and/or subcontractors. The efficacy of these actions is analysed annually by ROVI management in the system review.

Quality, security and efficacy: the keys to the business

Guaranteeing the quality, safety and efficacy of the products it places in the market is the principal objective of ROVI and all its professionals. It is a maxim in the group's day-to-day activity and, to do it, different procedures have been put in place to describe the controls performed at all the stages through which the manufacture of pharmaceutical forms passes, including product research and development, the receipt of raw materials, packaging materials, production, storage and distribution, until they are consumed by the customers.

The company holds a dual commitment to meet the highest internal quality standards and also to go above and beyond those imposed by the regulatory bodies that evaluate the different products on the portfolio marketed by ROVI.

QUERIES AND COMPLAINTS

_		Lab. Fcos Rovi	Pan Química			Rovi Biotech Limited (United Kingdom)	Rovi Biotech S.R.L. (Italy)	Rovi S.A.S (France)	SUB. DISTR.
General	Units manufactured / Units distributed	19,571,222	25,353	296,268	312,691	135,192	1,168,506	0	21,509,232
Customer	No. customer complaints	155	9	10	13	3	4	0	174
complaints	Complaints / million units	7.92	354.99	33.75	0	22	3	0	8.09
Customer queries	No. customer queries	237	0	9	171	19	0	0	246
- quality + therapeutic	Queries / million units	12.11	0	30.38	547	141	0	0	11.44



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At the same time, the aforementioned procedure are under constant evaluation through different mechanisms, such as regular and annual internal audits, reviews led by company management in which the main points of the organisations, plants, products and professionals that require improvement are analysed.

With the timing and frequency required by the legislation applicable to their products, all group companies are inspected by both the Spanish health authorities and those of the countries to which the products are exported. Quality audits are likewise carried out by external entities, showing ROVI's commitment to continuing improvement and maintaining the highest quality standards.

Pharmacovigilance and product safety

The safety of the patients to whom its medicines are administered is one of the key priorities of ROVI as a manufacturer and distributor of this type of products. Appropriate controls are in place to ensure patient safety and maintain the best benefit/risk balance, while a pharmacovigilance system has been implemented to detect any possible adverse reactions to the company's medicines and healthcare products.

ROVI has various means of communication in place, such as the e-mail address farmacovigilancia@rovi. es and a telephone number (+34 91 761 75 61) for notification of adverse reactions, in addition to ROVI's website (www.rovi.es), which explains how to proceed if one wishes to notify an adverse reaction. The company immediately activates its pharmacovigilance system to collect the greatest amount of information possible to enable it to establish the appropriate cause-and-effect relationship between taking the medicine and the adverse reaction.

In compliance with the guidelines established, a total of 870 adverse reactions were recorded in 2018 in relation to all the medicines marketed by ROVI.

Country	Telephone number	Email
Spain	+34 91 761 75 61 / +34 661 888 642	farmacovigilancia@rovi.es
Portugal	+351 213 105 617 / +351 918 466 100	farmacovigilancia@rovisa.com.pt
United Kingdom	+44 (0) 203 642 06 77	uk-pharmacovigilance@rovi.com
Germany	+49 8024 478255	pharmakovigilanz@rovi.com
Italy	+39 3457081782	farmacovigilanza@rovi.com
France	+33 476 969 621	fr-pharmacovigilance@rovi.com
Poland	+48 608 096 772	phv@pharmconsult.com.pl



HUMAN RESOURCES

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ROVI is aware that the key to its success are its employees. The target of having the best professionals and allowing them to develop with the company is sought through the design and implementation of the Human Talent Development Policies of the group, which, depending on its objectives, establishes its personnel needs and defines the talent management plans and programmes so that they integrate and combine the organisation's management priorities, the best human resources practices and talent management.

The company allocates significant resources to investment in human capital, through preparation and training that encourage evolution and professional growth, at the same time as it strives for and fosters good relations, good treatment and tolerance among its employees and external collaborators by means of training activities and programmes and by providing opportunities for dialogue and mediation.

The entire ROVI team, particularly each professional and his or her direct supervisors, is involved in this human development work. Less experienced employees have the support of veteran colleagues, who guide them and help to develop their technical skills. This transfer of knowledge and experience is one of the key aspects that ROVI fosters and that allows it to maintain a workforce that has a high professional value and is in constant growth and evolution.

103-1, 103-2, 103-3

102-8

BALANCE OF THE YEAR AND FUTURE CHALLENGES

In relation to human resource management, 2018 was, for ROVI, a year in which the sustained upward path of previous years continued. This is an accurate reflection of the growth strategy that the business has been undergoing, which entails a policy of adapting the workforce to ROVI's needs at any given moment.

As of 31 December, 2018, the workforce consisted of 1,224 employees (1,191 as of 31 December, 2017), which meant that a net number of 33 new jobs had been created. A highly-qualified professional workforce where the principle of equal opportunities prevails. Of the total, 666 were women (664 at 31 December, 2017) and 558, men. The percentage of the total represented by women employees was 54.4% in 2018, in comparison with 55.8% in 2017.

The company has maintained its strategy based on favouring stable employment and a workforce distribution where permanent contract and stable employment prevail. Although, when covering structural needs, ROVI's focus is always on permanent contracts, it maintains an appropriate balance and uses temporary contracts in the event of specific needs to reinforce the workforce, when the responsible and fair use of these contracts is appropriate.

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At the same time, also in 2018, there was a bet on both creating jobs for young people, thus supporting an important social demand -especially in Spain- and the recruitment of experienced workers, thus giving an opportunity to valuable professionals, who provide the workforce with balance and knowledge. Thus, ROVI establishes the optimal balance in its human capital, allowing the company's strategy to be implemented.

In 2018, the results of the Company's efforts to maintain and consolidate a balance between men and women in its workforce and to include and facilitate the access of candidates with disabilities under equitable conditions, consistent with the strategy of mainstreaming diversity and equal opportunities as part of its culture, may be observed.

