Researching to grow for health.
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FINANCIAL AND NON-FINANCIAL FIGURES

FINANCIAL FIGURES

Results

<table>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>382.5</td>
<td>304.8</td>
<td>277.4</td>
<td>266.7</td>
<td>247.0</td>
<td>240.9</td>
<td>218.9</td>
</tr>
<tr>
<td>EBITDA</td>
<td>60.9</td>
<td>29.5</td>
<td>29.9</td>
<td>39.3</td>
<td>31.8</td>
<td>36.6</td>
<td>32.4</td>
</tr>
<tr>
<td>EBIT</td>
<td>42.6</td>
<td>17.5</td>
<td>18.4</td>
<td>28.3</td>
<td>21.8</td>
<td>27.7</td>
<td>25.5</td>
</tr>
<tr>
<td>Net profit</td>
<td>39.3</td>
<td>17.9</td>
<td>17.2</td>
<td>26.1</td>
<td>19.8</td>
<td>24.1</td>
<td>23.0</td>
</tr>
<tr>
<td>Capex</td>
<td>40.5</td>
<td>26.4</td>
<td>19.9</td>
<td>18.1</td>
<td>19.9</td>
<td>25.1</td>
<td>24.7</td>
</tr>
<tr>
<td>Financial debt</td>
<td>84.8</td>
<td>34.2</td>
<td>43.2</td>
<td>33.8</td>
<td>42.8</td>
<td>36.3</td>
<td>31.0</td>
</tr>
<tr>
<td>Net financial debt</td>
<td>15.9</td>
<td>-62.8</td>
<td>1.1</td>
<td>-9.0</td>
<td>12.1</td>
<td>8.3</td>
<td>-5.8</td>
</tr>
</tbody>
</table>
Sales by activity

- **281.0** +30% Prescription-based pharmaceuticals
- **32.6** +10% Diagnostic imaging contrast agents and other hospital products
- **65.6** +20% Toll manufacturing
- **2.1** -3% Non-prescription pharmaceuticals (OTC) and other

Financial structure

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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Net debt/EBITDA</strong></td>
<td>0.26x</td>
<td>-2.13x</td>
<td>0.04x</td>
<td>-0.23x</td>
<td>0.38x</td>
<td>0.23x</td>
<td>-0.18x</td>
</tr>
<tr>
<td><strong>Net debt/Equity</strong></td>
<td>0.05x</td>
<td>-0.22x</td>
<td>0.01x</td>
<td>-0.05x</td>
<td>0.07x</td>
<td>0.05x</td>
<td>-0.04x</td>
</tr>
</tbody>
</table>
In February 2020, ROVI announced it would pay a dividend of 0.1751 euros per share with dividend rights out of the 2019 profit if the Shareholders General Meeting approved the application of the 2019 profit proposed by ROVI’s Board of Directors. This proposed dividend would mean an increase of 119% on the dividend paid out of the 2018 profit (€0.0798/share) and represents a 25% pay-out. **As a result of the Covid-19 crisis, ROVI has postponed the General Shareholders Meeting and has placed the dividend proposal under review.**
## Human resources

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average number of employees</td>
<td>1,310</td>
<td>1,224</td>
</tr>
<tr>
<td>Net jobs created</td>
<td>86</td>
<td>33</td>
</tr>
<tr>
<td>Diversity (men / women)</td>
<td>614 / 696</td>
<td>558 / 666</td>
</tr>
</tbody>
</table>

### By location

<table>
<thead>
<tr>
<th>Location</th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spain and Portugal</td>
<td>1,296</td>
<td>1,209</td>
</tr>
<tr>
<td>Germany</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>France</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Italy</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Poland</td>
<td>1</td>
<td>-</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hours of training</td>
<td>28,164</td>
<td>24,058</td>
</tr>
<tr>
<td>Turnover</td>
<td>3.3%</td>
<td>3.7%</td>
</tr>
<tr>
<td>Accident rate</td>
<td>2.78%</td>
<td>0.52%</td>
</tr>
<tr>
<td>Absence rate</td>
<td>2.52%</td>
<td>2.26%</td>
</tr>
</tbody>
</table>
Environment

<table>
<thead>
<tr>
<th>Metric</th>
<th>2019</th>
<th>2018</th>
<th>Variation</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO₂ emissions (tonnes)</td>
<td>11,949</td>
<td>11,389</td>
<td>4.9%</td>
</tr>
<tr>
<td>Tonnes CO₂ / million units produced</td>
<td>229.3</td>
<td>254.2</td>
<td>-9.8%</td>
</tr>
<tr>
<td>Hazardous waste generation (tonnes)</td>
<td>2,281</td>
<td>1,424</td>
<td>60%</td>
</tr>
<tr>
<td>Non-hazardous waste generation (tonnes)</td>
<td>3,381</td>
<td>2,084</td>
<td>62%</td>
</tr>
<tr>
<td>kWh electricity consumed</td>
<td>20,622,713</td>
<td>18,940,410</td>
<td>8.9%</td>
</tr>
<tr>
<td>kWh natural gas consumed</td>
<td>23,171,024</td>
<td>22,740,242</td>
<td>1.9%</td>
</tr>
<tr>
<td>Litres of vehicle fuel consumed</td>
<td>487,660</td>
<td>520,841</td>
<td>-6.4%</td>
</tr>
<tr>
<td>m³ of water consumed</td>
<td>148,632</td>
<td>142,742</td>
<td>4.1%</td>
</tr>
<tr>
<td>m³ of water / million units produced</td>
<td>2,170.1</td>
<td>2,358.4</td>
<td>-8%</td>
</tr>
</tbody>
</table>

* Due to a change in the method of calculating CO₂ emissions into the atmosphere, the figures shown above have undergone a minor change in relation to those reported in the 2018 Integrated Report, in order to allow said indicators to be compared.

Community

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Economic value generated (million euros)</td>
<td>382.5</td>
<td>304.8</td>
<td>277.4</td>
<td>270.8</td>
</tr>
<tr>
<td>Value distributed (million euros)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shareholders</td>
<td>9.8</td>
<td>4.5</td>
<td>6.0</td>
<td>9.1</td>
</tr>
<tr>
<td>Suppliers</td>
<td>219.2</td>
<td>172.7</td>
<td>154.7</td>
<td>153.5</td>
</tr>
<tr>
<td>Society</td>
<td>2.6</td>
<td>-1.2</td>
<td>0.3</td>
<td>1.8</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>29.3</td>
<td>32.4</td>
<td>28.3</td>
<td>17.5</td>
</tr>
<tr>
<td>Employees</td>
<td>72.5</td>
<td>70.2</td>
<td>64.0</td>
<td>60.5</td>
</tr>
<tr>
<td>Providers of capital</td>
<td>0.8</td>
<td>0.8</td>
<td>0.9</td>
<td>0.5</td>
</tr>
<tr>
<td>Amortisation and depreciation</td>
<td>18.6</td>
<td>12.0</td>
<td>11.5</td>
<td>11.0</td>
</tr>
<tr>
<td>Reserves (retained value)</td>
<td>29.6</td>
<td>13.4</td>
<td>11.8</td>
<td>17.0</td>
</tr>
</tbody>
</table>
ROVI is a specialised, 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 two major pillars of growth:

- The pharmaceutical specialties area, which contains three divisions:
  - The low-molecular-weight heparin (“LMWH”) division, which accounted for 47% of group sales in 2019.
  - The pharmaceutical specialties division in Spain, which has a diversified portfolio of its own and licensed innovative products, protected by patents.
  - The toll manufacturing division, with high-value-added products.
- The R&D area, focused on ROVI’s proprietary extended-release drug delivery platform ISM®.

Corporate information

Name: Laboratorios Farmacéuticos ROVI, S.A.
Address: Julián Camarillo, 35. 28037 Madrid. España
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.
Corporate structure

(See percentages and companies in the table below)

<table>
<thead>
<tr>
<th>CORPORATE NAME</th>
<th>ADDRESS</th>
<th>PARTICIPATION</th>
<th>ACTIVITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pan Química Farmacéutica, S.A.</td>
<td>Madrid, C/Rufino González, 50</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Gineladius, S.L.</td>
<td>Madrid, C/Rufino González, 50</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Rovi Pharma Industrial Services, S.A.U. (a)</td>
<td>Alcalá de Henares, Avenida Complutense, 140 Madrid</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Rovi Contract Manufacturing, S.L. (a)</td>
<td>Madrid, C/Julián Camarillo, 35</td>
<td>n/a</td>
<td>100%</td>
</tr>
<tr>
<td>Bemipharma Manufacturing, S.L. (a)</td>
<td>Madrid, C/Julián Camarillo, 35</td>
<td>n/a</td>
<td>100%</td>
</tr>
<tr>
<td>Bertex Pharma GmbH</td>
<td>Inselstr. 17, 14129 Berlin (Alemania)</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Rovi Biotech Limited</td>
<td>10-18 Union Street, London (United Kingdom)</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Rovi Biotech, S.r.l.</td>
<td>Via Monte Rosa 91, Milan (Italy)</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Rovi, GmbH</td>
<td>Ruhlandstr. 5, Bad Tölz (Germany)</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Rovi, S.A.S.</td>
<td>24 Rue du Drac, Seyssins (France)</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Rovi Biotech sp.z.o.o.</td>
<td>ul. Wincentego Rzymowskiego 53, Varsovia (Poland)</td>
<td>100%</td>
<td>n/a</td>
</tr>
<tr>
<td>Rovi Escúzar, S.L.</td>
<td>Madrid, C/Julián Camarillo, 35</td>
<td>100%</td>
<td>n/a</td>
</tr>
</tbody>
</table>

(a) In November 2019, the group companies Frosst Ibérica, S.A. (absorbing company), Rovi Contract Manufacturing, S.L. and Bemipharma Manufacturing, S.L. (absorbed companies) were merged. After this merger, Frosst Ibérica changed its corporate name to its current name of Rovi Pharma Industrial Services, S.A.U.

On 8 April, 2019, the company Rovi Biotech Ltda, established in Bolivia, was dissolved.

Activity
(1) Production, marketing and sale of pharmaceutical, healthcare and medicine products.
(2) Import, export, purchase, sale, distribution and marketing of articles related to integral female healthcare.
(3) Development, distribution and marketing of pharmaceutical products related to micro-particle technologies.
Shareholder composition
(March 2020)

63.11%  Norbel Inversores, S.L.
5.06%   Indumenta Pueri, S.L.
3.39%   T.Rowe Price International Funds, Inc
4.92%   Wellington Management Group, LLP
23.52%  Others
History

1946  Foundation of the company.

1981  Start of research into low-molecular-weight heparins.

1998  Launch of Bemiparin on the Spanish market and start-up of operations in Portugal.

2002  Internationalisation of ROVI following approval of Bemiparin outside Spain.

2003  Increased international coverage to 59 countries.


2009  Strategic agreement with Merck Sharp & Dohme (MSD).

2012  FDA certification of the injectables plant.

2013  Marketing agreements for products from Novartis and Medice.
2014 Registration process for an enoxaparin biosimilar with the EMA and FDA.

2015 Acquisition of the new injectables plant in San Sebastián de Los Reyes.

Successful completion of PRISMA-2 study of the clinical development of the new long-acting injectable Risperidone-ISM®.

2016 Agreement with Novartis for the marketing of Neparvis®.

2017 Commencement of the marketing of an enoxaparin biosimilar in Germany.

Beginning of Phase III clinical trial of Doria® (Risperidone-ISM®).

2018 Launch of an enoxaparin biosimilar in Spain, France, United Kingdom, Italy, Austria, Estonia and Latvia.

Conclusion of the PRISMA-3 and BORIS studies and end of the Clinical Research Programme of Risperidone-ISM® – Doria® in patients with schizophrenia and application for marketing authorisation in Europe.

Presence of enoxaparin biosimilar in 13 countries.

2019 Validation of the Doria® dossier and start of the product evaluation process in Europe.
Dear friends,

We started the year 2019 with forecasts of heavy growth in revenue in high-single-digit figures. In the course of the year, we raised those forecasts twice, until they reached high-teen figures. The final result surpassed all our expectations and it is a huge satisfaction to me to announce that ROVI achieved a 26% increase in its operating revenue, which rose to 381.3 million euros, accompanied by growth of 106% in EBITDA. Likewise, the net profit increased by 119% to 39.3 million euros.

These results were reflected in ROVI’s excellent trajectory on the Stock Exchange. In 2019, the ROVI share grew in value by 39.8%, in comparison with growth of 11.8% in the iBex-35. The quoted price of the ROVI share started at 17.45 euros in January and closed the year at 24.40 euros, reaching a high of 25.50 euros in the period.

Last year, our shareholders received a dividend of 0.0798 euros per share entitled to receive it, charged to the 2018 profit. This year, if the General Shareholders’ Meeting gives its approval, we will be able to reward the trust they have placed in us with a dividend of 0.1751 euros per share charged to the 2019 profit, which represents an increase of 119% and would entail the distribution of approximately 25% of the net consolidated profit for 2019.

**Drivers for the future**

At present, our growth is at an inflection point, driven by both our enoxaparin biosimilar, which will enable us to transform our European presence, and by Doria® and Letrozole-ISM®, both of which are candidates that validate our leading edge ISM® drug-delivery technology. These growth levers are firmly backed by very solid ongoing business based on our pharmaceutical specialities and toll manufacturing divisions, which, year after year, have been providing very favourable results. ROVI has demonstrated its ability to renew products (we have launched 14 in the last 12 years) and we are a partner of choice for many multinationals who select us to distribute their products in Spain, since we have one of the most extensive sales forces, aimed at the specialist niche, with more than 250 medical visitors. Furthermore, to ensure an appropriate production level, we are going to reinforce our manufacturing lines with the construction of a second plant for the active substance of low-molecular-weight heparins in Granada in the next three years, as well as a back-up ISM® plant in the future.

Returning to 2019, ROVI’s key success factor was its low-molecular-weight heparin (LMWH) division -enoxaparin biosimilar and bemiparin-, sales of which grew by 46%. Principally, we can highlight sales of the biosimilar, which totalled 80.9 million euros, with a leap of 167% in comparison with the 30.2 million euros of 2018, and showed, in its second full year of sales, its enormous business potential. This catalyst, together with the launch of Doria® in Europe and the United States, will drive our growth in forthcoming years and we hope to double our operating revenue in the period from 2018 to 2023 and multiply EBITDA by 2.5 in the same period. With bemiparin, we are present in almost 60 countries outside Spain. With the enoxaparin biosimilar, we have already reached 13 countries and have signed agreements to launch the product in 85 more countries. Currently, we are undergoing a phase of international ex-
pansion and hope that our enoxaparin biosimilar will allow us to be present in more than 120 countries in the long term. With these prospects, we can only express our enthusiasm at the potential of our LMWH division and we aspire to become a benchmark player in this field worldwide.

Likewise, the ISM® technology, under patent until 2033, is an innovative technology for one of the markets with the best future prospects: long-acting injectables (LAs). Applicable to many drugs, treatments and user profiles, it has a series of success factors that other alternatives do not enjoy:

- Its predictability: the phase I and II pharmacokinetic studies allow us to forecast a high degree of success in phase III;
- Its usability: it does not require a cold chain;
- Its flexibility: it allows the most convenient dose to be chosen depending on the clinical needs, since it may be administered at intervals of between 1 and 6 months;
- Its swift effect and the sustainability of the clinical effect: therapeutic concentrations in plasma may be reached as of day 1; and
- It is a patented technology and the manufacturing plants are fully integrated.

In this respect, in the first quarter of 2020, we commenced registration of Doria®, a long-acting injectable to treat schizophrenia, in Europe and we plan to begin registration in the United States in the second half of the year. If the product is approved in both these territories, we could be in the European market in 2021 and the United States in 2022. At the same time, we will be tackling the challenge of constructing a sales force specialised in psychiatry in Europe to launch the product.

The population is constantly ageing, with lower mortality. At the same time, we have seen how the impact of chronic complaints and the need for long-term care have increased. To tackle the progressive increase in the need to provide attention for chronic diseases and the problems this entails (higher healthcare spending, saturation of doctors’ surgeries and hospitals), the experts believe that it will be necessary to seek more support from technology and enhance prevention. Likewise, the healthcare sector’s great challenge is to constantly maintain a high level of research and development. The pharmaceutical industry is synonymous to R&D and ROVI upholds this idea each year by investing a major part of its revenue —29.3 million euros in 2019— in new developments.

In December 2017, ROVI announced that the European Investment Bank had granted it a credit to support its R&D&I investments. The amount of the credit was 45 million euros. As of 30 September, 2019, ROVI had drawn down 5 million euros of this credit line. As of 18 November, 2019, ROVI had drawn down the remaining 40 million euros. The credit matures in 2029 and provides for a three-year grace period and a fixed interest rate of 0.681%.

We trust that our bank borrowings, combined with ROVI’s excellent cash-generating capacity over forthcoming years, allow us to fund the company’s growth over years to come.

**Spain and coronavirus**

I would like to express my sincerest condolences to everybody who has lost a loved one and suffered the direct effects of this dreadful COVID-19 pandemic. Defending the life and health of our loved ones has also been the guideline that ROVI has followed to combat the health crisis.

I cannot ignore the impact of the COVID-19 pandemic both globally and locally. ROVI has a sound business position to withstand any possible adverse effects that the confinement measures adopted by the governments of Spain and all the other countries affected, which were appropriate and absolutely necessary to prevent the expansion of the pandemic, might have on the more industrial facet of production at its plants.

As a company that acts responsibly towards its employees, the necessary measures were put in place to safeguard the health of both our employees and anyone connected to the ROVI team. All the employees possible were instructed to work from home and the plants were kept duly aseptic, with the minimum number of employees that was indispensable for production to continue.

Furthermore, our leading position in the injectables manufacturing area places us in an unbeatable position to make Spain a benchmark in vaccine manufacturing. Our experience and knowledge of vaccine manufacturing is a value that we should highlight at this time, when a vaccine against COVID-19 is being sought and researched. As you know, we are one of the largest manufacturers of the flu vaccine for third
In this period of great social consternation as a result of the coronavirus pandemic, business commitment to sustainability is becoming increasingly necessary, **that’s why our commitment to factors such as attracting talent, research and environmental protection remains intact.**
ROVI is a leading pharmaceutical specialty company engaged in the research, development, manufacturing and marketing of small molecules and biological specialties.

22 · Identity and commitment

31 · Business units
IDENTITY AND COMMITMENT

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.

MISSION

We work for the well-being of society and to improve the quality of life of patients and the attention they receive, promoting human health through researching, manufacturing, marketing and distributing medicines and other healthcare products.

VALUES

Honesty, integrity and ethics
Consistency
Self-criticism
Equity
Justice
Honesty
Legality

Team, co-operation, involvement
Commitment
Co-operation
Empathy
Co-responsibility
Solidarity

VISION

We aspire to be recognised as a benchmark for our work in the research and development of new products and to be perceived as a trusted supplier due to our commitment to the manufacture, marketing and distribution of medicines and healthcare products.

Patient benefits
Commitment
Involvement
Empathy
Proximity
Proactiveness

Efficiency
Justice
Objectivity
Balance
Determination
Profitability

Respect
Consideration
Truthfulness
Honesty

Innovation
Proactiveness
Involvement
Creativity
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. The products the group markets are intended to improve people’s health and ROVI is constantly working to respond to these social needs, at the same time as it takes care with the impact and footprint it leaves on society and the environment.

The incorporation of CSR into the management of the ROVI group takes place through the General CSR Policy and the Management Committee is responsible for designing, evaluating and making general reviews of the Corporate Social Responsibility Policy. The Board of Directors has the tasks of overseeing and ensuring that Management meets the goals that have been fixed and respects the company’s corporate interests.

Furthermore, the duties of the Audit Committee include reviewing the Corporate Social Responsibility Policy, ensuring that it is orientated towards value creation, and monitoring CSR strategies and policies, assessing the degree of implementation thereof. This Committee also oversees and evaluates the processes concerning relations with the different stakeholder groups.

In 2017, a permanent internal body, called the Social Responsibility Committee/Social Performance Team, was created, with the capacity to inform, provide advice and make proposals. Within its sphere of action, as one of the duties assigned to it, this Committee reports annually to the Management Committee and the Nomination and Remuneration Commission on the degree of progress in implementing the CSR Policy and strategy. In 2019, participation in this Social Performance Team was extended to employees at other work centres that had not previously been represented, such as Granada, Panquímica and San Sebastián de los Reyes.

An example of recognition of the effort made to be a responsible company came from the Ministry of Industry, Tourism and Trade and the Ministry of Health, Social Services and Equality, which, in the Profarma Plan, classify the pharmaceutical companies in accordance with their contribution to the Spanish industrial fabric, taking their investment in technology, new manufacturing plants, research efforts, etc. as a reference. In April 2019, the results of Plan Profarma 2018 were issued and ROVI obtained the classification of Excellent for the thirteenth consecutive year.

CSR MANAGEMENT AT LABORATORIOS ROVI
CSR Policy goals and support tools

ROVI is aware that its economic development must be accompanied by ethical conduct socially, in the labour area, environmentally and in terms of respect for human rights. This is channelled through different action policies which are the materialisation of the commitment to business ethics and the action manual for any member of ROVI’s workforce in their relations with stakeholders.

- **Corporate Social Responsibility Policy**
- **Integrated Management Policy (Environment and Occupational Health and Safety)**
- **Code of Ethics**
- **Annual Social Corporate Responsibility Report**

All these elements have a series of action principles that form the backbone of ROVI’s day-to-day management and endow it with consistency.

**Legality**
Compliance with current [legal regulations](#) in the places where ROVI companies are located.

**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 the fight against corruption.

**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, the group 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.

**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.
ROVI's economic development must be accompanied by ethical conduct socially, in the labour area, environmentally and in terms of respect for human rights.

**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.

**Contribution**
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.

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

**Transparency**
Commitment to transparency as a way to transmit confidence and credibility among stakeholder groups. This will entail:
a. Providing stakeholders with relevant and accurate information, complying with any legal public information requirements that may exist.
b. Preparing and publishing financial and non-financial information, using, in the latter case, an internationally-accepted methodology, and submitting the information to the appropriate internal and external review processes that guarantee the reliability of the information and encourage continuing improvement.
The action principles applied through the aforementioned tools allow ROVI to achieve its permanent sustainability goals in its day-to-day:

GOALS

- Favour attainment of the group’s strategic objectives.
- Improve the group's competitiveness by implementing management practices based on innovation, equal opportunities, productivity, profitability and sustainability.
- Manage risks and opportunities derived from the changing environment responsibly, maximizing the positive impacts of the group’s activities in the different territories where it operates and minimizing any adverse impacts as far as possible.
- Promote a culture of ethical conduct and increase business transparency, in order to generate credibility and confidence among stakeholders, including society as a whole.
- Promote trust relationships and value creation for all stakeholders, providing all of them with a balanced and integrating response.

ROVI considers CSR to be a commitment acquired with society, given the importance of its activity associated to products that improve people’s health and quality of life. In this respect, the company has identified six groups and a series of goals it pursues in relation to each one of them, establishing different channels through which to communicate with these groups:

CHANNeLs

goAL

Employees

• Suggestion boxes: these may be found throughout the facilities and are intended to enable employees to submit anonymous communications concerning improvements.
• Confidential communication mechanisms for irregularities considered illegal, criminal or a breach of the principles of ROVI’s Code of Ethics.

To generate enthusiasm and provide training and motivation.
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.

Since the company was first listed on the securities markets, it has reported regularly on all its activities and applies its ‘Policy for Communication with Shareholders, Institutional Investors and Proxy Advisors’.

Direct investor communication channels:
- ir@rovi.es
- Web form at www.rovi.es/contact

If they so wish, shareholders have the possibility of receiving ROVI’s financial information automatically through an e-mail alert system and the group provides regular, prompt and relevant information on the company, such as presentations and legal documents on economic and financial aspects and corporate governance, which may be consulted on the corporate website www.rovi.es.

