

# Annual Report 2018



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# RECORDATI, AN INTERNATIONAL GROUP

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## Revenue

Million Euros

1,352.2

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## Net Income

Million Euros

312.4

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## Employees

Exceed 4,100



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*Recordati is a well-established growing international pharmaceutical group listed on the Italian Stock Exchange (now part of the London Stock Exchange) since 1984.*

The Group has its headquarters in Milan and is one of the oldest Italian pharmaceutical companies. Since it was founded in 1926 Recordati has grown constantly for more than ninety years thanks to the success of its products and to its strategy for growth and development based on internationalization and diversification through an acquisition strategy initiated in the 1990's and still ongoing. It actively seeks new opportunities and faces the challenges of a constantly changing marketplace with determination. In 2018 the Group generated revenues of € 1,352.2 million and has a staff of 4,142 employees.

Today the company has many subsidiaries, both in Europe and outside Europe. In addition to the countries in Western Europe the Group is also directly present in the Central European countries, in Russia and the other countries belonging to the Commonwealth of Independent States (C.I.S.), Ukraine, Turkey, Tunisia, U.S.A., Canada, Mexico, in some South American countries, Japan and Australia. Recordati sells its products in over 150 markets both directly and through license agreements. In addition to its geographical expansion the Group has enriched

its product portfolio by developing its own pipeline of products and by entering the segment dedicated to rare diseases. Recordati develops, produces and sells drugs for the treatment of rare diseases through Orphan Europe and Recordati Rare Diseases, two companies dedicated mainly to metabolic deficiencies of a genetic nature.

The Group's most important products are those, in the cardiovascular therapeutic area, based on lercanidipine, a latest generation calcium channel blocker indicated for the treatment of hypertension, discovered and entirely developed in the Recordati research laboratories, and its combination with enalapril, a widely prescribed ACE inhibitor. The Group's presence in this therapeutic area was further strengthened with the acquisition of the products based on metoprolol, a beta-blocker mainly indicated for the control of a range of conditions including hypertension, angina pectoris, disturbances of cardiac rhythm, maintenance treatment after myocardial infarction, and functional heart disorders with palpitations.

The company's commitment in the uro-genital therapeutic area and its know-how and expertise accumulated over 40 years of research and study has led to its being the European partner of established international pharmaceutical companies. Silodosin, a molecule used in the treatment of benign prostatic hyperplasia discovered by Kissei and developed for the European markets by Recordati, is one

of the Group's most important specialties. This product is now marketed successfully in 39 countries. Also pitavastatin, a latest generation statin for controlling hypercholesterolemia, discovered and developed by Kowa, was obtained under license for Europe.

Recordati has six pharmaceutical production facilities and a specialized packaging and distribution facility dedicated to rare disease products all of which operate with full respect for environmental protection regulations and in compliance with current Good Manufacturing Practices (cGMP). Recordati also produces a number of active ingredients and intermediates for the pharmaceutical industry. It has two pharmaceutical chemical plants one in Campoverde di Aprilia, Latina, Italy, and the other in County Cork, Ireland.

The broad geographical coverage achieved by the Group, its own efficient network of medical sales representatives in addition to its many years of experience in the regulatory field and its expertise in the management of highly specialized products, makes Recordati an ideal partner for the development and marketing of new products in all the territories where it is present with its marketing organizations.



## THE FUTURE OF THE GROUP

*Recordati's proven ability to generate profitable alliances with prominent players in the pharmaceutical industry is the basis of an increasingly intense activity directed at the identification and execution of new license agreements or partnerships for the development of innovative products.*

*In the future Recordati intends to reinforce its presence in the international pharmaceutical market and to extend its rare disease business worldwide.*





# LETTER TO OUR SHAREHOLDERS

*The financial results obtained in 2018 demonstrate the continued growth of the Group, with increased revenues and profitability.*



During 2018 an important transition in the majority ownership of our Group took place. An agreement was reached with a consortium of investment funds controlled by CVC Capital Partners, a highly respected investor group, for the indirect acquisition of 51.791% of the share capital of Recordati S.p.A.. This change in ownership ensures the continuity for management and employees and a commitment to keep building and developing the company going forward along the strategic lines that have been the drivers of the group's success over many years. In addition, our new majority shareholders will contribute with their expertise and global healthcare network to expand both our rare disease and core business by accelerating our growth strategy.

The financial results obtained in 2018 demonstrate the continued growth of the Group, with increased revenues and profitability. All business segments and the main corporate products contributed to these results. Group consolidated revenue for 2018 is € 1,352.2 million, up 5.0% over the preceding year. International sales are € 1,079.0 million, up 4.8% and now represent 79.8% of total revenue. EBITDA, at 36.9% of sales, is € 499.1 million, an increase of 9.8% over 2017. Operating income, at 32.7% of sales, is € 442.2 million, a growth of 8.8% compared with the preceding year. Net income is € 312.4 million, an increase of 8.2%, with a further improvement as margin on sales which is now 23.1%.

At 31 December 2018 the Group's net financial position records a net debt of € 588.4 million compared to net debt of € 381,8 million at 31 December 2017. During the period own shares were purchased for an overall disbursement of € 169.8 million, dividends were distributed for an amount of € 178.9 million. Furthermore, the Italian company Natural Point S.r.l. and the French company Tonipharm S.A.S. were acquired for a total value of around € 148 million. Shareholders' equity at 31 December 2018 is € 963.6 million.

In 2018 a number of initiatives were pursued in line with the group's strategy of continued growth and development.

In April an agreement with Mylan for the acquisition of the rights to Cystagon® (cysteamine bitartrate), indicated for the treatment of proven nephropathic cystinosis in children and adults, for certain territories, including Europe, was concluded. The product was previously commercialized by Orphan Europe (a Recordati group company) under license from Mylan. The definitive acquisition of the rights allows the Group to continue offering this life-saving treatment to patients.

In June Recordati acquired 100% of the share capital of Natural Point S.r.l., an Italian company, based in Milan, active in the food supplements market. Natural Point was established in 1993 with the objective of promoting a culture of healthy use of food supplements. It offers a wide portfolio of very efficacious supplements in highly bioavailable formulations, produced with safe active ingredients, to improve health and well-being. The company's main product is a particular formulation of magnesium carbonate and citric acid that has the characteristic of being easily assimilated into the body, apart from its having an agreeable flavor.

Recordati is the exclusive global partner of NovaBiotics Ltd, a biotechnology company based in Aberdeen, Scotland, for the commercialization of Lynovex®, a first-in-class oral intervention for acute infectious exacerbations associated with cystic fibrosis (CF). Cystic fibrosis exacerbations are major contributors to the irreversible decline in lung function and overall health of people with CF. Treatments that increase recovery from exacerbations might reduce the damaging effects of exacerbations. Lynovex® is designated as an orphan drug in Europe and in the U.S. and is the first multi-active therapy of its kind (anti-infective, mucolytic, anti-biofilm, antibiotic potentiating) to be developed specifically for alleviating the infectious trigger and symptoms of CF exacerbations. In July top line data from a recent clinical study (CARE CF 1) of oral Lynovex® in cystic fibrosis exacerbations were announced.

In November the European Commission (EC) granted Orphan Drug Designation to Orphan Europe's (a Recordati group company) investigational product REC 0545 for the treatment of maple syrup urine disease (MSUD). This is the first time that an Orphan Drug Designation has been granted in this indication. MSUD is a rare genetic metabolic disorder. People affected by this disease are unable to properly process certain amino acids (the building blocks of proteins) and suffer from decompensation episodes that can be life-threatening if untreated. In Europe around 3000 patients are affected by MSUD. Orphan drug designation applies to drugs that seek to treat rare diseases or conditions affecting fewer than 5 in 10,000 inhabitants in the EU, while providing significant therapeutic advantage over existing therapies. This designation provides the opportunity for ten years marketing exclusivity upon approval of the product in the designated indication. This also represents another important milestone for our company and demonstrates our commitment to the area of rare diseases.

In early December the FDA granted Orphan Drug Designation to Recordati Rare Disease's investigational product REC 0559 for the treatment of neurotrophic keratitis. REC 0559 is a low molecular weight non-peptidic human nerve growth factor (NGF) mimetic currently under global development by Recordati. REC 0559 was licensed in 2017 from MimeTech, an Italian-based development company founded by researchers from the University of Florence. Neurotrophic keratitis is a rare degenerative corneal disease which results from deficiency of the trigeminal nerve, usually caused by surgery, neoplasia, aneurysm or facial trauma. Impairment or loss of corneal sensory innervation is responsible for corneal epithelial defects, ulcer and perforation, with progression of the disease leading to dramatic impairment to patients' sight. Orphan drug designation applies to drugs that seek to treat rare diseases or conditions affecting fewer than 200,000 patients in the U.S. while providing significant therapeutic advantage over existing therapies. The designation can provide development and commercial incentives for designated compounds and medicines, including eligibility for a seven-year period of market exclusivity in the U.S., FDA assistance in clinical trial design and an exemption from FDA user fees.

During the month of December, a license agreement was signed between Orphan Europe, a Recordati group company, and Helsinn, a Swiss pharmaceutical group focused on building quality cancer care products, granting Orphan Europe exclusive rights to Ledaga® worldwide, excluding the United States, China, Hong Kong and Israel. The product has been granted Orphan Drug Designation in Europe and is approved by the European Commission. Ledaga® (chlormethine) is a novel gel formulation, applied once a day, indicated for the topical treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL), a rare disease characterized by the abnormal accumulation of malignant T-cells in the skin. MF-CTCL is the most common type of cutaneous lymphoma and first presents as patches and plaques on the skin. It is difficult to diagnose, particularly in the early stages as many of its features are non-specific. Chlormethine is an alkylating agent that inhibits quickly proliferating cells and Ledaga® is recognized to have a good efficacy profile with a confirmed treatment response achieved in 76.7% of the efficacy evaluable population in the pivotal trial (*Lessin S.R. et al JAMA Dermatol. 2013; 149(1): 25-32*). The treatment of this rare disease still represents an unmet medical need as existing treatments have either limited efficacy or are non-approved, non-reimbursed cumbersome pharmacy compounded formulations. Ledaga® has the potential to become a very important product and to significantly strengthen our rare disease portfolio globally. Launches are expected to start in the short term in countries belonging to the European Union and, following, in the rest of the territories provided for in the agreement.

On December 31 an agreement for the acquisition of 100% of the share capital of Tonipharm S.A.S., a French company based in Boulogne-Billancourt near Paris, active mainly in the self-medication market with over-the-counter (OTC) products was concluded. Tonipharm was established in 1991 and promotes a wide portfolio of self-medication products together with some prescription drugs. The company's sales are generated mainly by

the line of products sold under the umbrella brand Ginkor®, OTC treatments based on ginko biloba which are very well known on the French market. The company also promotes Alodontv®, a line of products used for oral hygiene. The acquisition of Tonipharm represents a further opportunity to enhance our portfolio in the French self-medication market with well-known brands and good market shares.

Going forward we will continue to develop the business, both by growing the existing product portfolio as well as through acquisitions of products or companies, with the objective of enhancing our presence in selected markets. The development of the segment dedicated to treatments for rare diseases and its expansion into new markets will continue to be a priority. Our Group already makes these treatments available through its own organizations throughout Europe, in the Middle East, in the U.S.A., Canada, Mexico, in some South American countries and more recently in Japan and Australia. Furthermore, we will continue to dedicate resources to research and development and strong emphasis will be placed on the enrichment of our product portfolio both through the development and launch of pipeline products as well as through the acquisition of new specialties.

During 2018 a number of initiatives related to business sustainability were put in place. In this context of strong growth, of commitment to research and innovation, our Group continues to develop a structured and organic sustainability process in order to share the social, environmental and economic objectives of our operations with our stakeholders. In view of the nature of our business, sustainability has always been an integral part of the strategy of our Group, aimed at providing benefits not only to patients but also to everyone with whom and for whom we work: our shareholders, our customers, our scientific and commercial partners, our collaborators and the local communities in which we operate. The preparation of non-financial information represents one of the many examples of our sustainability roadmap, through which we intend to highlight the objectives of the Group and the results obtained in terms of environmental, social and economic responsibility. We are confident that, with the inclusion of themes related to sustainability in our business dynamics, we will be able to achieve our objectives more effectively and with increased operational awareness, and therefore meet future challenges with optimism by appealing to our values.

We believe that the strict implementation of our strategy will enable us to be optimistic regarding the future, and we count, as always, on the entrepreneurship and determination of our management team, the professional skills of our employees and the trust of our shareholders. We would like to express our gratitude to all of them for their loyalty and support during 2018.

## DIVIDENDS

Based on the results obtained, the Board of Directors of the parent company will propose to the shareholders a dividend of € 0.47 per share, in full balance of the interim 2018 dividend of € 0.45, to be paid to all shares outstanding at ex-dividend date, excluding those in treasury stock, as from 25 April 2019 (record date 24 April 2019), with ex-dividend on 23 April 2019 (against presentation of coupon no. 23). The full 2018 dividend is therefore of € 0.92 per share (€ 0.85 per share in 2017).