DISTRIBUTION EMPLOYEES BY GENDER

(Number of employees)







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DISTRIBUTION EMPLOYEES BY AGE/GENDER

(Number of employees)

DISTRIBUTION EMPLOYEES BY COUNTRY/GENDER

(Number of employees)

_	MEN	WOMEN	TOTAL
18-30 years	78	106	184
31-40 years	156	216	372
41-50 years	195	213	408
51-60 years	109	114	223
>60 years	20	17	37
TOTAL	558	666	1,224

	MEN	WOMEN	TOTAL
Spain	550	654	1,204
United Kingdom	-	1	1
Germany	3	3	6
Italy	3	3	6
France	1	1	2
Portugal	1	4	5
TOTAL	558	666	1,224

DISTRIBUTION EMPLOYEES BY CONTRACT TYPE/GENDER

(Number of employees and Percentaje)

	MEN	WOMEN	TOTAL	DISTRIBUTION
Permanent Full-time	462	532	994	81%
Permanent Part-time	-	4	4	0%
Total permanent	462	536	998	82 %
Temporary specific project or service	2	3	5	0%
Temporary due to work backlog	47	55	102	8%
Temporary substitution contract	4	6	10	1%
Training/Apprenticeship	27	49	76	6%
Temporary part-time	15	17	32	3%
Temporary full-time – people with disabilities	1	-	1	0%
Total temporary	96	130	226	18%
TOTAL	558	666	1,224	





BUSINESS MODEL

STRATEGY CORPORATE GOVERNANCE

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DISTRIBUTION EMPLOYEES BY CONTRACT TYPE/AGE

(Number of employees)

	18-30	31-40	41-50	51-60	>60	TOTAL
Permanent	79	328	370	213	8	998
Temporary specific project or service	2	2]	-	-	5
Temporary due to work backlog	31	31	33	7	1	103
Temporary substitution contract	1	5	3	1	-	10
Training/apprenticeship	69	6	1	-	-	76
Temporary part-time	2	-	-	2	28	32
TOTAL	184	372	408	223	37	1,224

TURNOVER

DISTRIBUTION DISMISSALS BY GENDER

(Number of employees)

DISTRIBUTION
DISMISSALS
BY AGE/GENDER
(Number of employees)

(Number of employees)

2018	
17	
16	
33	

	MEN	WOMEN	TOTAL
18-30 years	2	0	2
31-40 years	3	4	7
41-50 years	5	8	13
51-60 years	3	2	5
>60 years	4	2	6
TOTAL	17	16	33



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EQUAL OPPORTUNITIES AND PROFESSIONAL DEVELOPMENT

In each and every one of the areas in which ROVI carries on its activity, including the selection and promotion of professionals, wage policy, training, working conditions, occupational health, the organisation of working hours and work-life balance, the company maintains a constant commitment to the principle of equal opportunities for men and women. As a result of these policies, the ROVI workforce has a higher percentage of women professionals than men.

ROVI's Equal Opportunities Plan sets out and ensures the implementation of policies that include equal treatment and opportunities for women and men and non-discrimination on the grounds of gender or any other personal characteristic in selection processes, promotions, professional development and the wage policy according to which workers are remunerated. ROVI's commitment to equality and non-discrimination is also reflected in the company's Code of Ethics and the principles that govern training programmes and actions.

This Equality Policy is likewise reflected in ROVI's Board of Directors, where the selection criteria for the appointment of directors is based on the candidates' merit (people of recognized knowledge, skills and experience) and potential candidates may include both men and women who meet these requirements. In this respect, the group's target is for the number of women directors to represent at least 30 percent of total Board members in 2020.

Responsibility for this area is held by the Equal Opportunities Commission, the principal mission of which is to monitor the measures implemented appropriately and ensure that ROVI meets its commitments in this respect. This Commission carries out constant activities to create actions and mechanisms in areas such as selection and recruitment, internal promotion and professional development, training, remuneration, work-life balance, gender violence and harassment prevention, and communication. The company rejects harassment and any form of violence

In this respect, at ROVI, its production centres and offices and, likewise, in its relationship with suppliers and partners, harassment is not tolerated and any form of violence, physical, sexual, psychological or moral harassment, the abuse of authority at work or any other form of harassment or conduct that generates an atmosphere that is intimidatory or offensive in respect of the employees' rights is rejected. Therefore, ROVI has introduced a Protocol for the Prevention and Handling of Cases of Moral and Sexual Harassment in the workplace, which all employees are obliged to know and respect.

This Protocol guarantees that any complaints that may be received because the Protocol itself, the Code of Ethics or any other approved policies or procedures have been violated. Employees, suppliers, trading partners, agents and external collaborators have an Ethics Channel available to them, which has regulations that govern the management and processing of the complaints and notifications received and ensure that, when faced with an action that potentially contravenes the company's principles and values, the company is able to react strictly, efficiently and diligently.




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RESPONSIBLE WORK-LIFE BALANCE

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ROVI is aware that its workforce has different personal and family situations. The company takes this challenge very seriously and, therefore, has created a set of measures to reconcile family life and work, aimed to create a work environment that allows its employees to develop a professional career without any problems, without this being a problem for their family life. In this respect, the company complies with current legislation and adds the enhancements introduced by the Collective Agreement of the Chemical Industry to the work-life balance measures contained therein.

These measures include, for example, flexible starting and finishing times for office and industrial structure personnel, freedom for co-workers to exchange shifts, shorter working days adapted to the needs of each person and a flexible holiday calendar, provided that the activity of the worker's area so permits, in addition to cover by a life insurance policy, paid by the company, for all permanent employees. This aspect also includes encouraging teleworking by providing the personnel who so require with laptop computers with connectivity to the company's intranet or the use of videoconferences and on-line meetings to avoid unnecessary trips and visits.