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

To create more value in a manner that can be sustained in the long term.
• There is a query channel for information requests from both international partners and direct customers, patients and professionals: **www.bemimed.com**.

• In the event of a complaint, the company opens an enquiry immediately in order to identify the cause and prevent any repetition.

• The company’s environmental policy is based on commitments to continuous improvement, legal compliance and additional voluntary requirements.

• In relation to environmental queries, ROVI has a corporate procedure (SOPc813 “Communication, Participation and Consultation”) through which it manages communications (queries, complaints, etc.) related to the environment and occupational health and safety.

• On the corporate website (www.rovi.es) the quality, environmental and occupational health and safety certifications held by group companies are available to the public.

• Finally, ROVI provides constant support to medical research and encouraging the prevention and knowledge of certain diseases.

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**Goal**

**To make an active contribution to social progress and environmental protection.**
Public authorities

ROVI follows a policy of transparency and constant communication with the public authorities. Furthermore, on the website www.rovi.es not only can the communications and other relevant information published be consulted, but also other types of information, such as press releases, regular economic and financial information and audits.

To create channels for cooperation with the public authorities.

During 2019, fifteen press releases were published with specific information on the company regarding its financial results, new developments concerning ROVI’s research programmes, new medicine distribution agreements and activities aimed at updating knowledge of pathologies such as venous thromboembolic disease (VTD), among others.

The company appeared in the press -both general and specialised- 1,227 times in 2019. Likewise in 2019, ROVI decided to create corporate profiles in social media (Twitter, LinkedIn and YouTube) through which to inform on new developments, as a supplementary channel for transmitting information of interest on the company.
Contribution to the SDGs

ROVI is aligned with the goals of the United Nations Global Compact and, on the basis of its activity and the matters identified in its materiality analysis, undertakes to act in favour of the following Sustainable Development Goals:

- **GOAL 3.8**
  - Contribution: Co-operation with Fundación Recover, an NGO that works to improve healthcare in Africa.

- **GOAL 4.3**
  - Contribution: Co-operation with academic organisations and centres to promote access to education and employability.

- **GOAL 8.2**
  - Contribution: Performing the gender breach study.

- **GOAL 8.5**
  - Contribution: Agreements with employment organisations for people with disabilities.

- **GOAL 8.6**
  - Contribution: Investment in R&D activities.

- **GOAL 8.8**
  - Contribution: Execution of policies for prevention of occupational hazards.

- **GOAL 9.5**

- **GOAL 12.4**
  - Contribution: Exhaustive control of the consumption indicators at each plant.

  - Contribution: Contracting a provider of energy from renewable sources.
ROVI is a leading pharmaceutical specialty company engaged in the research, development, manufacturing and marketing of small molecules and biological specialties. It has two major pillars of growth:

**Pharmaceutical specialties**

- **LMWH**: ROVI aspires to become one of the world leaders in low-molecular-weight heparins (LMWH) due to two products from its own research, Bemiparin and an enoxaparin biosimilar.

- **Diversified portfolio of its own products and in-licensed products with long-term patents.**

**Toll manufacturing**

- **Specialist in prefilled syringe solutions and solid oral forms.**

**R&D**

- **R&D policies**: Sound and low-risk.
Since 2017, the ROVI Group has been facing the challenge of expanding its international presence as result of the launch of the enoxaparin biosimilar, mainly through its recently-created subsidiaries. In forthcoming years, another of the pillars will be the development of new products linked to the ISM technology patented by ROVI. The first product, Doria® (Risperidone -ISM®), is already undergoing the approval process in Europe and is expected to be registered in the United States in the second half of 2020. It is expected to be marketed in Europe in 2021 and the United States in 2022.

Having a sound strategy and clear pillars of growth furnishes the company with a defensive profile that has allowed it to increase its profits every year. In 2019, the group’s revenue rose by 26%.

Growth pillars

<table>
<thead>
<tr>
<th>LMWH benchmark company</th>
<th>Revenue 2019</th>
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<tbody>
<tr>
<td></td>
<td>177.6 Mn€</td>
</tr>
<tr>
<td></td>
<td>+46% in 2019</td>
</tr>
<tr>
<td></td>
<td>2010-19 CAGR: 17%</td>
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<table>
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<tr>
<th>Leading Spanish pharmaceutical specialty company</th>
<th>Revenue 2019</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>138.1 Mn€</td>
</tr>
<tr>
<td></td>
<td>+9% in 2019</td>
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<tr>
<td></td>
<td>2010-19 CAGR: 7%</td>
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<tr>
<th>Toll manufacturing of prefilled syringes and solid oral forms</th>
<th>Revenue 2019</th>
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<tbody>
<tr>
<td></td>
<td>65.6 Mn€</td>
</tr>
<tr>
<td></td>
<td>+20% in 2019</td>
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<tr>
<td></td>
<td>2010-19 CAGR: 7%</td>
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</tbody>
</table>

| Solid R&D&i and extensive portfolio of products under development | Over 500 patents |

Operating revenue 2019: 381.3 Mn€

2010-19 CAGR 1: 10%

(1) CAGR: Compound annual growth rate.
Having a sound strategy and clear pillars of growth furnishes the company with a defensive profile that has allowed it to increase its profits every year.
Competitive advantages

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

Unique knowledge of LMWHs

Since it was founded in 1946, ROVI has been engaged mainly in the study and development of drugs based on heparin, a fast-acting anticoagulant. Since 1981, it has been focusing on its fractioned derivatives, low-molecular-weight heparins (LMWH). As a result of ROVI’s 70 years’ experience, its main product, Bemiparin, has positioned itself as one of the principal treatments for venous thromboembolic disease worldwide.

Likewise, in 2017, ROVI launched a biosimilar of enoxaparin, the leading molecule on the market, and aspires to become one of the leading companies in the LMWH field.

Diversified portfolio protected by patents

The company has over 40 products on its portfolio, including both its own and licensed products, for most of which there is growing demand and which are virtually unaffected by the reference pricing system in Spain. They are grouped into nine therapeutic areas and are indicated either for treating different complaints or as diagnostics systems:

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

ROVI has launched 14 new products since October 2005.
**Bemiparin has positioned itself as one of the principal treatments for venous thromboembolic disease worldwide**

**Infrastructure with operating advantages**
ROVI is one of the major companies in the toll manufacturing business in the sector and among world leaders in prefilled syringe production. It has one of the largest European plants for manufacturing oral solid forms, exporting to more than 60 countries.

Its production plants in Madrid and Alcalá de Henares, together with the San Sebastián de los Reyes plant acquired in 2015, which has allowed an expansion of injectables production lines since 2016, are approved by the European and/or United States regulators –the European Medicines Agency (EMA) and the Food and Drug Administration (FDA), respectively–.

**Low-risk innovation**
ROVI operates with a low-risk strategy, concentrating on diseases with extensive medical requirements. The company allocates a large part of its revenue to research, in order to remain in the vanguard in terms of both products and manufacturing and development systems.
International presence

ROVI has its headquarters in Spain but its mindset is clearly international. Expansion continues to be one of the strategic goals in both organisational and business terms, with subsidiaries in France, Germany, Italy, United Kingdom and Poland through which it markets -or will market- the enoxaparin biosimilar, among other products. It is expected to cover 26 European Union member states over the next few years, as well as other areas (North Africa, Middle East, Asia and South America), as a result of a series distribution agreements that have been signed.

ROVI operates directly in the following countries:

- **Spain**, where a large part of its marketing operations take place, as well as all its manufacturing services and Research & Development activities.
- **France**
- **Portugal**
- **Italy**
- **Germany**
- **United Kingdom**
- **Poland**

In the last six of these countries, ROVI has corporate structures through which it carries on pharmaceutical product marketing activities directly.

Additionally, through strategic alliances with international partners, at the end of 2019, ROVI was distributing its main product, Bemiparin, in approximately 60 countries all over the world and the enoxaparin biosimilar in Germany, Austria, Spain, Estonia, France, Italy, Latvia, United Kingdom, Portugal, Costa Rica, Poland, Finland and Sweden. Likewise, ROVI has three toll manufacturing plants and exports to over 60 countries.

*It is expected the company to be present in more than 120 countries over the next few years*
Global presence of Bemiparin

South and Central America
- Marketed: Argentina, Belize, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, Panama, Venezuela, Chile, Bolivia, Mexico, Brazil
- Approved: Ecuador, Peru, Colombia

Europe
- Marketed: Albania, Austria, Belarus, Bulgaria, Czech Republic, Georgia, Greece, Estonia, Hungary, Ireland, Italy, Latvia, Lithuania, Moldova, Poland, Romania, Russia, Slovakia, Slovenia, Turkey, United Kingdom, Ukraine
- Approved: Portugal
- Pending: Bosnia & Herzegovina, Kazakhstan, Switzerland, Azerbaijan
- In progress: Armenia, Kyrgyzstan, Croatia, Serbia & Montenegro, Tajikistan, Turkmenistan, Uzbekistan

Africa
- Marketed: Libya, Algeria, Morocco, South Africa, Sudan
- Pending: Tunisia, Egypt
- In progress: Botswana, Lesotho, Namibia, Swaziland

Middle East
- Marketed: Jordan, Kuwait, Yemen, Bahrain, Syria, Oman, Iraq, Saudi Arabia, Lebanon, Qatar, United Arab Emirates
- Pending: Iran
- In progress: Israel

Asia
- Marketed: Hong Kong, South Korea, India, China, Philippines, Thailand
- Approved: Pakistan
- Pending: Indonesia, Malaysia, Vietnam
- In progress: Taiwan, Singapore

10 countries where approval has been obtained:

14 countries where authorisation is in progress:

±60 countries where approval has been obtained:

±60 countries through strategic alliances:
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:

• Cardiovascular
• Osteoarticular/Women’s health
• Anaesthesia/Pain
• Radiodiagnostics contrasting agents
• Central nervous system
• Urology
• Endocrinology
• Respiratory system
• Primary healthcare

ROVI’s growth engines are Bemiparin, the distribution licence agreements (such as Neparvis® and Volutsa®), 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 low-molecular-weight heparins (LMWHs). To achieve this, it has two products from its own research: bemiparin (Hibor®) and the enoxaparin biosimilar. The low-molecular-weight heparin division accounts for 47% of total group sales.

**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 long-term treatment of patients who have suffered VTD. VTD is a serious and potentially fatal process, the main characteristic of which is the formation of a fibrin clot, thrombosis, inside the veins of the deep vein system, with the consequences that may result from the evolution of the venous thrombus, which may grow, progress and fragment. In the event of fragmentation, some of the fragments may reach the lung and cause pulmonary embolism.

Over recent years, Bemiparin has become one of the main treatments for this disease worldwide, having expanded its presence to around 60 countries as the result of a strategic alliance network. Currently, Bemiparin is ROVI’s principal product and accounts for 25.4% of the group’s operating revenue.

**Enoxaparina ROVI**

ROVI’s enoxaparin sodium biosimilar is an anticoagulant that belongs to the low-molecular-weight heparin group. It is used to treat and prevent deep vein thrombosis and pulmonary embolism. Enoxaparin sales were 80.9 million euros in 2019 and represented 21.2% of ROVI’s operating revenue.

The group commenced marketing of its enoxaparin biosimilar (low-molecular-weight heparin) in Spain in 2018 under the brand name “Enoxaparina ROVI”. With this launch, the company expanded its presence in Europe, which had begun in 2017 with the marketing of the product in Germany and, by the end of 2019, the product was being marketed in 13 countries. Furthermore, also in 2018, an agreement was signed with Biogaran SAS, the leading French pharmaceutical company in generics and biosimilars and a subsidiary of Laboratorios Servier, to market the enoxaparin biosimilar in France on a semi-exclusive basis.

As of 31 December, 2019, all the European countries where ROVI had applied for approval of the national registration of its enoxaparin biosimilar (26 countries) had approved said registration and, in addition to the European countries, the company had signed marketing agreements for the product in a further 85 countries.

The enoxaparin market totals more than 1,400 million euros worldwide (according to estimates based on the 2019 sales reported by Sanofi-Aventis), with a European market share of 75%, 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, in 2018, ROVI signed an agreement with Hikma Pharmaceuticals PLC, a listed multinational pharmaceutical group, for the exclusive distribution and marketing of its enoxaparin biosimilar in 17 countries in the Middle East and North Africa: Saudi Arabia, Jordan, Algeria, Egypt, Tunisia, Sudan, Syria, Yemen, Iraq, Oman, United Arab Emirates, Kuwait, Qatar, Bahrain, Libya, Palestine and Lebanon. Furthermore, ROVI signed 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, Ar-
gentina, 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.

ROVI manufactures and packages its enoxaparin biosimilar in Spain thanks to its four production plants. In 2019, it announced the future construction of a second plant in Granada for the active substance of heparins, in which ROVI will invest 24 million euros over the next three years. This new plant will double the group’s LMWH production capacity and will have an initial workforce of 38 employees.

With the enoxaparin biosimilar, ROVI, due to the competitive edge provided by the vertical integration of processes in the group, aspires to become one of the main European -and, in the medium- and long-term, world players in a market of more than 700 million euros (Europe) where there are only two other biosimilars, likewise increasing its presence in emerging markets, with a potential of 500 million euros.

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

**Licensed products**

**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.

**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.

**Hirobriz® Breezhaler® and Ulunar® Breezhaler®**

In the last quarter of 2014, ROVI commenced the marketing of Hirobriz Breezhaler (indacaterol maleate) and Ulunar Breezhaler (indacaterol maleate and glycopyronium bromide) in Spain. Both these active substances are long-acting bronchodilators indicated for the maintenance treatment of Chronic Obstructive Pulmonary Disease (COPD) in adult patients and administered by inhalations through the Breezhaler device. ROVI markets the two products under licence from Novartis.

**Vytorin®, Orvatez® and Absorcol®**

Vytorin® (ezetimibe and simvastatin), Orvatez® (ezetimibe y atorvastatin) and Absorcol® (ezetimibe) are Merck Sharp & Dohme (“MSD”) products used as adjunctive therapy to diet in patients with hypercholesterolemia. 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 competitiveness. In addition, Orvatez® price is expected to be re-
New products in 2019

In the first quarter of 2019, ROVI announced the acquisition of two products, Falithrom® and Polaramine®. These purchases form part 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 in the Sandoz Division of Novartis, in order to distribute it directly in Germany through its subsidiary.

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® and Polaracrem™

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 to a group of medicines known as antihistamines. They are indicated for the symptomatic treatment of seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis, mild, uncomplicated 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.

Likewise, in November 2019, ROVI announced the acquisition of a sodium heparin in Italy, which it will be marketing in the near future.

Tetridar®

Due to the delay in availability of the product at the scheduled launch date, ROVI will not finally be distributing Tetridar® (teriparatide), a TEVA product for the treatment of osteoporosis in adults, in Spain. However, ROVI is analysing other opportunities with a similar market value with TEVA.
ROVI is one of the market leaders in the marketing of contrast agents, which are hospital products for imaging diagnosis (computed tomography, magnetic resonance imaging, ultrasound scan, etc.). This area, which accounts 9% of the company’s revenue, comprises a broad product portfolio, including those marketed under licence from Bracco: Iomeron® and Iopamiro® (for computed tomography and intervention), Multihance® and Prohance® (for magnetic resonance imaging), Sonovue® (for ultrasounds), and Bracco Injeenering: EmpowerCTA+®, EmpowerMR® and CT Expres (contrast injection systems and compatible disposable material).

The hospital product portfolio is completed by healthcare products for the care and maintenance of intravenous catheters (Fibrilin®).

**Toll manufacturing**

ROVI has positioned itself strategically to take advantage of the growing trend among pharmaceutical companies to outsource their manufacturing processes. Thus, it makes good use of the high manufacturing capacity available at its facilities by providing the whole range of manufacturing services, mainly in the areas of injectables and oral solid forms.

Through three production plants –two of which are engaged in injectables (Madrid and San Sebastián de los Reyes), while the other specialises in oral solid forms (Alcalá de Henares)–, the
company provides toll manufacturing services in a wide range of pharmaceutical forms, including prefilled syringes, vials, suppositories, 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 strength of Laboratorios Farmacéuticos ROVi in the toll manufacturing area was consolidated in 2019 through the unification of the companies ROVi Contract Manufacturing and Frosta Ibérica under a single corporate name: ROVi Pharma Industrial Services, S. A. U. The new company combines the decades of experience working to the highest and most demanding quality standards of the Madrid, Alcalá de Henares and, more recently, San Sebastián de los Reyes plants.

The contracts signed with its customers have long terms, which helps to generate a considerable and 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” or “partners”.

Toll manufacturing is divided into:

**Injectables**

ROVi is currently one of the leading prefilled syringe manufacturers in Europe in terms of the number of units manufactured (filled) per year. With a total annual production capacity of 270 million units, there are very few competitors in 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 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 at full capacity in 2017 and 2018.

In addition to being among the world leaders in prefilled syringe production, ROVi is today one of the main companies in the high-value-added toll manufacturing sector, with exports to more than 60 countries and a high degree of technological specialisation in the manufacturing of vaccines, biological products and biosimilars, all of which enjoy recognised therapeutic value.

**Oral solid forms**

ROVi has a solid form plant in Alcalá de Henares 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 a global annual capacity of 3,000 million tablets, 300 million hard capsules
and 30 million sachets, using different production lines. Furthermore, it has storage capacity for 9,000 pallets.

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

At the Alcalá de Henares plant, in 2019, ROVI constructed a centre of excellence for the packaging of injectables, with a total of 13 packaging lines. These new injectables packaging activities in Alcalá are a result of the redirection of the toll manufacturing activities towards products with higher value-added, which has implied a greater degree of specialisation by the plants in differentiated niches.

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

ROVI is continuing to bet on its research work and allocates a large part of its revenue to this end. The goal is to remain in vanguard in terms of both products and manufacturing and development systems. The strategy it has been following is marked by a bet on low risk, focusing on chronic diseases with extensive medical requirements and setting up international strategic alliances.
Commitment to research and technology

In a market like the one that exists at present, where innovation sets the pace of business, research, development and technology are strategic factors and constitute the basic tools for competition and differentiation that ROVI uses to remain in the vanguard of the sector. At the same time, a cautious attitude that protects know-how is required, which is why the group is strategically supported by protection of the R&D&I results through the patent system and the industrial secrets protection system. This enables it to safeguard its portfolio, composed by over 500 patent dosiers, 408 of which have now been granted, while 96 are in the examination and evaluation phase.

Research and development (R&D) expenses in 2019, related mainly to the ISM® technology platform, dropped to 29.3 million euros, 9% lower than the 32.4 million euros of 2018. These expenses are principally related to development of the Phase III trial of Risperidone-ISM® and the Phase I of Letrozol-ISM®.

ROVI coordinates all its research activity in 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, it is present in the creation of large strategic national research consortia. 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. Additionally, in recent years it has led other, smaller research project consortia.

At the same time, ROVI is very much involved in driving and supporting both academic research and research within the national business fabric through small and medium-sized companies. To do this, 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. In this respect, it constantly 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.

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 programme promotes the recruitment of doctors to carry out industrial research and experimental development programs or prior viability studies, in order to favour the professional careers of the researchers, 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 workforce has been reinforced by the recruitment of 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

Finally, ROVI also receives support from leading entities such as the Industrial Technological Development Centre and the Technological...
Corporation of Andalusia. In 2019, as in previous years, it received funding for its main research line: the development of new controlled-release systems based on ISM® technology, through the following projects:


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-20170717 - “Phase I clinical trial, with single increasing doses of letrozole using a prolonged-release injectable system” (2017-2019).

IDI-20190622 - “Development of the active substance to obtain a prolonged-release injectable system for letrozole” (2019-2020).

Areas of research

ROVI has an extensive portfolio of products in the research and development phase, mainly focused on three technological areas: (i) glycomics, (ii) drug release technologies, and (iii) multi-layer technologies for urethral catheters. Taking account of these three areas of expertise, the most prominent milestones over recent years have materialised in the development and optimisation of heparin-based products and other glycosaminoglycans and how to obtain them, and the development of new controlled-release drug delivery systems based on ROVI’s patented ISM® technology.

ISM® technology and long-acting injectables

Long-acting injectables (LAIs) are becoming the benchmark drug-release system for the treatment of certain complaints, such as schizophrenia, replacing oral medication. This is because they ensure an improvement in patient adherence to treatment, meaning that both the treatment and the dose are followed more strictly.

In this field, ISM® technology represents an excellent alternative for treatment of chronic diseases with unmet medical needs. Through the ISM® platform, ROVI aims to develop new products to replace the administration of drugs that require a daily dose in chronic or prolonged treatments. In this respect, pathologies such as schizophrenia or certain types of cancer may be highlighted, the expectations of which would improve enormously as a result of the ISM®-based controlled-release drug delivery systems.

ISM® is a technological drug release platform, based on the formation in situ of biodegradable matrices that contain an active substance after the intramuscular administration of a carrier liquid into the patient’s organism. 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 of
the formulation, which is prepared at the time of use. Once it has been injected, the medicine precipitates in the patient’s muscle, giving rise to formation of a solid or semi-solid implant by spreading the carrier through the patient’s own corporal fluids. This technology increases the stability of the product considerably, avoiding the need for cool storage and allowing clinically significant release profiles to be obtained as of the first day after the injection, maintained over time and reproduced without the need for any oral supplement or the establishment of initial treatment guidelines.

ISM® technology belongs exclusively to ROVI and is protected internationally by patents until 2033. ISM® has been designed by ROVI to overcome most of the disadvantages of oral or prolonged-release injectable presentations and, consequently, presents significant technical advantages, such as its versatile administration, its high efficiency in encapsulating the active substance, the stability of the biodegradable matrix formed, or greater control in the initial release of the drug, providing clinically significant release profiles as of the first day, among others.

The first two product developments using this technology, which are also candidates for licensing to third parties, are 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 2019 (page 102), 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 (CTDI) and the Technological Corporation of Andalusia (CTA).

The degree of specialisation and expertise 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 low-molecular-weight heparin with an antithrombotic effect), marketing of which commenced in 2017 and which, in 2019, was already one of the company’s fundamental pillars of growth for forthcoming years.

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 the microorganisms using antibiotics.

During 2019, 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.
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.

**Madrid**
- **304** employees
- **309 syringes**: 150 million
- **309 suppositories**: 150 million

**San Sebastián de los Reyes**
- **92** employees
- **356 syringes**: 120 million
- **356 vials**: 60 million

**DORIA® - RISPERIDONE ISM®**
- Pilot plant built to carry out the Doria® clinical trials.

**Madrid**
- **50** employees

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- 2019 REPORTING PERIOD
- ABOUT THIS REPORT
ROVI is going to reinforce its manufacturing lines with the construction of a second LMWH plant in Granada.

**Granada**
- Employees: 75
- International units (MUIs): 120 billion

**Alcalá de Henares**
- Employees: 286
- Tablets: 3,000 million
- Hard capsules: 300 million
- Sachets: 30 million
- 13 packaging lines, 6 of them for injectables

**Madrid**
- Employees: 50
- Pilot plant built to carry out the Letrozole ISM® clinical trials.

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[2] Employees shared between the two ISM® manufacturing plants
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MARKET ENVIRONMENT

In 2019, at least until December, the pharmaceutical market followed the path indicated in the latest IQVIA Institute report, “The Global Use of Medicine in 2019 and Outlook to 2023” which suggested growth expectations that would take global billing up to over 1.5 billion dollars. The accuracy of these forecasts and the favourable evolution of the sector could be seen last year when the MSCI World Health Care Total Return, an investment fund that replicates the return on an index composed of variable-yield securities in the healthcare sector in developed markets, rose by 22%.