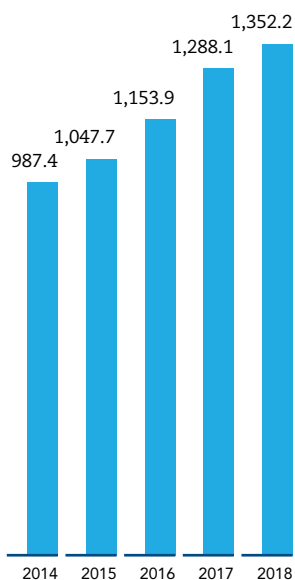
**Andrea Recordati**  
Chief Executive Officer



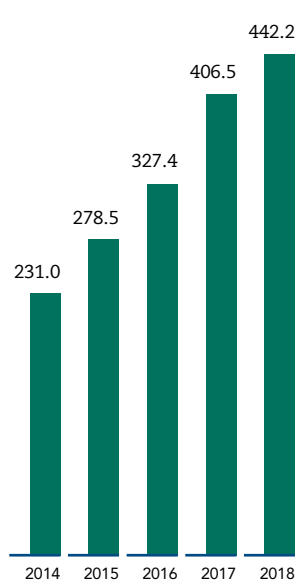


# THE GROUP IN FIGURES

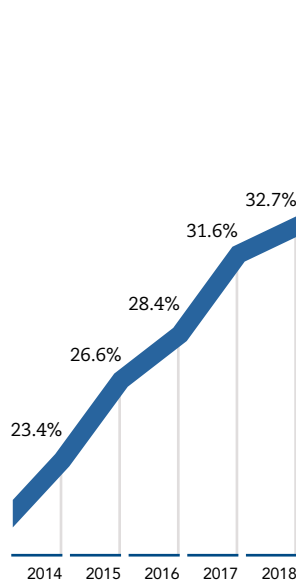
**Revenue**  
Millions of Euro



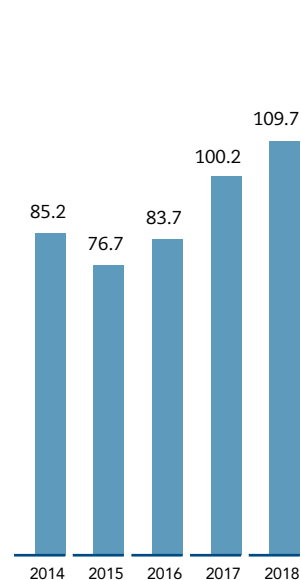
**Operating Income**  
Millions of Euro



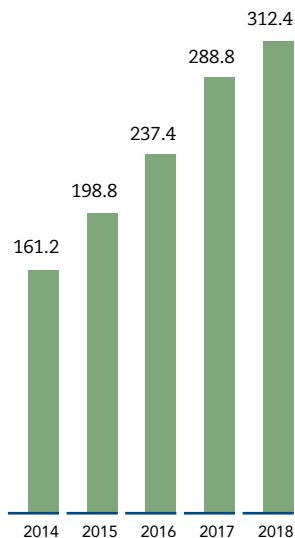
**Operating Income as % of Revenue**



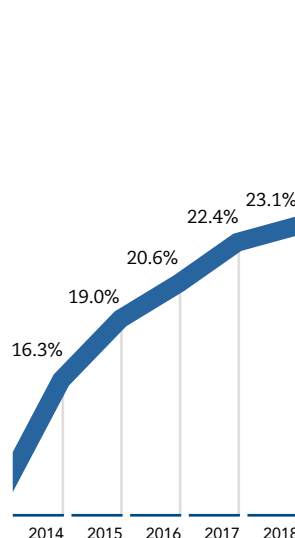
**R&D Expenses**  
Millions of Euro



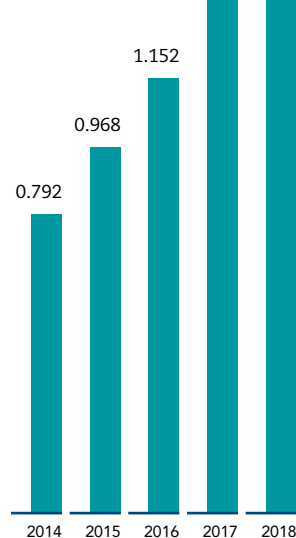
**Net Income**  
Millions of Euro



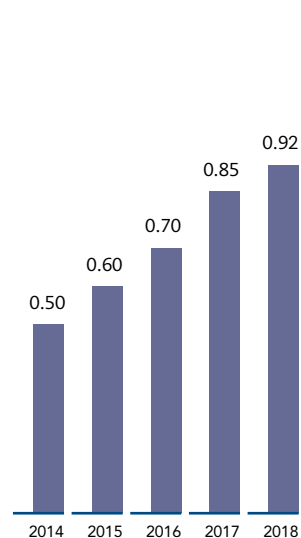
**Net Income as % of Revenue**



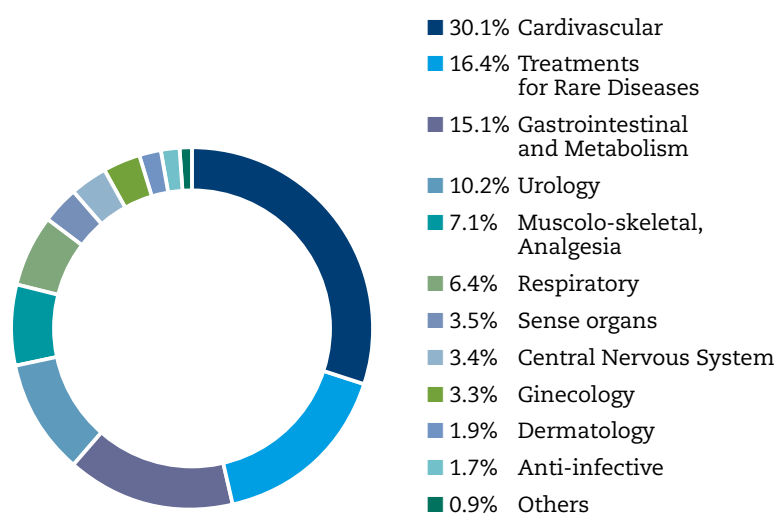
**Net Income per Share**  
Euro



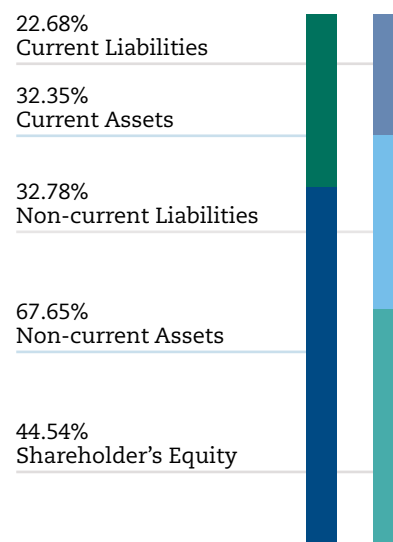
**Dividend per Share**  
Euro



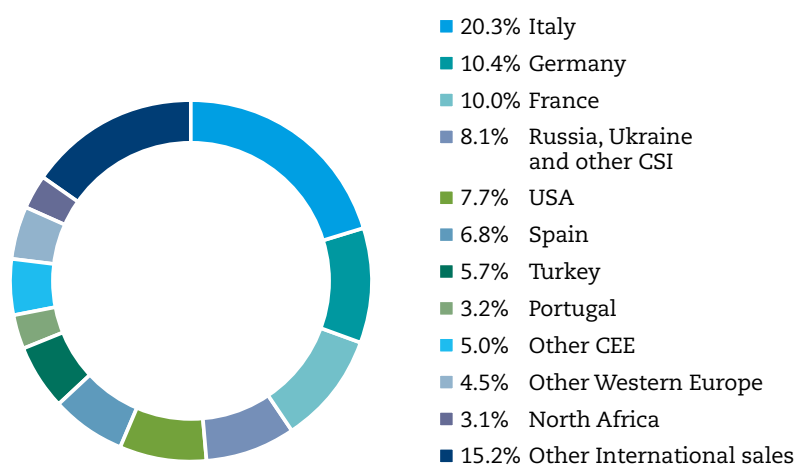
## Geographical composition of pharmaceutical sales



## Balance sheet at 31 December 2018



## Pharmaceutical sales by therapeutic area



## Shareholder's equity

Milions of Euro

963.6

## Net financial position

Milions of Euro

(588.4)

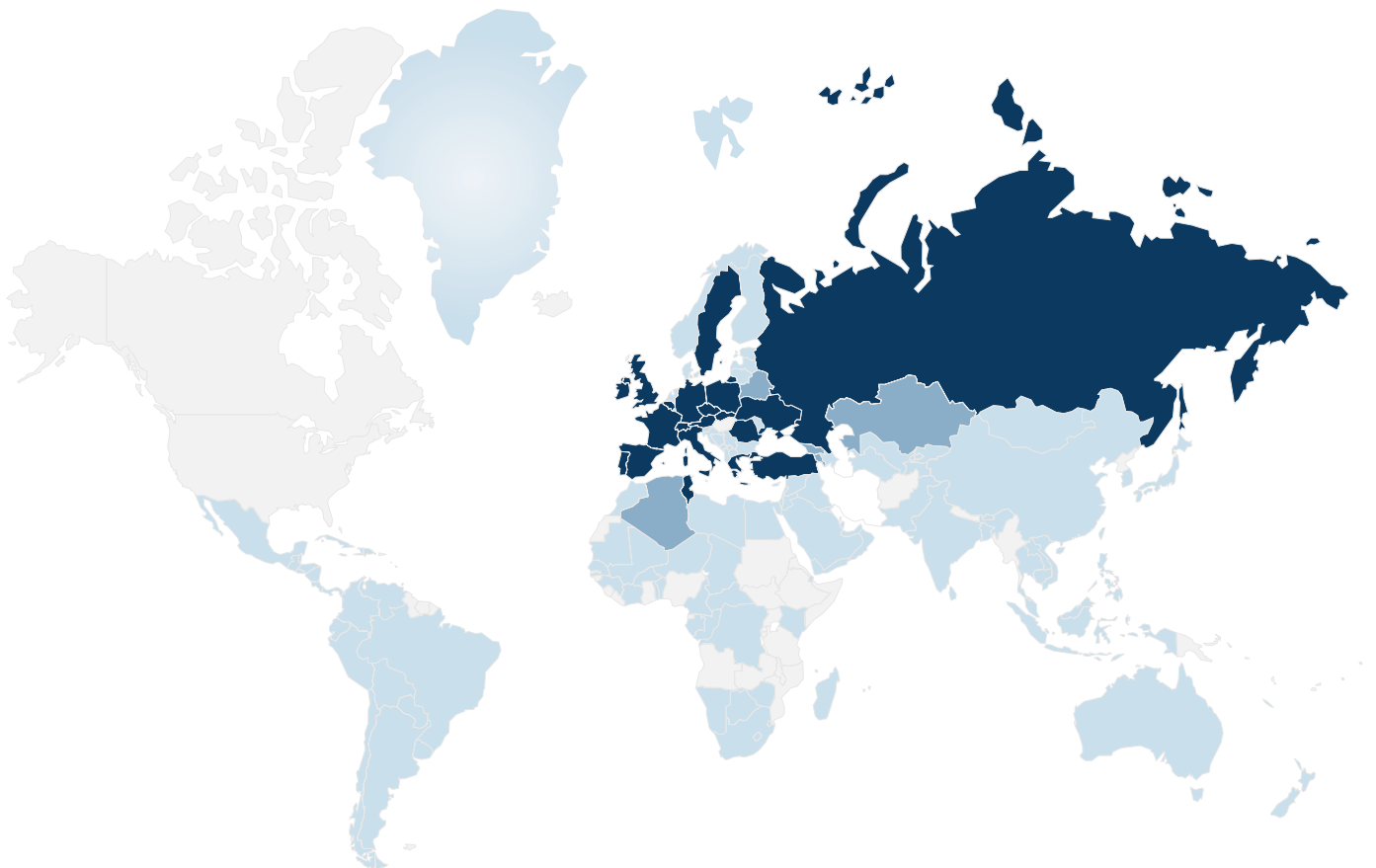


# GEOGRAPHICAL PRESENCE

More than **150** countries

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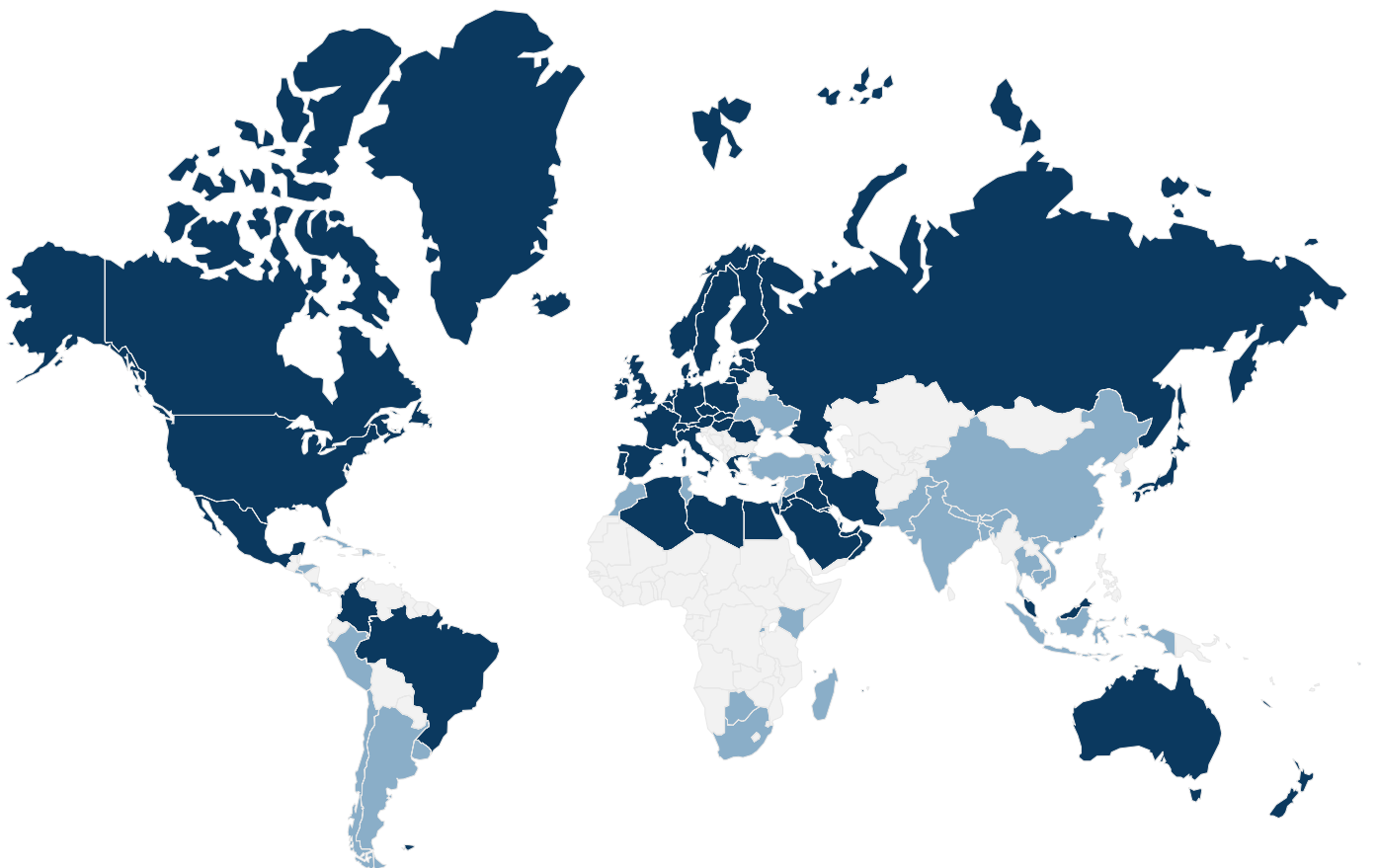
## Specialty & Primary care



- Subsidiaries
- Branches and other forms of territorial presence
- Countries where Recordati products are sold (under license or export)

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## Treatments for Rare Diseases



■ *Subsidiaries and direct presence of orphan drug representatives*

■ *Commercial agreements and direct delivery*



## GROUP ACTIVITIES

*The Recordati group operates in a wide and differentiated field which comprises primary and specialty care, self-medication and rare diseases.*

*In addition to being present in the field of cardiovascular disease, and in particular in hypertension, Recordati also operates in the area of urology with treatments for benign prostatic hyperplasia as well as for male sexual functional disorders.*

*The Group has developed a growing presence in the segment dedicated to rare diseases, where it researches, develops and markets a number of orphan drugs.*





## HEALTH, A GLOBAL OBJECTIVE

The World Health Organization (WHO) defines health as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. To improve health, it is therefore necessary to intervene on a number of determining factors, such as the social, physical and economic conditions under which people are born, live and work, including healthcare assistance systems. In this context, in addition to institutions and governments, pharmaceutical companies must also develop strategies for the improvement of healthcare systems, in terms of availability, accessibility and quality of the healthcare structures and of the goods and services provided.