In particular, within its measures to improve the work-life balance, ROVI ensures that maternity does not represent any decrease in the usual income of a pregnant woman. Thus, the Company pays a wage supplement that completes the benefit received from the Social Security to 100% of her salary. It also offers salary options, with the availability of nursery school vouchers, restaurant vouchers and health insurance in its "a la carte" salary proposal. Additionally, at work centres where street parking is difficult, the company makes a series of parking spaces available to pregnant women to make it easier for them to get to work.

In 2018, 39 people enjoyed a shorter working day in order to reconcile their personal and professional lives (49 people in 2017).

Finally, over recent years, ROVI has also endeavoured to protect and foment real disconnection from work for its employees, so that they can enjoy their time-off with the family appropriately. In this respect, communication with employees through any channel (telephone, e-mail, etc.) is avoided unless there is an urgent, unforeseen need and their participation is clearly indispensable. Likewise, meetings in the later part of the working day are avoided, so that the professionals' personal or family commitments after working hours are not affected.

ROVI ensures that maternity does not represent any decrease in the usual income





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ABSENCE RATE

For ROVI, good management in this respect has a direct effect on the workforce's health and wellbeing and, consequently, on productivity, the company's economic performance and attaining strategic goals.

ROVI's absence levels are below those in the sector where it carries on its activity, in spite of the fact that the number of days' absence in 2018 was 9,972 (up from 8,943 in 2017), equivalent to 79,776 working hours lost, representing an absence rate of 2.09%.

ABSENCE RATE LEVELS

(Percentage)

(Felecincage)	201	18	2017		
	Economic group	Comp. Sector	Economic group	Comp. Sector	
Total absolute absence rate	2.25%	3.44%	2.03%	3.20%	
Absolute absence rate WA + PD	0.16%	0.20%	0.19%	0.22%	
Absolute absence rate OD	2.09%	3.23%	1.84%	2.98%	

ABSENCE RATE

(Days and percentage)

2018			2017				
Days of sick leave	Days worked	Absence rate	Sector absence rate	Days of sick leave	Days worked	Absence rate	Sector absence rate
9,972	443,803	2,25%	3,44%	8,943	440,817	2.03%	3.20%

Source: Mutua de Accidentes de Trabajo FREMAP. Global Annual Absence Report ROVI GROUP



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EVALUATION AND REMUNERATION OF EMPLOYEES

The average employee remuneration in 2018 was 38,735 euros, representing an increase of 1% in comparison with 2017.

The average remuneration of the members of the company's Management Committee in 2018, including fixed and variable remuneration and remuneration in kind, was 234,142 euros for men and 135,462 euros for women. The difference is because, in the case of the men, three of them are also Executive Directors and their salaries reflect the additional responsibilities they hold. In the case of women, some women joined the Management Committee in 2018 and the salary used for the calculation will be reviewed in 2019.

The average employee remuneration increased by 1% in 2018

AVERAGE REMUNERATION OF MANAGEMENT COMMITTEE

(Euros)

	MEN	WOMEN	AVERAGE
Fixed remuneration	163,430 €	93,419€	128,425€
Variable remunera-tion	61,960 €	36,763€	49,362€
Remuneration in kind	8,752 €	5,280€	7,016€
TOTAL	234,142 €	135,462 €	184,802 €





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WAGE GAP

ROVI applies the principle that employees should receive equal pay for equal work, irrespective of their gender or characteristics, effectively. This conviction is the basis of its wage policy and is applied when fixing the initial salaries of company employees and in subsequent revisions throughout the employee's working life at ROVI.

In 2018, ROVI engaged the audit firm PricewaterhouseCoopers to carry out a limited assurance review of wage group indicators by professional classification in group lcompanies. This was in line with the company's interest in monitoring the gender wage gap in its workforce. The results of this work will be the basis for a regular evaluation of indicators that show wage differences by job and gender, so that action can be taken if necessary or if any gender discrepancy is detected in the remuneration for the same job.

The aforementioned indicators allow a diagnostic analysis of the group's workforce to be made to find out the differences between the remuneration of men and women who have the same jobs. In the auditors' analysis of these indicators, it was certified that there is not currently any gender wage gap or any differences in remuneration that are not based on personal factors (level of training, work experience, length of service, etc) or the job (duties performed, level of responsibility, working hours, etc.).

AVERAGE REMUNERATION BY GENDER

(Euros)	2018	2017	TOTAL VARIATION
Men	40,733€	40,953€	-1%
Women	36,738 €	35,534€	3%
AVERAGE	38,735 €	38,244 €	1%





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AVERAGE REMUNERATION⁵ BY PROFESSIONAL GROUP⁶/GENDER

(Euros and percentage)

	20	018	2017		
	MEN	WOMEN	MEN	WOMEN	TOTAL VAR.
1	15,311 €	14,892€	0€	17,472 €	73%
2	16,677 €	17,012€	16,170 €	16,194€	4%
3	19,000 €	19,266 €	18,209€	19,065€	3%
4	25,082 €	23,432€	25,641 €	23,736€	-2%
5	42,078 €	40,546€	41,099€	38,237€	4%
6	50,426 €	36,687€	52,153 €	37,993 €	-3%
7	51,208 €	47,265€	54,958€	44,413€	-1%
8	105,465 €	105,050 €	153,205 €	146,637 €	-30%
0	202,978 €	130,182€	197,584 €	112,505€	7%
Subsidiaries	87,949€	72,367€	106,499€	103,300€	-24%

AVERAGE REMUNERATION BY AGE/GENDER

(Euros and percentage)

	20	018	2017		
	MEN	WOMEN	MEN	WOMEN	TOTAL VAR.
18-30 years	21,966 €	21,983 €	21,099 €	19,787 €	7%
31-40 years	30,535€	34,460 €	29,625€	32,108 €	5%
41-50 years	47,312 €	45,095€	46,989€	45,167 €	0%
51-60 years	58,097 €	41,546 €	55,003€	28,357€	20%
>60 years	33,459 €	11,908 €	53,148 €	14,612 €	-33%

(5) Does not include scholarship remuneration, since scholarship-holders do not have a Professional Group

(6) Professional Group in accordance with the XIX Chemical Industry Collective Agreement



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ATTRACTING AND RETAINING TALENT

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The Human Resources Department is responsible for the design and management of the Selection Policies, which include management principles such as equal opportunities, objectivity and impartiality, confidentiality, and attracting talent from among young people and excluded groups or differentlyabled persons, together with the promotion and reinforcement of internal candidatures.