However, a year ago, nobody could have predicted the appearance of coronavirus (COVID-19) in December 2019 or the tremendous impact that this would have. The consequence are not yet clear since, although it may seem that the pharmaceutical industry overall will benefit, either directly, through the development or manufacture of antiviral medicines, or indirectly, given the sudden demand for diagnostic kits, masks, gloves, etc. to combat the crisis that broke out from February 2020 onwards, the dimension of the situation is still being studied.

We should not forget that the measures imposed by the authorities in the worst months of the infection, which confined most citizens to their homes, as in the case of the State of Alarm declared in Spain, have an economic impact on companies and, as in the case of ROVI, especially those that have manufacturing processes that were restricted by these measures to control the rise in the cases of infection and, primarily, protect the healthcare system from collapse, even though they were necessary and appropriate.

At business level, it is true that the pharmaceutical sector is the one with the best prospects, given the defensive nature of the industry. Medicines are a basic necessity and are able to withstand economic slowdowns like the one that may come after the coronavirus epidemic. The expected fall in Chinese exports, especially in the pharmaceutical sector, is a factor that may benefit laboratories whose production is based in Europe or the United States, have their own development and do not depend on the supply of active substances from the East.
We cannot ignore the fact that the first symptom that the sector will become a haven for investors in 2020 is the growth of over 40% in the capitalisation of some Chinese pharmaceutical companies, a stock market surge that, according to some experts, both the United States and European markets are expected to replicate. However, other experts, such as Moody’s Investors Service have dampened the euphoria, stating that, “To the extent that the Chinese economy slows or healthcare resources are diverted to the coronavirus, growth in other pharmaceutical categories could decelerate”.

Beyond coronavirus: updated prospects

In its latest report dated 26 February, 2020, the consultancy firm IQVIA continues to bet on growth of between 3% and 6% until 2023. Three therapeutic areas will accumulate around 70% of the total absolute growth: oncology, anti-diabetics and autoimmune diseases.

Over the last five years (2015-2019) 52 new molecules have been launched in the oncology area, which shows the dynamic nature of the oncology market for both solid and haematological cancers. The oncology market is growing considerably, 21% in the last year, and new molecules launched since 2015 already account for 43% of this market, which had total billing of 3,582 million euros in 2019. Immunotherapy (the number of patients treated has tripled in the last two years), drugs for solid tumours and haematology launches are currently leading this growth.

Approximately 62 new molecules and 66 new indications are currently at advanced stages of study and those intended for treatment of gastrointestinal, oncohaematological and lung cancers may be highlighted.

The market of biological therapies for autoimmune diseases (AiB - Autoimmune Biologics) has been affected by the launch of biosimilars, which already total 39% of consumption of unpatented molecules. Likewise, the new molecules account for 18% of the total AiB market.

According to IQVIA, positive growth is expected in the hospital area until 2023, although there will be deceleration in comparison with previous years. As positive factors for the growth in value, it mentions:

- Ageing of the population.
- Large number of launches of innovative medicines: 239 products in the last five years with total consumption of ~ 4,261 million euros.
- Launch of orphan drugs.
- Increase in volume of patients treated:
  - Early diagnosis.
  - Updating of clinical guidelines.
  - Increase in life expectancy.
  - Chronic pathologies.

On the other hand, possible brakes that will be placed on growth in terms of value will be:

- New generic medicines and biosimilars.
- Centralised purchasing for hospital products.
- Innovative agreements: shared risks, payment for results in accordance with the cost efficiency of the treatment.
Evolution and prospects of the pharmaceutical market in Spain

Although the impact of coronavirus in Spain on the pharmaceutical sector may be positive in respect of short-term sales, the challenge will be to maintain the business’s long-term viability in the possible economic recession that may come afterwards. Before the current Spanish prime minister was sworn in on 7 January, the PSOE (Socialist Party) and UP (Unidas Podemos) published “Progressive Coalition: a new agreement for Spain”. This agreement includes 14 healthcare-related points that will set the guidelines for managing the healthcare system in Spain during this government’s term of office. From among them, two are particularly relevant to the pharmaceutical industry:

- Elimination of co-payment.
- Prioritisation of efficiency and transparency in medicine price fixing.

IQVIA’s latest report, dated February 2020, on the evolution of the pharmacy market in Spain said that the Spanish pharmaceutical market had changed its composition over the last five years, growth being driven by the hospital segment, calculated at +1.6% in value and +0.2% in units in the cumulative total for the last 12 months. The foregoing did not yet include the impact of product sales derived from the COVID-19 crisis. Up until then, the average consumption per inhabitant had grown more in value than in units, due to the increase of the average price to €12.05 (4.5%). In the last year, the hospital market had represented revenue of 11,439 million euros for the industry, with growth of 79.9%, accounting for 53% of the total, in comparison with the 10,282 million euros of the pharmacies (growth: 1.6%).

The average sales of a pharmacy have grown by 1.8% in the last year, 30% of these sales relating to consumer health products (consumer OTC, personal healthcare, patient care and nutrition). However, in spite of the good prospects the market has shown to date, there is a significant question mark in the light of a deteriorated economic situation that may have a great effect precisely on this product segment.

Since 2015, the penetration of generics in the market has remained stable, with a share of 40% in units and 21% in values. This is not expected to change because, as Farmaindustria has said, the branded pharmaceutical and the generic product cost the same in Spain. Therefore, there is no extra cost for either the patients or the National Health Service, which has meant that, in the first few months of 2020, branded products grew more than generics in values, reversing the trend of 2018 and 2019.

Evolution and prospects of the schizophrenia market

Schizophrenia is a chronic, progressive disorder that affects 21 million people worldwide and has an increasingly high lifetime prevalence.

Long-acting injectable technologies are becoming increasingly critical in this market and are becoming the option preferred by psychiatrists when tackling some of the essential unmet needs of the schizophrenia market.

The most important aspect is that they help improve patient adherence to treatment, which, in turn, lowers the rate at which patients stop taking their medication and, thus, reduces relapses and hospitalisations in cases of schizophrenia. Adherence to treatment is extremely important because each relapse leads to progressive and irreversible brain damage.

Long-acting injectables also reach therapeutic concentrations in plasma in a much faster and more sustained manner.
With regard to the scale of opportunities in the schizophrenia market and long-acting injectables in the United States and Europe:

- United States is the main schizophrenia market, with long-acting injectables sales of 4,000 million dollars, although penetration continues to be very low, with 5.9% in terms of units. The injectables market for schizophrenia in the United States grew by 21.9% from 2015 to 2018.

- Europe: (penetration of 8.3% in units) in a market of 1,500 million euros that grew by 7.9% from 2015 to 2018.

There is a very attractive opportunity for new players who can provide a differentiated long-acting injectable product, given certain features of this market.

The market is marked by three specific factors:

1. **A high rate of treatment changes.** Psychiatrists do not hesitate to change the treatment of patients who show a poor response due to secondary effects or relapses, until they find the drug most suited to the patient;

2. **There is a particularly attractive target market** of psychiatrists specialised in schizophrenia that any new player can cover with a small sales force; and

3. **The efficiency of long-acting injectables** is driving an increasingly early use of these injectables in the treatment paradigm, potentially acting in the initial phase or first episode of the disorder, rather than just after relapses (e.g. they are now used after the second relapse, while a few years ago they were used on the fourth relapse).

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Evolution and prospects of the hormone-dependent breast cancer market

The hormone receptor-positive (HR+) breast cancer market has fairly high lifetime prevalence and is expected to grow significantly over the next ten years.

It is forecast that revenue in the United States, Japan and the five most important EU markets will grow by 16.7% between 2015 and 2024. It is necessary to adhere strictly to treatment for at least three years to prevent relapses.

LAIs are not present in this market, although the easier dosing system will become the benchmark treatment, given the improved adherence to treatment and efficacy.

In the graph, the size of the market of oral letrozole and anastrozole, which are aromatase inhibitors, may be seen in units. It is a world market of 986 million units, in which Europe represents the largest market share (43%), with the United States in second place (32%).

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5 Data Monitoring Committee 2017.
6 LAI means Long-Acting Injectable.
7 IQVIA-Midas 2018: EUR is the whole of Europe; RoW, Rest of World, excludes Europe and United States.
The fact that LAIs do not exist in the market leads one to think that they may be a high rate of change from the oral medicine to the injectable. Likewise, there is a high percentage of the dynamic new treatment market that could use LAIs directly.

Attention should likewise be drawn to the fact that no new molecules are expected to replace the aromatase inhibitors. New treatments appearing in the market will be additional to hormone suppression treatments, since the risk/benefit profile of the aromatase inhibitors is already sufficiently good.

No company is researching in this field. The only company researching in the hormone-dependent breast cancer market is ROVI.

The world market of letrozole and anastrozole in units is 986 million. These units refer to daily tablets which, converted into annual treatments, would give a figure of 2.7 million treatments per year.

The potential market for Letrozole-ISM® would be 2.7 million annual treatments. The price of a Letrozole-ISM® injection is unknown but, as may be seen above, it is a very important market in which there are currently no players.

In addition, there is a third oral molecule, exemestane, also an aromatase inhibitor, that could be another candidate for replacement by LAIs. This molecule sells 117 million units worldwide, which represents an additional 322,000 treatments that could be added to the potential market of oral letrozole and anastrozole.

Since there are no competitors in the breast cancer market, the prostate cancer market is shown below. Breast cancer can be compared to prostate cancer because its behaviour is similar in terms of prevalence.

Gosrelin, histrelin, degarelix, leuprorelin and triptorelin are the molecules used to treat prostate cancer. These five molecules had a total market, in values, of 2.1 billion dollars in the United States and Europe in 2018. Unlike breast cancer, LAIs have a very significant presence in prostate cancer, accounting for 93% of the total market of LAIs and oral treatments in the United States and Europe.
STRATEGIC AND FINANCIAL PRIORITIES

ROVI’s forecasts for 2019 were amply surpassed by the results. Operating revenue forecast were raised twice during the year, the first time from a high single-digit to a low-teens figure and the second time from a low-teens to high-teens figure. Finally the operating revenue achieved was 26%, exceeding all expectations.

For 2020, ROVI expects the growth rate in operating revenue to be in mid-single-digit figures (i.e. between 0% and 10%). The company expects to continue growing by more than the 2019 growth in pharmaceutical spending in Spain, which was 3.0%, according to the figures published by the Ministry of Health, Consumption and Social Welfare.

Notwithstanding, given the uncertainties associated to the development of the Covid-19 pandemic (which ROVI will continue to monitor closely) and the duration of the State of Alarm, it is not yet possible to make a precise assessment of the impact that the pandemic will have on the current year. ROVI expects the main negative impact on group sales to take place in the second quarter of 2020.

Likewise, the potential increase in the discounts to the National Health System as a result of the Covid-19 impact may affect attainment of these growth forecasts.
Pharmaceutical specialties and toll manufacturing, two pillars for the success of the business

In 2019, the pharmaceutical specialty business, sales of which grew by 27%, amply surpassing the behaviour of the pharmaceutical market, and the toll manufacturing business, which grew by 20%, drove the growth in the company’s operating revenue up to 26%.

It is, therefore, likely that ROVI will continue to grow in forthcoming years as a result of the potential of its R&D product portfolio. The potential of the ISM® technology is particularly significant. A Phase III trial has been concluded, the dossier of which has already been registered in Europe, while registration in the United States is planned for the second half of 2020. Likewise, a Phase I trial is being developed for another candidate, also using ISM® technology, and the enoxaparin biosimilar is already being marketed in 13 countries, obtaining sales of 80.9 million euros in 2019, scarcely two years after the product was launched. ROVI is in an international expansion phase with the goal of its enoxaparin biosimilar being present in more than 120 countries in the long term.

ROVI expects its growth engines to be bemiparin, the distribution licence agreements, such as those for Neparvis® and Volutsa®, the enoxaparin biosimilar, the existing pharmaceutical specialty product portfolio, and the new products acquired recently (Falithrom® and Polaramine®).

Furthermore, at the end of last year, ROVI Pharma Industrial Services was born as a result of combining the company’s toll manufacturing management units (ROVI Contract Manufacturing y Frosst Ibérica). This entity inherits the good performance of the business and will be responsible for managing its future growth. 2019 sales rose by 20% in comparison with 2018, totalling 65.6 million euros, mainly due to the redirection of the toll manufacturing activities towards products with a higher value-added.

ROVI expects toll manufacturing to increase by a low-teens rate by the end of 2020, through new agreements with customers and use of the idle capacity of the manufacturing plants.

R&D&I, effort today for success tomorrow

ROVI remains convinced of the potential furnished by its solid R&D&I project portfolio. In this respect, it invests heavily in this aspect, given that it represents the company’s key growth factor in the future. In particular, ROVI’s confidence is placed principally in the ISM® technology, which belongs exclusively to ROVI and which, in 2019, continued to focus on developing the Phase III trial for Risperidone ISM® (Doria) and the Phase I of Letrozole ISM®.

Numerous scientific studies provide evidence that long-acting injectables (LAIs) are an important alternative to oral treatment for schizophrenia and, with DORIA®, ROVI aims to attain a prominent position in the schizophrenia treatment market. It is estimated that, in the United States and Europe, LAIs will represent a total market value of 5.5 billion dollars in 2018, 4.0 billion dollars in the United States and 1.5 billion dollars in Europe (source: IQVIA).

In 2019, the ROVI group concluded the development of its long-acting injectable (LAI) antipsychotic Risperidone ISM®, the first candidate of its leading-edge drug-release technology ISM®. The last phase of this included: (i) development of the pivotal study of Risperidone ISM® “PRISMA-3”, where the key primary and secondary endpoints were achieved with the doses evaluated to treat patients with acute exacerbation of schizophrenia; (ii) registration in the United States in the second half of 2020; and (iii) the registration dossier was approved by the European Medicines Agency (EMA) in February 2020.

(8) https://clinicaltrials.gov/ct2/show/NCT03160521. This clinical programme has enjoyed the support of the Industrial Technological Development Centre (CDTI).
and (ii) the development of the BORIS® study, in which the bioavailability of multiple doses of oral risperidone was compared with that of multiple doses of Risperidone ISM® in patients with stable schizophrenia, thus ending the Clinical Research Programme. Likewise, an open-label extension of the PRISMA-3® study has now concluded and will provide clinical and safety data on the long-term use of Risperidone ISM® (an additional 12 months).

In January 2020, after the documentation filed to obtain marketing authorisation for Doria® in the European Union (EU) had passed the validation process, the dossier registered by the company commenced its evaluation process. It is estimated that the evaluation phase of the Centralised Procedure used by the company to register Doria® in the EU may take approximately one year as from validation. It is also planned to initiate the process of registering Doria® with the United States regulatory authorities, the U.S. Food and Drug Administration (FDA), during the second half of 2020.

In addition, the company has announced the commencement of the clinical development of Letrozole ISM®, which is the second candidate based on ROVI’s ISM® technological platform. This new medicine (in the clinical research phase) will be the first long-acting injectable aromatase inhibitor drug for treatment of hormone-dependent breast cancer.

The first Phase I clinical trial (the LISA-1™ study) of Letrozole ISM® is currently underway and, due to the design of the study (“dose escalation”) and its exploratory nature, the date of finalisation cannot be forecast. Notwithstanding, preliminary data confirm that the ISM® formulation provides a prolonged release of letrozole that produces sustained suppression of the oestrogenic hormones.

Finally, ROVI’s R&D team has recently begun to develop a new three-monthly formulation of Risperidone ISM®, which would complement the present formulation of Doria® for maintenance treatment in patients with clinically stable schizophrenia. This development is still at an initial pre-clinical stage.”

ISM® technology: the future of ROVI’s products and licences

ROVI’s ISM® technology is an innovative drug-release platform, developed internally and patented by the company, that allows the sustained release of compounds administered by injection. Its success is guaranteed by factors such as a highly-efficient medicine retention, excellent stability of the active substance and a high degree of control over the initial drug release. In addition, the ISM® technology has the advantage of eliminating the need for cool storage of the commercial product, providing flexible dosing from one to six months, and patent protection until 2033.

ROVI’s ISM® technology has been developed in order to overcome the disadvantages of the prolonged release that has existed to date, providing injectable formulations that furnish greater simplicity, efficacy and stability. There is great potential for extensive application of ISM® technology to new chronic therapeutic areas, including psychiatry and oncology. Our vertical integration and experience in manufacturing prefilled syringes place us in a leading position in the market.

Additionally, attention should be drawn to the fact that ROVI has designed a research financing plan for its ISM® technology platform, running from 2018 to 2021. The formula used is based on a combination of the funds obtained from the capital increase conducted in October 2018, the internal cash flow generated by the group and its debt capacity. In the fourth quarter of 2019, 40 million euros were drawn down against a credit line granted by the European Investment Bank (EIB) in 2017.

(9) https://clinicaltrials.gov/ct2/show/NCT03527186
(10) Study to Evaluate the Efficacy and Safety of Risperidone ISM® in Patients With Acute Schizophrenia: Open Label Extension (PRISMA-3_OLE). Clinicaltrials.gov# NCT03870880
(11) Evaluation of IM Letrozole ISM® Pharmacokinetics, Safety, and Tolerability in Healthy Post-menopausal Women (LISA-1). Clinicaltrials.gov#NCT03401320 This clinical programme has enjoyed the support of the Industrial Technological Development Centre (CDTI).
There is great potential for extensive application of ISM® technology to new chronic therapeutic areas.

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<th>Key Highlights of ISM® Platform</th>
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| **Vertical integration** | • Technological barriers  
• Strong IP  
• Manufacturing capabilities | • Protected technology  
• Fully integrated manufacturing plants |
Impact of Covid-19 on ROVI’s strategy

At the time this document was under preparation, the company was expecting an adverse impact in the sales of the second quarter of 2020, due to the uncertainty created by the pandemic and the measures that governments all over the world were taking to contain it.

At any event, the health crisis does not change ROVI’s plans as far as implementing its strategy is concerned. ROVI’s low-molecular-weight heparins, bemiparin and the enoxaparin biosimilar, have been recommended by the World Health Organisation (WHO) as essential medicines for patients hospitalised in intensive care units with Covid-19, which will presumably offset the decrease in the consumption of these medicines due to the reduction of surgical operations during the period of confinement. R&D activities have not been affected and no delay is expected in the approval process for Doria® in Europe or the registration of said medicine in the United States. However, given the circumstances that affect the health authorities, neither can changes in the forecast calendars be ruled out. The company has implemented measures to ensure that all the plants operate normally and productivity has only been slightly impaired by the various preventive sanitisation and safety measures related to Covid-19. The company, which commenced the year with a sound financial position, has signed new credit policies to ensure liquidity.

In summary, in spite of the uncertainty, ROVI is continuing with its process of transformation and the implementation of its strategic plan focused on the expansion of its enoxaparin biosimilar and its products Doria® and Letrozole-ISM®, candidates that validate its prolonged drug release technology, ISM®.
At ROVI, CSR is a key factor in its business strategy. The group considers it vital in ensuring the company’s long-term sustainability and reinforcing the confidence of the different stakeholder groups with which it is involved. It is a commitment acquired with society, given the importance of ROVI’s work and the impact of its products on improving people’s health and quality of life.

Thus, a response is sought to certain social demands related to the impacts of our activities on society and the environment. For this reason, the group has put policies in place that express ROVI’s commitment in respect of business ethics and corporate social responsibility and serve as guidance for the actions taken by the Board of Directors and other group bodies in their relations with stakeholders.

These policies materialise in elements such as the Annual CSR Report, the Integrated Management Policy or the Code of Ethics, which are considered tools to achieve the 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 general action principles, which appear in the General CSR Policy (see page 24).
66 · Corporate governance model
67 · Corporate governance bodies
75 · Remuneration policy
77 · Ethics framework
79 · Risk management
CORPORATE GOVERNANCE MODEL

The corporate governance of Laboratorios Farmacéuticos Rovi, S.A. (the “Company” or “Rovi”) takes current recommendations on the subject into account both nationally and internationally. In particular, its 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 proper and transparent management of the company as an essential factor in generating value therein, improving financial efficiency, reinforcing the confidence of investors and stakeholders, and ensuring that the interests of all 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 may 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 ensuring 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. To this end, each year, Rovi presents an Annual Corporate Governance Report and Annual Director Compensation Report and regularly submits the mandatory financial information on the company and its group to the CNMV to be disclosed publicly to the market. Furthermore, Rovi 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 (which amended 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, in relation to non-financial information and diversity). The statement of non-financial information and diversity 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 the group’s principal managers, headed by the CEO.
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 regularly, 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 deemed to be 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 identify him/herself and show 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.
General Shareholders’ Meeting 2019

The most recent Ordinary General Shareholders’ Meeting of Laboratorios Farmacéuticos Rovi, S.A. was held in Madrid on 12 June, 2019 on the first call, with a total of 50,584,362 shares in attendance (36,172,584 present and 14,411,778 represented), representing 90.218% of the share capital (64.514% present and 25.704% represented).

Among the resolutions passed at the Meeting were: (i) approval of the individual and consolidated annual accounts; (ii) approval of the statement of non-financial information included in the consolidated management report for the reporting period ended 31 December, 2018; (iii) approval of the proposed application of the individual profit for the reporting period ended 31 December, 2018; (iv) approval of the management and performance of the Board of Directors during the reporting period ended 31 December, 2018; (v) re-election of Mr José Fernando de Almansa Moreno-Barreda and Mr Marcos Peña Pinto as independent external directors for the bylaw-stipulated term; (vi) approval of the maximum annual remuneration of the Board of Directors in their capacity as such for the 2019 reporting period; (vii) approval of the director remuneration policy for the period 2020-2022; (viii) authorisation of the Board of Directors for the derivative acquisition of treasury shares by the company and/or its subsidiaries in the terms set out in current legislation; (ix) delegation to the Board of Directors of the power to increase the share capital under the terms and conditions of article 297.1.b) of the Capital Companies Act for a maximum period of five years, including the power to exclude pre-emptive subscription rights; (x) delegation to the Board of Directors during the reporting period ended 31 December, 2018; (xi) delegation of powers to formalise and register the resolutions passed by the General Meeting and carry out the mandatory filing of the accounts.

Board of Directors

The Board of Directors is the company’s highest decision-making, supervision and control body, except in matters reserved to the General Shareholders’ Meeting. It is currently formed by seven members: three executive directors, one proprietary director and three independent directors. The independent directors were appointed on the basis of their professional 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 general supervisory duties. This implies guiding 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 the company’s compliance with laws and regulations and fulfilment of its obligations and contracts in good faith, as well as respect for the customs and good practices of the sectors and territories where it carries on its activities and observance of the additional social responsibility principles that it has accepted voluntarily. Likewise, its functions include ensuring that no one person or small group exercises decision-making power within the company without being submitted to counterweights and controls and that no shareholder is treated more favourably than others.

Its 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 2019, the Board of Directors met on eight 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 2019 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 annual evaluation of the performance of the Board of Directors in 2017 was drawn up with the support of an external advisor, Price-waterhouseCoopers 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 RO-VI’s Board of Directors and did not give rise to significant changes in its internal organisation or the procedures applicable to its activities.