Healthcare expenditure represents an important indicator of the growing attention to the subject of health: on a global level, the value of expenditure on healthcare represents around 10% of GDP. A significant component of healthcare expenditure is pharmaceutical spending, which, on a global level, is estimated to be \$ 1,205 billion in 2018 and is expected to continue to grow reaching \$ 1,500 billion by 2023. This significant attention placed on health has allowed investment in research and the development of innovative medicines, together with the creation of new and more efficient healthcare assistance models to maximize benefits for patients also through the growing utilization of technology. Other than in the more industrialized countries, steady growth of global healthcare expenditure has been and will continue to be seen in emerging countries, going from 13% in 2007 to 23.7% in 2018. In these countries access to medical care is progressively expanding, thus

generating significant growth in the demand for medicines, especially in primary care.

As regards therapeutical segments, new products and loss of exclusivity of older products will continue to drive the dynamics of developed markets, while product mix will continue to shift towards specialty products and treatments for rare diseases. Globally, over the past five years, there has been a significant increase in the number of new active pharmaceutical ingredients and of their relative cost, in particular in the more industrialized markets where they were first launched. Between 2014 and 2018, the average expenditure for new branded drugs was of \$ 43.4 billion. New products to be launched from 2019 to 2023 will probably account for a slightly higher level of expenditure, around \$ 45.8 billion. Together with the growing number of launches, the type of drugs will continue to shift towards specialty products, those for rare diseases, biologics and oncological treatments. Specialty products may represent close to two thirds of new launches over the next five years.

*Source: IQVIA – The Global Use of Medicine in 2019 and Outlook to 2023.*

Over the counter (OTC) products, which have reached a total value of \$ 139 billion (MAT June 2018, up by 4.2% - *Source: Nicholas Hall's OTC Dashboard*), are expected to continue to grow. In developed economies, growth drivers are linked mainly to the increasing average age of the population and to the relative increased attention to prevention. Furthermore, the pharmaceutical spending cost containment measures introduced by public healthcare schemes favour de-listing and

conversion to OTC of a number of therapeutic classes, together with the diversification of distribution channels (for example, mass-market or internet). In emerging economies, growth will be driven by population increase and improved access to medication, including the development of assistance programs for the middle class (for example in the main Asian countries, like India).

Furthermore, increased attention will be paid to the treatment of rare diseases. In 2018, \$ 138 billion (+9.0% over 2017) were spent for treatments for rare diseases, a market estimated to grow on average by 10%, reaching \$ 240 billion by 2023 when it will represent 20% of the global prescription drug market, excluding generics (*source: Evaluate Pharma*).

In this dynamic and competitive context, pharmaceutical companies must be constantly committed on a number of fronts:

- internationalization, in order to guarantee a more extended market on which to make products sold available;
- relationship with opinion leaders, fundamental for both research and development activities and the education and training of company medical representatives;
- education, training and updating of physicians regarding new pharmaceutical products;
- development of relationships with national governments, patient associations and public administrations in order to make pharmaceutical products available on the market.

## CORPORATE PRODUCTS

*The Recordati group markets a wide range of innovative products originated by its own research, developed in-house or obtained under license.*

### ZANIDIP®/CORIFEO®/LERCADIP® (lercanidipine)

Is an antihypertensive drug discovered and developed entirely in the Recordati research laboratories.

Lercanidipine, the Group's main product, is effective in gradually lowering blood pressure values to optimal levels avoiding episodes of reflex tachycardia and reducing the risk of cardiovascular events and their related mortality. Its lipophilicity and high selectivity are properties which render lercanidipine effective with a superior tolerability profile. It ensures protection of the kidneys and the endothelium of the blood vessels.

Thanks to this organ protection characteristic and its metabolic neutrality lercanidipine is well tolerated by patients suffering from other diseases such as diabetes and nephropathy.

Lercanidipine, twenty years from its initial launch, is still a first line treatment widely used by primary care physicians and by specialists in more than 100 countries for the control of hypertension, as shown by clinical documentation constantly published in support of the drug.

To celebrate this important achievement, the meeting "Current Perspective on the use of Calcium Channel Blockers in the treatment of Hypertensive Patients" was held

in Stresa (Italy) on the 28<sup>th</sup> and 29<sup>th</sup> of June 2018. Major experts in the field from countries around the world participated. The meeting was an important moment of reflection and the occasion to review antihypertensive therapy with a special focus on lercanidipine.

### ZANIPRESS®/ZANEXTRA®/ LERCAPREL®/LERCARIL® (lercanidipine + enalapril)

Is an antihypertensive drug developed by Recordati. It associates lercanidipine, a latest generation calcium channel blocker, with enalapril, a widely prescribed ACE inhibitor, allowing the simultaneous administration of two active ingredients. The administration of a single pill, for a patient who often takes a number of different medicines every day, increases compliance which is an important success factor in the treatment of hypertension. As stated by the European Society of Hypertension, combination therapy should be considered as first line treatment for hypertensive patients at high risk for cardiovascular events. Most hypertensive patients, and those with other associated risk factors in particular, require more than one antihypertensive drug to keep their blood pressure at desired levels.

The benefits of the combination of these two active ingredients have been confirmed by the results

CELEBRATING  
Lercanidipine



of a number of clinical trials which have shown its significant antihypertensive efficacy, good tolerability in addition to renal and vascular protection from damage caused by hypertension.

A new dosage form combining 20mg of lercanidipine with 20mg of enalapril (20/20) was launched in recent years. The new form, which is based on an increased dosage of lercanidipine, provides higher antihypertensive activity and improved organ protection (heart, kidneys and brain) while maintaining its good tolerability profile unchanged. Together with the existing 10/10 and 10/20 dosage forms this new form provides a wide choice of treatments.

#### UROREC® (silodosin)

Silodosin is a drug indicated for the treatment of benign prostatic hyperplasia (BPH), a frequent disease in men over the age of fifty which is increasing due to the ageing of the population in general.

BPH manifests with problems linked to urination, such as reduced urine stream, increased frequency and urgency and nocturia, symptoms which significantly reduce quality of life.

Silodosin is a powerful antagonist of the  $\alpha_1$  adrenergic receptors with a higher affinity for  $\alpha_{1A}$  receptors than other drugs in the same class. Blocking of the  $\alpha_{1A}$  receptors leads to a rapid increase in urine flow even within 2 to 6 hours from administration, with

an improvement in both irritative symptoms (frequency, urgency, nocturia) and obstructive symptoms (hesitancy, incomplete emptying of the bladder, intermittency, weak stream) over 3 to 4 days.

Symptom improvement is maintained during long term treatment.

The low incidence of orthostatic and vasodilatory side effects make it a well-tolerated treatment even in patients who take antihypertensive medication.

The results of a large phase IV clinical study conducted on more than 1000 patients in Europe (the SIRE study) confirmed, in clinical practice, the efficacy of silodosin in the relief of the more frequent symptoms associated with BPH.

Another recently published study (Fusco et al, 2018) furthermore showed the efficacy of silodosin in significantly reducing bladder outlet obstruction in patients with severe BPH, by using urodynamic testing. This result is particularly interesting as it is widely recognized that there is a direct correlation between bladder obstruction and remodelling, leading to a consequent progressive loss of organ function.

The efficacy of silodosin on the urodynamic parameters therefore translates, not only into immediate symptomatic relief, but also into the possible prevention, over the long term, of bladder degeneration, potentially postponing the need for surgical intervention.

Silodosin is the result of original

research by the Japanese pharmaceutical company Kissei Pharmaceutical Co. Ltd. and was obtained under license by Recordati who conducted the clinical development for the whole of Europe, and a number of countries in the Middle East and Africa.

Recordati has successfully launched the drug in 39 countries including France, Germany, Italy, Spain, Portugal, the C.I.S. countries, Tunisia, Turkey and Switzerland.

#### LIVAZO®/ALIPZA® (pitavastatin)

Pitavastatin is an innovative statin for the treatment of dyslipidemia, a condition characterized by altered levels of blood cholesterol and other lipids and associated with an increased risk for heart disease and stroke.

Pitavastatin is indicated for the reduction of elevated total cholesterol (TC) and LDL cholesterol (LDL-C), in adult patients with primary hypercholesterolemia and combined (mixed) dyslipidemia when response to diet and other non-pharmacological measures is inadequate. In controlled clinical trials involving more than 1,600 patients it was shown that pitavastatin induces not only a reduction in LDL-cholesterol (the “bad” cholesterol that contributes to formation of atherosclerotic plaques) but also an increase in HDL-cholesterol (the “good” cholesterol that is removed from the arterial walls), a dual effect that should be regarded as highly relevant, since it



appears to reduce the relative risk for cardiovascular complications.

Furthermore, it has been shown that pitavastatin is minimally metabolized by the enzymes of the Cytochrome P-450 family, enzymes that play a key role in the metabolism of many drugs, thus minimizing the potential risk for unpredictable responses to treatment or for interaction with drugs metabolized by this pathway.

Pitavastatin was obtained under license by Recordati from the Japanese pharmaceutical company Kowa for many European markets including Russia, other CIS and Turkey. The drug has already been successfully launched in Spain, Portugal, Switzerland, Ukraine, Greece, Russia, Georgia and Turkey.

#### **SELOKEN®/ SELOKEN® ZOK/ SELOZOK®/ BETALOC® ZOK (metoprolol succinate)**

Seloken® and Seloken® ZOK are metoprolol based medicines

belonging to the beta-blocker class of drugs widely used in the treatment of angina pectoris, disturbances of cardiac rhythm, hypertension, myocardial infarction and functional heart disorders. These drugs have been widely studied in large and important clinical trials such as MAPHY and MERIT-HF and are frequently used in primary care and by cardiologists to treat cardiac disturbances and hypertension.

Supported by long term use in clinical practice, metoprolol represents a benchmark in cardiovascular therapy. Long term mortality studies (Seloken®/Seloken® ZOK Core Data Sheet) have shown that the use of metoprolol reduces the rates of general mortality, cardiovascular mortality, sudden death and the progression of heart failure.

Recordati acquired the commercialization rights for the drug in Europe. The product is available under the international

brands Seloken®, 100 and 200 mg dosage forms, and Seloken® ZOK/ Betaloc® ZOK, 23.75 mg, 47.5 mg, 95 mg and 190 mg.

#### **LOGIMAX® (metoprolol succinate + felodipine)**

Logimax® is a fixed association of metoprolol with felodipine which over the years has shown high antihypertensive efficacy. The use of metoprolol together with felodipine enables the reduction of possible episodes of reflex tachycardia induced by the calcium channel blocker, while felodipine associated with metoprolol facilitates vasodilation by reducing peripheral vascular resistance.

This mechanism of action explains why a therapy based on the association of a beta-blocker with a calcium channel blocker, administered to patients suffering from hypertension associated with ischemic cardiopathy, is one of the therapeutical combinations mostly

## THE 31<sup>ST</sup> ECNP CONGRESS, BARCELONA



The annual Congress of the European College of Neuro-psychopharmacology (ECNP), dedicated to brain research and the treatment of its disorders, is the most important scientific meeting in Europe. Every year it attracts neuroscientists, psychiatrists, neurologists and psychologists from all over the world and is also attended by a vast public of researchers in neurosciences as well as clinicians.

The 31<sup>st</sup> ECNP Congress, dedicated to the future of CNS treatments, took place in Barcelona from the 6<sup>th</sup> to the 9<sup>th</sup> of October of 2018. This well attended high profile meeting brings together the most important schools of psychopharmacological

research in Europe with the intent of ensuring that the progress in the comprehension of brain function and human behaviour leads to better treatments for patients and improved public health.

The satellite symposium “New trends in schizophrenia research and therapeutic practices”, chaired by professor Stephan Leucht, deputy director of the Department of Psychiatry and Psychotherapy of the Technische Universität of Munich (Germany), was met with success. The meeting counted the participation of Pierre Michel Llorca, professor of psychiatry at the University of Clermont-Ferrand and director of the Department of Psychiatry of the University Medical Center in Clermont-Ferrand (France), who presented the results of an original study that showed that schizophrenic patients with prevalent negative symptoms responded less to non pharmacological treatments. Silvana Galderisi, Professor of Psychiatry at the University of Naples (Italy), further analysed the subject of the negative symptoms in schizophrenic patients and Stephen Stahl, Adjunct Professor of Psychiatry at the University of California (San Diego, U.S.A.), as well as distinguished psychiatrist and well-known pharmacologist, described the mechanism of action of cariprazine, underlining its originality and innovation. The molecule is, in fact, efficacious also on the negative symptoms of schizophrenia thanks to its unique action on the dopamine D3 receptors.

The symposium was attended by around 500 psychiatrists who took the opportunity to visit the large stand dedicated to Reagila® (cariprazine) and pick up further documentation on this new antipsychotic.

mentioned and recommended by the European ESH/ESC guidelines.

A recent meta-analysis of 208 clinical studies involving 90,000 patients, supported by extensive documentation, with the objective of evaluating the antihypertensive profile of the various therapeutic combinations available, has confirmed that the association of metoprolol with felodipine is one of the most efficacious.

### REAGILA® (cariprazine)

Reagila® (cariprazine) is a new drug for the treatment of schizophrenia, a third generation antipsychotic, which, thanks to its pharmacological peculiarity can be considered unique in the panorama of this therapeutic class.

It, in fact, is capable not only of acting on the “positive” symptoms of the disease, such as delirium, hallucinations, thought dissociation, etc., but also on the “negative” component such as apathy, anhedonia, antisocial behaviour.

Cariprazine also has the additional advantage of having reduced neurological and metabolic collateral effects and low cardiovascular impact.

The drug has a long half life and is administered orally once daily.

Its clinical efficacy has been shown by a number of clinical studies involving over 2,000 patients.

Reagila® was obtained under license for the Western European countries and during 2018 was launched in Germany, Switzerland, Italy, Benelux, the United Kingdom, Sweden, Denmark and Finland.

### TERGYNAN®

A fixed combination of different active ingredients, this product is used for the topical treatment of vaginal infections and the prevention of gynecological infections thanks to its distinct antimicrobial, antiinflammatory,

antiprotozoal and antimycotic activity.

Tergynan® is a leading brand within the class of antiinfective and antiseptic gynecological medicines in the countries in which it is marketed, in particular, in Russia, in the other countries belonging to the Commonwealth of Independent States, in Ukraine, Mongolia and Romania.

### CITRAFLEET® and PHOSPHOSODA®

Both brands are bowel cleansers used in preparation for any diagnostic procedure which requires emptying of the intestines, such as colonoscopy.

These products are sold mainly in Spain and in Germany. Thanks to the constant product portfolio integration process among the group's subsidiaries, the presence of Citrafleet® was extended to many other countries including Italy, France and Portugal mainly, while the presence of Phosphosoda® was extended mainly to France, Russia and Turkey.

### POLYDEXA®, ISOFRA® and OTOFA®

These are fixed combinations of different drugs used in the treatment of ear, nose and throat (ENT) infections. They are sold mainly in Russia and are constantly growing.