The group is aware that, without any doubt, its success requires talent to be selected and retained transparently and effectively. One of the methods it uses to seek talent is the scholarship and training programmes that it carries out jointly with educational institutions. In this respect, 20 agreements with Spanish universities are in place at national level, so that undergraduates in their last year and students studying for a Master's degree or doctorate can carry out their practical training in different areas of the company, while professional training students can obtain their practical training credits with one of the group companies.

Around 85% of the people who obtain a scholarship with ROVI finally join the company with a contract, thus giving young talents the opportunity to train and ROVI the opportunity to have a workforce focused on maintaining an appropriate level of renewal for future challenges.



Around 85% of the people who obtain a scholarship with ROVI finally join the company





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TRAINING IN SKILLS AND VALUES

ROVI's training investment in 2018 was 247.2 euros per employee (428.1 euros in 2017), with an average number of training hours per professional of 20.3 (25.75 hours in 2017). 78% of the workforce used an e-learning system for this training, with a total of 24,057 employee training hours.

Awell-prepared and qualified workforce is indispensable to reach ROVI's short-, medium- and long-term goals. This is why it applies significant sums to investment in human capital, in order to foment the evolution and professional growth of its employees. This task involves both the interested parties and their direct supervisors and, in particular, the more experienced professionals are encouraged to mentor the younger ones. ROVI thus promotes the transfer of the knowledge and experience acquired by its competent senior team, one of the company's most valuable assets, to the new generations.

TRAINING HOURS BY PROFESSIONAL CLASSIFICATION

(Training hours)										
PROFESSIONAL CLASSIFICATION	1	2	3	4	5	6	7	8	0	TOTAL
TRAINING HOURS	-	973.4	3,014.1	3,860,6	8,735.4	2,996.0	4,180.8	170.1	127.5	24,057.9





ROVI identifies the training needs in each area of the company and designs, with the participation of human resources, management and middle management, the annual training plans, which are aligned with the strategic and business goals. Each employee has an individual Development Plan to encourage their professional growth through self-responsibility and commitment. 10% of development and learning takes place through training actions in the classroom or in virtual or e-learning format and 20% takes place through feed-back, observation or with the support of mentors, coaches, professional associations, opportunities for reflection, conversations with other people, leaders, etc. Lastly 70% of development and learning takes the

form of job experience, applying new learning in real situations, problem-solving, participating in projects and new challenges, rotating through different departments, etc., always taking the professional profile and the needs of each area into account.

At the same time as ROVI strives to provide its employees with the best training in professional skills, the company strives to keep its employees informed of its corporate policies, such as those concerning Corporate Social Responsibility, the Code of Ethics for Employees or the Group's Anti- Corruption Policy, either in the classroom or using the different technological tools at its disposal.





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Trade union information and relations with the workers' representatives

ROVI maintains smooth and ongoing dialogue with the workers' representatives using all the means available. It has a calendar for regular meetings, to which specific meetings held at the request of either the company or the unions are added, allowing it to monitor the situation of the agreements and swiftly solve any day-to-day incidents.

Seventeen regular meetings and five extraordinary meetings were held in 2018 between the company and the workers' representatives at the different work centres, which allowed permanent dialogue and a constructive relationship based on trust. During the year, two significant sets of negotiations were conducted concerning wage items, a substantial change in working conditions and a move from one work centre to another, which concluded successfully.

All ROVI's employees in Spain work under the employment conditions regulated in the XIX Collective Agreement of the Chemical Industry, last updated and signed in 2018. Not only does the company abide by the law, but it also implements certain enhancements, such as paying a supplement to Social Security benefits in the event of sick leave. Employees of the subsidiaries in the rest of Europe are also governed by the pertinent collective labour agreement, except in cases where local legislation states they are subject to general labour legislation, given the low number of employees at the subsidiary.

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HEALTH, SAFETY AND OCCUPATIONAL HAZARD MANAGEMENT

ROVI has an Integrated Environmental and Occupational Hazard Prevention Management Policy, applicable to the whole group, the objective of which to protect the life, physical integrity and health of all the workers, including both the group's own workers and those of the companies who work with it. This Policy is based on a series of corporate procedures, as well as local procedures or work instructions specific to each centre.

In 2018, the application of different policies and procedures at ROVI helped, for a further year, to meet the accident target in all the group companies (1.5% with sick leave and 3% without sick leave).

The principal occupational hazards identified by ROVI, following the corporate procedure for identifying hazards, assessing risks and determining controls, are mainly those inherent to a production plant: contact with and exposure to chemical products, noise exposure, overexertion, etc. Furthermore, each plant defines specific prevention objectives, such as acquisition of a system for neutralising chemical products that allows injuries caused by contact with chemicals to be minimised in laboratory and production jobs (San Sebastián de los Reyes and Madrid plants); increase in Production Area workers with broader prevention training (Granada); or reduction in the moderate risk category associated to falling to a different level in the task of installing/ removing the rotary valve of the roller compactor (Alcalá de Henares plant).