Board of Directors

<table>
<thead>
<tr>
<th>Position</th>
<th>Type of Director</th>
<th>Nomination and Remuneration Commission</th>
<th>Audit Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mr Juan López-Belmonte López</td>
<td>Chairman</td>
<td>Proprietary</td>
<td></td>
</tr>
<tr>
<td>Mr Juan López-Belmonte Encina</td>
<td>Chief Executive Officer</td>
<td>Executive</td>
<td></td>
</tr>
<tr>
<td>Mr Iván López-Belmonte Encina</td>
<td>First Deputy Chairman</td>
<td>Executive</td>
<td></td>
</tr>
<tr>
<td>Mr Javier López-Belmonte Encina</td>
<td>Second Deputy Chairman</td>
<td>Executive</td>
<td></td>
</tr>
<tr>
<td>Mr José Fernando de Almansa Moreno-Barreda</td>
<td>Director</td>
<td>Independent</td>
<td>Chairman</td>
</tr>
<tr>
<td>Mr Marcos Peña Pinto</td>
<td>Lead Director</td>
<td>Independent</td>
<td>Member</td>
</tr>
<tr>
<td>Ms Fátima Báñez García</td>
<td>Director</td>
<td>Independent</td>
<td>Member</td>
</tr>
</tbody>
</table>
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 President of the Madrid Chamber of Commerce from March 2016 to April 2018. Likewise, he has been President of Asociación para el Autocuidado de la Salud (ANEFP) and Vice President 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 at the General Meetings of 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 from Universidad Complutense de Madrid in 1993. He is a shareholder of Norbel Inversiones, S.L., in which he holds 26.67% (and which is also the company’s controlling shareholder), and the General Manager and CEO of ROVI. 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 in different professional areas of important international pharmaceutical companies in the United States and United Kingdom. He has been working for the company since 1994, was appointed General Manager in October 2001 and, since October 2007, has been the company’s CEO. He was initially appointed to the company’s Board of Directors on 27 July, 2007 when ROVI was first listed on the securities markets and was re-elected at the General Shareholders’ Meetings of 2012 and 2017. Currently, Mr. López-Belmonte Encina is a member of the Boards 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. 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 is a shareholder of Norbel Inversiones, S.L., in which he holds 26.67% (and which is also the company’s controlling shareholder) and First Deputy Chairman of ROVI’s Board of Directors. He began his professional career in Germany, working in companies like Amersham, engaged in nuclear medicine, and Hexal AG, specialised in generics. He has been working for the company since 1995 and has been ROVI’s Corporate Development Manager since September 2007. He was initially appointed to the company’s Board of Directors on 27 July, 2007 when ROVI was first listed on the securities markets and was re-elected at the General Shareholders’ Meetings of 2012 and 2017. Currently, Mr. López-Belmonte Encina is a member of the Boards of Directors of Norbel Inversiones, S.L. and Norbepa Inversiones, S.L., the joint and several administrator of Bertex Pharma GmbH, and Chairman and legal representative of Enervit Nutrition, S.L.

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 is a shareholder of Norbel Inversiones, S.L., in which he holds 26.67% (and which is also the company’s controlling shareholder) and Second Deputy Chairman of ROVI’s Board of Directors. He began his professional career in the banking sector in 1998, working for Argentina, S.A. in the United Kingdom as an analyst, and in the pharmaceutical sector with Medeva Pharma, also in the United Kingdom. He joined ROVI in the year 2000 and has been Chief Financial Officer since 2001. He was initially appointed to the company’s Board of Directors on 27 July, 2007 when ROVI was first listed on the securities markets and was re-elected at the General Shareholders’ Meetings of 2012 and 2017. He has been Vice President of CEIM, a member of its Management Board and Chairman of its Health Commission. Likewise, he has been a member of the Social Council of the Universidad Autónoma de Madrid representing CEIM and a member of the Board of Trustees of Fundación Universidad Autónoma de Madrid, representing the Social Council of the Universidad Autónoma de.
Mr. José Fernando de Almansa Moreno-Barreda

Mr. Almansa holds a degree in law from the University of Deusto (Bilbao). Diplomat. 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 Subdirektorat-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 Sub-director General for Eastern Europe, reporting to the Directorate-General of Foreign Policy for Europe. From 1993 to 2002, H.M. King Juan Carlos I appointed him as Head of the Royal Household with the rank of minister and he was appointed as a privy councillor of His Majesty King Juan Carlos I. He was a member of the Board of Directors of Telefónica, S.A. from 2003 to 2016, holding the position of chairman of the International Affairs Commission of its Board and forming part of several subsidiaries of Telefónica, S.A. in Latin America as a Board member. Likewise, from 2003 until 2015, he formed part of the Board of the Mexican bank BBVA BANCOMER. Currently, he is a director of Teléfonica Móviles, S.A. in Mexico. He has been a director of ROVI since 9 June, 2015, having been re-elected at the 2019 Ordinary General Meeting.

Mr. Marcos Peña Pinto

Mr Peña Pinto holds a law degree from the Universidad Complutense de Madrid and passed the official examination to become a Technical Labour and Social Security Inspector. From 1984 to 1989, Mr Peña held the position of Labour Attaché at the Spanish Embassy in Italy. Subsequently, from 1991 to 1996, he was the Secretary-General for Health at the Ministry of Health and Consumption and Secretary General for Employment and Labour Relations at the Ministry of Labour. Between 2005 and 2006, he was appointed an expert member of the Economic and Social Council, which he presided until April 2019. Likewise, Mr Peña Pinto has been a member of the Council of State due to his position as president of the Economic and Social Council. Regarding his other professional activities, special mention should be made of the fact that Mr Marcos Peña is specialised in collective bargaining and has held the position of chairman of the Bargaining Committee for many collective labour agreements (e.g. Telefónica, Renfe, Repsol, Alcatel, Endesa, Astilleros, etc.). Furthermore, Mr Peña Pinto has been an arbitrator and mediator in various labour conflicts on a nationwide scale and is the author of numerous publications, often publishing articles in the written press. He was appointed as an independent director of the company by co-option, accepting his appointment on 9 May, 2019 and being re-elected at the Ordinary General Shareholders’ Meeting of 12 June, 2019.

Ms. Fátima Báñez García

Ms Báñez García holds a combined degree in Law and Economic and Business Sciences from the Universidad Pontificia de Comillas -ICADE E-3- and continued her academic education with a postgraduate degree in Company Administration from the University of Harvard, Boston, MA, likewise completing the Public Management Leadership Programme at the IESE Business School. She was Minister of Employment and Social Security in the Spanish government from December 2011 to June 2018, and provisional Minister of Health, Social Services and Equality from August to November 2016. Also in the public area, she was member of the Spanish Congress of Deputies for Huelva (2009-2019), holding important responsibilities in the economic area of the Popular Parliamentary Group, as well as the position of chairperson of the Foreign Affairs Commission of the Lower Chamber (2018-2019). Previously, from November 1997 to June 2000, she was a member of the Board of Directors of Televisión de Andalucía. She began her professional life in the private sector as head of Corporate Strategy and Development of her family’s company group (1993-1997) and returned to private activity as a business consultant and advisor in November 2019. She has extensive international experience, having represented Spain on the EPSCO Council, at the G-20, at the Ibero-American Summits and at meetings of the OECD and ILO, as well as at international employment forums. She was appointed as a director of the company by co-option and accepted the position on 20 December, 2019.
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 chairperson is also an independent director and must be replaced every four years, although they can be re-elected when one year has elapsed since they left the position. The Commission’s main role is to report 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 remuneration policy for directors and senior management, established by the company and approved by the General Shareholders’ Meeting, is observed and is transparent. In 2019, it met on seven 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 chairperson is also an independent director, likewise appointed on the basis of their knowledge and experience in accounting, auditing or both, and must be replaced every four years, although they can be re-elected when one year has elapsed since they 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 2019, the Committee held eight meetings. Therefore, its meetings were sufficiently frequent to allow it to carry out its duties correctly.

The Audit Committee and the Nomination and Remuneration Commission are formed by independent directors
Management Committee

The Management Committee has 12 members drawn from Group senior management 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. Javier López-Belmonte Encina. Chief Financial Officer.
- Mr. Iván López-Belmonte Encina. Corporate Development Manager.
- Mr. Francisco Javier Ángulo García. Human Resources Manager.
- Ms. Mercedes Benítez del Castillo Sánchez. Legal Department Manager.
- Mr. Pedro Carretero Trillo. Hospital Network Manager.
- Mr. Miguel Ángel Castillo San Román. International & Business Development Manager.
- Mr. Fernando Martínez Garljo. Sales Effectiveness Manager.
- Mr. Miguel Ángel Ortega Sánchez. Industrial Manager.
- Ms. Beatriz Ávila Alcalde. Sales Manager- Line B.
- Mr. Juan López-Belmonte Encina. Chief Executive Officer.
- Mr. Ibon Gutierrez Aduriz. Corporate R&D Manager.

This Committee reflects Rovi’s commitment to promoting a policy of equal opportunities for men and women, avoiding discrimination based on gender or other factors 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 approximately 25% of the total members.
Incorporation of CSR into management

ROVI considers Corporate Social Responsibility (CSR) 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 promote the prevention and knowledge of certain diseases.

Likewise, we wish to highlight the fact that 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 and article 12.e) of the Regulations of the NRC, 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 2019, subsequent to a favourable report from the Nomination and Compensation Commission, the Board of Directors examined and approved the Corporate Social Responsibility Report for the period, 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.
REMUNERATION POLICY

In compliance with article 14 of the Regulations of the company’s Board of Directors, which incorporates the provisions of article 529 quindices, 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 Remuneration Commission (NRC) prepared a remuneration policy for the company’s senior management in 2019, which was submitted to the Board of Directors for approval.

Likewise, in accordance with article 529 novodecies of the Capital Companies Act, at the proposal of the Board of Directors subsequent to a report from the Nomination and Remuneration Commission, the General Shareholders’ Meeting of ROVI held on 12 June, 2019 approved the company’s Director Remuneration Policy, the text of which was made available to shareholders when the General Meeting was called and which replaced the remuneration policy approved at the General Meeting held on 31 May, 2016, which was in force until the end of 2019. This new policy is applicable for the period 2020-2022, unless the General Meeting agrees to change or replace it during said period.

Consequently, the Company distributed among its members a sum of 510,000 euros of the aforementioned maximum amount approved by the General Meeting as fixed annual remuneration for Board members for performing their duties as such in 2019. The sum was allocated taking account of the duties and responsibilities attributed to each director and whether or not he or she was a member of Board committees. All the foregoing was in accordance with a prior proposal from the NRC.

Likewise, the Board decided to distribute fixed global annual remuneration of 787,000 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 NRC.

Regarding the variable incentive for the executive directors, the Board distributed 383,000 euros at the proposal of the Nomination and Remuneration Commission, taking account of the company’s results for 2019 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 attainment of strategic alliances during the year, that 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 2019, 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.

Finally, the total remuneration paid to senior management personnel in 2019, excluding the sum received by the executive directors, was 1.894 million euros (1.773 million euros in 2018).
The body responsible for ensuring compliance with the Code of ethics is the Audit Committee

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, 2018, 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, team work, efficiency, or the competitiveness that always 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, 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 Audit Committee, which delegated the day-to-day exercise of these powers to the ROVI group’s Compliance Function, to which, in accordance with the “Regulatory Compliance Function Charter”, approved by the Audit Committee on 25 July, 2017, the supervision of ROVI’s Code of Ethics is assigned, among many other duties.
Employees and suppliers

In 2019, ROVI personnel received training in the Code of Ethics, imparted by the Compliance area. Said training had two main goals:

- 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.
- To provide training on all the action principles 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 respect not only 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.

Ethics Channel

ROVI has “Regulations of the Ethics Channel for Employees and Suppliers”, the latest update of which was approved by the Audit Committee on 7 May, 2019. They establish that the management body of ROVI’s ethics channels is the Ethics Channel Management Committee, which is likewise responsible for ensuring that all complaints submitted through the channel receive attention and are managed appropriately, in full and confidentially. Said body is responsible for analysing cases of non-compliance and proposing corrective actions. Possible sanction 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 canal@ROVI.es, or by physical mail.

Likewise, ROVI has an Ethics Channel for suppliers, partners, external collaborators, etc. that allows them to report any irregularity they may detect or any breach of the ROVI group’s Code of Ethics for Suppliers 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 canaletico-proveedores@rovi.es is included, as well as a physical mailbox at ROVI’s offices.

Human Rights

ROVI undertakes to actively support the Universal Declaration of Human Rights and requires its employees to comply with said principles in their day-to-day activity in the group. The company combats practices contrary to human dignity and workplace discrimination.

Good Governance Code

The group also strives to monitor 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.

Internal Regulations on Conduct

Finally, ROVI has Internal Regulations on Conduct in the Securities Markets, the latest version of which was approved by the Board of Directors on 7 May, 2019. 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 securities market-related legislation.

No complaints related to the financial reporting were received in 2019.
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:

1st line

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.

2nd line

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.

3rd line

The third line of defence is Internal Audit, which supervises the internal control and risk management systems by auditing both the first and second lines of defence.
Responsibility for risk control, monitoring and management

According to the 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, last updated in November 2019, which includes ROVI’s general risk management principles, was approved. According to this Policy, the bodies involved in said management are:

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<thead>
<tr>
<th>Audit Committee</th>
<th>Management Committee</th>
<th>Head of Risk Management and Control System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body responsible for reviewing and supervising the company’s internal control and risk management systems, as well as their efficacy, so that the main risks can be appropriately identified, managed and made known.</td>
<td>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.</td>
<td>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 any risks that may have materialised.</td>
</tr>
</tbody>
</table>

The Risk Management and Control Policy was updated in November 2019
Risk Control and Management Process

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

**Fixing the risk level**
Annually, the Audit Committee establishes a risk assessment scale in accordance with the possible impact (financial, strategic, reputational, etc.) and the probability of occurrence.

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

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

**Determination of the response to a risk**
Measures are adopted to tackle any risks identified as efficiently and economically as possible, minimising exposure. At the same time, mechanisms and procedures must be put in place to allow management to supervise the implementation of actions to neutralise any risk detected and control the efficacy of these actions.

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

**Reporting to the Audit Committee**
The Audit Committee is informed regularly on the following aspects of risk management:

- 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.
Risk map

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

### Strategic risks

- Changes in the conditions for the supply of raw materials and other packaging materials necessary for the manufacture of its products.
- Failure to conclude successfully -or as expected- the Research & Development products that are underway at ROVI.
- Actions by the competition that cause a negative impact on ROVI’s sales.
- Changes in the prescription criteria or in the market regulations aimed to contain pharmaceutical spending (price control, reference prices, reinforcement of generic products, co-payment, purchasing platforms).

### Compliance risk

- Tax risk inherent to the activity of companies of the size and complexity of the group.

Response and supervision plans for ROVI’s main risks

ROVI permanently monitors and is alert to any risks that might have an adverse effect on its business activities, applying the appropriate mechanisms to manage them and continually developing contingency plans able to reduce or offset their impact. Among them, we highlight the fact that ROVI:

- Continues with the diversification of suppliers of raw materials and other packaging materials necessary for the manufacture of its products.
- Continues to pursue its goal of constantly opening up new markets through its international expansion project.
- Continues to enhance its processes and controls, including those related to the internationalisation process.
- Is working intensively to maintain broad and diversified portfolios of products and customers.
- Perseveres each year with an internal savings plan, which has focused mainly on improving the efficiency of its internal and external operating processes.
- Performs strict credit control and carries out effective cash management, which assures that sufficient working capital is generated and maintained to permit day-to-day transactions to be performed.
- Has an exhaustive tax risk control system and external tax advisors who review the preparation and filing of the various taxes, as well as the tax decisions made by the group.
Risks materialised in 2019

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

The principal raw material for manufacture of our two low-molecular-weight heparins (bemiparin and the enoxaparin biosimilar) is sodium heparin, which is obtained from pig mucosa. Therefore, any disease that affects pigs may have an effect on the global heparin market by affecting either the supply or the prices.

Since the end of 2018, there has been an outbreak of swine fever in China, the main producer of pork and pork derivatives worldwide, which has already had an effect on prices, which have increased. In 2020, the upward trend is expected to continue.

Regulatory difficulties in respect of local requirements

Due to ROVI’s swift international expansion, which has led to the opening of five subsidiaries and the direct marketing of its products in a number of European countries in a short time period, ROVI has had to make adjustments to comply with local regulatory requirements, given that the pharmaceutical market in each country is heavily regulated, specific requirements exist in this respect in each country and, even within the same country, regulations may differ depending on the region.

Incident Management and Crisis Resolution

Additionally, in 2019, the ROVI group created an IMCR (Incident Management and Crisis Resolution) work team, which furnishes the company with a work procedure that favours an appropriate sizing and handling of incidents. The team is permanently composed of members of the group’s Industrial, Compliance and Communication Departments and, in addition, the heads of other areas whose presence is required to handle and solve any incidents detected may also take part in IMCR.

The procedure initiates when any of the following incidents are detected:

- Reputational risk, in any of its categories, for the company.
- Natural disasters: floods and earthquakes.
- Extortion.
- Threats.
- Workplace or trade union-related incidents or strikes affecting the business.
- Significant environmental or workplace health and safety incidents.
- Serious pharmacovigilance or quality incidents when a product is being marketed.

If any of these situations is detected, an internal communication chain is activated, in order to gather information on the incident, its potential origin and its potential scope. The matter will be passed to the IMCR team so that, after analysing and assessing the incident, it will adopt the appropriate measures in accordance with the specific needs for each incident.
Contingency plans for Covid-19

Since the beginning of the propagation of Covid-19 in the first quarter of 2020, ROVI put in place the contingency plans necessary to guarantee the health and safety of its employees and the people who work with it and ensure the continuity of the business, as well as to fulfil its responsibility of supplying medicines to the hospitals of Spain and Europe.

Among the measures taken, ROVI reduced the processes that must be performed in person at its facilities to a minimum, so that employees could work from a distance. Where home working is not possible, especially at the manufacturing plants, ROVI has kept its production activities at a relatively normal level, with the relevant safety measures.
Control and management systems in relation to the process of issuing financial information (ICFR)

As a listed company, an important part of ROVi’s risk management is related to the system of Internal Control over Financial Information (ICFR), the purpose of which is to ensure reasonable certainty that the financial reporting is reliable and which requires an assessment of the risk of error or fraud in said information. The bodies responsible for ICFR are:

**Board of Directors**

Responsible for the existence and continuity of an appropriate and effective ICFR in accordance with the version of the Regulations of the Board of Directors approved on 26 April, 2016.

**Senior Management**

Performs the functions of implementing and designing the ICFR, as is likewise set out in the aforementioned Regulations.

**Audit Committee**

Is the body responsible for overseeing ICFR, as stated in the company’s Bylaws, the Regulations of the Board of Directors and the Regulations of Audit Committee, which assign the following responsibilities, among others, to it:

- To oversee the process of preparing and presenting the official financial reporting of the company and, where applicable, the group, and ensure it is complete, reviewing compliance with legal requirements, the correct delimitation of the consolidated group and the proper application of accounting policies, and to put forward recommendations or proposals aimed to safeguard the integrity of the financial reporting to the Board of Directors.

- To regularly review and oversee the internal control and risk management systems and the efficacy thereof, in order for the main risks to be identified, managed and made known appropriately.

- To review the clarity and integrity of all the financial reporting and related non-financial reporting that the entity makes public, such as the financial statements, management reports, risk management and control reports and corporate governance reports, evaluating in which cases the statutory auditors should be involved in reviewing any of the reports in addition to the financial statements.

The risk identification process in the ICFR area takes account of the effect of other types of risk, such as operating, technological, legal, reputational and environment risks, etc., which may have a material impact on the financial reporting.

These risks are managed and assessed as set out in the Risk Management and Control Policy.
88 · Results for the period

110 · Customers patients and professionals

114 · Human resources

134 · Suppliers

137 · Society and public authorities

144 · Environment
RESULTS FOR THE PERIOD

In 2019, ROVI amply surpassed its growth forecasts, with an increase of 26% in operating revenue, equivalent to a figure of 381.3 million euros, mainly due to the strength of its pharmaceutical specialty business, which grew by 27%, well above the growth rate in the rest of the pharmaceutical market. Another of the pillars of the group’s good results last year was the toll manufacturing business, sales of which increased by 20%.

Total revenue was 382.5 million euros, 25% higher than in 2018. This is a milestone and represents more than three times ROVI’s sales in 2007, when the company was first listed on the securities markets.

Sales outside Spain grew by 50% in comparison with the preceding year, totalling 149.0 million euros in 2019, 41.6 million euros of which (i.e. 28% of the total) related to sales at the international offices, mainly of the enoxaparin biosimilar. Sales outside Spain accounted for 39% of operating revenue in 2019, in comparison with 33% in 2018.

Gross profit rose by 23% in comparison with the preceding year, totalling 215.9 million euros in 2019, reflecting a 1.5 percentage point decrease in the gross margin, which dropped to 56.6%, in comparison with 58.1% in 2018. This fall in the gross margin was mainly due to the increase in sales of the enoxaparin biosimilar, which contributed lower margins in 2019 after the launch of the product in five new markets; and the increase in raw material prices for low-molecular-weight heparins, which, in 2019, were around 44% higher than the 2018 prices. ROVI predicts that this upward trend in raw material prices for low-molecular-weight heparins will increase in 2020. The foregoing, combined with the uncertainty as to the possible impact of the coronavirus, makes it difficult, as of today’s date, for the company to forecast the effect of these aspects on its 2020 gross margin.
EBITDA rose by 106% in comparison with the preceding year, totalling 60.9 million euros in 2019 and reflecting an increase of 6.2 percentage points in the EBITDA margin, which increased to 16.0% in 2019 from the 9.7% of 2018. EBIT increased by 144% on the previous year, totalling 42.6 million euros, which represented a 5.4 percentage point increase in the margin to 11.2% in 2019 from 5.8% in the preceding year. Finally, net profit rose to 39.3 million euros in 2019, a 119% increase on 2018.

Likewise, if the same amount of R&D expenses as recorded in 2018 is maintained in 2019 and the impact of non-recurring expenses excluded, EBITDA would have grown by 89% in comparison with the preceding year, totalling 57.8 million euros in 2019 and showing an increase of 5.1 percentage points in the EBITDA margin, which would have risen to 15.2% in 2019 from 10.1% in 2018. EBIT would have risen by 113% on the previous year, to 39.6 million euros in 2019, with growth of 4.3 percentage points in the EBIT margin, from 6.1% in 2018 to 10.4% in 2019, and the net profit would have risen by 91% in comparison to the preceding year, totalling 36.4 million euros.
Results of the pharmaceutical specialties business

According to IQVIA, the innovative product market rose by 2% in Spain in 2019 in comparison with 2018. The strength of ROVI’s business model has allowed it to take advantage of this situation, obtaining a 30% increase in prescription-based pharmaceutical sales and a sales figure of 281.0 million euros, which surpassed the result of the overall market by 28 percentage points.

**Low-molecular-weight heparin**

Sales of the low-molecular-weight heparin (LMWH) division increased by 46% to **177.6 million euros in 2019**. The enoxaparin biosimilar and bemiparin business accounted for 47% of operating revenue in 2019, in comparison with 40% in 2018.

**Enoxaparin biosimilar**

Sales of the enoxaparin biosimilar were multiplied by 2.7 and totalled 80.9 million euros in 2019. This was especially satisfactory for a product that was first marketed in 2017, when marketing commenced in Germany, subsequently continuing in 2018 in United Kingdom, Italy, Spain, France, Austria, Latvia and Estonia, and, in 2019, reached Portugal, Poland, Costa Rica, Sweden and Finland.

**Bemiparin**

Sales of bemiparin, ROVI’s low-molecular-weight heparin (LMWH) behaved positively in Spain in 2019 through the brand Hibor®. They grew by 3% to 69.6 million euros. However, where they stood out was in international sales, where bemiparin sales increased by 14% to 27.2 million euros, mainly due to the positive contribution of some countries where the product had already been present in 2018, such as Turkey and the Czech Republic. Total sales rose by 6% to 96.8 million euros in 2019.
Enoxaparin biosimilar: ROVI’s present and future

ROVI began to market its enoxaparin biosimilar in Germany in September 2017 and in the United Kingdom, Italy, Spain, France, Austria, Latvia and Estonia in 2018. Likewise, ROVI began to market it in Portugal, Poland, Costa Rica, Finland and Sweden in 2019.