### REUFLOR®/CASENBIOTIC®/ BIORALSUERO®/REUTERI®/ GASTRUS® (lactobacillus reuteri protectis)

These are food supplements based on lactobacillus reuteri protectis. Gastrus®, an association of two strains of lactobacillus reuteri purposely studied for the treatment of conditions involving helicobacter pilory infection, Casenbiotic®, Bioralsuero® and Reuteri® are products widely used in Spain.

Casenbiotic® is available also in

Portugal, Reuflor® is marketed in Italy.

Reuflor® is a benchmark in the treatment of gastrointestinal functional disorders thanks to its efficacy in rebalancing the intestinal bacterial flora in adults and children. It consists of live active lactic bacteria with probiotic action which colonize the intestine. It is able to have a beneficial effect on the balance of intestinal bacteric flora at all ages, from infants to adults, as shown by robust scientific documentation.

Recent scientific evidence has suggested the use of Reuflor® to help stimulate the immune system. Therefore, as from 2017, a new formulation with vitamin D3 has been added which increases the benefit of immune system stimulation.

### PROCTO-GLYVENOL® (tribenoside)

Is an OTC product indicated for the treatment of internal and external hemorrhoids and is a leading brand in its class.

Procto-Glyvenol® is successfully marketed by Recordati in the Central and Eastern European markets as well as in Portugal, Turkey and it will soon be distributed directly also in the Baltic countries.

In 2017 the product line was completed with the introduction of wet wipes that have been launched in Poland, the Czech Republic and Slovakia.

### THE HEXA LINE OF PRODUCTS

The Hexa line of products comprises the brands Hexaspray®, Helaxyse® and Hexapneumine®, a series of antibacterial drugs containing biclotimol used for infections of the oral cavity, which are particularly successful in France and North Africa, in Russia and the other CIS countries, in Ukraine and Mongolia.

The main brand is Hexaspray®, a spray for sore throats and leader in its class in France. The product line

has recently been enhanced with the launch of Hexatoux®, a spray treatment for cough available in France and Georgia.

#### **LOMEXIN®/FALVIN® (fenticonazole)**

Lomexin® (fenticonazole), originated by Recordati, is an antimycotic that is widely used. Indicated for the treatment of dermatological and gynaecological infections from fungi, molds, yeasts and gram positive bacteria, fenticonazole destroys fungal cells by means of its dual mechanism of action which prevents the formation of ergosterol and inhibits the aspartic proteinase of the candida.

Lomexin® has a wide range of action and is also effective at low concentrations without creating resistances. It is available in different forms and very flexible doses and is well tolerated.

Fenticonazole is a modern drug and is supported by years of experience in clinical practice. In some countries it has obtained OTC status thus making the product more competitive and accessible to patients.

#### **CASENLAX®/LAXBENE® and FLEET ENEMA®**

The laxatives Casenlax® and Fleet Enema® are gastrointestinal products indicated for constipation. The first is successfully marketed in a number of Western European countries and in Germany under the brand Laxbene®.

It is available in the form of individual ready to drink liquid sachets in Spain. Fleet Enema® is also indicated for bowel cleansing in preparation for surgery.

#### **TRANSACT® LAT (flurbiprofen transdermal patch)**

TransAct®LAT is a transdermal patch containing flurbiprofen, a

non steroidal antiinflammatory drug (NSAID), indicated for the symptomatic relief of localized pain involving the musculoskeletal system.

The underlying technology, the excipients and the active ingredient all contribute to the treatment's effectiveness, to its constant release over a twelve-hour period and to its localized antiinflammatory and analgesic action, acting only where the patient feels pain, thereby avoiding the problems connected with the use of NSAIDs delivered systemically.

All these characteristics and the efficacy of flurbiprofen, demonstrated by numerous clinical studies, make TransAct®LAT a highly appreciated specialty among doctors and the patients themselves.

It is available in a number of countries in Europe, among which Italy and Portugal where it is successfully marketed by Recordati.

#### **GENURIN®/URISPAS® (flavoxate)**

Flavoxate, a Recordati original research product, is a muscle relaxant of the urinary tract. It is indicated for the symptomatic treatment of dysuria, urgency, nocturia, frequency and incontinuity and the treatment of bladder and urethral spasms. It is able to control symptoms associated with urgency and hyperactivity of the detrusor, thanks to its action on the transmission of the reflex impulse to empty the bladder.

Flavoxate is the first Italian drug to be approved by the American Food and Drug Administration and to be marketed in the United States of America, and is widely used in many countries.

#### **KENTERA® (oxybutynin transdermal patch)**

Kentera® is an oxybutynin transdermal system indicated

for the treatment of symptoms associated with disorders of the lower urinary tract, such as incontinence, frequency and urgency.

This product is indicated for all patients with overactive bladder as it combines the effectiveness of oxybutynin (considered the 'gold standard' for this disorder) with its excellent tolerability, thanks to the reduced first pass liver effect, and with the ease of use of a patch applied twice a week which constitutes a valid alternative to oral medications.

It is currently marketed by Recordati in seventeen European countries through its own subsidiaries and licensees.

#### **RUPAFIN®/WYSTAMM® (rupatadine)**

Rupatadine is a second generation antihistamine. It is a histamine antagonist with selective peripheral H1 receptor antagonist activity. It effectively blocks the receptors of the platelet activating factor (PAF), a characteristic which distinguishes it from other specialties belonging to the same class of drugs.

Rupatadine inhibits allergic effects affecting both the nasal mucosa and other organs targeted by the allergic reaction, such as the skin, controlling symptoms such as sneezing, itching, rhinorrhea, nasal congestion, wheals and rashes. Its pharmacokinetic properties allow quick and effective control of allergies, rapid relief from symptoms and a long-lasting antihistamine action.

It is marketed in Italy, Germany and France.

#### **LOPRESOR® (metoprolol)**

Lopresor® belongs to the beta-blocker class of drugs and is indicated for the treatment of hypertension either alone or in association with other

antihypertensive agents. This selective beta blocker is also indicated for long term treatment of angina pectoris.

Lopresor® is available in a number of European countries and is particularly successful in Greece and in Germany.

### ABUFENE® and MUVAGYN®

Abufene® and Muvagyn® are two gynaecological products indicated in the treatment of the symptoms of menopause.

Abufene® is a non-hormonal medicine used for the control of hot flashes present in menopause which is very well known in France.

Muvagyn® is a line of OTC gynecological gels.

It is a regenerative non-hormonal treatment of the vaginal mucus indicated mainly for vaginal dryness that was also launched in Italy in 2015 to complement Recordati's gynecological offering.

### LACDIGEST® (tilactase)

Lacdigest® is a well known preparation based on the enzyme tilactase indicated in cases of lactose intolerance due to primary and secondary lactase deficiency. Lactase is normally present in the intestines and its function is to separate lactose into its two absorbable constituent monosaccharides, glucose and galactose. If this enzyme is absent or deficient, the lactose that is ingested is not absorbed and can result in cramps, abdominal

swelling, flatulence and diarrhea, a very common syndrome which progresses with the aging of the population.

Lacdigest® contains the enzyme tilactase which is able to divide lactose into its two constituents which can be intestinally absorbed. Its dosing is extremely flexible and can be adapted case by case according to the severity of the symptoms and the amount of lactose ingested.

The product is sold in Italy and in Switzerland where it is market leader.

### VITAROS®/VIRIREC® (alprostadil)

Is the first topical cream for the treatment of erectile dysfunction. It is indicated for men at least 18 years' old who are unable to achieve or maintain a penile erection sufficient for satisfactory sexual performance.

Its innovative formulation with specific excipients enhances the rapid absorption in situ of the active ingredient alprostadil, a synthetic analogue of prostaglandin E1, a potent vasodilatory substance naturally present in the human body. The product is characterized by fast onset of action, between 5 and 30 minutes, and its effect lasts between 1 and 2 hours. Its efficacy was shown in extensive phase III trials conducted on more than 1,700 patients.

The topical administration and local mechanism of action minimizes any systemic adverse reaction

or interaction with other drugs, food or alcoholic beverages, and therefore Vitaros® can be considered an effective and safe alternative to existing orally administered products.

Launched successfully in Spain the product is now on the market in Portugal, Ireland, the Czech Republic, Slovakia and was recently launched in Greece, Romania and Poland.

### FORTACIN® (lidocaine+ prilocaine)

Fortacin® is a spray formulation of lidocaine and prilocaine for the treatment of premature ejaculation. It is the first topical treatment approved for this specific condition and is distinguished by its high safety profile, ease of use and fast acting efficacy.

Together with erectile dysfunction, premature ejaculation is one of the most frequent male sexual disorders. As shown by the results of the PEPA (Premature Ejaculation Prevalence and Attitude) study conducted on European and American men between the ages of 18 and 70, premature ejaculation presents important repercussions on the sexual and psychological sphere of the patient and the couple.

Fortacin®, which, thanks to its innovative excipient free formulation allows rapid efficacy, ease of use, high tolerability, has been included in the EAU (European Association for Urology) Guidelines as one of the reference treatments for premature ejaculation.

Currently, Fortacin® is available in Italy, Spain, Portugal, Germany and France, but will also be available in the UK and other European countries as well as in the C.I.S. soon.



## OUR PRIMARY AND SPECIALTY CARE SUBSIDIARIES



*Some products or product lines marketed locally by Recordati's subsidiaries detain prominent positions in their markets of reference.*

### Italy

Successfully present on the Italian market since 1926, Recordati has grown constantly and has brilliantly exceeded ninety years of activity.

Recordati offers a broad range of medications in this country through its organizations Recordati S.p.A., Innova Pharma S.p.A., Italchimici S.p.A. and Natural Point S.r.l. and provides doctors and specialists with up-to-date support of high scientific value.

In addition to its historic and established presence in the cardiometabolic field, the Italian product portfolio also boasts quality medicines in urology, in gastroenterology and in pain control.

#### Cardiometabolic area

In the cardiometabolic area Recordati offers a number of treatments. Two antihypertensive products entirely developed in-house are Zanedip®/ Lercadip® (lercanidipine) and Zanipress®/ Zanipril® (lercanidipine+enalapril), available in a number of dosage forms to enhance flexibility in the treatment of hypertension.

Two well-appreciated treatments belonging to the beta-blocker class are Cardicor® (bisoprolol) and

Seloken® (metoprolol). The first a drug indicated for the treatment of chronic, stable, moderate to severe heart failure, associated with reduced systolic ventricular function. Administered in addition to ACE inhibitors and diuretics, it is today considered a gold standard.

The second, widely used in clinical practice for the control of hypertension and angina pectoris, is present in the product portfolio as from 2017.

Rextat® (lovastatin), a well-tolerated and trustworthy statin, is used in first line pharmacological treatment of dyslipidemia.

#### Urology area

Urorec® (silodosin) is appreciated by physicians in Italy and reinforces the company's presence in the field of urology and in particular in benign prostatic hyperplasia.

Recoprox® is a food supplement based on serenoa repens which is widely used in clinical practice to improve the urinary tract and prostate functions.

During 2018 Fortacin®, a new treatment for premature ejaculation, was launched. It is a topically applied spray based on lidocaine and prilocaine which acts rapidly, is safe and easy to use. The scientific literature confirms this product's efficacy (prolonged latency and ejaculation control) and underlines its capacity to relieve the patient's emotional stress and improve the couple's well-being.

#### Gastrointestinal area

Peptazol® (pantoprazole), a proton pump inhibitor frequently used for the treatment of gastro esophageal reflux disease and in the prevention of gastro duodenal ulcers caused by NSAIDs, belongs to a large and competitive market. It is one of the most important products in



the portfolio and one of the most stable brands in its market segment. Its lower risk of pharmacological interactions is widely recognized by doctors because the greatest users of this class of drugs are patients who simultaneously take a number of different treatments.

In the field of gastrointestinal disorders, the probiotic Reuflor® (a dietary supplement based on *Lactobacillus reuteri*) is a live active lactic bacterium with probiotic action which colonizes the intestine and is efficacious in rebalancing the intestinal bacterial flora in adults and children.

Peridon® (domperidone) is a gastroprokinetic widely used in adults for the symptomatic treatment of nausea, vomiting, abdominal discomfort and gastric regurgitation. PeridoNatural® is a line of food supplements based on ginger, camomile and vitamin B which is well appreciated as a natural adjuvant in the treatment of digestive disorders in children and adults due to its optimal safety profile.

Completing the product portfolio in this area are Citrafleet® (sodium picosulfate), a bowel cleanser used in the preparation of colonoscopy procedures, Casenlax® (macrogol), an osmotic laxative particularly indicated in chronic constipation and Lacdigest®, a preparation based on the enzyme *tilactase* indicated in cases of lactose intolerance due to primary and secondary lactase deficiency.

#### ENT area

In this therapeutic area Recordati offers Isocef® (ceftibuten), a third generation easy to use oral cephalosporin thanks to its once a day dosing regimen, and Diezime® (cefodizime), an injectable antibiotic used specifically in the treatment of severe bacterial infections resistant to the most common antibiotics. This specialty is particularly

indicated for debilitated and/or immunosuppressed patients.

The line of antibiotics is further enhanced with the Unicexal™/Cexidal® (ciprofloxacin and corticosteroid for topical use) line that represents a valid treatment option in primary care for ear, nose and throat infections.

Aircort® (budesonide) is a corticosteroid based line of products available in a number of formulations widely used in the symptomatic treatment of disorders of the respiratory tract of both infective or allergic nature.

Rupafin® (rupatadine), an antiallergy antihistamine is a valid therapeutic solution for the treatment of seasonal or perennial allergic syndromes such as rhinitis by due to its particular mechanism of action.

#### Pain and inflammation area

Tora-Dol® (ketorolac tromethamine) is an effective fast-acting non-steroidal anti-inflammatory drug which has always been a leader in its class. It is considered by a large number of both specialists and general practitioners as one of the most effective drugs for pain control. It is used both in hospitals and out-patient clinics for the treatment of acute and severe pain.

#### Psychiatric area

In December 2018 Recordati launched Reagila® (cariprazine), a new drug for the treatment of schizophrenia, in Italy. This third generation antipsychotic has the advantage of being efficacious in treating both the positive and negative symptoms of schizophrenia, having reduced neurological and metabolic side-effects and a good cardiovascular safety profile.

The clinical efficacy of the drug is shown by numerous clinical trials involving more than 2,000 patients.

#### Self-medication area

Recordati also has an excellent reputation at the pharmacy level and continues to grow in the self-medication market, thanks to its large offering in a number of therapeutic areas such as oral hygiene, eye cure, nose and throat care.

A number of historical brands such as Alovex®, Proctolyn®, Eumill®, Dentosan®, Imidazyl®, Naprosyn®, hold leading positions in their reference markets.

The Alovex® line, dedicated to the treatment of aphthas and mouth sores, the treatment of lip herpes as well as pain and irritation caused by teething, was enhanced in 2018 by a new topical formulation, Alovex® ferite, for the treatment of scratches and superficial sores, with regenerating and healing characteristics.

Proctolyn® in the antihemorrhoids segment reinforced its leadership, while TransAct®LAT, a transdermal patch containing flurbiprofen, a non-steroidal anti-inflammatory drug, is well positioned in its market of reference.

In the natural eye drops segment the Eumill® line consolidates its leading position thanks to the performance of Eumill, Eumill® Protection and Eumill® Naso for adults and children.