These risks are managed through highlighting and providing training in these aspects. Furthermore, the risks identified are managed in accordance with specific procedures created to regularly verify and monitor actions, such as those that regulate work permits, safety inspections and identification and assessment of legal requirements.

In general, throughout the group, the professionals who so require are provided with a laptop, which avoids unnecessary travel and trips while, at the same time, reduces the risk of accidents while travelling. Special attention is given to pregnant employees, who are offered the possibility of teleworking in the weeks before maternity leave is taken, as well





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as special parking spaces during the time they are working at the work centre.

In addition, the company fosters attitudes and behaviour intended to provide its employees with a healthier lifestyle. Since 2015, it has been reinforcing initiatives such as healthy breakfasts, healthy and nutritive vending at the plants and the practice of sports, both at nearby sports centres and by promoting the presence of employees in charity races, organised by ROVI's Corporate Social Responsibility area.

FREQUENCY RATE FOR WORK-RELATED ACCIDENTS* BY GENDER

(No. accidents / No. of hours worked * 1000000)

Men	3.176
Women	4.662
TOTAL	3.919

WORK-RELATED ACCIDENTS SEVERITY RATE* BY GENDER

(No. of working days lost / No. of hours worked * 1000)

TOTAL	0.177
Women	0.125
Men	0.229

WORK-RELATED ACCIDENTS INCIDENCE RATE* BY GENDER

(No. accidents / No. workers * 100)

TOTAL	0.524
Women	0.674
Men	0.375



The application of all these measures helped to meet the accident rate target for 2018 in all the group companies, which was lower than 1.5% of accidents to number of workers at all the centres.

Note: accidents while travelling and data of ROVI group employees are included. Information on personnel hired through temporary employment companies is excluded.



SUPPLIERS

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The company's internationalisation strategy stimulated the engagement of local suppliers in each country

In 2018, ROVI worked with 7,819 suppliers from 35 countries. However, the specific weight of Spanish suppliers stands out about the rest, with 76% of total suppliers coming from Spain and 14% being from other European Union countries. This means that 90% of ROVI's suppliers operate within the European Union, while the remaining 10% operate elsewhere.

The company's internationalisation strategy, with the opening of subsidiaries in the major European markets during the year, stimulated the engagement of local suppliers in each one of the countries in which ROVI is present with new offices. ROVI now has a large number of Portuguese, French, British and Italian service providers, which, although they have less weight in the billing than the Spanish providers, demonstrate the internationalisation that is impregnating every aspect of the group's business for the future.

In this respect, both inside and outside Spanish borders, the supplier payment policy introduced in 2013 is applied. This establishes a framework for relations with suppliers and creditors that is shared by the entire group. It is a vital element to ensure full efficiency in accounting for invoices, an appropriate policy for payment on a due and timely basis, and greater consistency in negotiations with suppliers and the approval thereof. In this respect, in 2018, the average payment period for ROVI suppliers was 51 days, in accordance with the maximum limits fixed in Law 17/2010, which was amended by Law 11/2013.

PURCHASING POLICY, SUPPLIER APPROVAL AND EQUAL OPPORTUNITIES

Suppliers are a group of strategic interest in ROVI's activities and, therefore, a set of specific action principles, aligned with the company's principles and values, has been put in place. This strategy is intended to reinforce the sustainability and competitive edge of the supply chain.

First, the group has a supplier selection policy that establishes a series of criteria that are indispensable in order to for the company to initiate a relationship with a service provider. For this purpose, an initial valuation has been established, followed by regular further evaluations, which allows a list of approved suppliers, managed by the Quality Department, to be drawn up.

At the same time, the aforementioned Policy on contracting and paying supplier states that suppliers who bill an annual amount of more than 100,000 euros to ROVI must have a duly signed contract, in addition to regulating how invoices should be sent and recorded and the means of payment accepted by the company.



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ANTI-BRIBERY AND ANTI-CORRUPTION MECHANISMS AND POLICIES

Any interaction of any ROVI employee with professionals, health organisations or systems, pharmacies, stores, purchasers, distributors, suppliers, trading partners, public employees or any third party related to the group must be guided by lawfulness and ethics, thus aligning with ROVI's values set out in the company policy and industry standards.

ROVI applies the same standards to its suppliers as it requires of itself in its Code of Ethics. Thus, any practice that includes bribery or corruption as a way to reach an agreement is rejected. At the same time, any practice intended to do business using undue or immoral means is strictly prohibited.

No ROVI employee may offer a third party any type of benefit intended to influence illicitly or offered with the intention of illicitly influencing the third party's capacity to adopt objective and legitimate business decisions. Likewise, ROVI employees are expressly prohibited from accepting any kind of corruption or bribery offered by a third party and doing so could, if discovered, lead to severe disciplinary measures.

RSC IN THE SUPPLY CHAIN: CODE OF ETHICS FOR SUPPLIERS

In the same way as internally, ROVI invites all its suppliers to guarantee factors such as equal opportunities, occupational safety or care of the environment and to declare their commitment to basic principles of ethics and professional conduct. Likewise, it strives to involve suppliers and subcontractors in the adoption of the best corporate social responsibility practices in order to regulate their activities in accordance with the standards included in the certifications SA-8000, SGE-21 or similar.

This is why the company, over recent years, has taken a further step forward and created a Code of Ethics for Suppliers, which is mandatory and through which anyone who provides services to ROVI must undertake to respect the protection of fundamental human and labour rights recognised internationally. Likewise, it expressly requires compliance with the following principles:





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Additionally, ROVI has two mechanisms to ensure and encourage, as far as it is able, the adoption of good CSR 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 noncompliances 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 employees do not suffer abuse or discrimination.

Thus, through the use of management principles, application of the Code of Ethics for Suppliers and monitoring through the aforementioned mechanisms, the risk that any ROVI supplier might breach its Human Rights obligations is unlikely, limited and under control. Furthermore, 90% of the ROVI Group's suppliers operate in countries belonging to the European Union and the rest operate in countries that enjoy recognised prestige in the international community.