In addition to the aforementioned European countries, as of December 2019, ROVI had signed marketing agreements for its enoxaparin biosimilar in 85 countries. Among these, we may highlight the agreements with Hikma Pharmaceuticals PLC, a listed multinational pharmaceutical group (LSE:HIK) for the exclusive marketing of the enoxaparin biosimilar in 18 MENAI (Middle East and North Africa) countries, and Sandoz, a division of Novartis AG and a world leader in generic medicines and biosimilars, for distribution and marketing of the product in 14 countries/regions (Australia, New Zealand, Philippines, Hong Kong, Singapore, Vietnam, Malaysia, Canada, South Africa, Brazil, Colombia, Argentina, Mexico and Central America).

Through its two flagship products, bemiparin and the enoxaparin biosimilar, ROVI is betting on becoming one of the main European players in this market, the size of which is approximately 1.4 billion euros worldwide. To achieve this, in 2019, it announced the future construction of a new manufacturing plant for the active substance of low-molecular-weight heparins (LMWH), for which it has acquired industrial land in the Metropolitan Industry and Technological Park in Escúzar, Granada.

This operation will require an investment of around 24 million euros over the three years following the announcement; it will double the ROVI group’s LMWH production capacity; and is intended to ensure the company’s future production capacity and respond to its strategic growth in the LMWH field.

ROVI thus continues to support the development of the province of Granada and of Andalusia, where, in a first phase that will last until 2023, the construction of the new plant will create estimated net employment of 38 jobs.
Sales of Neparvis®, a prescription-based product belonging to the company Novartis and indicated in adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction, which ROVI has been distributing in Spain since December 2016, increased by 62% to 22.0 million euros (13.6 million euro in 2018).

Sales of Volutsa®, a prescription-based product of the company Astellas Pharma indicated for treatment of moderate to severe storage systems and voiding symptoms associated with benign prostatic hyperplasia, increased by 18% to 13.3 million euros.

The following products appeared on ROVI’s portfolio for the first time in 2019:

**Falithrom®**
A medicine used to prevent and treat 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 this product which, in Germany alone, where it is marketed directly by ROVI, obtained sales of 3.5 million euros in 2017.

**Polaramine® (tablets, syrup and cream) y Polaracrem™ (cream)**
The result of the agreement with Merck Sharp and Dohme (MSD) to acquire certain rights for the dexchlorpheniramine maleate product line. In addition to these two products, distribution rights in France for the injectable presentation were also acquired. According to MSD, this product line obtained sales of around 6.3 million dollars in Spain and France in 2017 and belongs to the group of antihistamine medicines, indicated for symptomatic treatment of seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis, minor allergic cutaneous manifestations without complications of urticaria or angioedema; and reactions to blood or plasma. It is also indicated, together with adrenaline or other appropriate measures, for treatment of anaphylactic reactions, together with adrenaline or other appropriate measures, once the acute manifestations have been controlled. These products often relieve cutaneous manifestations such as allergic eczema, atopic and contact dermatitis, insect bites, dermatophisms and drug reactions.

The strength of ROVI's business model has allowed it to obtain a 30% increase in prescription-based pharmaceutical sales.
Hirobriz® Breezhaler® and Ulunar® Breezhaler®

Both of which are inhaled bronchodilators belonging to Novartis, aimed at patients with respiratory difficulties due to a lung disease known as Chronic Obstructive Pulmonary Diseases (COPD), and which ROVI began to market in Spain in the fourth quarter of 2014, decreased by 5% in comparison with the preceding year, with total sales of 14.6 million euros in 2019.

Vytorin®, Orvatez® and Absorcol®

the first of the five MSD licences indicated as adjunctive therapy to diet in patients with hypercholesterolemia, dropped by 12% in 2019, to 31.8 million euros.

Tetridar®

Due to the delay in availability of the product for the scheduled launch date, ROVI will not finally be distributing Tetridar® (teriparatide), a TEVA product for the treatment of osteoporosis in adults, in Spain. However, ROVI is analysing other opportunities concerning products with a similar market value with this company.

Medicebran® and Medikinet®

The results of prescription products of the company Medice indicated for treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children and adolescents, which ROVI distributes on an exclusive basis in Spain, fell by 22% in comparison with the preceding year, with total sales of 5.8 million euros in 2019.
Results

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>382.5</td>
<td>304.8</td>
<td>277.4</td>
<td>266.7</td>
<td>247.0</td>
<td>240.9</td>
<td>218.9</td>
</tr>
<tr>
<td>EBITDA</td>
<td>60.9</td>
<td>29.5</td>
<td>29.9</td>
<td>39.3</td>
<td>31.8</td>
<td>36.6</td>
<td>32.4</td>
</tr>
<tr>
<td>EBIT</td>
<td>42.6</td>
<td>17.5</td>
<td>18.4</td>
<td>28.3</td>
<td>21.8</td>
<td>27.7</td>
<td>25.5</td>
</tr>
<tr>
<td>Net profit</td>
<td>39.3</td>
<td>17.9</td>
<td>17.2</td>
<td>26.1</td>
<td>19.8</td>
<td>24.1</td>
<td>23.0</td>
</tr>
<tr>
<td>Capex</td>
<td>40.5</td>
<td>26.4</td>
<td>19.9</td>
<td>18.1</td>
<td>19.9</td>
<td>25.1</td>
<td>24.7</td>
</tr>
<tr>
<td>Financial debt</td>
<td>84.8</td>
<td>34.2</td>
<td>43.2</td>
<td>33.8</td>
<td>42.8</td>
<td>36.3</td>
<td>31.0</td>
</tr>
<tr>
<td>Net financial debt</td>
<td>15.9</td>
<td>-62.8</td>
<td>1.1</td>
<td>-9.0</td>
<td>12.1</td>
<td>8.3</td>
<td>-5.8</td>
</tr>
</tbody>
</table>

Sales by activity

- **Prescription-based pharmaceuticals**: $281.0 million, +30%
- **Diagnostic imaging contrast agents and other hospital products**: $32.6 million, +10%
- **Non-prescription pharmaceuticals (OTC) and other**: $2.1 million, -3%
- **Toll manufacturing**: $65.6 million, +20%
Sales by product

**Bemiparin (Hibor®)**
- 96.8Mn€
- +6%

**Enoxaparin biosimilar**
- 80.9Mn€
- +167%

**Neparvis®**
- 22.0Mn€
- +62%

**Volutsa®**
- 13.3Mn€
- +18%

**Vandtorin®, Orvatez®, and Absorcol®**
- 31.8Mn€
- -12%

**Hirobriz® and Ulunar®**
- 14.6Mn€
- -5%

**Medicebran® and Medikinet®**
- 5.8Mn€
- -22%

**Other**
- 33.7Mn€
- +12%
**Toll manufacturing, significant increase in results**

ROVI has undertaken an important adjustment to its toll manufacturing business. The measures adopted gave rise to an immediate result in 2019, with *sales increasing by 20%* in respect of the preceding year, *totalling 65.6 million euros in 2019*, mainly due to redirecting the strategy of the activities towards products with a higher value-added.

In November 2019, the toll manufacturing management units, ROVI Contract Manufacturing and Frosst Ibérica, merged into a single entity, ROVI Pharma Industrial Services, which operates providing manufacturing services with the highest standards of quality and competitiveness. It is foreseen that the full integration of the production processes will allow the company to achieve greater synergies and levels of efficiency in its industrial operations.

ROVI expects toll manufacturing services to have increased by low-teens figures by the end of 2020.

**Contrast agents, other hospital products and OTC products**

Sales of diagnostic imaging contrast agents and other hospital products *rose by 10%, totalling 32.6 million euros*, which places ROVI as the leading company in contrast agents in Spain.

Sales of Perspirex® accounted for 55% of non-prescription pharmaceutical ("OTC") and other sales in 2019, which showed a global figure of 2.1 million euros (2.8% down on 2018). The Perspirex® distribution agreement ended on 30 June, 2019, meaning that ROVI ceased to distribute the product from the third quarter of 2019 onwards. Therefore, ROVI has completed its disinvestment in the OTC division.

Likewise, ROVI ceased to distribute the products of Norgine B.V. (Sintrom®, Salagen®, Cordiplast® and Estraderm®) at the end of 2019. Consequently, no sales of these products will be recorded in 2020. In 2019, sales of Norgine B.V. products totalled 14.5 million euros.
Sales of the low-molecular-weight heparin (LMWH) division increased by 46%

Sales breakdown

<table>
<thead>
<tr>
<th>Category</th>
<th>2019</th>
<th>2018</th>
<th>VAR. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>381,313</td>
<td>303,203</td>
<td>25.8%</td>
</tr>
<tr>
<td>Sales of goods</td>
<td>315,663</td>
<td>248,628</td>
<td>27.0%</td>
</tr>
<tr>
<td>Prescription-based pharmaceuticals</td>
<td>281,011</td>
<td>216,783</td>
<td>29.6%</td>
</tr>
<tr>
<td>LMWH franchise</td>
<td>177,647</td>
<td>121,508</td>
<td>46.2%</td>
</tr>
<tr>
<td>Enoxaparin biosimilar (Enoxaparin Becat)</td>
<td>80,863</td>
<td>30,246</td>
<td>167.4%</td>
</tr>
<tr>
<td>Hibor</td>
<td>96,784</td>
<td>91,262</td>
<td>6.1%</td>
</tr>
<tr>
<td>Sales in Spain</td>
<td>69,627</td>
<td>67,441</td>
<td>3.2%</td>
</tr>
<tr>
<td>International sales</td>
<td>27,157</td>
<td>23,820</td>
<td>14.0%</td>
</tr>
<tr>
<td>Neparvis</td>
<td>22,022</td>
<td>13,557</td>
<td>62.4%</td>
</tr>
<tr>
<td>Ulunar &amp; Hirobriz</td>
<td>14,563</td>
<td>15,279</td>
<td>-4.7%</td>
</tr>
<tr>
<td>Volutsa</td>
<td>13,268</td>
<td>11,221</td>
<td>18.2%</td>
</tr>
<tr>
<td>Vytorin &amp; Absorcol &amp; Orvatez</td>
<td>31,805</td>
<td>36,050</td>
<td>-11.8%</td>
</tr>
<tr>
<td>Medikinet &amp; Medicebran</td>
<td>5,766</td>
<td>7,381</td>
<td>-21.9%</td>
</tr>
<tr>
<td>Other products</td>
<td>33,710</td>
<td>30,039</td>
<td>12.2%</td>
</tr>
<tr>
<td>Discounts to National Health System</td>
<td>-17,771</td>
<td>-18,252</td>
<td>-2.6%</td>
</tr>
<tr>
<td>Contrast agents and other hospital products</td>
<td>32,556</td>
<td>29,688</td>
<td>9.7%</td>
</tr>
<tr>
<td>Non-prescription pharmaceuticals (&quot;OTC&quot;) and other</td>
<td>2,096</td>
<td>2,157</td>
<td>-2.8%</td>
</tr>
<tr>
<td>Services provided</td>
<td>65,650</td>
<td>54,575</td>
<td>20.3%</td>
</tr>
</tbody>
</table>
Sound financial situation

ROVI remains firm in its commitment to maintain low leverage in capital management. However, as a result of the application of IFRS 16, ROVI’s total debt had increased to 84.8 million euros as of 31 December, 2019. Debt with government entities, at a 0% interest rate, accounted for 14% of the total debt.

Even so, ROVI showed a gross cash position of 68.9 million euros in 2019, in comparison with the 97.0 million euros of 2018, and net debt of 15.9 million euros (variable-income securities, plus deposits, plus financial derivatives, plus cash and cash equivalents, less current and non-current financial debt), in comparison with net cash of 62.8 million euros in the preceding financial year.

As of 31 December, 2019, bank borrowings had increased by 29.4 million euros. In December 2017, ROVI announced that the European Investment Bank (EIB) had granted it a loan to support its investments in Research, Development and Innovation. The credit was for 45 million euros. As of 30 September, 2019, ROVI had drawn down 5 million euros of this credit line at a variable interest rate of EURIBOR at three months + 0.844%. The latest interest rate paid (January 2020) was 0.421%. As of 31 December, 2020, ROVI had drawn down the remaining 40 million euros. This credit matures in 2029, has a three-year grace period and a fixed interest rate of 0.681%. This is added to the information disclosed in 2018, when ROVI increased its equity by 88 million euros. The net transaction-related expenses were 3.9 million euros and, therefore, the net capital increase was for 84.1 million euros.

Debt maturity chart

<table>
<thead>
<tr>
<th>Year</th>
<th>Net debt/EBITDA</th>
<th>Net debt/equity</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>0.26x</td>
<td>0.05x</td>
</tr>
<tr>
<td>2018</td>
<td>-2.13x</td>
<td>-0.22x</td>
</tr>
<tr>
<td>2017</td>
<td>0.04x</td>
<td>0.01x</td>
</tr>
<tr>
<td>2016</td>
<td>-0.23x</td>
<td>-0.05x</td>
</tr>
<tr>
<td>2015</td>
<td>0.38x</td>
<td>0.07x</td>
</tr>
<tr>
<td>2014</td>
<td>0.23x</td>
<td>0.05x</td>
</tr>
</tbody>
</table>
## Consolidated income statement

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
<th>VAR. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net revenue</td>
<td>381,313</td>
<td>303,203</td>
<td>25.8%</td>
</tr>
<tr>
<td>Recognition of grants on non-financial fixed assets and other</td>
<td>1,151</td>
<td>1,587</td>
<td>-27.5%</td>
</tr>
<tr>
<td><strong>Total operating revenue</strong></td>
<td>382,464</td>
<td>304,790</td>
<td>25.5%</td>
</tr>
<tr>
<td>Cost of sales</td>
<td>-166,606</td>
<td>-128,612</td>
<td>29.5%</td>
</tr>
<tr>
<td><strong>Gross margin</strong></td>
<td>215,858</td>
<td>176,178</td>
<td>22.5%</td>
</tr>
<tr>
<td>%</td>
<td>56.6%</td>
<td>58.1%</td>
<td>-1.5pp</td>
</tr>
<tr>
<td>R&amp;D expenses</td>
<td>-29,304</td>
<td>-32,376</td>
<td>-9.5%</td>
</tr>
<tr>
<td>Sales, overhead and administrative expenses</td>
<td>-125,495</td>
<td>-113,206</td>
<td>10.9%</td>
</tr>
<tr>
<td>Other expenses</td>
<td>-1,094</td>
<td>n,a</td>
<td>n,a,</td>
</tr>
<tr>
<td>Share in profit/(loss) of joint ventures</td>
<td>-195</td>
<td>24</td>
<td>n,a,</td>
</tr>
<tr>
<td><strong>EBITDA</strong></td>
<td>60,864</td>
<td>29,526</td>
<td>106.1%</td>
</tr>
<tr>
<td>%</td>
<td>16.0%</td>
<td>9.7%</td>
<td>6.2pp</td>
</tr>
<tr>
<td>Amortisation or depreciation</td>
<td>-18,216</td>
<td>-12,044</td>
<td>51.2%</td>
</tr>
<tr>
<td><strong>EBIT</strong></td>
<td>42,648</td>
<td>17,482</td>
<td>144.0%</td>
</tr>
<tr>
<td>%</td>
<td>11.2%</td>
<td>5.8%</td>
<td>5.4pp</td>
</tr>
<tr>
<td>Finance income</td>
<td>51</td>
<td>16</td>
<td>218.8%</td>
</tr>
<tr>
<td>Finance costs</td>
<td>-927</td>
<td>-712</td>
<td>30.2%</td>
</tr>
<tr>
<td>Impairment and gain/(loss) on measurement of financial instruments</td>
<td>159</td>
<td>-23</td>
<td>n,a,</td>
</tr>
<tr>
<td>Exchange rate differences</td>
<td>-51</td>
<td>-83</td>
<td>n,a,</td>
</tr>
<tr>
<td><strong>Net finance costs</strong></td>
<td>-768</td>
<td>-802</td>
<td>-4.2%</td>
</tr>
<tr>
<td><strong>Profit before tax</strong></td>
<td>41,880</td>
<td>16,680</td>
<td>151.1%</td>
</tr>
<tr>
<td>Income tax</td>
<td>-2,607</td>
<td>1,215</td>
<td>-314.6%</td>
</tr>
<tr>
<td>Effective rate</td>
<td>6.2%</td>
<td>-7.3%</td>
<td>13.5pp</td>
</tr>
<tr>
<td><strong>Profit for the period</strong></td>
<td>39,273</td>
<td>17,895</td>
<td>119.5%</td>
</tr>
</tbody>
</table>
## Consolidated statement of financial position

<table>
<thead>
<tr>
<th></th>
<th>31-DIC-19</th>
<th>31-DIC-18</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASSETS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Non-current assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Property, plant &amp; equipment</td>
<td>131,608</td>
<td>95,837</td>
</tr>
<tr>
<td>Intangible assets</td>
<td>45,079</td>
<td>34,650</td>
</tr>
<tr>
<td>Investment in joint venture</td>
<td>1,843</td>
<td>2,038</td>
</tr>
<tr>
<td>Deferred tax assets</td>
<td>14,660</td>
<td>16,036</td>
</tr>
<tr>
<td>Variable-income securities</td>
<td>71</td>
<td>70</td>
</tr>
<tr>
<td>Trade and other receivables</td>
<td>65</td>
<td>65</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td>193,326</td>
<td>148,696</td>
</tr>
<tr>
<td><strong>Current assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inventories</td>
<td>158,811</td>
<td>94,861</td>
</tr>
<tr>
<td>Trade and other receivables</td>
<td>81,541</td>
<td>60,180</td>
</tr>
<tr>
<td>Current tax assets</td>
<td>10,104</td>
<td>3,414</td>
</tr>
<tr>
<td>Financial derivatives</td>
<td>-</td>
<td>17</td>
</tr>
<tr>
<td>Prepaid expenses</td>
<td>3</td>
<td>21</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>67,426</td>
<td>95,511</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td>317,885</td>
<td>254,004</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td>511,211</td>
<td>402,700</td>
</tr>
<tr>
<td><strong>EQUITY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capital and reserves attributable to company shareholders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Share capital</td>
<td>3,364</td>
<td>3,364</td>
</tr>
<tr>
<td>Share premium</td>
<td>87,636</td>
<td>87,636</td>
</tr>
<tr>
<td>Legal reserve</td>
<td>673</td>
<td>600</td>
</tr>
<tr>
<td>Treasury shares</td>
<td>-10,341</td>
<td>-8,812</td>
</tr>
<tr>
<td>Retained earnings and voluntary reserves</td>
<td>201,784</td>
<td>186,792</td>
</tr>
<tr>
<td>Profit for the period</td>
<td>39,273</td>
<td>17,895</td>
</tr>
<tr>
<td>Other reserves</td>
<td>-3</td>
<td>-3</td>
</tr>
<tr>
<td><strong>Total equity</strong></td>
<td>322,386</td>
<td>287,472</td>
</tr>
<tr>
<td><strong>LIABILITIES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Non-current liabilities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Financial debt</td>
<td>72,104</td>
<td>16,589</td>
</tr>
<tr>
<td>Deferred tax liabilities</td>
<td>1,078</td>
<td>1,243</td>
</tr>
<tr>
<td>Contractual liabilities</td>
<td>5,793</td>
<td>6,263</td>
</tr>
<tr>
<td>Deferred revenue</td>
<td>3,141</td>
<td>3,621</td>
</tr>
<tr>
<td><strong>Total liabilities</strong></td>
<td>82,116</td>
<td>27,716</td>
</tr>
<tr>
<td><strong>Current liabilities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Financial debt</td>
<td>12,701</td>
<td>17,635</td>
</tr>
<tr>
<td>Trade and other payables</td>
<td>91,914</td>
<td>68,165</td>
</tr>
<tr>
<td>Contractual obligations</td>
<td>1,566</td>
<td>1,159</td>
</tr>
<tr>
<td>Deferred revenue</td>
<td>528</td>
<td>553</td>
</tr>
<tr>
<td><strong>Total liabilities</strong></td>
<td>106,709</td>
<td>87,512</td>
</tr>
<tr>
<td><strong>Total liabilities</strong></td>
<td>188,825</td>
<td>115,228</td>
</tr>
<tr>
<td><strong>Total equity and liabilities</strong></td>
<td>511,211</td>
<td>402,700</td>
</tr>
</tbody>
</table>
Investments

ROVI continues to invest in research and development. R&D expenses recognised in profit and loss were 29.3 million euros in 2019, mainly related to developing the Phase III clinical trial of Risperidone-ISM® and the Phase I of Letrozole-ISM®

Additionally, the company invested 27.0 million euros in fixed assets in 2019, compared with 17.4 million euros in the preceding year. In property, plant and equipment, most of the new assets were related to investments in ROVI’s bemiparin and enoxaparin production plant in Granada and investments in the pilot plants to develop ISM® technology. Among the investments made, the following may be highlighted:

- **1.6 million euros**
  were invested in the injectables plant (2.7 million euros invested in 2018)

- **4.3 million euros**
  were invested in the San Sebastián de Los Reyes plant (2.8 million euros invested in 2018)

- **5.9 million euros**
  were invested in the Granada plant (3.0 million euros invested in 2018)

- **8.3 million euros**
  were invested in the Alcalá de Henares plant (5.5 million euros invested in 2018)

- **3.5 million euros**
  were invested in the industrialisation of ISM® (1.1 million euros invested in 2018)

- **3.4 million euros**
  were spent on investment in maintenance and other (2.3 million euros invested in 2018).

Furthermore, in 2019, new intangible assets of 13.5 million euros were included in relation to the acquisition of the product Polaramine®.
DORIA®, the first of the products developed using ROVI’s ISM® platform, completed its clinical development phase in 2019 and, if the timing goes as planned, could be launched in the European market in 2021 and in the United States in 2022.

Doria® is based on ISM® technology and uses the risperidone molecule, which has been known to be effective and clinically safe for years. Its unique pharmaceutical profile has shown therapeutic plasma levels two hours after the injections, with a single monthly dose and no need for more injections or oral supplements. In patients treated with LAIs (long-acting injectables), a significant increase in treatment adherence has been noted, as well as a reduction in the hospitalisation and relapse rates and in the risk of accidental or deliberate overdose.

With Doria®, ROVI is endeavouring to occupy a prominent position in the market of schizophrenia treatments with LAIs, which has a value of over 5.5 billion euros in the United States and Europe and very significant growth potential, given the low market penetration of long-acting injectables. The profitability forecast is very high, since the market niche -psychiatrists- is small and only needs a limited sales force to tackle it.
In 2019, the PRISMA-3 and BORIS studies concluded, this completing the Clinical Research Programme of Risperidone ISM®, in which over 679 subjects were included. All the data collected and analysed in this programme have been included in the registration dossier to apply for marketing authorisation for Doria® for the treatment of schizophrenia in the European Union and United States in a first phase and, subsequently, in other countries.

The final results of the pivotal PRISMA-3 clinical study confirm the superiority of Risperidone ISM®, a novel investigational antipsychotic for the treatment of schizophrenia with once-monthly injections, over the placebo. The prespecified primary efficacy endpoint in the study was the mean total score on the Positive and Negative Syndrome Scale (PANSS) after twelve weeks. The reductions in comparison with the baseline values obtained in the PANSS with monthly doses of 75 mg or 100 mg of Risperidone ISM® were statistically higher than those observed with the placebo (p<0.0001).

Likewise, both dosage strengths of Risperidone ISM® (75 mg and 100 mg, once monthly) showed statistically significant reductions greater than those observed with the placebo (p<0.0001) in the total score on the Clinician Global Impression-Severity (CGI-S) scale at week 12, which was the prespecified key secondary efficacy endpoint in the study. ROVI has included long-term safety data on more than 100 patients from the open-label extension of the PRISMA-3 study, exposed to at least one year of treatment with Doria®, in the registration dossier, as recommended in the International Conference on Harmonization (ICH) Guidelines E1. After recruiting 215 patients, the open-label extension of the pivotal PRISMA-3 study mentioned above has concluded recently and will provide further clinical data on the long-term use of Risperidone ISM®.