In the decongestant and antihistamine eye drops market, the Imidazyl® brand maintains its leading position in both reference markets.

In the oral care market Dentosan®, a brand well-known both by doctors and pharmacists mainly thanks to the chlorhexidine based mouthwash line, represents a benchmark in the treatment of bacterial plaque.

In the gastrointestinal field, products available include ClismaFleet®, a rectally administered solution for occasional constipation, and Losipaco®, a fixed combination of loperamide

and simeticone indicated in the treatment of diarrhoea attacks associated with abdominal cramps, swelling and flatulence.

#### *Food supplements and nutrition area*

In 2018 Recordati acquired Natural Point S.r.l., an Italian company active in the market for food supplements and products developed to improve health and well-being. It offers a wide and differentiated portfolio of products produced with carefully selected active ingredients in highly bioavailable and efficacious formulations.

The company's main product is Magnesio Supremo, a particular formulation of magnesium carbonate and citric acid that has the characteristic of being easily assimilated into the body.

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### France

Laboratoires Bouchara Recordati S.A.S. is solidly established in the French pharmaceutical market thanks to a number of prescription drugs and a line of OTC products with well-known brands in France.

The French subsidiary holds significant positions in a number of therapeutic areas, such as the cardiovascular area with Zanextra® (lercanidipine+enalapril), Logimax® (metoprolol succinate+felodipine), Seloken® (metoprolol tartrate) and Selozok® (metoprolol succinate), the urology area with Urorec® (silodosin) and Leptoprol® (leuprorelin acetate), a treatment indicated in patients with advanced hormone dependent prostate cancer, the anti-allergy segment with Wystamm® (rupatadine) and the gastrointestinal area with Citrafleet® and Colopeg®, bowel cleansers in preparation for in preparation for endoscopic exploration, Transipeg® and TransipegLib®, macrogol based laxatives for the treatment of symptomatic constipation in adults.

Laboratoires Bouchara Recordati

produces and markets methadone, a synthetic opioid analgesic, used as a substitute for heroin in somatic abstinence syndromes, in disintoxication from opiates and in maintenance programs. Highly specialized staff and dedicated resources lie behind the success of the disintoxication programs. The benefits of treatment with methadone are universally recognized. The most important are the decrease in deaths resulting from the use of narcotics, the reduction of the diffusion of viral infections (HIV, HCV), reduced health, legal and social costs related to the use of drugs and improvements in the health and rehabilitation of addicts. A new capsules formulation contributes to expand its use.

Laboratoires Bouchara Recordati has a historical presence in the French OTC market. The Hexa line of products (Hexaspray®, Hexalyse®, Hexamer® and Hexatoux®, the first 100% natural spray cough medication) maintain their leadership and notoriety in the segment of winter maladies and Exomuc® is now the best-known and leading mucolytic containing N-acetyl cysteine.

In December 2018 the Recordati group acquired the French company Tonipharm S.a.S. headquartered in Boulogne-Billancourt, near Paris. The company, present on the French self-medication market since 1991 with well-known brands and good market shares, is known mainly for its Ginkor® line of OTC products based on ginko biloba as well as the Alodont® line for oral hygiene. The Tonipharm brands represent a valid complement to enhance our presence in the French OTC segment, which remains a growing market and an important diversification area.

The company has also developed an important international presence and continues to expand in the Maghreb area, in French-speaking

Africa and in Asia. Through its dynamic export and promotion activities it distributes a number of specialties from its product portfolio in over 30 different countries.

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### Germany

In addition to its consolidated presence in a number of therapeutic areas, Recordati Pharma GmbH offers various products well appreciated by primary care physicians and specialists.

Over time it has developed a strong presence in orthopedics and offers first class products to specialists in this field. The most important of these includes Ortoton® (methocarbamol), a muscle relaxant used for back pain which is considered the gold standard for this condition. It is the main product of the subsidiary and is leader in its class. A new formulation, Ortoton® Forte (methocarbamol), which was launched successfully in February 2018, has extended the product line.

Recosyn® (hyaluronic acid), which is available in four different formulations for specific treatment regimens, and Binosto® (alendronic acid), a treatment for osteoporosis that often arises during menopause, which was added to the portfolio in 2017, are well-appreciated products. Binosto® is presented as effervescent tablets, a unique and innovative formulation, which reduces the risk of vertebrae and hip fractures and has a lower risk of gastrointestinal side effects.

The orthopaedics product line also includes Lipotalon® (dexamethasone palmitate) and SportVis™ (biocompatible hyaluronic acid adapted for soft tissues).

The German subsidiary is well positioned in the cardiovascular

area offering a number of treatment options ranging from the calcium channel blocker antihypertensives Zanidip® and Zanipress® to the beta blocker Seloken®.

During 2018 Recordati Pharma launched Fortacin®, a new topical treatment for premature ejaculation which satisfies an unmet medical need in the area of urology, a therapeutic area in which the company also offers Urorec® (silodosin), a drug for the treatment of benign prostatic hyperplasia, and Kentera®, an oxybutynin based transdermal patch used in the treatment of symptoms associated with diseases of the lower urinary tract.

Always in 2018, the German subsidiary entered a new therapeutic area, psychiatry, with the launch of Reagila® (cariprazine), a third generation antipsychotic which, compared to other drugs, is more efficacious in addressing the negative symptoms of schizophrenia and has a better side effect profile.

An important part of the German subsidiary's operations is linked to its traditional presence in the gastroenterological area and in particular in that of chronic inflammatory intestinal diseases such as Crohn's disease and ulcerative colitis. The "gold standard" treatment for these diseases is the administration of mesalazine. Claversal® (mesalazine), the established Recordati Pharma brand, is the third largest in its class

and offers specialists in the field a full range of formulations, which was further enhanced by a new version formulated as micropellets without aspartame or lactose.

Citrafleet® and Fleet® Phosphosoda, bowel cleansers used in preparation for colonoscopy, contributed to expand the German subsidiary's offering in the field of gastroenterology.

Recordati Pharma has also developed a strong presence in the field of urology. In addition to Urorec® (silodosin), a drug for the treatment of benign prostatic hyperplasia, the German subsidiary also successfully markets Kentera® (oxybutynin transdermal patch), indicated for urinary incontinence.

The German subsidiary markets a line of OTC products with a specific sales organization which operates in a growing market and is dedicated to a number of brands the best-known of which are: Rhinopront® for rhinitis, JHP-Rödler®, a cough and cold medicine, and Laxbene® Junior, a product for the treatment of constipation in children over six months of age, that has created important synergies between the gastrointestinal specialist line and the OTC presence. During 2018 the Mirfulan® line, a leading brand for diaper rash, was extended with the launch of Mirfulan® Hydrolind, a new cream for the treatment of atopic dermatitis. Based on ectoine it ensures superior healing of the skin.

## Russia, other C.I.S. countries, Ukraine, Central Asia

Rusfic LLC, FlC Médical S.A.R.L and Recordati Ukraine LLC are our subsidiaries which operate successfully in Russia, in other markets of the C.I.S. (Commonwealth of Independent States), in Ukraine and in Central Asia. The success of our organizations in these territories is largely based on the progressive success of a line of anti-infective products and of a well-appreciated portfolio of self-medication products.

Tergynan® is a leading product in the class of gynaecological anti-infective and antiseptic drugs and is widely used in all the countries of the Commonwealth of Independent States and in Ukraine and is available also in Mongolia.

In Russia, Polydexa® and Isofra®, indicated for the treatment of ear, nose and throat (ENT) disorders and the dietary supplement Alfavit®, recently re-launched in Ukraine where it is locally produced in five different formulations allowing significant development, continue to increase their market shares.

Corporate products Procto-Glyvenol®, Urorec® and Lomexin® continue to grow as well as the success of Livazo® which is always well-appreciated by the specialists in the sector.

In Russia a dedicated sales organization markets five lines of





self-medication products. These are mainly well-known dietary supplements such as Alfavit® which holds a leading position on the market for vitamins and minerals formulations and Qudesan®, based on coenzyme Q10, for the prevention and treatment of chronic fatigue and metabolic dysfunction. The oral cavity antibacterials belonging to the Hexa line of products, Hexalyse® and Hexaspray®, and White Carbo®, an intestinal adsorbent, are also well appreciated brands.

Fic Médical, with its four representative offices in Kazakhstan, Belarus, Georgia and Armenia ensures the Group's direct presence in the C.I.S., in the Caucasian region and in Central Asia, territories in which the group's geographical coverage has significantly increased.

The organization successfully markets Urorec® in Armenia and Kazakhstan further reinforcing the urological product portfolio, Alfavit® and Qudesan® in Armenia and Kirghizstan following the success of these supplements in Russia, Kazakhstan and Belarus, Polydexa® in Mongolia, Lomexin® in Turkmenistan, Hexalyse® and Hexaspray® in the two latter countries. During 2017 Fic Médical successfully launched the vitamin supplement Alfavit® in Mongolia and Livazo® in Georgia which, widely appreciated in the cardiological field, has extended the product portfolio alongside well-

known brands such as Zanidip® and Coripren®.

In 2018 Recordati's product portfolio in Mongolia, which includes Tergynan®, the ENT brands Hexalyse®, Hexaspray® and Polydexa®, and the line of food supplements led by Alfavit®, was extended with the launch of Klimalanin® (beta-alanine), a new product for the well-being of women.

In October 2018 the Recordati group entered Uzbekistan, one of the most populated countries in Central Asia, with the introduction of the corporate products Zanidip® and Urorec®. The intention is to make further treatments available in this market.

## Turkey

Recordati İlaç, the Group's subsidiary in Turkey, continues to strengthen its position on the Turkish pharmaceutical market thanks to the success in the medical community of a number of products.

It has a strong consolidated presence in the fields of urology and cardiology as well as of gynecology and physical medicine and rehabilitation.

The corporate products Lercadip®, Zanipress®, Alipza®, Urorec®, Kentera®, Gyno-Lomexin® and Procto-Glyvenol® and Phosphosoda®, together with the local brands Mictionorm® and Mictionorm SR®

(propiverine hydrochloride), a treatment for hyperactive bladder and urinary incontinence, Kreval® (butamirate citrate) indicated for the control of acute cough, Pankreoflat® (pancreatin), a treatment indicated for digestive problems, Nazofix® (mometasone), a treatment for allergic rhinitis, Prepagel® (escin, salicylic acid), for use in cases of bruises, sprains, hematoma, and the antibiotic Ciprasid® (ciprofloxacin), all continue to perform well.

During 2018 the product portfolio in Turkey was extended to include the 20/20 formulation of Zanipress®, Citrafleet® and Kreval Max®.

Recordati İlaç invested in the construction of a new production plant in Cerkerzkoy which has a production capacity of 80 million packs per year. The plant manufactures solid oral forms (tablets, film coated tablets, capsules, sachets, etc.), semi solid forms (creams, ointments and gels) and liquids (solutions, suspensions and drops). Declared GMP compliant by the Turkish authorities in 2016, in 2018 it produced a number of different products for various therapeutic indications for a total of 57 million packs

## Spain

Casen Recordati S.L., the Spanish subsidiary of the Recordati group with headquarters in Madrid and



production facilities in Utebo, Zaragoza, markets an extensive and substantial portfolio of products belonging to the cardiovascular, urological, gastrointestinal, pediatric, gynaecological therapeutic areas as well as primary care.

The company operates successfully in the fifth largest European pharmaceutical market recording significant growth during the year.

The subsidiary's products for bowel cleansing and oral rehydration are well appreciated and belong to market segments in which the company is an undisputed leader. Worth mentioning are the well-known brands Citrafleet® and Fleet®Enema, bowel cleansers, and the rehydrating solution Bi-OralSuero®, all leaders in their classes.

Reuteri® drops, a complete treatment in drops form for gastrointestinal disturbances, regurgitation and colic in infants and Casenbionic® drops, indicated in cases of diarrhea in infants, are growing products based on lactobacillus reuteri protectis and are leaders in their markets of reference.

Other highly appreciated products that have contributed to the development of the Spanish subsidiary are the statin for hypercholesterolemia Livazo® and the treatment for benign prostatic hyperplasia Urorec®, which continue to grow thanks to their efficacy.

Completing Casen Recordati's urological portfolio are Virirec®, the first topical cream treatment for erectile dysfunction which is growing significantly since reimbursement status was granted by the public healthcare system, and Fortacin®, a treatment for premature ejaculation recently launched.

### Tunisia

Recordati has a direct presence in North Africa through its subsidiary Opalia Pharma S.A. which is headquartered in Tunis. It markets a number of proprietary and corporate products and promotes others belonging to the French subsidiary.

Opalia Pharma ranks high in the Tunisian pharmaceutical market and is one of the largest local pharmaceutical companies. A number of the company's own branded generic drugs are leading brands in dermatology, gastrointestinal and respiratory therapeutic areas.

Among the main products are the antihypertensive Zanidip®, two treatments for asthma and chronic obstructive pulmonary disease (COPD), Eolide® (budesonide) and Notos® (formoterol+fumarate dehydrate), Urorec®, Goldix® Duo, a medication for colds and flu, and Psoriasone® (calcipotriol and betamethasone), a gel for topical use widely used in the Tunisian

market for the treatment of psoriasis.

In November 2018 the Tunisian subsidiary launched Notos®.Combi, an adjustable long term treatment for asthma and chronic bronchopulmonary obstruction (BPCO), which, thanks to the easy-to-use device, helps patients optimally control their treatment and extends the line of respiratory medicines.

Opalia manufactures most of its products in a modern, cGMP certified production facility specialized in liquid and semi-solid forms.

### Portugal

Jaba Recordati S.A. is well positioned in the Portuguese pharmaceuticals market, mainly in the cardiovascular, urological, gastrointestinal and pain control fields and in the market for self-medication products.

Its established presence in the cardiovascular area stems from the strong appreciation shown by the medical community and specialists for the subsidiary's products.

Jaba Recordati's main products are Livazo®, an innovative and much appreciated statin for the treatment of dyslipidemia, Zanipress® the fixed combination of lercanidipine and enalapril, which today is the leading brand in the calcium channel blocker + ACE inhibitor market in units, and Urorec® leader in its class for the treatment of

benign prostatic hyperplasia.

The Portuguese subsidiary recently launched Fortacin<sup>®</sup>, the new treatment for premature ejaculation.

TransAct<sup>®</sup> LAT, is a leading product in the market for transdermal patches within the topical anti-rheumatic class of drugs and Egostar<sup>®</sup> in the vitamin D3 market.

Citrafleet<sup>®</sup>, a bowel cleanser used in preparation for diagnostic procedures which require intestinal evacuation, is an important product in this subsidiary and has achieved a primary position in its reference market.

Among the self-medication products Guronsan<sup>®</sup>, a leader in the market for detoxification therapies and tonics for fatigue, is the most important. Alocclair<sup>®</sup>, for the treatment of mouth sores, has also achieved encouraging results, as has Biogaia<sup>®</sup> in the probiotics segment.

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## Poland

Recordati Polska Sp. z o.o. is the Group's subsidiary in Poland. It markets a diversified and well positioned product portfolio in the urological, gynaecological and cardiovascular therapeutic areas as well as in self-medication.