SUPPLIERS BY GEOGRAPHICAL AREA

(Percentage)







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SOCIETY AND PUBLIC AUTHORITIES

The group is aware of the impact of its activity on society at different levels, both through the contribution to the well-being and health of the patients that consume its products and in the development of the social and labour fabric of the environments in which its production plants and work centres are located.

Therefore, ROVI accepts this impact, assessing and managing the non-financial, ethical, reputational, social and environmental risks, and commits itself to those social initiatives or activities that benefit society. In this respect, the group is strongly committed to a series of social action areas, such as: ROVI assesses and manages the non-financial, ethical, reputational, social and environmental risks





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2018, results of ROVI's social commitment

ROVI has a close relationship with the university and research world. For this reason, it holds co-operation agreements with public and private entities to combine efforts to increase scientific, technological and educational activities, as well as spreading knowledge, while, at the same time, it assigns a substantial part of its resources to promoting medical research.

Support of training of the best health professionals

Primarily, in order for qualified students to access a work environment with guarantees, improve their skills and knowledge and obtain their first job ROVI has a training programme in the company whereby it has set up co-operation agreements with 73 educational centres (universities, institutions, official training centres and business schools) throughout Spain.

Like others in previous years, during 2018, 49 people had the opportunity to begin their working life in a top-class professional atmosphere.

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Decided bet on research

ROVI's activity of research, development and manufacture of pharmaceutical products is carried on entirely in Spain, distributed over the Madrid and Granada centres. The company is, therefore, fully committed to innovation in national territory and this involvement is shown by figures such as:

- R&D investment was 32.4 million euros in 2018, exceeding, for a further year, investment in the preceding years, which was 28.3 million euros in 2017 and 17.5 million euros in 2016.
- Capex was 17.4 million euros in 2018, distributed over investments in the injectables plant (3.8 million), the San Sebastián de los Reyes plant (2.8 million), the Granada plant (3 million) and the Alcalá de Henares plant, as well as maintenance investment and other (2.3 million).

Furthermore, ROVI is committed to supporting co-operative research. Thus, it holds co-operation agreements with different public bodies and universities, such as the agreement it holds with the University of Granada to combine efforts to increase scientific, technological and educational activities, as well as spreading knowledge.

The Company likewise co-operates with scientific associations and societies of different types, such as the SEFH/ROVI Hospital Pharmacy Development awards, which have been awarded jointly with the Spanish Hospital Pharmacy Society (SEFH) for the last two years and recognise projects that represent the contribution of innovative solutions that are beneficial to patient well-being and quality of life.

ROVI, an agent that contributes to the society closest to it

ROVI's activity has a palpable impact on society and the groups with which it has relations. In particular, looking at the data of recent years, it has been a key agent in the areas where it is installed, stimulating both local employment and the business of local suppliers.

ECONOMIC VALUE GENERATED AND DISTRIBUTED

(Millions of euros)

	2018	2017	
Economic value generated	304.8	277.4	
Economic value distributed			
Shareholders	4.5	6.0	
Suppliers	172.7	154.7	
Society	-1.2	0.3	
R&D	32.4	28.3	
Employees	70.2	64.0	
Providers of capital	0.8	0.9	
Amortisation and depreciation	12.0	11.5	
Reserve	13.4	11.8	





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The effective tax rate in 2018 was -7.3%, generating revenue of 1.2 million euros under the "income tax" caption, compared with 1.6% in 2017 (expense of 0.3 million euros). This favourable effective tax rate was due to the tax credit for research and development expenses and the capitalisation of negative tax bases. As of 31 December, 2018, the group's negative tax bases totalled 36.3 million euros, 1.4 million euros of which were used for the 2018 corporate income tax.

While the Phase III trial of Risperidone-ISM®, which contributes higher R&D expenses, remains in progress, ROVI expects a very advantageous tax rate to apply, even leading to revenue under the "income tax" caption. Notwithstanding, when R&D expenses return to normal after completion of the Phase III trial, the company expects the effective tax rate to be in mid-single-digit figures (between 0% and 10%) in forthcoming years.

In this respect, the company's relations with the public authorities and its meticulous responsibility in tax matters are particularly important. ROVI, as a provider of active substances, medicines and

healthcare products, has an ongoing relationship with the health authorities. The group actively strives to be vigilant and for strict observation of the health authorities' requirements in all its activities – industrial development, manufacturing and supply of products, as well as supplying units for clinical trials-, always carried out in an environment of strict compliance with all legal and regulatory requirements that apply, as well as the authorisations granted by the authorities.

ROVI has a Corporate Tax Policy that establishes its commitment to strict compliance with tax requirements by applying good tax practices and acting transparently, paying taxes responsibly and efficiently and promoting relationships of cooperation with governments, endeavouring to avoid material risks and unnecessary conflicts. As support to its tax practices, ROVI has engaged the services of an external tax advisor, who keeps the group updated on new tax developments and advises on any doubts that arise. Additionally, the tax advisor reviews the preparation and filing of the different taxes, as well as group decision-making on tax matters.