Likewise, the BORIS clinical trial, in which the bioavailability of multiple doses of oral risperidone was compared with that of multiple doses of Risperidone ISM® in patients with stable schizophrenia, concluded recently. The results of this study support the registration of Doria® with the United States authority, the Food and Drug Administration (FDA), and the European health authority, the European Medicines Agency (EMA), as a hybrid application\(^\text{12, 13}\), i.e. based on own studies and studies of the reference medicine.

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\(^\text{12}^\text{) NDA 505(b)(2) Section of Federal Food, Drug, and Cosmetic Act}\\\(^\text{13}^\text{) Hybrid Application, Article 10(3) – Directive 2001/83/EC}
After the conclusion of the phase of validation of the documentation submitted, the European health authorities commenced the assessment process to grant marketing authorisation in the European Union (EU). ROVI filed its application for marketing authorisation for Doria® with the EMA through the Centralised Procedure on 27 December, 2019. After passing the validation phase satisfactorily, the dossier was admitted for evaluation on 30 January, 2020.

It is forecast that the assessment phase of the Centralised Procedure used by the Company to register this medicine in the EU may take around one year as from the validation. It should, however, be noted that the assessment process is subject to interruptions and delays in the event that the European health authorities require additional information. Likewise, mention should be made of the fact that the outcome of the registration process (which may be positive or negative) cannot be known until it has concluded.

Doria® is, therefore, at the gateway and is positioned to capture a significant portion of an attractive market, in which only around 6% of the patients in the United States and 8% in Europe are treated with long-acting injectables.

Schizophrenia is a chronic progressive disease and it is necessary to adhere strictly to treatment schedules to avoid relapses. It affects 21 million people all over the world, according to the epidemiological data in the Kantar Health Epi Database. The number of schizophrenia patients in the United States, United Kingdom, Germany, Spain, France and Italy combined is expected to rise by 12%, from 3.2 million in 2013 to 3.6 million in 2035, and it is thought that the United States market will account for over half the forecast patients.

It is a large and growing market, in terms of both units and value, with a high rate of changes of treatment, where LAIs (long-acting injectables) are increasingly becoming the standard treatment of choice for schizophrenia, due to the numerous advantages they have over oral antipsychotics in terms of costs. These treatments use second-generation antipsychotics (SGAs), which have a predictable efficacy and safety profile, and risperidone is among the most widely-used active substances.
ROVI announced the commencement of the clinical development of Letrozole ISM®, which is the second candidate based on ROVI’s ISM® technological platform. This new medicine (in the clinical research phase) will be the first long-acting injectable aromatase inhibitor drug for treatment of hormone-dependent breast cancer in postmenopausal women.

The first Phase I clinical trial (the LISA-1 study) of Letrozole ISM® is currently ongoing and, given the design of the study (“dose escalation”) and its exploratory nature, the date of finalisation cannot be known. This is an open-label study, with single escalating doses, to evaluate the pharmacokinetic profile, safety and tolerability of intramuscular injections of Letrozole ISM®, with different concentrations, for healthy postmenopausal women. Notwithstanding, preliminary data confirm that the ISM® formulation provides a prolonged release of letrozole which produces a sustained suppression of oestrogenic hormones.

At ROVI, there is a firm conviction that medicines targeted at hormone receptors provide a unique opportunity to use its ISM® platform. According to Datamonitor, the combined hormone receptor-positive (HR+) breast cancer market in the United States, Japan, the United Kingdom, Germany, Spain, France and Italy will grow by 16.7% between 2015 and 2024.

ROVI’s goal with Letrozole ISM® is to obtain a long-acting (several months) injectable formulation of letrozole that allows treatment adherence to improve. At present, third-generation aromatase inhibitors (AI) are administered orally with a daily dose over a period of at least five years. This means that non-adherence is frequent and some patients even stop following the treatment early, which may affect the survival results.

According to the information publicly available, Letrozole ISM® is the first injectable of this type under development and could provide potential advantages, such as enhancing the quality of life of patients, reducing healthcare costs, and improving the rate of therapeutic adherence.

This represents an opportunity for Letrozole ISM®, since it could improve on the results of the present oral treatment and gain market share. Furthermore, lower, but more sustained, doses are being studied, which could reduce adverse secondary effects, such as loss of bone mass and dyslipidaemia, in comparison with the oral treatment, due to lower exposure to the drug. This enhanced safety profile, if demonstrated in the clinical trials, has the potential to have a significant favourable impact on treatment adherence.
SECURITIES MARKET INFORMATION

In 2019, the ROVI share was revalued by 39.8%, rising from 17.45 euros to 24.40 euros. In the same period, the IBEX 35 grew by 11.8% to 9,542.20 points. The group’s stock market capitalisation at 31 December, 2019 was 1,368.1 million euros. Average daily trading from January to December 2019 was 20,878 shares, including the volume traded on the block market. If we consider only the volume traded on the stock market, it was 9,565 shares (in comparison with 6,691 in 2018). The average daily volume (without blocks) increased by 43% in 2019 in comparison with 2018.

The ROVI share ended 2019 with a value of 24.40 euros per share. Its lowest price was 16.93 euros per share and its highest price in the period was 25.50 euros. After a flat start to 2019, in the second half of the year, the ROVI share began to show constant growth, which, quarter by quarter, brought the year to an outstanding conclusion.

Evolution of the share

Evolution of the share in comparison with the IBEX-35
In 2019, shareholders received a dividend of 0.0798 euros per share entitled to receive it, charged to the 2018 profit. In February 2020, ROVI announced it would pay a dividend of 0.1751 euros per share with dividend rights out of the 2019 profit if the Shareholders General Meeting approved the application of the 2019 profit proposed by ROVI’s Board of Directors. This proposed dividend would mean an increase of 119% on the dividend paid out of the 2018 profit (€0.0798/share) and represents a 25% pay-out. As a result of the Covid-19 crisis, ROVI has postponed the General Shareholders Meeting and has placed the dividend proposal under review.

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of shares</strong></td>
<td>56,068,965</td>
<td>56,068,965</td>
</tr>
<tr>
<td><strong>Closing price</strong></td>
<td>24.40 euros</td>
<td>17.45 euros</td>
</tr>
<tr>
<td><strong>Capitalisation at 31/12</strong></td>
<td>1,368,082,746 euros</td>
<td>978,403,439 euros</td>
</tr>
<tr>
<td><strong>Total dividend</strong></td>
<td>4,474,000 euros</td>
<td>6,035,000 euros</td>
</tr>
<tr>
<td>Dividend per share paid in 2019 charged to the 2018 profit</td>
<td>0.0798 euros</td>
<td>0.1207 euros</td>
</tr>
<tr>
<td>Proposed dividend per share charged to the 2019 profit</td>
<td>0.1751 euros*</td>
<td>-</td>
</tr>
<tr>
<td>Pay-out (as % of the net consolidated profit)</td>
<td>25%</td>
<td>35%</td>
</tr>
<tr>
<td>Profit per share</td>
<td>0.70 euros</td>
<td>0.32 euros</td>
</tr>
<tr>
<td><strong>PER</strong></td>
<td>34.8</td>
<td>54.7</td>
</tr>
</tbody>
</table>

*Under review due to Covid-19 crisis.
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 contained in the official records of the National Securities Market Commission as of 31 December, 2019, are the following:

<table>
<thead>
<tr>
<th>Percentage of voting rights</th>
<th>DIRECT</th>
<th>INDIRECT</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norbel Inversiones, S.L.</td>
<td>63.107%</td>
<td>-</td>
<td>63.107%</td>
</tr>
<tr>
<td>Indumenta Pueri, S.L.</td>
<td>-</td>
<td>5.057%</td>
<td>5.057%</td>
</tr>
<tr>
<td>T. Rowe Price Associates, Inc</td>
<td>-</td>
<td>3.390%</td>
<td>3.390%</td>
</tr>
<tr>
<td>Wellington Management Group, LLP</td>
<td>-</td>
<td>4.924%</td>
<td>4.924%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>63.107%</td>
<td>13.371%</td>
<td>76.478%</td>
</tr>
</tbody>
</table>

In the course of 2019, ROVI acquired a total of 224,449 of its own shares (68,603 in 2018), paying the amount of 4.72 million euros for them (1.14 million euros in 2018). Likewise, it resold a total of 232,548 of its own shares (58,731 in 2018) for an amount of 4.87 million euros (986,000 euros in 2018). These shares had been acquired at a weighted average cost of 3.19 million euros (733,000 euros in 2018), giving rise to a profit of 1.68 million euros on the sale (256,000 euros in 2018), which was taken to reserves. At 31 December, 2019, ROVI held 686,956 treasury shares (695,055 at 31 December, 2018).

The significant shareholders hold 76.478% of ROVI’s capital. The company Norbel Inversiones, S.L. holds 63.107% 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 López’s interest in ROVI at the end of 2019 was 12.621%, while those of Messrs Juan, Iván and Javier López-Belmonte Encina were 16.829% each at the end of 2019.

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.
- **T Rowe 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, economic, financial and corporate governance documents, may be consulted on the group’s website.

Investor relations activity

True to its principles of accessibility and transparency, ROVI carries on continuous activity throughout the year via meetings, forums and events with investors. During 2019, ROVI held 11 roadshows, participated in 15 events with investors and made 34 visits to investors and teleconferencing calls. In total, this represented attention to more than 150 investors.

Furthermore, throughout the year, in order to provide communication channels that supplemented those that already existed, ROVI created three social networking profiles (Twitter, LinkedIn and YouTube), through which it shares new developments in the group, including its significant events, such as press releases and other corporate social responsibility-related activities.

Analyst cover

As of 31 December, 2019, ROVI was covered by 13 analysts. In 2019, the consensus of the analysts was a buy recommendation for ROVI, with an average target price of 24.98 euros, 2% higher than the closing price of the share at 31 December, 2019, which was 24.40 euros.
CUSTOMERS, PATIENTS AND PROFESSIONALS

ROVI has a triple commitment with patients, customers and professionals in order to meet their needs and expectations through a range of a la carte toll manufacturing services, offering the best treatment options to provide health professionals with the tools necessary to enable them to work better and, finally, enhance the patients’ lives through products that include the latest advances and are the best medicines for treatment of their complaints.

Through these mechanisms, it is sought to achieve a high degree of satisfaction among these three groups and establish solid and long-lasting relationships of trust. And they are constructed in a service where the prevalent factors are quality and experience, action principles in ROVI’s General CSR Policy in relation to these stakeholder groups, which are the basis of the company’s business.

The activities of ROVI through which it relates to these groups are toll manufacturing and the distribution of products, either manufactured at its plants or marketed under a licence. Thus, the group has the possibility of offering other laboratories the chance to take advantage of its facilities to outsource their pharmaceutical form manufacturing processes, ranging from prefilled syringes to vials, suppositories, tables, hard capsules or sachets.

Derived from this activity, the group has a differentiated group of customers encompassing subsidiaries and international partners, pharmaceutical wholesalers, pharmacies and hospitals all over Spain, to which it distributes both its own products and those of other companies through its profile as a marketing partner for medicines and medical devices.

COMMUNICATIONS

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 furnish such actions with transparency and veracity.
Proximity, service and trust

Proximity, a permanent wish to provide service, and trust are the pillars on which the long-lasting business relationships that ROVI considers essential to its relations with these groups are built. In this respect, patients and professionals have several query channels available to them for information requests, such as the portal exclusively for international partners (www.bemimed.com), which has been active since 2008.

ROVI pursues a high degree of satisfaction among these three stakeholder groups and seeks to establish solid and long-lasting relationships of trust. And they are constructed in a service where the prevalent factors are quality and experience, action principles in ROVI’s General CSR Policy in relation to these stakeholder groups, which are the basis of the company’s business.

Thus, ROVI’s permanent commitment to protect and safeguard personal data of customers, patients and professionals is strengthened even further. This is not only based on the 2019 legislation, but has been materialising throughout ROVI’s history through the adoption of different measures and the implementation of procedures that ensure the integrity, confidentiality and availability of the data processed, likewise safeguarding people’s rights and freedoms.

The ROVI group has specific procedures that regulate personal data processing in both the pharmacovigilance and clinical operations area.

The ROVI group has reviewed and updated its privacy policies in depth to ensure fair, transparent and lawful processing of personal information in relations with health professionals, properly establishing the lawful bases for the processing and the mechanisms necessary to obtain the consent on which the data processing is based.

The ROVI group applies current legislation to ensure the security of the data of its employees and others which must be processed in order to perform the contractual relationship and prevent the alteration, loss and unauthorised processing of said data or access thereto.
Quality, the key concern

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 implement 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. All group companies have procedures that provide detailed descriptions of the controls performed in all the phases of the processes, including product research and development, the receipt of raw materials, packaging materials, production, storage and distribution, until the products are consumed by the customers.

The company holds a dual commitment to both the highest internal standards and those imposed by the regulatory bodies that assess the products on the portfolio marketed by ROVi. To assess compliance with each and every one of them, regular internal audits are performed at all the group’s facilities and Management performs annual reviews in which the main points that require improvement in the organisations are analysed.

Furthermore, quality audits are performed by external entities, showing, once again, the commitment to continuing improvement and upholding the highest standards of quality. In addition, depending on the frequency established in the legislation applicable to the products, inspections are carried out by either the Spanish health authorities or those of the countries to which the products are exported.

Quality data 2019

<table>
<thead>
<tr>
<th></th>
<th>LAB, FCOS, ROVI</th>
<th>PAN QUIMICA</th>
<th>PORTUGAL</th>
<th>GERMANY</th>
<th>UK</th>
<th>ITALY</th>
<th>FRANCE</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Units manufactured /Units distributed</td>
<td>17,343,883</td>
<td>27,513</td>
<td>57,932</td>
<td>603,395</td>
<td>144,641</td>
<td>1,998,454</td>
<td>0</td>
<td>20,175,818</td>
</tr>
<tr>
<td>Customer complaints No. of customer complaints</td>
<td>100</td>
<td>0</td>
<td>11</td>
<td>118</td>
<td>11</td>
<td>12</td>
<td>0</td>
<td>252</td>
</tr>
<tr>
<td>Complaints/million units</td>
<td>5.77</td>
<td>0.00</td>
<td>189.88</td>
<td>0</td>
<td>76.05</td>
<td>2.00</td>
<td>0</td>
<td>12.09</td>
</tr>
<tr>
<td>Customer queries / QUALITY / Therapeutic No. of customer queries</td>
<td>340</td>
<td>0</td>
<td>37</td>
<td>247</td>
<td>19</td>
<td>2</td>
<td>0</td>
<td>645</td>
</tr>
<tr>
<td>Queries/million units</td>
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<td>0.00</td>
<td>638.68</td>
<td>409.35</td>
<td>131.36</td>
<td>1.00</td>
<td>0</td>
<td>31.97</td>
</tr>
</tbody>
</table>

2019 REPORTING PERIOD
With patient safety as the main priority, ROVI has a Pharmacovigilance System that allows any possible adverse reactions, i.e. any harmful and unintended responses to any of its medicines or healthcare products, to be detected.

ROVI’s Pharmacovigilance Department has communication channels in place by e-mail (farmacovigilancia@rovi.es) or telephone ([+34] 91 021 30 00), both of which may be accessed through the Company’s website (www.rovi.es). This system means that, if an adverse reaction is notified, the Pharmacovigilance Department analyses whether it could be due to a quality and/or safety problem, thus initiating the signal detection process that ROVI has implemented, which allows any change in the benefit/risk balance of ROVI’s medicines to be identified.

This system likewise allows constant monitoring of all the products, evaluating the safety information received through different channels, such as, for example, spontaneous notifications from patients and health professionals or health authorities, or scientific studies or publications. In the event that, while a complaint is being studied, a possible risk for the patient and/or health professional is identified, the Quality Department informs Pharmacovigilance, so that the case can be handled correctly. The investigations may involve several departments (Quality, Pharmacovigilance or Medical Science Liaison) in both Spain and the subsidiaries, or may even extend to suppliers and/or subcontractors. The efficacy of these actions is analysed annually by ROVI management in the system review.

**In 2019 a total of 1,230 adverse reactions were recorded in relation to all the medicines that ROVI markets.**
HUMAN RESOURCES

It is the human team that makes a company successful and capable of achieving and surpassing its goals, as occurred with ROVI in 2019. The group is aware of the vital role played by the professionals in its workforce and, therefore, both ensures their development as professionals throughout their career and promotes the best employment practices at all its centre.

Thus, at ROVI, a safe and comfortable work environment is ensured, promoting good relations, correct treatment and tolerance among all its employees and external collaborators. At the same time, a decided bet is placed on training, aware that having professionals with the best abilities and skills is vital in maintaining the company’s innovative drive. Furthermore, a policy of favouring permanent employment is followed, in order to create a stable environment, generating high-quality employment and favouring both professional growth and the reconciliation of the latter with family responsibilities and the personal desires of each of the people who work for ROVI.

New internal communication channels

ROVI uses all the means available to maintain a healthy and productive relationship. To achieve this, it needs transparent, easily-reached and accessible communication channels between the company and its workforce. It has traditionally used, and still uses, various mechanisms to communicate different matters of general interest, company milestones, agreements or organisational changes, such as newsletters, the internal television channel, notice boards or e-mails, always seeking to use all the technical means available to reach its entire workforce, irrespective of whether or not they have access to the necessary technical resources.

In July 2019, ROVI Rocks was launched. This is an application for mobile devices for the exclusive use of the ROVI workforce.

ROVI Rock’s

- Allows the employee to keep updated on new developments in the company, as well as including some very useful information, such as an employee directory with telephone numbers, the confidential consultation channel Ethics Channel, or the Ideas ROVI section, through which employees may submit proposals to improve the company.

- Give access to an area of exclusive discounts and groups for ROVI employees and also includes a virtual library section (called RO-Viteca), where they can access a catalogue of more than 2,000 titles of all kinds: novels, educational publications, magazines, children’s books, classics, etc.
In 2019, human resources management continued to focus on high-quality job creation at the same time as it covered business needs effectively. Thus it continued to foster a balance between permanent and temporary contracts, using the former to cover the structural workforce needs and the latter for specific or seasonal requirements of the activity.

### Distribution employees by contract type/gender

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
<th>TOTAL variation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Men</td>
<td>Women</td>
<td>Men</td>
</tr>
<tr>
<td>Permanent full-time</td>
<td>496</td>
<td>526</td>
<td>1,022</td>
</tr>
<tr>
<td>Permanent part-time</td>
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<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Permanent reduced hours</td>
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<td>35</td>
<td>39</td>
</tr>
<tr>
<td>Total permanent</td>
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<td>569</td>
<td>1,069</td>
</tr>
<tr>
<td>Temporary specific project or service</td>
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<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Temporary work backlog</td>
<td>61</td>
<td>48</td>
<td>109</td>
</tr>
<tr>
<td>Temporary substitution contract</td>
<td>6</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>Training/apprenticeship</td>
<td>31</td>
<td>51</td>
<td>82</td>
</tr>
<tr>
<td>Temporary part-time</td>
<td>14</td>
<td>19</td>
<td>33</td>
</tr>
<tr>
<td>Temporary full-time – people with disabilities</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total temporary</td>
<td>114</td>
<td>127</td>
<td>241</td>
</tr>
<tr>
<td>TOTAL</td>
<td>614</td>
<td>696</td>
<td>1,310</td>
</tr>
</tbody>
</table>
## Distribution employees by contract type/age

<table>
<thead>
<tr>
<th></th>
<th>18-30</th>
<th>31-40</th>
<th>41-50</th>
<th>51-60</th>
<th>&gt;60</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Permanent</strong></td>
<td>181</td>
<td>311</td>
<td>360</td>
<td>203</td>
<td>14</td>
<td>1,069</td>
</tr>
<tr>
<td><strong>Temporary specific project or service</strong></td>
<td>1</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>3</td>
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<tr>
<td><strong>Temporary work backlog</strong></td>
<td>45</td>
<td>41</td>
<td>19</td>
<td>3</td>
<td>1</td>
<td>109</td>
</tr>
<tr>
<td><strong>Temporary substitution contract</strong></td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>2</td>
<td>-</td>
<td>14</td>
</tr>
<tr>
<td><strong>Training/apprenticeship</strong></td>
<td>71</td>
<td>9</td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>82</td>
</tr>
<tr>
<td><strong>Temporary part-time</strong></td>
<td>9</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>24</td>
<td>33</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>310</td>
<td>366</td>
<td>386</td>
<td>209</td>
<td>39</td>
<td>1,310</td>
</tr>
</tbody>
</table>

## Distribution employees by contract type/professional group

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>0</th>
<th>Subsids.</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Permanent</strong></td>
<td>5</td>
<td>10</td>
<td>129</td>
<td>195</td>
<td>359</td>
<td>136</td>
<td>196</td>
<td>4</td>
<td>17</td>
<td>18</td>
<td>1,069</td>
</tr>
<tr>
<td><strong>Temporary specific project or service</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td><strong>Temporary work backlog</strong></td>
<td>-</td>
<td>31</td>
<td>23</td>
<td>18</td>
<td>24</td>
<td>12</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>109</td>
</tr>
<tr>
<td><strong>Temporary substitution contract</strong></td>
<td>-</td>
<td>4</td>
<td>6</td>
<td>1</td>
<td>3</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>14</td>
</tr>
<tr>
<td><strong>Training/apprenticeship</strong></td>
<td>-</td>
<td>-</td>
<td>4</td>
<td>10</td>
<td>46</td>
<td>22</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>82</td>
</tr>
<tr>
<td><strong>Temporary part-time</strong></td>
<td>2</td>
<td>-</td>
<td>9</td>
<td>11</td>
<td>10</td>
<td>-</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>33</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>7</td>
<td>46</td>
<td>171</td>
<td>235</td>
<td>443</td>
<td>171</td>
<td>197</td>
<td>4</td>
<td>17</td>
<td>19</td>
<td>1,310</td>
</tr>
</tbody>
</table>
The sustained upward trend in the workforce continued last year and is expected to continue over years to come, due to projects like the new production plant in Granada (38 new jobs planned). The total ROVI workforce at the end of 2019 consisted of 1,310 employees, 86 more than in 2018. The average number of employees in 2019 was 1,293, in comparison with 1,209 in the preceding year.

ROVI has a workforce of highly-qualified professionals in which the principle of equal opportunities prevails, promoting the inclusion and access of differently-abled candidates and balance and equality in the conditions of men and women. Thus, the strategy of consolidating equal opportunities and diversity remains a defining aspect of its culture. At the end of the period, women occupied 696 of the total jobs (666 at 31 December, 2018) and men occupied 614 (558 in 2018).