The company's main products are Betaloc<sup>®</sup> ZOK (metoprolol succinate), a product widely used for the treatment of angina pectoris and other cardiac disorders, Procto-Glyvenol<sup>®</sup> for the treatment of haemorrhoids, Uprox<sup>®</sup> (tamsulosin) for lower urinary tract disturbances associated with enlargement of the prostate, Finxta<sup>®</sup> (finasteride) for benign prostatic hyperplasia and the antihypertensives Lercan<sup>®</sup> (lercanidipine) and Lercaprel<sup>®</sup> (lercanidipine-enalapril).

Recordati Polska successfully launched the corporate products

Gynoxin<sup>®</sup> Optima in the OTC market as well as Citrafleet<sup>®</sup>.

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## Czech Republic and Slovakia

Herbacos Recordati s.r.o., the group's subsidiary present in the Czech Republic and in Slovakia, successfully markets pharmaceutical products belonging to a number of therapeutic areas, including analgesic, anti-inflammatory and dermatological medicines.

It is particularly strong on the market for self-medication products such as Procto-Glyvenol<sup>®</sup>, an increasingly well appreciated treatment for haemorrhoids which together with the cream and suppository forms also presents wet wipes, the analgesics Valetol<sup>®</sup> and Acylpyrin<sup>®</sup> which are among those most used in the country, Veral<sup>®</sup> Gel for muscular and articular pain relief, Lipovitan<sup>®</sup>, a hepatic supplement, Avilut<sup>®</sup> and Rybilka<sup>®</sup> for eye health and childcare respectively.

The growing success of the corporate products Urorec<sup>®</sup>, Kentera<sup>®</sup>, Vitaros<sup>®</sup> and Lomexin<sup>®</sup> reinforce the presence of our subsidiary in the therapeutic areas of urology and gynaecology.

In 2017 Herbacos Recordati's product portfolio was significantly extended with the introduction of Betaloc<sup>®</sup> (metoprolol succinate) indicated in the treatment of hypertension and other cardiac disorders, Mictonorm<sup>®</sup> (propiverine hydrochloride), a urological treatment for hyperactive bladder, and Avilut<sup>®</sup> GOLD (lutein, zeaxanthin), a dietary supplement which combats macular degeneration due to aging, which further enlarges the Avilut<sup>®</sup> line offering with renewed packaging both in the Czech Republic and Slovakia.

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## Greece

Recordati Hellas Pharmaceuticals S.A. has a growing presence on the cardiovascular market also thanks to the introduction of new corporate products such as Logimax<sup>®</sup>. In the same therapeutic area, it successfully markets Zanidip<sup>®</sup> and Lercadip<sup>®</sup> (lercanidipine) and their fixed combinations with enalapril Lercaprel<sup>®</sup> and Zaneril<sup>®</sup>, Livazo<sup>®</sup> and Lopresor<sup>®</sup>, a selective beta-blocker indicated for the treatment of various cardiovascular diseases and in particular for hypertension and angina pectoris. Sales of Urorec<sup>®</sup>, a treatment for benign prostatic hyperplasia, continue to grow.

The following products also contribute to the subsidiary's development and complete its diversified product portfolio: the antimycotic Lomexin<sup>®</sup>, leader in its market of reference, and Citrafleet<sup>®</sup>, a bowel cleanser used in the preparation of any diagnostic procedure which requires emptying of the intestines which in 2018 recorded significant growth.

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## Switzerland

The Recordati group is present in Switzerland through Recordati AG which is headquartered in Zug and also operates in Austria. It markets the Group's corporate products and in particular the anti-hypertensives Zanidip<sup>®</sup> and Zanipress<sup>®</sup>, the statin Livazo<sup>®</sup> and Urorec<sup>®</sup>, a treatment for benign prostatic hyperplasia, as well as specialties in selected therapeutic areas.

The main brands are Lactigest<sup>®</sup> (tilactase), used in lactose intolerance, Tretinac<sup>®</sup> (isotretinoin), a treatment for severe acne, and Urocit<sup>®</sup> (potassium citrate) for the prevention of kidney stones.

In 2018 the Swiss portfolio was enhanced in the cardiovascular and gastrointestinal therapeutic areas with the introduction of the corporate products Betaloc® ZOK, Logimax® and Citrafleet®.

In November Recordati AG entered the CNS therapeutic area with the launch of Reagila®, an innovative product for the treatment of schizophrenia in adults.

## Romania

Through Recordati Romania S.R.L., Recordati is also present in this Eastern European country. The Romanian subsidiary promotes both prescription and OTC products successfully. In 2017 Recordati Romania has extended its product portfolio with the introduction of Betaloc® (metoprolol succinate), indicated in the treatment of arterial hypertension and other cardiac disorders, which is now its largest product.

The company's main products also include Procto-Glyvenol®, a growing tribenoside based treatment for hemorrhoids, Lomexin®, Tergynan® an anti-infective product used in gynecology, and Urorec®.

The subsidiary also markets Revada® (diosmin) which is prescribed for venous insufficiency and other indications and Caldefix®

(calcium and vitamin D3) for the treatment of osteoporosis.

Growing importance in their reference markets is being achieved by Casenfibra®, an innovative solution based on vegetable fibre for the prevention and treatment of slight constipation, and Citrafleet®, a bowel cleanser used in preparation for diagnostic procedures which require emptying of the intestines.

The subsidiary's presence in the urological area was reinforced with the launch of Vitaros®, an innovative topical treatment in cream form for erectile dysfunction.

Recordati Romania also sells Recordati's products in the Republic of Moldavia through an agreement with a local distributor.

## Benelux

In March 2018 the Recordati group, through its subsidiary Recordati BVBA, has strengthened its presence in Belgium for the direct distribution in Belgium, the Netherlands and Luxembourg of its lercanidipine and metoprolol based products in the cardiovascular area, Citrafleet®, Cleen Enema and Phosphosoda® in the gastrointestinal area and is preparing the launch of Reagila®.

## Nordic Countries

The Recordati group, in March 2018, has also potentiated its subsidiary Recordati AB in Sweden with operates also in Denmark, Norway, Finland and Iceland.

Based in Stockholm it markets a number of corporate products, in particular those belonging to the gastrointestinal portfolio Citrafleet®, Cleenenema and Phosphosoda®. From June to September, Reagila®, the new antipsychotic drug for the treatment of schizophrenia, was launched in Sweden, Denmark and Finland.

## UK e Ireland

Recordati Ireland is the group's organization that operates in Ireland while Recordati Pharmaceuticals markets Recordati's products in the United Kingdom.

In September the UK subsidiary successfully launched Reagila®, which was received with interest by the medical community, and is preparing the launch of Fortacin®, a new treatment for premature ejaculation which will be available during 2019.

**GYNOXIN OPTIMA**  
Pierwszy lek na grzybicze zakażenia pochwy dostępny bez recepty\*\*  
Tylko 3 dni terapii\*  
Tylko 1 kapsułka dziennie\*  
Ta sama substancja czynna co w leku na receptę\*

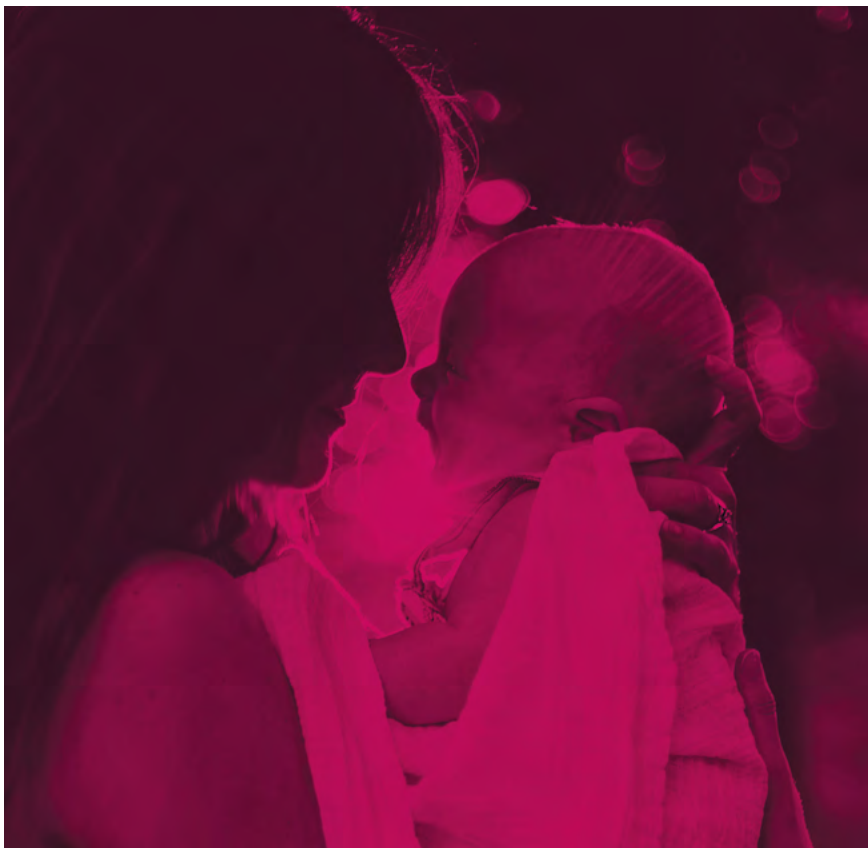
**Citrafleet**  
απόφαση επιλογής για την προετοιμασία του εντέρου  
Γιατί αυτή την επιλογή;  
**Citrafleet**

**REAGILA**  
CARIPRAZINE  
Re-embrace life  
Geregistreerd voor de behandeling van schizofrenie bij volwassenen!  
Significante verbetering van de negatieve symptomen, terwijl de positieve symptomen onder controle blijven.\*  
Volledig vergoed!

NU BESCHIKBAAR IN NEDERLAND!

## RARE DISEASES AND ORPHAN DRUGS

A HEALTHCARE PRIORITY, A RECORDATI PRIORITY



Rare diseases bring great suffering to millions of affected people worldwide. They are mostly genetic diseases that can affect patients of any age, sex or ethnic origin and involve any type of medical specialization. They are chronic diseases which can be fatal or severely invalidating and have a strong impact on patients, their families and society in general.

In most cases sufferers are newborns, children and young adults.

An orphan drug is a medicinal product developed for the treatment of a rare disease. A rare disease is defined as a condition that affects fewer than 5 per 10,000 inhabitants in Europe or fewer than 200,000

Americans in the U.S.A., and is fatal or severely debilitating. Over 30 million people are affected in Europe alone.

There are over 7,000 known rare diseases but today treatment exists for only around 300 of these.

Due to the extensive spectrum of existing diseases physicians may never see a patient with a rare disease. For that reason and due to the scarcity of available information there's always a risk that when a baby is born with a rare disease a correct diagnosis may not be made and timely appropriate treatment may not be provided.

Limited number of patients and scarcity of relevant knowledge and

expertise are the specificities of rare diseases. To ensure that scarce knowledge and available resources are made available these are often shared through international cooperation channels.

Patient numbers are so small that a rare disease is often not "adopted" by the pharmaceutical industry and hence the expression "orphan drug".

To provide care for people with a rare disease and to encourage pharmaceutical and biotechnology companies to invest in treatments for rare diseases governments have created various legal and financial incentives. In 1983 the Orphan Drug Act was introduced in the U.S.A. and European legislation passed in 1999 explicitly recognized the unmet need for targeted treatments for orphan diseases and created regulatory pathways and incentives for manufacturers to develop orphan drugs. From April 2000, when the EU orphan drug regulation came in to effect, many hundreds of drugs received orphan drug designation from the European Medicines Agency (EMA). Of those designated drugs, over 100 have received marketing authorization (MA). 40% of the orphan medicines were licensed for oncological and haematological conditions and about 30% of the orphan drug market consists of drugs for rare inborn errors of metabolism.

Reports show that orphan drugs are estimated to account for between 1.7% and 4% of the total drugs expenditure.

Lately, there is a surge of international research investment from different funding bodies to boost the number of new authorized treatments.



## ORPHAN EUROPE AND RECORDATI RARE DISEASES: THE RECORDATI COMPANIES DEDICATED TO ORPHAN DRUGS

The Recordati group operates in the rare disease segment worldwide through its dedicated subsidiaries Orphan Europe (renamed Recordati Rare Diseases as from April 2019) and Recordati Rare Diseases who share the conviction that each person with a rare disease has the right to the best possible treatment.

Our specialties indicated for the treatment of rare and orphan diseases are marketed directly all over Europe, in the Middle East, in the U.S.A., Canada, Russia, Australia, Japan and in some Latin American countries, and through selected partners in other parts of the world. In June 2017 a representative office was opened in Malaysia with the intention of extending operations to the Asia-Pacific regions and during 2018 the subsidiaries in Australia and Japan were established.

The main products in the segment dedicated to rare disease treatments are Carbaglu® (carglumic acid) indicated for the treatment of hyperammonaemia due to N-acetylglutamate synthase deficiency (NAGS deficiency) and due to any of the three main organic acidaemias, Panhematin®/

Normosang® (human haemin) indicated for the treatment of acute attacks of hepatic porphyria, Cosmegen® (dactinomycin) used mainly in the treatment of three rare cancers: Wilms' tumor, childhood rhabdomyosarcoma and choriocarcinoma, Cystadane® (betaine anhydrous) used in the treatment of homocystinuria to lower the blood levels of homocysteine, and Cystadrops® (cysteamine chlorhydrate), recently launched, used in the treatment of the ocular manifestations of nephropathic cystinosis.

The Recordati group received two international awards: the NORD (National Organization for rare Disorders) prize in the United States of America and the EURORDIS (European Organization for Rare diseases) prize in Europe, which recognized the important results obtained by the group in the development of orphan drugs and the efforts made to improve the diagnosis and treatment of rare diseases.

The growth of Orphan Europe, the success of Recordati Rare Diseases in the U.S.A., the establishment of dedicated companies in Canada, Australia and Japan the consolidation and development of our presence in Latin American

countries (Brazil, Mexico and Colombia) are confirmation of Recordati's commitment to becoming a worldwide player in the segment dedicated to rare diseases.

## NEW ACTIVITIES AND DEVELOPMENTS

In recent years, important and innovative research projects have been initiated to reinforce the Group's product pipeline. In February 2017 an exclusive worldwide licensing agreement with the Meyer Hospital in Florence (Italy) for the development of a treatment for pre-term babies affected by retinopathy of prematurity (ROP) was signed. Retinopathy of prematurity (ROP) is a potentially blinding eye disorder that primarily affects premature infants. During the same year, Recordati signed an exclusive license agreement with MimeTech, an Italian development stage company founded by scientists from the University in Florence, for the development and subsequent commercialization on a global basis of a low molecular weight peptidomimetic of human nerve growth factor (NGF) for the treatment of neurotrophic keratitis,



a rare degenerative corneal disease which in its more severe forms affects less than one person out of 10,000 worldwide. In December 2018 this experimental product REC 0559 was granted orphan drug designation by the FDA which provides, apart from other benefits, marketing exclusivity in the approved indication for 7 years.