TAXES (Thousands of euros)	PROFIT BEFORE	INCOME TAX	GOVERNMENT GRANTS
(mousures of curos)	TAX	PAID	RECEIVED
Laboratorios Farmacéuticos Rovi, S.A.	11,444	(3,108)	1,587
Laboratorios Farmacéuticos Rovi, S.A Portugal	(343)	(33)	=
Laboratorios Farmacéuticos Rovi, S.A Poland	(2)	-	_
Laboratorios Farmacéuticos Rovi, S.A Germany	-	-	
Rovi Contract Manufacturing, S.L. (*)	16,348	-	_
Bemipharma Manufacturing, S.L. (*)	(36)	-	-
Pan Química Farmacéutica, S.A. (*)	531	-	-
Gineladius, S.L. (*)	(9)	-	_
Frosst Ibérica, S.A. (*)	5,351	-	-
Bertex Pharma GmbH	-	-	-
Rovi Biotech, Limited	(30)	-	-
Rovi Biotech, S.R.L.	9	-	-
Rovi Biotech, GmbH	(82)	-	_
Rovi S.A.S.	(729)	-	_
Rovi Biotech, Ltda.	-	-	_
TOTAL		(3,141)	1,587



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SOCIAL INCLUSION AND MAINSTREAMING OF DIFFERENTLY-ABLED GROUPS

ROVI is firmly convinced that the company is enriched and creates differentiation value through the contribution made by differently-abled people and is aware that people with disabilities form one of the groups at greatest risk of workplace and social exclusion.

Therefore, the group is committed to mainstreaming these groups of people in the workplace and encourages hiring them. As of 31 December, 2018, 25 persons with disabilities were wording at ROVI, 20 of whom formed part of its direct workforce, while 5 were working through temporary employment companies, such as:

- ISS Facility Services (Gelim). ROVI has contracted out the cleaning of its offices to people with disabilities.
- Ilunion, with which ROVI has contracted the laundry service.
- Fundación Manantial, which has the purpose of integrating people with severe mental disorders. This foundation is certified for the secondary packaging of the company's products, in addition to catering services at group offices.

In 2018, the Fundación Prodis also joined the list of organisations with which ROVI works in workplace integration, assisting the company in recruiting a person with Down's syndrome for ROVI's Human Resources Department. Its programme supporting the workplace inclusion of people with intellectual disabilities has allowed ROVI to discover that these people have social, personal and employment capacities that enable them to perform high-quality work when they receive proper training and support.

ELIMINATION OF ARCHITECTURAL AND MENTAL BARRIERS TO DISABILITY

Another aspect of inclusion on which ROVI is currently working is to make all its work centres accessible to people with some kind of permanent or temporary mobility problem. In this respect, the group is aware that problems of physical accessibility to workplaces and the difficulty in the use of objects and products are barriers that hinder the full integration of persons with disabilities in both workplace and social environments, irrespective of their technical, cognitive or physical capacities, while, at the same time, accessibility improves the conditions of the work centre to allow employees who have suffered an accident or, particularly, pregnant women to return to normality.

Consequently, ROVI is executing a remodelling plan at its work centres, in order to make them accessible to everyone safely, comfortably and autonomously. At present five of the group's seven work centres are now 100% accessible and it is planned to adapt the two remaining centres during 2019.

In addition, ROVI endeavours to make the products it markets accessible and safe to enable the visually impaired to use them autonomously and, therefore, all of them include labelling in Braille.

Lastly, ROVI fosters the sensitisation of both its workforce and the society which surrounds it, with the firm conviction that this is the primary and most important tool for removing the rest of the barriers to people with disabilities. It carries out corporate volunteering activities with different NGOs in this respect, aimed at the social mainstreaming of people with mental and intellectual disabilities. These activities are then broadcast on the company's internal television channel and included in the different publications it sends to its employees, in order to share the group's commitment with them, raise disability awareness and combat the discrimination suffered by this group of people.



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ACTIVITIES

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Charity Race for Mental Health, of Fundación Manantial **17 February**

Adaptive ski-ing campus with Fundación También, also in Sierra Nevada, Granada **17 March**

Mother's Day volunteering with Fundación Recover in Fuenlabrada **6 May**

Eco-trekking with Fundación Deporte & Desafío, in Madrid **2 June**

I MedicusmundiSur Charity Race in Granada, of MedicusmundiSur **1 July**

Adaptive descent of the River Sella, with Fundación También, in Asturias **27 July**

Multi-sports Day with Fundación Deporte & Desafío at the Somontes Sports Complex in Madrid **15 September**

Charity Race to help children, of the Granada Red Cross, in Granada **28 October**

También Madrid Charity Race, of Fundación También, in Madrid **28 October**

VOLUNTEERING, SOCIAL ACTION, SPONSORSHIP AND PATRONAGE

ROVI is committed to social action in several areas, always seeking to help in solving any problems there may be in its immediate environment and, in particular, to promote a healthy lifestyle and cooperate with non-profit entities that work for the inclusion of groups at risk or to improve healthcare all over the world.

For the last three years, ROVI has had a corporate volunteering programme, which is the backbone of a considerable part of the company's social action. Through this programme, employees have the chance to play a leading role in change by cooperating with the NGOs and foundations with which the company works. Specifically, in 2018, 135 ROVI employees took part in the activities planned by the CSR area (see the attached list).

In 2018, for the first time, the company sponsored a number of charity races, such as the VII Charity Race for Mental Health, organised by Fundación Manantial in Madrid, or the I Medicusmundi Sur Charity Race of Medicusmundi Sur (Granada).

Special mention is merited by the financial cooperation with a number of non-profit organisations focused on the workplace and social integration of people with intellectual disabilities, as well as the cooperation with special employment centres to cover several services in different areas of the company's activity.





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On the one hand, the company continued to be on cooperation with entities that work on the integration and mainstreaming of people with disabilities through sport, such as Fundación También and Fundación Deporte & Desafío. On the other hand, Fundación Prodis, which began to work with ROVI in 2018 through its programme for the workplace integration of people with intellectual disabilities, also acted as a supplier of sports material for corporate volunteers (T-shirts, caps, etc.) to ROVI's Corporate Responsibility Department through its Special Employment Centre.