At the same time, as in previous years, special attention was paid to creating jobs for young people, thus supporting an important social demand, especially in Spain, which was complemented by the recruitment of experienced professionals. ROVI still believes that, to follow the company’s strategy, a balanced workforce of young talents and experienced veterans is necessary. This can be seen in the tables showing the distribution of employees by age, where a balance in the distribution of the employees among the different age brackets may be observed.
### Distribution employees by age/gender

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>18-30 years</td>
<td>88</td>
<td>222</td>
<td>310</td>
<td>78</td>
<td>106</td>
<td>184</td>
<td>68%</td>
</tr>
<tr>
<td>31-40 years</td>
<td>179</td>
<td>187</td>
<td>366</td>
<td>156</td>
<td>216</td>
<td>372</td>
<td>-2%</td>
</tr>
<tr>
<td>41-50 years</td>
<td>210</td>
<td>176</td>
<td>386</td>
<td>195</td>
<td>213</td>
<td>408</td>
<td>-5%</td>
</tr>
<tr>
<td>51-60 years</td>
<td>116</td>
<td>93</td>
<td>209</td>
<td>109</td>
<td>114</td>
<td>223</td>
<td>-6%</td>
</tr>
<tr>
<td>&gt;60 years</td>
<td>21</td>
<td>18</td>
<td>39</td>
<td>20</td>
<td>17</td>
<td>37</td>
<td>5%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>614</td>
<td>696</td>
<td>1,310</td>
<td>558</td>
<td>666</td>
<td>1,224</td>
<td>7%</td>
</tr>
</tbody>
</table>

### Distribution employees by country/gender

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Spain</td>
<td>606</td>
<td>685</td>
<td>1,291</td>
<td>550</td>
<td>654</td>
<td>1,204</td>
<td>7%</td>
</tr>
<tr>
<td>UK</td>
<td>-</td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>1</td>
<td>1</td>
<td>0%</td>
</tr>
<tr>
<td>Germany</td>
<td>3</td>
<td>2</td>
<td>5</td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>-17%</td>
</tr>
<tr>
<td>Italy</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>-33%</td>
</tr>
<tr>
<td>France</td>
<td>3</td>
<td>-</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>50%</td>
</tr>
<tr>
<td>Poland</td>
<td>-</td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Portugal</td>
<td>1</td>
<td>4</td>
<td>5</td>
<td>1</td>
<td>4</td>
<td>5</td>
<td>0%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>614</td>
<td>696</td>
<td>1,310</td>
<td>558</td>
<td>666</td>
<td>1,224</td>
<td>7%</td>
</tr>
</tbody>
</table>
FAIR AND RESPONSIBLE TURNOVER

Like any other company, ROVI has a percentage turnover of employees, both voluntarily and due to business needs. In this respect, the company ensures the greatest diligence in safeguarding the employees’ rights and achieving a transition with all legal guarantees while, at the same time, always maintaining the intention of re-employing the professionals in question if business circumstances so permit.

Distribution dismissals by gender

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
<th>VARIATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>22</td>
<td>17</td>
<td>29%</td>
</tr>
<tr>
<td>Women</td>
<td>17</td>
<td>16</td>
<td>6%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>39</td>
<td>33</td>
<td>18%</td>
</tr>
</tbody>
</table>

Distribution dismissals by age/gender

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
<th>VARIATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>Women</td>
<td>TOTAL</td>
<td></td>
</tr>
<tr>
<td>18-30 years</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>31-40 years</td>
<td>5</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>41-50 years</td>
<td>8</td>
<td>5</td>
<td>13</td>
</tr>
<tr>
<td>51-60 years</td>
<td>8</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>&gt;60 years</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>TOTAL</td>
<td>22</td>
<td>17</td>
<td>39</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
<th>VARIATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>Women</td>
<td>TOTAL</td>
<td></td>
</tr>
<tr>
<td>18-30 years</td>
<td>2</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>31-40 years</td>
<td>3</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>41-50 years</td>
<td>5</td>
<td>8</td>
<td>13</td>
</tr>
<tr>
<td>51-60 years</td>
<td>8</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>&gt;60 years</td>
<td>4</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>TOTAL</td>
<td>17</td>
<td>16</td>
<td>33</td>
</tr>
</tbody>
</table>
The sustained upward trend in the workforce continued last year and is expected to continue over years to come.
EQUAL OPPORTUNITIES AND PROFESSIONAL DEVELOPMENT

ROVI has policies that actively seek to ensure equal treatment and opportunities for men and women, with no discrimination on the grounds of gender, race or any other personal characteristic in either selection processes or promotions, or in the professional development or remuneration policy for persons working in the group. It particularly monitors situations where indirect discrimination may arise, i.e. situations where a rule, criterion or practice that is apparently neutral places a person of one gender at a specific disadvantage in relation to persons of the other.

Both the company’s Code of Ethics and the Equal Opportunities Plan ensure that these principles of equality and non-discrimination are implemented, leading to the creation and incorporation of actions and mechanisms in areas such as selection, recruitment, internal promotion, professional development, training, remuneration, work-life balance, gender violence, harassment prevention and communication.

The Equal Opportunities Commission is the body responsible for proper monitoring of the measures that are implemented and strives to keep the group’s commitment to these matters active and updated. The policies it develops are reflected in the Board of Directors, where director appointments are based solely on the candidates’ merits, seeking people of recognised knowledge, skills and experience, regardless of their gender or race. The group maintains its goal for female directors to represent 30% of the total Board members in 2020, the current representation being around 15%.

Likewise, harassment and violence are not tolerated at ROVI and any form of physical, sexual, psychological or moral harassment or violence, abuse of authority or any other form of these conducts that generates an atmosphere that is intimidatory or offensive in respect of the employees’ rights is rejected. The group has 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.

The company has made an Ethics Channel available to its employees, suppliers, business partners, agents and external collaborators, through which they may report any breach of the aforementioned Protocol. This channel has its own 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.
Responsible reconciliation between work and family life

The different personal and family situations that exist are a particularly enriching part of the diversity of ROVI’s workforce. Therefore, the company strives to apply, not only the work-life balance measures required by the public authorities and those included in the chemical industry collective agreement, but also to furnish its own set of measures that expands and enhances them.

The different options the group presents are aimed to create a work environment that provides a higher quality of life and harmony between development of the employees’ personal and family facet and their professional career and promotion.

### Working hours and time off

- Flexible starting and finishing times for office and industrial structure personnel.
- Changes of shift or day between co-workers in the industrial area and reductions in working hours adapted to each person’s needs.
- Flexibility in holiday calendars, provided the activity of the employee’s area is compatible.

### Remuneration

- Salary supplement for the most vulnerable groups, such as pregnant women, to ensure that no conditioning factors, such as a decrease in their usual income, exist. The benefit they receive from the Social Security is completed to 100% of their salary and nursery school vouchers, restaurant vouchers and medical insurance are available in the *a la carte* salary proposal.
- All permanent employees are offered cover by the life insurance policy paid by the company.
In 2019, 13 employees requested reduced working hours to enable them to reconcile their personal life with their professional life.

### Travel

- All personnel who so require are provided with laptop computers with connectivity to the company’s intranet, in order to avoid unnecessary trips and visits.
- Use of videoconferencing and on-line meetings is encouraged.
- If the type of work so permits, the possibility of teleworking is arranged in the last few weeks of pregnancy.
- 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.

### Disconnection from work

- Communication with employees through any channel (telephone, e-mail, chat, etc.) outside working hours is actively avoided, unless there is an urgent, unforeseen or indispensable need that cannot be met otherwise.
- Meetings at the end of the working day that might mean overstepping working hours and, thus, affect workers’ attention to their family duties are avoided.
Evaluation of employee remuneration and the pay gap

ROVI is convinced of the need to apply the principle of equal pay for equal work effectively and takes this principle as the basis of its wage policy, applying it in its salary-fixing practice upon recruitment of the employee and in salary reviews throughout the employee's working life.

In order to ensure application of the principle of wage equality, ROVI monitors the gender pay gap by periodically assessing indicators that show pay gaps by job and gender. The goal is to identify any possible deviations, follow up on the differences and reduce them as much as possible.

In 2018, ROVI engaged the audit firm PricewaterhouseCoopers Auditores S.L. to carry out a limited assurance review of wage group indicators by professional classification in Group companies. The indicators related to the annual period running from 1 April, 2017 to 31 March, 2018 and the reports were prepared on the basis of the methodology published in January 2015 by the Ministry of the Presidency, Parliamentary Relations and Equality in relation to calculating the gender pay gap.

The aforementioned indicators make a diagnostic analysis of the group's workforce to find out the differences in the remuneration of men and women with the same jobs. The analysis of the indicators shows that there is no gender-based pay discrimination or difference in remuneration that is not based on personal factors (qualifications, work experience, length of service, etc.) or position (duties, degree of responsibility, working hours, etc.).

In 2019, ROVI updated the figures as of 31 December and the indicators obtained lead to the same conclusion: there is no gender-based wage discrimination or pay differences that are not based on personal or job-related factors.
Average employee remuneration in 2019 was 36,013 euros.

### Average remuneration by gender

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
<th>TOTAL VARIATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>36,782 €</td>
<td>40,733 €</td>
<td>-10%</td>
</tr>
<tr>
<td>Women</td>
<td>35,244 €</td>
<td>36,738 €</td>
<td>-4%</td>
</tr>
<tr>
<td>AVERAGE</td>
<td>36,013 €</td>
<td>38,735 €</td>
<td>-7%</td>
</tr>
</tbody>
</table>

### Average remuneration by age/gender

<table>
<thead>
<tr>
<th>Age Group</th>
<th>2019</th>
<th>2018</th>
<th>TOTAL VARIATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-30 years</td>
<td>22,813 €</td>
<td>28,091 €</td>
<td>16%</td>
</tr>
<tr>
<td>31-40 years</td>
<td>29,893 €</td>
<td>34,909 €</td>
<td>0%</td>
</tr>
<tr>
<td>41-50 years</td>
<td>44,772 €</td>
<td>41,400 €</td>
<td>-7%</td>
</tr>
<tr>
<td>51-60 years</td>
<td>48,836 €</td>
<td>40,914 €</td>
<td>-10%</td>
</tr>
<tr>
<td>&gt;60 years</td>
<td>51,672 €</td>
<td>36,987 €</td>
<td>95%</td>
</tr>
</tbody>
</table>

### Average remuneration* by professional group**/gender

<table>
<thead>
<tr>
<th>Professional Group</th>
<th>2019</th>
<th>2018</th>
<th>TOTAL VARIATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>16,000 €</td>
<td>17,262 €</td>
<td>10%</td>
</tr>
<tr>
<td>2</td>
<td>17,117 €</td>
<td>18,095 €</td>
<td>5%</td>
</tr>
<tr>
<td>3</td>
<td>19,137 €</td>
<td>21,510 €</td>
<td>6%</td>
</tr>
<tr>
<td>4</td>
<td>26,350 €</td>
<td>25,951 €</td>
<td>8%</td>
</tr>
<tr>
<td>5</td>
<td>36,492 €</td>
<td>33,925 €</td>
<td>-15%</td>
</tr>
<tr>
<td>6</td>
<td>43,960 €</td>
<td>34,910 €</td>
<td>-9%</td>
</tr>
<tr>
<td>7</td>
<td>53,905 €</td>
<td>50,705 €</td>
<td>6%</td>
</tr>
<tr>
<td>8</td>
<td>104,044 €</td>
<td>102,851 €</td>
<td>-2%</td>
</tr>
<tr>
<td>0</td>
<td>226,024 €</td>
<td>132,203 €</td>
<td>8%</td>
</tr>
<tr>
<td>Subsidiaries</td>
<td>71,545 €</td>
<td>66,091 €</td>
<td>-14%</td>
</tr>
</tbody>
</table>

* Does not include scholarship remuneration, since scholarship-holders do not have a Professional Group.
** Professional Group in accordance with the XIX Chemical Industry Collective Agreement.
Furthermore, ROVI has a Policy for the Reimbursement of Expenses and Payment of Per Diem Allowances for a series of stipulated items, in order to prevent items related to the employees’ work from representing an extra expense for them. The reimbursement of expenses is preceded by the pertinent expense note, which must be accompanied by the documentary support of the expenses (invoices, etc.). To prevent fraud, employees must settle the expenses incurred in providing their services preferably with the corporate credit card and must minimise cash payments.

In the specific case of the average remuneration of the members of the company’s Management Committee in 2019, including fixed and variable remuneration and remuneration in kind, it was 251,787 euros for men and 148,644 euros for women. The reason for the difference is that, in the case of the men, three of them are also Executive Directors and their salaries reflect the additional responsibilities they hold.

### Average remuneration of management committee/gender

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
<th>TOTAL</th>
<th>VARIATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Men</strong></td>
<td><strong>Women</strong></td>
<td><strong>AVERAGE</strong></td>
<td><strong>Men</strong></td>
<td><strong>Women</strong></td>
</tr>
<tr>
<td>Fixed remuneration</td>
<td>179,399 €</td>
<td>113,333 €</td>
<td>146,366 €</td>
<td>163,430 €</td>
</tr>
<tr>
<td>Variable remuneration</td>
<td>61,144 €</td>
<td>28,333 €</td>
<td>44,889 €</td>
<td>61,960 €</td>
</tr>
<tr>
<td>Payment in kind</td>
<td>10,944 €</td>
<td>6,977 €</td>
<td>8,960 €</td>
<td>8,752 €</td>
</tr>
<tr>
<td><strong>AVERAGE TOTAL</strong></td>
<td>251,787 €</td>
<td>148,644 €</td>
<td>200,215 €</td>
<td>234,142 €</td>
</tr>
</tbody>
</table>

**Attracting and retaining talent and training**

ROVI’s success necessarily requires the best talent to be attracted and retained. This is the basis required for the business to grow and, to achieve it, the Human Resources Department designs and manages both the Selection Policies, governed principally by elements such as equal opportunities, objectivity and impartiality, confidentiality, favouring the attraction of young talent, excluded groups or differently-abled people, as well as the promotion of internal candidates, and the different training activities.

One of the main channels for capturing talent is through scholarship and training programmes, in collaboration with educational institutions, with which ROVI has established 73 collaboration agreements (universities, institutes, official training centres and business schools) all over Spain, in order to provide practical training that serves as a bridge to allow students to begin their working lives in a professional environment. Through them, undergraduates in their last year, student’s studying for a Master’s degree or doctorate and professional training students have the possibility of obtaining their practical training credits in different areas of one of the group companies, thus accessing their first real contact with a work environment and enhancing their skills, knowledge and experience.
The possibilities for young talents to train and the investment the group makes in this training is indispensable in order to have a reserve ready for the future. Around 85% of the people who obtain a scholarship with ROVI finally join the company with a contract.

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

- **90%** of the ROVI group's scholarships are remunerated
- **90%** of the scholarships are full time
- **90%** of the scholarships last for 6+6 months
Training in skills and values

ROVI invests significant time and resources in training, with 16.6 hours of training per worker (20.3 hours in 2018) and investment of 252.1 euros per worker in 2019 (247.2 euros in 2018), in order to prepare its entire workforce and thus optimise the potential of its human team. Not only the interested parties are involved in this training, but also their direct superiors, and the transfer of knowledge from the more veteran generations to those with less experience is fostered as one of the company’s most important values.

A well-trained and qualified workforce is indispensable for attaining ROVI’s short, medium and long-term goals. But everything starts with the structuring of the development plans, taking account of:

- **The immediate needs** of the job.
- **The long-term requirements** that may derive from the use of new technologies, equipment or instruments or from assuming greater responsibilities with a view to future promotion or new projects.

All the employees have an Individual Development Plan, designed with the goal of efficiently helping people to co-operate and contribute value in achieving ROVI’s strategic goals, while, at the same time, they grow as professionals in their area. This Plan requires personal commitment on the part of the employees, aware of the need to seek their own improvement as professionals.

The methodology is structured into 10% of development and learning through training actions in the classroom or in virtual or e-learning format; 20% through feedback, observation or with the support of mentors, coaches, professional associations, spaces for reflection, conversations with other people, leaders, etc.; and the remaining 70% through practical job experience, applying new knowledge to real situations to solve problems, taking part in new projects and challenges, rotating through different departments, etc.
Basic principles of ROVI Group’s training programmes/actions

- Training programmes will contain aspects related to respect for human rights and will foster an ethical culture.

- No discrimination on the grounds of gender, age or origin. Professionals with equal positions and professional development have the same training opportunities.

- Training actions will respect the current regulatory framework and the demands of the work and business environment. ROVI will provide training in new legislation, so that workers know and comply with current laws.

- The use of different training tools is favoured (classroom, on-line, platforms, etc.).

- Sharing the knowledge that exists in the Company, continuous learning and cultural exchange will be encouraged.

Average hours of training by professional group* in 2019

<table>
<thead>
<tr>
<th>Group</th>
<th>Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.0</td>
</tr>
<tr>
<td>2</td>
<td>16.1</td>
</tr>
<tr>
<td>3</td>
<td>21.3</td>
</tr>
<tr>
<td>4</td>
<td>22.9</td>
</tr>
<tr>
<td>5</td>
<td>23.2</td>
</tr>
<tr>
<td>6</td>
<td>21.8</td>
</tr>
<tr>
<td>7</td>
<td>21.4</td>
</tr>
<tr>
<td>8</td>
<td>15.3</td>
</tr>
<tr>
<td>0</td>
<td>7.2</td>
</tr>
</tbody>
</table>

**AVERAGE 16.6**

* Professional group according to the XIX Collective Agreement of the Chemical Industry.

All the employees have an individual Development Plan, designed with the goal of efficiently helping people to co-operate and contribute value.
Total hours of training by professional group*

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>0</th>
<th>TOTAL 2019</th>
<th>TOTAL 2018</th>
<th>VAR. TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0</td>
<td>740.6</td>
<td>3,684.9</td>
<td>5,358.6</td>
<td>10,231.2</td>
<td>3,727.8</td>
<td>4,237.2</td>
<td>61.2</td>
<td>122.4</td>
<td>28,163.9</td>
<td>24,057.9</td>
<td>17%</td>
</tr>
</tbody>
</table>

* Professional group according to the XIX Collective Agreement of the Chemical Industry.

At the same time as ROVI strives to provide the best training in professional skills to its employees, it also devotes part of its training effort to actions to ensure that its Code of Ethics and its different CSR and sustainability policies are understood and applied. In 2019, the company provided CSR training to all new employees and held 22 Compliance training sessions related to the Ethics Channel, FarmaIndustria’s Good Practice Code, the Anti-bribery and Anti-corruption Policy, etc.

Trade union information and relations with the workers’ representatives

As usual, in 2019, labour relations between ROVI and its workforce ran normally with no conflictive incidents. The company constructs dialogue and smooth communication using all the means available. In particular, it tries to arrange a meeting calendar for both regular and specific meetings, which either the company or the workers’ representatives are free to establish. This constant and flexible relationship allows the status of the agreements between the two parties to be monitored and any incident identified in the day-to-day activity to be solved swiftly.

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. The 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. 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.

An important aspect of our works councils is that they are highly representative and participate in the Occupational Health and Safety Committees. On these committees, the company’s actions in these areas are regularly consulted, debated and proposed, as well as any incidents that have arisen and proposals for corrective measures in areas such as the evaluation and assessment of occupational hazards, the provision of individual protection equipment, the protection facilities, and information and training on occupational hazards, among other subjects.
Health, safety and management of occupational hazards

The workers’ health -both mental and physical- is the health of the company as an organisation and is a factor with a direct influence on ROVi’s value creation. The company, therefore, has a dual commitment:

• To minimise occupational hazards
• To promote healthy conduct in the workplace

The management of employee health and safety risks is the task of the Health and Environment Department, which also holds exclusive responsibility for aspects related to environmental 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 employees and those of the companies who work with it. This Policy is constructed on the basis of a series of corporate procedures, as well as local procedures or work instructions specific to each centre.

Likewise, all ROVi’s industrial plants hold OSHAS 18001:2007 Occupational Health and Safety Management Certifications, published on ROVi’s website. Furthermore, the group has a number of Health and Safety Committees on which all ROVi employees are represented.

The ROVi Group set a goal of an accident rate (No. of accidents / No. of workers * 100) of 1.3% with sick leave and 3% without sick leave. In addition, each plant, individually, defines specific prevention objectives. Examples of these are:

• Reduction in the trend of accidents with sick leave due to overexertion by 20% in comparison with the period January 2018 – June 2019 (18 months).
• Implementation of an Industrial Hygiene Programme to reduce the workers’ exposure to active substances.
• Increase in the number of technical staff in the Maintenance Area with broader prevention training by 20% (in respect of the total) in comparison with 2018.

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 category of moderate risk associated to falling to a different level in the task of installing/removing the rotary valve of the roller compactor (Alcalá de Henares plant).

ROVi set a goal of an accident rate of 1.3% with sick leave and 3% without sick leave
The promotion of healthy attitudes is another of the most decisive factors in reducing job-related occupational hazards. Furthermore, it provides the workers with a higher quality of life and ROVI has been actively committed in this respect for more than five years, with actions such as:

- Healthy breakfasts.
- Healthy vending at the plants.
- Agreements with nearby sports centres so that employees can practise sports.
- Participation in fun runs and charity races.

Throughout the group in general, the professionals who so require are provided with laptops, to avoid unnecessary trips and visits, while, at the same time, reducing the risk of accidents on the way to work. The use of videoconferencing and on-line meetings is actively encouraged and teleworking is fomented whenever possible, especially for pregnant women, who also have access to parking spaces inside the company to facilitate their mobility.

Prevention during the Covid-19 pandemic

In March 2020, ROVI implemented measures to reduce the risk of infection by coronavirus. The company reduced the processes that had to be performed in person at its facilities to a minimum and enabled a significant part of the workforce to work from a distance. In cases where home working was not possible, such as the manufacturing plants, ROVI adopted the relevant safety measures to maintain the production activities at a reasonably normal level, in order to ensure that its medicines continued to be available to patients throughout the health crisis.

For professionals who needed to be physically in their workplace, in order to avoid the use of public transport, the company assumed the cost of private transport and parking spaces. Furthermore, in recognition of their commitment and responsibility, ROVI approved a bonus consisting of 20% of their wages for the duration of the State of Alarm decreed by the Spanish government.
Accident rate and absence rate

These concepts are related and good accident prevention management not only benefits the health and well-being of the workforce, but also reduces the absence rates. In addition, they are key factors in indicators such as productivity, the company’s financial performance and the attainment of strategic goals.

### Work accident frequency rate (*) by gender

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th></th>
<th>2019</th>
<th></th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>7.678</td>
<td>Women</td>
<td>11.540</td>
<td>Men</td>
<td>0.604</td>
</tr>
<tr>
<td>TOTAL</td>
<td>9.652</td>
<td>TOTAL</td>
<td>0.503</td>
<td>TOTAL</td>
<td>2.778</td>
</tr>
</tbody>
</table>

* Rate calculated as No. accidents / No. hours worked * 1000000

### Work accident severity rate (*) by gender

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>0.604</td>
</tr>
<tr>
<td>Women</td>
<td>0.405</td>
</tr>
<tr>
<td>TOTAL</td>
<td>0.503</td>
</tr>
</tbody>
</table>

* Rate calculated as No. of days lost / No. of hours worked * 100

### Work accident incidence rate (*) by gender

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>2.280</td>
</tr>
<tr>
<td>Women</td>
<td>3.161</td>
</tr>
<tr>
<td>TOTAL</td>
<td>2.778</td>
</tr>
</tbody>
</table>

* Rate calculated as No. accidents / No. workers *100

Note: accidents on the way to work and data of ROVI group employees are included. Information on personnel hired through temporary employment companies is excluded. In addition, a working day of 8 hours has been used to calculate the number of working days lost.

The indicators show that the level of absences in ROVI in 2019 was below those of the sector which it operates.

### Summary of absolute absence rates in the period

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total absolute absence rate</td>
<td>2.52%</td>
<td>3.43%</td>
</tr>
<tr>
<td>Absolute absence rate WA + OD</td>
<td>0.26%</td>
<td>0.20%</td>
</tr>
<tr>
<td>Absolute absence rate OSL</td>
<td>2.26%</td>
<td>3.23%</td>
</tr>
</tbody>
</table>

WA: Work-related accident - OD: Occupational disease - OSL: Ordinary sick leave

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

ROVI’s suppliers are a strategic stakeholder group in relation to the company’s activities. Therefore, ROVI has put in place a series of specific action principles aimed to reinforce the sustainability and the competitive edge of the value chain through a series of commitments where selection criteria and transparent information prevail.

During 2019, ROVI worked with approximately 3,700 suppliers from 35 countries. In this respect, Spanish suppliers have a prominent specific weight, since they account for 86% of the total. One of the principles of the supplier engagement policy is to work with local service suppliers. This means that the 90% of the suppliers on the portfolio are from the European Union, mainly from countries where ROVI is present with subsidiaries: Germany, Portugal, France, United Kingdom, Italy and Poland.