In November, the European Commission (EC) granted Orphan Drug Designation to investigational product REC 0545 for the treatment of maple syrup urine disease (MSUD). This is the first time that an Orphan Drug Designation has been granted in this indication.

MSUD is a rare genetic metabolic disorder in which the body is unable to properly process certain amino acids (the building blocks of proteins). This condition is characterized by lack of appetite, vomiting, lack of energy (lethargy), seizures, abnormal movements and developmental delay. The condition gets its name from the distinctive sweet odour of affected infants' urine. Patients with Maple syrup disease suffer from decompensation episodes that can be life-threatening if untreated. In Europe around 3000 patients

are affected by MSUD.

In Europe, orphan drug designation applies to drugs that seek to treat rare diseases or conditions affecting fewer than 5 persons in 10 000 while providing significant therapeutic advantage over existing therapies. The designation provides the opportunity for ten years marketing exclusivity upon approval of the product in the designated indication.

In December, Recordati obtained a license from Helsinn, a Swiss pharmaceutical group focused on building quality cancer care products, for the exclusive marketing rights to Ledaga® worldwide, excluding the United States, China, Hong Kong and Israel.

Ledaga® (chlormethine hydrochloride) is a novel gel formulation, applied once a day, indicated for the topical treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL), a rare disease characterized by the abnormal accumulation of malignant T-cells in the skin. MF-CTCL is the most common type of cutaneous lymphoma and first presents as patches and plaques on the skin. It is difficult to diagnose, particularly

in the early stages as many of its features are non-specific. Chlormethine is an alkylating agent that inhibits quickly proliferating cells and Ledaga® is recognized to have a good efficacy profile with a confirmed treatment response achieved in 76.7% of the efficacy evaluable population in the pivotal trial. The product has been granted Orphan Drug Designation in Europe, is approved by the European Commission (for patients with MT-CTCL at all stages) and will be commercialized following the completion of post approval commitments.

#### IN EUROPE, MIDDLE EAST, AFRICA

Recordati operates directly in Europe, the Middle East and Africa through Orphan Europe, a company entirely dedicated to the research, development and marketing of treatments for rare diseases. The company markets treatments mostly for inborn errors of metabolism and focuses on drugs for some of the most uncommon diseases.

It has developed worldwide



ORPHAN EUROPE  
RECORDATI GROUP

**BIG THINKING FOR PEOPLE  
WITH RARE DISEASES**

**OE** Orphan Europe - Recordati Group is a long-established key partner in promoting innovation and in building networks between patients and their families, healthcare professionals, policy makers, regulators & the scientific community.

**ORPHAN EUROPE**  
RECORDATI GROUP  
www.orphan-europe.com

coverage, through its dedicated subsidiaries and commercial agreements with qualified distributors and has also designed a direct distribution and packaging system able to efficiently deliver very small quantities of specialist products to people around the world at a moment's notice. Recordati operates a new manufacturing site for the treatments for rare diseases in Nanterre. It occupies a surface area of 1,200 sq. m., is GMP certified and is entirely dedicated to the packaging, storage and shipping of rare disease products in all countries.

Recently, Cystadrops® (mercaptopamine hydrochloride), the first eye-drop solution containing mercaptopamine hydrochloride approved in the European Union for "the treatment of corneal cystine crystal deposits in adults and children from 2 years of age with cystinosis" was launched. Cystinosis is a rare congenital lysosomal storage disorder recognized as a severe life threatening condition. It is characterized by an accumulation of cystine crystals which negatively affects all organs in the body, especially the kidneys and eyes. Cystinosis benefits from systemic treatment with cysteamine orally

administered. However, oral cysteamine does not adequately address ocular cystinosis because of the non-vascularization of cornea. The benefit of Cystadrops® is its ability to reduce corneal cystine crystal accumulation. Without a proper, continued, local eye treatment, cystine crystals accumulate in the cornea, leading to severe consequences and possibly to blindness in the long term.

Orphan Europe has undertaken a number of initiatives to spread and make available the most up-to-date and clinically useful information. In Europe it organized various international scientific events such as the "International Young Metabolicians Day" in Vienna (Austria) that was the first stand-alone meeting on the management of patients suffering from hyperammonaemia due to organic acidemias and NAGS deficiency treated with Carbaglu®.

It was Gold Sponsor of the SSIEM Congress (Society for the Study of Inborn Errors of Metabolism) which was held in Athens (Greece) at which a symposium entirely dedicated to Carbaglu® was presented.

To support patients suffering from

cystinosis and put them in contact with the medical community, Orphan Europe organized a Patient-Experts Day for the first time with the objective of improving their understanding of the disease and the treatment they must undergo, increasing their ability to manage their condition, and disseminating knowledge within the medical community and the association.

In London, the "3<sup>rd</sup> Ophthalmology Cystinosis Forum (OCF)" was organized and was attended by more than 90 participants. The objective was to share experiences between the two main specialties involved in the diagnosis and follow-up of cystinosis, nephrology and ophthalmology, and facilitate the medical-scientific discussion and help to identify solutions for the correct use of therapies.

Orphan Europe also participated in the "51<sup>st</sup> annual scientific meeting of the European Society for Paediatric nephrology (ESPN 2018)" in Antalya (Turkey) with the organization of a symposium during which the commitment over twenty years of the Society to cystinosis and the uniqueness of Cystagon® and Cystadrops®, the first and only available treatment for the ocular



manifestations, were illustrated.

A number of initiatives were also undertaken in the Middle East to support opinion leaders, metabolic and cystinosis centres and patient associations, such as the “14<sup>th</sup> Middle East Metabolic group” that was held in Athens (Greece), at which cutting edge advances in genomics, in molecular based metabolic disorders and in innovative treatments were presented by 34 speakers from 13 countries.

### IN NORTH AMERICA

The Recordati group has established a consolidated presence in North America where it has subsidiaries in both the U.S.A. and Canada.

Recordati Rare Diseases Inc., the group’s U.S. subsidiary dedicated to treatments for rare diseases, offers a portfolio of products the main ones of which are Panhematin®

(haemin for injection) for the amelioration of recurrent attacks of acute intermittent porphyria, Carbaglu® (carglumic acid) indicated for the treatment of hyperammonaemia due to N-acetyl glutamate synthase deficiency (NAGS deficiency), Cystadane® (betaine anhydrous) used in the treatment of homocystinuria to lower the blood levels of homocysteine and Cosmegen® (dactinomycin for injection) used mainly in the treatment of three rare cancers.

The Canadian subsidiary Rare Diseases Canada Inc. is committed to make rare disease treatments available to all patients who need them and is the exclusive provider of several treatments including Carbaglu®, Cystadane®, Cosmegen® and, more recently Panhematin®, the first medicinal product approved by Health Canada for the treatment of recurrent attacks of intermittent acute porphyria.

The North American subsidiaries work closely with the FDA and Health Canada to register treatments or additional indications already available in Europe, in order to make these precious therapies also available to U.S. and Canadian patients. Among these is the indication for the use of Carbaglu® in acute hyperammonaemia due to the main organic acidemias and Cystadrops® for the treatment of corneal deposits of cysteine crystals in patients suffering from cystinosis.

Recordati Rare Diseases, committed to reduce the impact of these extremely rare and devastating diseases, works closely with specialists, healthcare professionals, patients’ families and patient groups to meet the needs of people affected by these disorders, spread the scarce knowledge available, improve and facilitate patient access to treatment.

## Main treatments for rare diseases in our portfolio

name	active ingredient	indication
<b>CARBAGLU®</b>	carglumic acid	Treatment of hyperammonemia due to N-acetylglutamate synthase deficiency (NAGS deficiency) and some organic acidemias (isovaleric acidemia, methylmalonic acidemia and propionic acidemia)
<b>NORMOSANG®/PANHEMATIN®</b>	human hemin	Treatment of acute attacks of hepatic porphyria
<b>COSMEGEN®</b>	dactinomycin injectable	Treatment of three rare cancers
<b>CYSTADANE®</b>	betaine anhydrous	Treatment of homocystinuria
<b>CYSTADROPS®</b>	cysteamine chlorhydrate	Treatment of the ocular manifestations of cystinosis
<b>PEDEA®/ NEOPROFEN®</b>	ibuprofene iv	Treatment of patent ductus arteriosus (PDA)
<b>CYSTAGON®</b>	cysteamine bitartrate	Treatment of nephropathic cystinosis
<b>VEDROP®</b>	tocofersolan	Treatment or prevention of vitamin E deficiency in paediatric patients and adolescents suffering from congenital or hereditary chronic cholestasis
<b>CHEMET®</b>	dimercaptosuccinic acid (DMSA)	Treatment of heavy metals poisoning
<b>WILZIN®</b>	zinc acetate	Treatment of Wilson’s disease

## IN NEW MARKETS

The Recordati group continues to extend its activities dedicated to rare diseases outside Europe, the Middle East, Africa and North America to an increasing number of countries and into new geographical areas.

In 2017 a representative office was opened in Malaysia with the intention of extending operations to the Asia-Pacific regions, an area in which the Group's commitment to make its rare disease products available was reinforced in 2018.

In March 2018 the Japanese subsidiary of Recordati Rare Diseases was established in Tokyo and as from October it is directly commercializing Carbaglu® for the treatment of hyperammonaemia due to NAGS deficiency and some organic acidemias. Japan, the second largest pharmaceutical market, will from now on be included, together with Europe

and the U.S.A., in the global development plans for new products.

In July, Recordati Rare Diseases Australia was established in Sydney and will be covering both Australia and New Zealand, two countries with a high level of medical education where Recordati staff will be able to roll out its portfolio for the treatment of rare diseases.

It continues to consolidate its presence in Latin American countries in some of which such as in Brazil, Colombia, and Mexico, it operates through its own subsidiaries.

In Brasil, at Atibaia, Recordati Rare Diseases Brazil has set up its own warehouse which was inspected and authorized by the local health authorities. Here, the regulatory process for the approval of Panhematin®, Carbaglu® and Cystadane® has started.

In Colombia the local medicines agency (INVIMA) provided a positive opinion for the approval of Panhematin® and Cystadrops® and efforts continue in order to make its product portfolio available to all the main reference centres which treat hyperammonaemia, intermittent acute porphyria and nephropathic cystinosis.

In Mexico our subsidiary obtained the inclusion in the National Formulary List of key products such as Pedeia®, Cosmegen® and Cystagon®. In Mexico, the "Consejo de Salubridad" (National Board of Health) included the key products Carbaglu®, Cystadane® and Normosang® in the national formulary.

In Russia Recordati's organization guarantees access to treatments to patients living in the more remote areas of the country.

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## RECORDATI RARE DISEASES FONDATION D'ENTREPRISE

### OUR COMMITMENT TO RARE DISEASES

Working in the field of rare diseases is an important responsibility to patients and healthcare professionals and we put this at the heart of our commitment.

The Recordati Rare Diseases Foundation was instituted to provide unconditional grants for training in rare diseases to the scientific community. High-level courses are organized under the supervision of an independent scientific committee. The overall aim is to share experience in the management and outcome of rare disorders where individual knowledge is by its nature limited.

The Foundation offers specialists the opportunity to enrich their knowledge, develop new ideas and establish scientific relationships.

A number of live events are held each year bringing together clinicians and scientists from all over the world to discuss innovations and new diagnostic and management strategies.

In 2018 more than 100 specialists from a number of different countries attended 3 international courses which took place in Brazil, Belgium and France.

The Foundation also provides online e-learning courses which aim to provide physicians world-wide with clinically useful and the most up-to-date information concerning current knowledge and recommendations for care.

Furthermore, we work in partnership with recreational camps for children with serious debilitating disease through our staff volunteering program. We also support the work of European reference networks in providing equal and equitable care for all patients with a rare disease.



## RESEARCH AND DEVELOPMENT

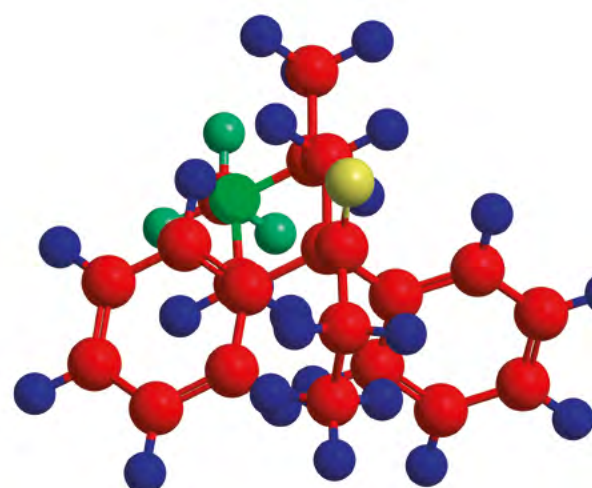
*In 2018 research and development activities were concentrated on programs in rare diseases and urology.*



In 2018 research and development activities were concentrated on programs in rare diseases and urology. Regarding the rare diseases segment, the pharmaceutical and clinical development of the projects REC 0551 (treatment of retinopathy of prematurity), REC 0559 (treatment of neuropathic keratitis) and REC 0545 (treatment of Maple Syrup Urine Disease) progressed. New formulations continued to be

developed as part of the the life cycle management of carginic acid, hemin and cysteamine.

During 2018 marketing approval in France was received for the use of methadone in the palliative treatment of cancer related pain, while cariprazine, already granted European approval in 2017, received marketing approval in Switzerland.



## Product development pipeline

name	originator	indication	development status
<b>CYSTADROPS®</b>	Recordati	Corneal cysteine crystal deposits in patients with cystinosis	Development of new formulations in EU and in USA
<b>FORTACIN™</b>	Plethora Solutions	Premature ejaculation	Post-marketing
<b>REAGILA®</b>	Gedeon Richter	Schizophrenia	Pediatric post-approval development plan
<b>methadone</b>		Treatment of cancer-related pain in cases of resistance or intolerance to opioids	Approved in France. Market access activities underway.
<b>CARBAGLU®</b>	Orphan Europe (Recordati)	Hyperammonaemia due to NAGS deficiency and to the main organic acidemias	Development of new formulations in EU and USA. Filed in the USA for the organic acidemias indication.
<b>REC 0551</b>	Recordati/Meyer Hospital (Florence)	Retinopathy of Prematurity (ROP)	Formulation development Phase II in Italy
<b>LYNOVEX®</b>	NovaBiotics	Acute infectious exacerbations associated with cystic fibrosis	Phase II
<b>REC 0438</b>	Recordati/UFPeptides	Overactive bladder in patients with spinal lesions	Proof of concept ongoing in EU
<b>REC 0559</b>	Recordati/MimeTech	Neurotrophic keratitis	Formulation development. Clinical development planning.
<b>REC 0545</b>	Recordati/AP-HP	Acute decompensation episodes in MSUD	Formulation development. Retrospective study in France and Germany.

The introduction in the pipeline of new products, both through our discovery programs as well as through alliances with other research companies and institutions, has been of

fundamental importance also in 2018 to enrich our pipeline and ensure the group's future growth. At the same time, important and intense registration and regulatory activities were carried out to obtain

marketing approvals for Recordati products in new territories.