In addition, in 2018, co-operation with the Granada Red Cross in its child assistance and protection projects continued; with Proyecto Hombre Granada, for the continuity of its social reintegration activities; and with Fundación Recover, co-operating in its programmes to improve healthcare in Africa. Fundación Prodis began to work with ROVI in 2018 through its programme for the workplace integration



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ENVIRONMENT

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ROVI is aware that its work has an impact on the environment and on workplace safety and health in a number of ways, since each one of its companies is in a different context, depending on whether it is engaged in manufacturing or marketing and where it is located. Therefore, ROVI undertakes to reduce the effects of its activity to a minimum when and where this is possible, likewise allocating all the resources necessary to guarantee people's safety and health.

Environmental care is one of the action principles included in the group's General CSR Policy and the Integrated Environmental Management and Occupational Risk Prevention Policy for sustainable action, materialising in actions aimed to prevent pollution, manage resources efficiently and foster environmental responsibility.

The group has a Department that is exclusively responsible for environmental management-related aspects and those concerning workplace safety and health, which, in 2018, managed a budget of 1,042,972 euros, used for a number of actions based on continuing improvement in compliance with both legal requirements and additional voluntary requirements through implementation of efficient energy solutions, the rational management of natural resources and the recycling of the waste produced, aspects that are the basis of the company's environmental strategy.

CONSUMPTION REDUCTION

In 2018, ROVI maintained its commitment to combat climate change through a reduction in resource consumption. For a further year, it succeeded in reducing gas consumption by 6%. Total energy consumed by the group in kWh also dropped from 19.3 million kWh in 2017 to 18.9 kWh in 2018 (2% less)

CONSUMPTION EVOLUTION

(kWh, litres and percentage)

	2018	2017
kWh electricity consumed	18,940,410	19,313,337
Variation	-2 %	
kWh natural gas consumed	22,740,242	24,103,226
Variation	-6%	
Litres vehicle fuel	520,841	469,620
Variation	+11%	





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ENERGY CONSUMPTION ⁷

(kWh and fuel litres)

	ROVI GRANADA	ROCM	FROSST	DISTRIBUTION
kWh electricity consumed	3,002,572	7,206,775	8,100,711	630,352
kWh energy / million units produced	10	65,863	238,256	29,306
kWh natural gas consumed	1,941,716	6,371,676	14,426,850	0
kWh natural gas / million units produced	6	58,231	424,319	0
Litres vehicle fuel	500	409	1,279	518,653

In addition, water consumption was reduced by 7%, which is another aspect to highlight in industrial production. Total cubic metres consumed dropped from 152,827 m3 in 2017 to 142,742 m³ in 2018.

WATER CONSUMPTION 303-1

(m³ and percentage)	2018	2017	VARIATION
m ³ of water consumed	142,742	152,827	-7%

NATURAL RESOURCE CONSUMPTION ⁷

m³ water / million units produced	0.1	473.8	1,838.7	45.8
m ³ water con-sumed	27,399	51,842	62,516	985
(m³ water)	ROVI GRANADA	ROCM	FROSST	DISTRIBUTION

Attention should be drawn to the fact that ROVI is also focusing on consuming sustainable energy and, therefore, in 2018, signed a contract with a provider of 100% renewable energy for its Distribution business.

(7) Figures for the last month of 2018 are an estimated based on the information for preceding periods.



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WASTE MANAGEMENT AND GREENHOUSE GAS EMISSIONS

Another important aspect of ROVI's environmental impact is waste generation at its plants and work centres and the measurement of CO2 emission from its natural gas and diesel consumption, derived from electricity and vehicles, as well as other substances that act to destroy the ozone layer generated in its industrial activity.

Waste generation is inherent to ROVI's activity and, precisely for this reason, treating and reducing it is an essential part of the company's commitment to pollution prevention. The processes related to waste treatment are mainly focused on reducing it to a minimum in production processes and proper management thereof once it has been produced, favouring its use and placing a value on it wherever possible. The increase in production in 2018 also led to a minor increase in waste generation, which totalled 3,508 tonnes.

Recycling and dumping have been treated more responsibly, following the highest industry standards and ensuring that they do not represent any kind of problem for the environment or people's health.

Total greenhouse gas emissions remained insignificant, well below the levels established by law.

WASTE⁸

(Tonnes)

INTEGRATED

REPORT 2018



	ROVI GRANADA	ROCM	FROSST	DISTRIBUTION
Tonnes of haz-ardous waste generated	1,037	186	176	25
Tonnes of non-hazardous waste generated	1,336	464	283	1
TOTAL waste	2,373	651	459	25
Tonnes hazardous waste/million units	0.003	1.70	5.17	1.15
Tonnes non-hazardous waste/million units	0.004	4.24	8.31	0.03
TONNES WASTE/MILLION UNITS	0.008	5.95	13.49	1.18

(8) Figures for the last month of 2018 are an estimated based on the information for preceding periods.



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ATMOSPHERIC EMISSIONS 9

(Tonnes)

	ROVI GRANADA	ROCM	FROSST	DISTRIBUTION
Tonnes of C02 emitted	1,135	3,073	4,936	290
Tonnes of CO2 / million units	0.004	28.08	145.18	13.47

Additionally, ROVI works under the commitment to carry on an activity that is sustainable and committed to environmental care and, for this reason, has drawn up a Mobility Plan for the distribution business, in order to decrease fuel and electricity consumptions, the only emission made by the company.

ENVIRONMENTAL CERTIFICATIONS

The key tool to ensure correct management of environmental aspects is the introduction of an environmental management system based on the criteria established by the international standard ISO 14001:2004 and the Eco Management and Audit Scheme Regulation (EMAS).

These certifications recognise the quality of ROVI's environmental management system and assure its commitment to the environment in terms that go beyond current national legislation. At present, the group companies Laboratorios Farmacéuticos Rovi, S.A., Rovi Contract Manufacturing S.L. and Frosst Ibérica S.A. hold environmental management systems certified under ISO 14001:2007. In 2018, these systems were likewise certified under the new version of the international standards, ISO 14001:2015.

(9) Figures for the last month of 2018 are an estimated based on the information for preceding periods.





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