Both inside and outside the Spanish borders, the Supplier Engagement and Payment Policy is applied in order to establish a framework common to the whole company in its relations with suppliers and creditors. This Policy states that suppliers with an annual volume of over 100,000 euros must always have a duly-signed contract and regulates how invoices should be sent and recorded and the means of payment accepted. This element ensures full efficiency in accounting for invoices, an appropriate payment policy and greater consistency in negotiations. In this respect, in 2019, ROVI’s average payment period to suppliers was 52.52 days, within the maximum legal periods stipulated in Law 17/2010, amended by Law 11/2013.

During 2019, ROVI worked with approximately 3,700 suppliers from 35 countries.
Smooth and constant communication

This smooth relationship with suppliers is possible because ROVI promotes regular communication. As an example, in 2019, internal training was imparted to employees who deal with local and foreign suppliers, in order to inform them on the importance of the residency certificate in relation to the Double Taxation Treaty and avoid running any tax risks.

Along the same lines, due to a merger by absorption process in our company group Laboratorios Farmacéuticos ROVI and subsidiaries, a Communication and Transparency Policy was implemented vis-à-vis our suppliers, sending communications with full tax information on the merger, both electronically and, for the less digitalised companies, on paper. At the same time, guidance was given so that they could update the master data of our companies in their systems and several telephone lines were provided to resolve any queries on invoicing or orders.

Purchasing policy, supplier approval and equal opportunities

ROVI’s Supplier Selection Policy includes the specific criteria applied when beginning to work with another company, as well as those applicable to monitoring the latter’s activity and its relationship with the group.

Among other procedures, the Policy provides for an initial evaluation and another periodic evaluation, which are tools that allow a list of approved suppliers, kept by the Quality Department, to be drawn up. These evaluations are performed through on-site audits to check that suppliers operate in accordance with national and local regulations and observe the best practices in respect of workplace safety and that there are no practices that violate the workers’ rights, in addition to ensuring that a safe work environment exists, environmental legislation is respected and employees are not subjected to abusive or discriminatory conduct.

Anti-bribery and anti-corruption mechanisms and policies

ROVI applies the standards set out in its Code of Ethics, rejecting any practice that includes bribery or corruption as a way to reach an agreement. At the same time, any practice intended to do business using undue or immoral means is strictly prohibited. Any interaction between a ROVI employee and health professionals, organisations or systems, pharmacies, stores, purchasers, distributors, suppliers, trading partners, public officials or any other 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.

No ROVI employee may offer a third party any type of benefit intended to unlawfully influence or offered with the intention of unlawfully 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.

The group has an Anti-Corruption Policy that regulates giving and accepting gifts. This policy must be known and observed by all the professionals. At any event, accepting or giving gifts can never be used as a ruse for bribery or the concealment of an unlawful action.
CSR in the supply chain: Code of Ethics for Suppliers

ROVI considers it indispensable to ensure a supply chain that respects the corporate social responsibility principles assumed by the group. Therefore, it undertakes to promote CSR-related values among its goods and services suppliers and subcontractors.

ROVI's Code of Ethics for Suppliers is binding on anyone who provides services to ROVI. Suppliers undertake to respect the protection of internationally-recognised fundamental human and labour rights and are expressly required to comply with the following principles:

- Elimination of forced labour.
- Elimination of child labour.
- Respect for the right of association and collective bargaining.
- Equal opportunities and non-discrimination.
- The supplier must provide a fair work environment, free of any kind of violence.
- Respect for current legislation on working hours and remuneration.

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

Particularly in environmental matters, the company is committed to making a combined effort with its suppliers and contractors to minimise the impact of their activities on the environment and the risks derived for both their safety and health and that of their workers.

ROVI has two mechanisms to promote the adoption of the best corporate responsibility practices in its supply chain:

- **A voluntary document, “CSR Commitment”** is periodically sent to all the group’s suppliers and subcontractors, requesting certifications such as the SA-8000 or urging them to adopt good practices. At present, more than 55% of these companies have signed the commitment to social responsibility. ROVI’s goal is that all the suppliers should adhere to the initiative.

- **On-site audits**, which check that suppliers operate in accordance with national and local regulations.

Through the use of the management principles, application of the Code of Ethics for Suppliers and the utilisation of monitoring mechanisms, the risk that any ROVI supplier will breach its Human Rights obligations is unlikely, limited and under control. This is also supported by the fact that 90% of the company’s suppliers operate in a European Union country or other country that enjoys recognised prestige in the international community.
ROVI is aware of the social impact of its activity at different levels of society. This is why, going beyond its business activity, the group is permanently involved in supporting medical research and committed to higher education in Spain, likewise acting responsibly in relation to its both its tax obligations and its role as an employer and economic agent in its immediate environment.

The group accepts its impact on society, assessing and managing the non-financial, ethical, reputational, social and environmental risks and committing itself to those initiatives that benefit society. ROVI thus focuses on a series of priority areas for social action, such as fomenting research, the mainstreaming of people with disabilities in the workplace, promoting health, commitment to training and corporate volunteering.

ROVI’s social commitment and its results in 2019 are linked to its close relationship with the university and research world, which is always its first choice for collaboration agreements to combine the efforts of the sector agents or 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.

The company likewise strictly observes its tax obligations to society and the finance authorities, at the same time as it does not forget its role as a catalyst to social action, in both integration and promoting employment in the immediate area of its plants.
Support of training of the best health professionals and research

ROVI’s relationship with the academic world is dual. First, it is a social and employment agent involved in enabling qualified students to access a workplace environment with guarantees, enhance their skills and knowledge and obtain their first job experience.

For this reason, it has the scholarship programme described in the Human Resources section (page 114) of this Integrated Report, under which, last year, 45 people had their first job opportunity in a top-level professional environment.

At the same time, it has intensive in-house activity in the research, development and manufacture of pharmaceutical products, which is carried on entirely in Spain, divided between the Madrid and Granada centres. This bet on promoting “Spanish brand” R&D involves a significant investment each year. In 2019, it was 29.3 million euros, slightly less than the 32.4 million euros invested in 2018, mainly due to the conclusion of the Phase III trial of Risperidone-ISM®.

At the same time, ROVI is intensively involved in co-operative research, holding collaboration agreements with different government entities and universities, such as the agreement it holds with the University of Granada to combine efforts to increase scientific, technological and training activities, as well as to spread knowledge.

The group strives to promote, spread and communicate scientific progress in different fields. It supports initiatives such as the TedxTalks Realejo, a local conference event the topics of which focus on innovation and entrepreneurship, based on different types of personal experiences. The first edition was held in May 2019 and was sponsored by ROVI. It also took part, last year, in the IV OCARE Prizes (Observatory of Corporate Responsibility Communication and Action), which recognise the best communication campaigns by companies in the CSR area and that, for a further year, were sponsored by ROVI, as well as the SEFH/ROVI Hospital Pharmacy Development awards, which have been awarded jointly with the Spanish Hospital Pharmacy Society (SEFH) for the last three years and which recognise projects that represent the contribution of innovative and beneficial solutions for patient well-being and quality of life. In a similar spirit, ROVI co-operated with the 2019 Prize for the Best Oral Communication on Treatment of Venous Thromboembolic Diseases, presented at the Congress of the Spanish Thrombosis and Haemostasis Society (SETH).

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

The group is firmly convinced that social responsibility begins by duly meeting all the obligations that companies have to society, particularly tax obligations, aware that this sustains the welfare state for society overall.

This commitment leads to strict compliance with tax requirements and the application of good tax practices: acting transparently, paying taxes responsibly and efficiently and promoting relationships of co-operation with governments, avoiding material risks and unnecessary conflicts.

The effective tax rate in 2019 was 6.2% (expense of 2.6 million euros), compared with -7.3% in 2018 (revenue of 1.2 million euros), due mainly to the reduction in R&D expenses in 2019 in comparison with the preceding year, which led to lower deductible research and development expenses. ROVI has adhered to the Code of Good Practice of the Tax Agency and, to assist in compliance with its tax obligations, uses the services of an independent external tax advisor, who keeps company management updated on these matters and solves any possible conflicts or queries that may arise. The advisor also reviews the preparation and presentation of the different taxes, as well as tax-related decision-making.
## Economic value generated and distributed

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Economic value generated</td>
<td>382.5</td>
<td>304.8</td>
</tr>
<tr>
<td>Economic value distributed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shareholders</td>
<td>9.8</td>
<td>4.5</td>
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<tr>
<td>Suppliers</td>
<td>219.2</td>
<td>172.7</td>
</tr>
<tr>
<td>Society</td>
<td>2.6</td>
<td>-1.2</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>29.3</td>
<td>32.4</td>
</tr>
<tr>
<td>Employees</td>
<td>72.5</td>
<td>70.2</td>
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<tr>
<td>Providers of capital</td>
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<td>0.8</td>
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<tr>
<td>Amortisation and depreciation</td>
<td>18.6</td>
<td>12.0</td>
</tr>
<tr>
<td>Reserves</td>
<td>29.6</td>
<td>13.4</td>
</tr>
</tbody>
</table>

Finally, the company’s relations with the public authorities are of special importance, as well as its strict responsibility as a manufacturer and marketer of medicines and health products. ROVI strives to maintain a constant, effective and transparent relationship with the health agencies, meticulously observing and monitoring all the requirements made by these bodies in all its activities, including industrial development, manufacturing and the supply of products or units for clinical trials. In respect of clinical trials, ROVI always ensures that they are carried out in an environment of strict compliance with all the applicable legal requirements and authorisations granted.

**ROVI strives to maintain a constant, effective and transparent relationship with the health agencies**
## Tax table 2019

<table>
<thead>
<tr>
<th>Company Name</th>
<th>Profit before tax (Thousand euros)</th>
<th>Income tax paid (Thousand euros)</th>
<th>Government grants received (Thousand euros)</th>
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</thead>
<tbody>
<tr>
<td>Laboratorios Farmacéuticos Rovi, S.A.</td>
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<td>-8,085</td>
<td>1,151</td>
</tr>
<tr>
<td>Laboratorios Farmacéuticos Rovi, S.A. permanent establishment Portugal</td>
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<td>-15</td>
<td>-</td>
</tr>
<tr>
<td>Laboratorios Farmacéuticos Rovi, S.A. permanent establishment Poland</td>
<td>-58</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Laboratorios Farmacéuticos Rovi, S.A. permanent establishment Germany</td>
<td>270</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Rovi Pharma Industrial Services, S.A. (*)</td>
<td>33,131</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Pan Química Farmacéutica, S.A. (*)</td>
<td>602</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Gineladius, S.L. (*)</td>
<td>-42</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Rovi Escúzar, S.L.</td>
<td>-19</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Bertex Pharma GmbH</td>
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<td>-</td>
<td>-</td>
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<tr>
<td>Rovi Biotech, Limited</td>
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<td>Rovi Biotech, GmbH</td>
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<td>Rovi S.A.S.</td>
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<td>Rovi Biotech spółka z o.o</td>
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<tr>
<td>Rovi Biotech, Ltda.</td>
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<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>-8,129</strong></td>
<td></td>
<td><strong>1,151</strong></td>
</tr>
</tbody>
</table>

(*) These companies form part of tax group 362/07 of which Laboratorios Farmacéuticos Rovi, S.A. is the parent.
Social inclusion and mainstreaming of differently-abled groups

ROVI continues to be mindful of its activity as a key agent in the areas where it has its facilities, both as a catalyst for local employment and in relation to business for suppliers in the area. It maintains intensive and enriching co-operation with a series of entities involved in the protection of groups that are especially vulnerable to social and financial exclusion and is very much involved in the mainstreaming of groups who find social and workplace integration difficult.

People with disabilities are one of the groups at the greatest risk of this type of discrimination. The company is convinced that the integration of differently-abled people is enriching and creates a differential value. Therefore, the group is committed to mainstreaming these groups in the workplace and encourages hiring them. In 2019, 34 people with disabilities worked for ROVI (vs 25 in 2018).

At the same time, to engage certain services, the company uses companies that favour the integration of people with disabilities, such as ISS Facility Services (Gelim), which carries out cleaning services; Ilunión, which provides the laundry service for clothing from the plants; or Fundación Manantial, the aim of which is to integrate people with serious mental illnesses and is certified to work in the secondary packaging of pharmaceutical products and catering services for the offices.

Precisely in 2019, together with Fundación Manantial, ROVI started a job bank for people with mental illnesses at the Alcalá de Henares plant, allowing 5 employees to join the workforce.

Not only did ROVI work with the organisations mentioned above in 2019, but also with the following, many of which it has been co-operating with for a number of years:

Down Granada
which works helping young people in Granada with Down’s Syndrome to enter the labour market in local companies and has co-operated with ROVI in training one of its young people to perform administrative tasks at the plant in the Health Technology Park (Granada).

Cruz Roja Granada
with which ROVI co-operates in its assistance and protection projects for children and elderly people in the province of Granada.

Donation of material to the fight against Covid-19

Among its contribution to improve the health situation in Spain caused by the coronavirus epidemic, ROVI donated a million surgical masks and 1,000 special protection suits to the Ministry of Health, Consumption and Social Welfare, aware of the difficulties that the National Health System has been undergoing in obtaining individual protection equipment during this crisis.
In addition to its direct involvement in different social initiatives, ROVI also regularly makes donations to health, social and humanitarian organisations. Among the proposals for social and humanitarian donations approved in 2019, those allocated to international co-operation may be highlighted, such as the donation to Fundación Recover, which is given help for its health assistance programmes in Africa, as well as Fundación para el Desarrollo Integral de los Pueblos, with which ROVI co-operates in the acquisition of teaching and learning material for schools in Callao, Peru.

In addition, some examples of donations for the social protection of the underprivileged can be mentioned, such as the donation to Fundación La Sal de la Tierra of Alcalá de Henares, to which industrial cooking material was donated, which they reused for the soup kitchens they have in in the same city, as well as in Alicante and Vigo. In 2019, ROVI also co-operated with Fundación Pilares, which is engaged in guidance and assistance for people who are highly dependent on others, as well as Club Deportivo Elemental Entrevías-El Pozo, a non-profit club involved in sports and the participation in sports competitions for children and adolescents at risk of social exclusion.

All these contributions are managed by the Donations Committee, which, on the basis of the Donation Management Procedure –in force since 2018 and amended in 2019– evaluates the applications, verifies that they are legal and, as appropriate, approves or rejects them, also observing the Code of Good Practices of the Pharmaceutical Industry, ROVI’s Code of Ethics and the Corporate Social Responsibility Policy.
Volunteering, social action, sponsorship and patronage

ROVI is involved in numerous corporate volunteering activities with a series of NGOs, which it subsequently broadcasts on the company’s internal television network and reports in the different publications it sends to its employees, in order to share the group's commitment with the latter and raise awareness of different causes. In these activities, ROVI seeks to promote a healthy lifestyle and co-operate with non-profit entities that work for the inclusion of groups at risk or to improve healthcare worldwide.

For more than three years, ROVI's corporate volunteering programme has been 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 co-operating with the different NGOs and foundations with which the company works.

In 2019, 121 ROVI employees took part in one of the activities programmed by the CSR area. 16.5% of them participated in two or more volunteering activities during the period, such as the Adaptive Ski-ing Campus in Sierra Nevada (Granada), the Adaptive descent of the River Sella (Asturias), the VII “También Solidario” Fun Run in Madrid, the adaptive cycling route through the Anillo Verde (Green Ring) (Madrid) or the Multisports Day (Madrid).

Additionally, last year, in line with its promotion of a healthy lifestyle and the practice of sports, the group continued to co-operate with fun runs and emblematic events, such as the VIII Charity Race for Mental Health and the XX Carrera de las Empresas (“Companies Race”) of Actualidad Económica in Madrid, or the II Medicusmundi Sur Charity Race and the Granada Red Cross “Crossing the Line” Race, both in Granada.

ROVI has been working with most of the above mentioned organisations for a number of years, but a new one joined the list in 2019. Apadis, an association of relatives of people with intellectual disabilities in San Sebastián de los Reyes, carried out its first activity with the group by organizing a corporate volunteering activity in which a group of employees and their families, together with volunteers from the foundation, painted the entrance hall of its occupational centre in San Sebastián de los Reyes.

Elimination of architectural and mental barriers to people with disabilities

In 2019, ROVI completed the remodelling plan at its work centres, intended to make them accessible safely, comfortably and autonomously for everyone. All the group’s work centres are now 100% accessible and, thus, all the barriers to people with permanent or temporary mobility problems have been eliminated.

Problems of physical access to the workplace and difficulties in using objects and products are barriers that hinder the full integration of people with disabilities in both social and workplace 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.

At the same time, ROVI has extended this initiative to break down architectural barriers and barriers to the use of its products to trying to make them more accessible and safer, including labelling in Braille, so that the visually impaired can use them autonomously and safely.
ENVIRONMENT

In the same way as ROVI is, due to the activity, processes and materials handled at its plant, concerned about the health of its workers, it also endeavours to reduce the impact on its business on the environment to a minimum. The group is firmly committed to minimising the effect of all its activities, from the manufacturing of its products to their distribution, when and where this is possible, implementing the measures necessary to guarantee people’s health and safety both inside and outside the facilities.

The General CSR Policy pays special attention to care of the environment as one of its key principles, establishing it as an indispensable factor in both decision-making and the day-to-day work at all the plants. At the same time, ROVI observes a series of sustainable management principles from an environmental standpoint, which materialise in actions aimed at managing resources efficiently and promoting environmental responsibility on the part of its workforce and suppliers, as set out in the Integrated Environmental Management and Occupational Hazard Prevention Policy.

All these actions are centralised in a department that is exclusively responsible for environmental management-related aspects and, likewise, those concerning workplace health and safety, since many of them are present in and affect both these areas. In 2019, it administered a budget of 2.9 million euros, which was allocated to maintaining, among other things, the commitment to continuing improvement and compliance with legal requirements. Furthermore, this department was also responsible for managing different voluntary requirements by implementing energy efficiency solutions at the plants, responsible natural resource management and waste recycling, the pillars on which the company’s environmental strategy is based.

Reduction in consumption

ROVI maintains the commitment to use all the means available to it to combat climate change, which it channels mainly through the constant evaluation, optimisation and reduction of resource consumption.

Due to the production increase, in 2019, electricity consumption rose to 20.6 million kWh, with 23.1 million kWh of natural gas. However, the key factor was that electricity consumption per unit manufactured was reduced in all the facilities and in the distribution area. Regarding water, the total of cubic metres consumed was 148,632 m3, representing a 4.1% increase.

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. Additionally, at all the plants, a monthly check is made of the water, electricity and gas indicators, detecting any possible deviations in order to always keep the consumption of these utilities in an optimal situation.
Due to the production increase, in 2019, electricity consumption rose to 20.6 million kWh, with 23.1 million kWh of natural gas consumed.
Waste management and greenhouse gas emissions

ROVI’s activity entails the generation of several types of potentially hazardous waste. Therefore, the company’s main priorities include the treatment and, where possible, the reduction of this waste. The goals pursued each year are to reduce its impact and prevent its pollutant effects, which the related processes are principally aimed to control, as well as managing it correctly when it is generated, in such a way as to facilitate the use or recycling of this waste, as appropriate.

Another important aspect of ROVI’s environmental impact is measuring the CO2 emissions from natural gas and diesel consumption, as well as other substances generated in its industrial activity that act to destroy the ozone layer. In this respect, in 2019, to reduce its carbon footprint even further, in line with the goal of rationalising the fossil fuel consumption, the company completed the renewal of its vehicle fleet for the sales network and corporate use. The change in vehicles has had a favourable impact on the rationalisation of the company’s average fuel consumption, reducing the litres of fuel consumed by the company’s vehicles by 6.3%.

The production increase in 2019 led to an increase in the hazardous waste generated to 2,281 tonnes and the non-hazardous waste to 3,381 tonnes.

Waste recycling and disposal have been treated in the most responsible manner possible, following the highest industry standards and ensuring that it does not cause any type of environmental or health problem. Total greenhouse gas emissions have remained insignificant, well before the legally-established levels, although they were not negative as in previous years.

### Waste Management

|                  | Granada | Madrid & SSRR | Alcalá de Henares | Distrib, | Granada | Madrid & SSRR | Alcalá de Henares | Distrib, | Gr | Mad & SSRR | AH | Distr, |
|------------------|---------|---------------|-------------------|----------|---------|---------------|-------------------|----------|    |            |    |        |
| **Tonnes of hazardous waste generated** | 1,910 | 236 | 120 | 15 | 1,037 | 186 | 176 | 25 | 84% | 27% | -32% | -39% |
| **Tonnes of non-hazardous waste generated** | 2,282 | 658 | 440 | 1 | 1,336 | 464 | 283 | 1 | 71% | 42% | 56% | -30% |
| **TOTAL WASTE** | 4,192 | 894 | 560 | 15 | 2,373 | 651 | 459 | 26 | 77% | 37% | 22% | -39% |
| **Tonnes hazardous waste/million units** | 0.004 | 1.78 | 3.53 | 0.74 | 0.003 | 1.70 | 5.17 | 115 | 5% | 5% | -32% | -35% |
| **Tonnes non-hazardous waste/million units** | 0.004 | 4.97 | 12.94 | 0.02 | 0.004 | 4.24 | 8.31 | 0.03 | -3% | 17% | 56% | -25% |
| **Tonnes waste/million units** | 0.008 | 6.76 | 16.47 | 0.77 | 0.008 | 5.95 | 13.49 | 1.18 | 0% | 14% | 22% | -35% |
Atmospheric emissions

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
<th>TOTAL VARIATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tonnes of CO₂ emitted</td>
<td>1,569</td>
<td>3,644</td>
<td>5,446</td>
</tr>
<tr>
<td>Tonnes CO₂ / million units.</td>
<td>0.003</td>
<td>27.54</td>
<td>137.86</td>
</tr>
</tbody>
</table>

(*) Some of the data relating to the last month of 2019 is an estimate based on information from previous periods.

Environmental certificates

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 14001:2015. These certifications recognise the quality of ROVI’s environmental management systems and assure its commitment to the environment in terms that go beyond those of current national legislation. At present, the group companies Laboratorios Farmacéuticos ROVI, S.A., ROVI Contract Manufacturing S.L. and Frosst Ibérica S.A. (now ROVI Pharma Industrial Services, S. A. U.) have their environmental management systems certified under the standard ISO 14001:2007 and, since 2018, also under the standard ISO 14001:2015.

All the environmental systems held by the ROVI companies are available to interested parties on the corporate website (www.rovi.es).
ABOUT
THIS REPORT
150 · Preparation and scope

151 · Materiality analysis

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PREPARATION AND SCOPE

This Annual Report includes relevant information on ROVI in relation to financial and strategic aspects and ESG (environment, social and governance) in 2019 in the group companies shown in the Corporate Structure table on page 12. The previous report was drawn up in June 2019 and included information on the 2018 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 coverage or material issues and no information has been restated.

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

In 2019, 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:

Investor Relations

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28224, Pozuelo de Alarcón (Madrid)
Tel: +34 91 244 44 22
email: ir@rovi.es
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-assessment 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

**WORK ENVIRONMENT**
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
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.
<table>
<thead>
<tr>
<th>ID.</th>
<th>INDICATOR</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>102-1</td>
<td>Name of the organisation</td>
<td>11</td>
</tr>
<tr>
<td>102-2</td>
<td>Activities, brands, products and services</td>
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</tr>
<tr>
<td>102-3</td>
<td>Location of headquarters</td>
<td>11</td>
</tr>
<tr>
<td>102-4</td>
<td>Location of operations</td>
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<td>102-5</td>
<td>Ownership and legal form</td>
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<td>102-6</td>
<td>Markets served</td>
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<td>102-7</td>
<td>Scale of the organisation</td>
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<td>102-8</td>
<td>Information on employees and other workers</td>
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<td>102-9</td>
<td>Supply chain</td>
<td>134</td>
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<td>102-10</td>
<td>Significant changes to the organisation and its supply chain</td>
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This report has been prepared in accordance with the GRI Standards: Essential Option

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View Non-Financial Information Statement 2019

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