The main research and development activities during 2018 are summarized in the following paragraphs.

## Urology and andrology

### RESEARCH IN UROLOGY

Recordati's discovery programs in urology are primarily focused on the search for innovative treatments to address micturition disorders, which are frequent in the elderly, but also afflict groups of patients suffering from conditions often defined as rare, such as *spina bifida*.

#### REC 0438

REC 0438 is a product candidate which would be administered by intravesical means in patients suffering from hyperactive bladder of neurological origin who must repeatedly use self-catheterization methods to empty their bladder. The objective of the treatment is to reduce bladder hyperactivity and incontinence episodes which have an important impact on patients' quality of life.

Following the completion of the single dose study conducted in healthy volunteers and in adult patients with spinal lesions of a post-traumatic nature, in 2018 a second European multicenter study in patients with spinal lesions was initiated in order to evaluate the tolerability of repeated administrations by the patients themselves at home, of the drug. This study will be

considered a "Proof of Concept" because the efficacy of the drug in reducing bladder hyperactivity of neurological origin, using urodynamic testing, is evaluated. During the year a first cohort of patients taking 1 mg was completed and the initiation of the second cohort (2 mg) was authorized by the drug Safety Monitoring Committee as no severe adverse reactions were seen. If positive results are obtained, this trial could lead to the development of the drug in a pediatric population with neuropathic hyperactive bladder secondary to *spina bifida*.

#### UROREC® (silodosin)

In 2018 the use of silodosin in patients with a more severe degree of benign prostatic hyperplasia, including those slated for surgery, was investigated. As expected, because the drug is highly selective, silodosin was seen to significantly reduce the index of bladder neck obstruction (BOOI) in the urodynamic trials, and the integrated statistical analysis both of the randomized controlled pre-registration studies and the extended Phase IV studies, confirmed the drug's efficacy in the more severe patients. Particularly interesting was the observation of a marked improvement in quality of life in 44% of the severe patients.

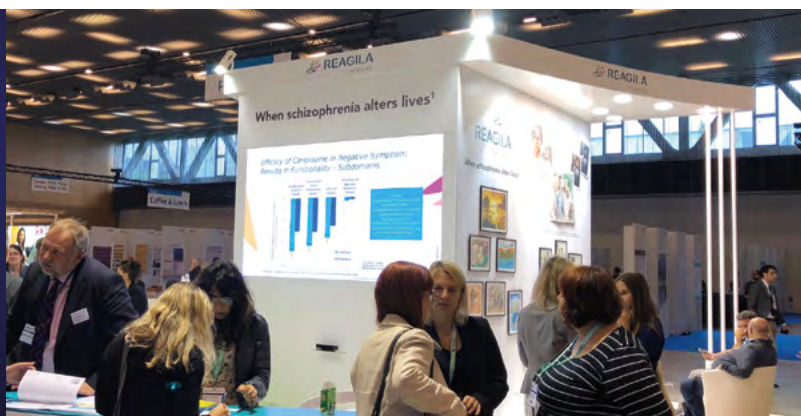
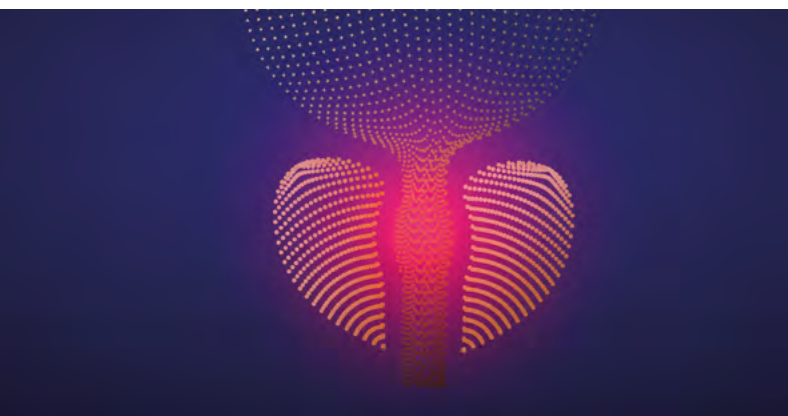
#### FORTACIN™ (lidocaine+prilocaine)

Fortacin™ is an easy-to-use fast acting topical spray formulation of lidocaine and prilocaine for the treatment of premature ejaculation. Premature ejaculation is a common form of sexual dysfunction in men. Epidemiological studies conducted in the U.S.A. and in Europe indicate a prevalence of 20% to 30% in men of all ages. During 2018 the European Medicines Agency renewed the product's marketing approval and waived the need for a post-authorization study (Drug Utilization Study) to evaluate the utilization of the drug in clinical practice through the monitoring of prescription databases.

## Cardiology and metabolic disorders

#### ZANIDIP®/ZANIPRESS® (plain lercanidipine/ lercanidipine+enalapril)

In confirmation of the continued clinical interest in our anti-hypertensive drug lercanidipine, an original calcium channel blocker fully developed by Recordati (used in monotherapy or in association with enalapril), during 2018 the Pan-European procedure put in place with the objective of updating and harmonizing the information directed at the medical community and patients in the





European Union, was concluded. A cumulative analysis of the data collected over the years from the numerous interventional and observational clinical trials conducted with the drug, and of the extensive worldwide post-marketing experience, was made.

#### **SELOKEN® (metoprolol) and LOGIMAX® (metoprolol + felodipine)**

During 2018 the regulatory activities needed to transfer the European marketing authorizations of the AstraZeneca (AZ) products based on metoprolol and metoprolol + felodipine to Recordati, were initiated. These are original well-established AZ products which reinforce Recordati's presence in the cardiovascular therapeutic area.

### **Psychiatry**

#### **REAGILA® (cariprazine)**

Cariprazine is a new antipsychotic drug approved in Europe for the treatment of schizophrenia, a psychic disorder characterized by a severe alteration of behavior and perception (hallucinations) and thought (delusions) disturbances. The delusions and hallucinations are also referred to as positive or productive symptoms which

are accompanied by negative symptoms, characterized by apathy, loss of affectivity and poor ideation which are responsible for the patient's loss of contact with reality and his or her withdrawal into a world incomprehensible to others.

The clinical trials conducted in adults for registration purposes demonstrated the efficacy of cariprazine, not only in the improvement of the positive symptoms but also of the negative symptoms associated with schizophrenia. This finding is of particular importance.

During 2018, as provided for in the agreement between Recordati and Gedeon Richter, the first pharmacokinetic clinical trial of the pediatric clinical program in Europe was completed.

### **Other therapeutic areas**

#### **Methadone**

Following the completion of the phase III-b study EQUI METH2 conducted in France in 18 clinical centers specialized in the treatment of cancer related pain, the French authorities approved the use of methadone for this condition. Market access activities are currently ongoing for the definition of the price of the product.

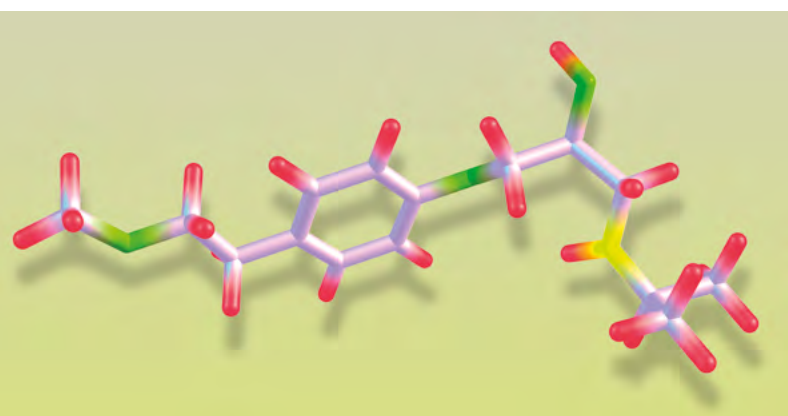
#### **LOMEXIN® (fenticonazole)**

Fenticonazole is a topical antimycotic drug originated by Recordati. During 2018 an *in vitro* study was completed to test the molecule's antimycotic and antibacterial activity on strains of microorganisms isolated from patients. This data confirmed the drug's potential for the treatment, not only of mycosis, but also of mixed vaginal infections. This information is particularly interesting as 20-30% of women with bacterial vaginitis are also infected with *Candida*.

During 2018 an analysis of post marketing experience was concluded with the objective of reevaluating the product's safety profile. Based on this analysis, an updating and harmonization process involving the product's information leaflets in all countries was initiated and is expected to be completed in 2019.

### **Treatments for rare diseases**

Recordati is expanding its commitment to the discovery and development of treatments for rare diseases, and has a number of projects in the pipeline in various phases, from new formulations to phase III and post-approval studies. Furthermore, various



collaborations with the best Universities worldwide are in place with the objective of finding new therapeutic uses for the current treatments as well as to promote research and development in the more relevant areas (metabolic diseases, neonatology).

### **CARBAGLU® (carglumic acid)**

This product is an orphan drug approved in the European Union by the European Commission and in the U.S. by the Food and Drug Administration (FDA) for the treatment of hyperammonaemia due to N-Acetyl Glutamate Synthase (NAGS) deficiency. NAGS deficiency is an extremely rare inherited metabolic disorder affecting the urea cycle which leads to accumulation of ammonia in the blood. If not adequately and quickly treated, hyperammonaemia causes irreversible brain damage, coma, and eventually death. Carbaglu® is the only existing specific treatment for this genetic disorder which requires life-long treatment. In 2011 Carbaglu® obtained approval in Europe for the extension of its use to treat hyperammonaemia due to the three main organic acidemias (OA): isovaleric acidemia, methylmalonic acidemia and propionic acidemia. In 2014 Carbaglu® was granted Orphan Drug Designation (ODD) by the

FDA for its use in the treatment of organic acidemias and is currently being filed in the U.S.A. for this indication.

Recordati is developing a new formulation of Carbaglu® with the objective of increasingly satisfying patients' needs.

### **CYSTADROPS® (cysteamine hydrochloride)**

Nephropathic cystinosis is a generalized congenital disorder which affects all body organs and benefits from systemic treatment with cysteamine (Cystagon®) orally administered. Cystinosis also affects the eyes and without quick, continued and proper treatment, cystine crystals accumulate in the cornea. Cystagon® does not adequately address ocular cystinosis due to the poor vascularization of the cornea. The accumulation of cystine crystals in the cornea results in visual disturbances such as photophobia (sensitivity to light), retinal damage and frequent corneal ulceration and eye infections that can degenerate causing corneal erosion and consequent blindness.

Cystadrops® are gel based eye drops containing cysteamine chlorhydrate developed by Recordati for the specific treatment of the ocular manifestations of cystinosis.

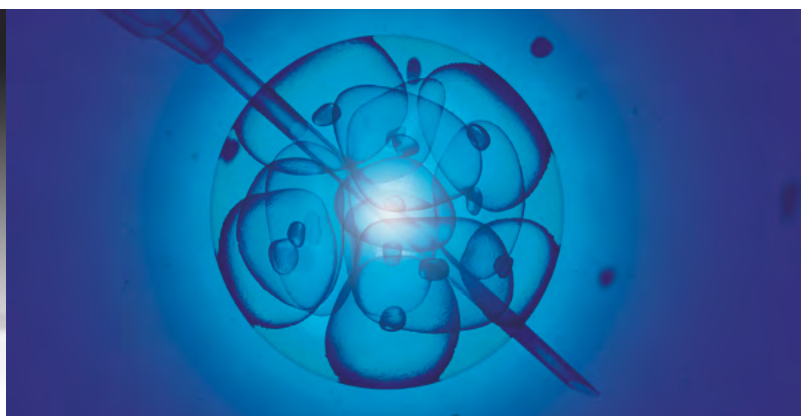
This treatment acts directly on the

accumulations of cystine crystals in the eyes and therefore reduces, and eventually eliminates, the crystals improving the symptoms.

Currently new innovative formulations of Cystadrops® are being developed with the objective of increasingly satisfying patients' needs.

### **REC 0551**

In February 2017 an exclusive worldwide licensing agreement covering the know-how developed by the Meyer Hospital in Florence (Italy) for the development of a treatment for pre-term babies affected by retinopathy of prematurity (ROP) was signed. Retinopathy of prematurity (ROP) is a potentially blinding eye disorder that primarily affects premature infants weighing about 1.25 kg or less that are born before 31 weeks of gestation (a full-term pregnancy has a gestation of 38–42 weeks). The smaller a baby is at birth, the more likely that baby is to develop ROP. This disorder—which usually develops in both eyes—is a rare condition, and is one of the most common causes of visual loss in childhood that can lead to lifelong vision impairment and blindness. The phase II clinical trial, conducted by the Meyer Hospital in Florence, was completed in June 2018. Taking into account the encouraging results, it was



decided to continue the clinical development of REC 0551.

#### **LYNOVEX® (cysteamine)**

Research of safer and efficacious long term treatments for cystic fibrosis (CF) remains a priority, given the medical need of these patients. Every therapeutic strategy aimed at fighting the respiratory disorders associated with this condition must take into account the altered pulmonary physiology and the severe and recurrent microbial infections involving the respiratory system. Recordati is the exclusive partner of NovaBiotics Ltd, a biotechnological company based in Aberdeen, Scotland, for the global commercialization of Lynovex®, an innovative oral treatment for the pulmonary exacerbations associated with cystic fibrosis. Lynovex®, designated as an orphan drug in Europe and in the U.S., is the first multi-active therapy of its kind (anti-infective, mucolytic, anti-biofilm, antibiotic potentiating) to be developed specifically for alleviating the infectious trigger and symptoms of CF exacerbations. In July top line data from a recent clinical study (CARE CF 1) of oral Lynovex® in cystic fibrosis exacerbations, conducted by NovaBiotics Ltd, was announced. Contacts are now ongoing with the regulatory authorities to define the clinical development plan requirements.

#### **REC 0559**

In June 2017 Recordati and Orphan Europe signed an exclusive license agreement with MimeTech, an Italian development stage company founded by scientists from the University in Florence, for the development and subsequent commercialization on a global basis of a low molecular weight peptidomimetic of human nerve growth factor (NGF) for the treatment of neurotrophic keratitis. Neurotrophic keratitis is a rare degenerative corneal disease initiated by an impairment of trigeminal nerve. In its more severe forms it affects less than one person out of 10,000 worldwide. The progression of the disease can result in corneal ulcers and perforation with a dramatic impact on the patient's vision. Clinical trials in humans are expected to start in 2020.

#### **REC 0545**

Maple syrup urine disease (MSUD), also called branched-chain ketoaciduria, is a rare metabolic disorder affecting branched-chain amino acids (leucine, isoleucine and valine) which results in a build up of these amino acids and their metabolites. This build-up manifests with severe symptoms affecting all organs right from the beginning of a newborn's life which, if not adequately diagnosed

and treated result in the child's death. Even when chronically treated, patients may be subject to acute metabolic decompensation episodes that manifest with severe neurological symptoms which if not addressed can be life-threatening.

Various therapeutic approaches exist but to date none is specifically approved for the management of the acute phases. Preliminary data show that REC 0545 acts quickly on the build up levels of the amino acids and their metabolites, thus considerably reducing symptoms and patient mortality.

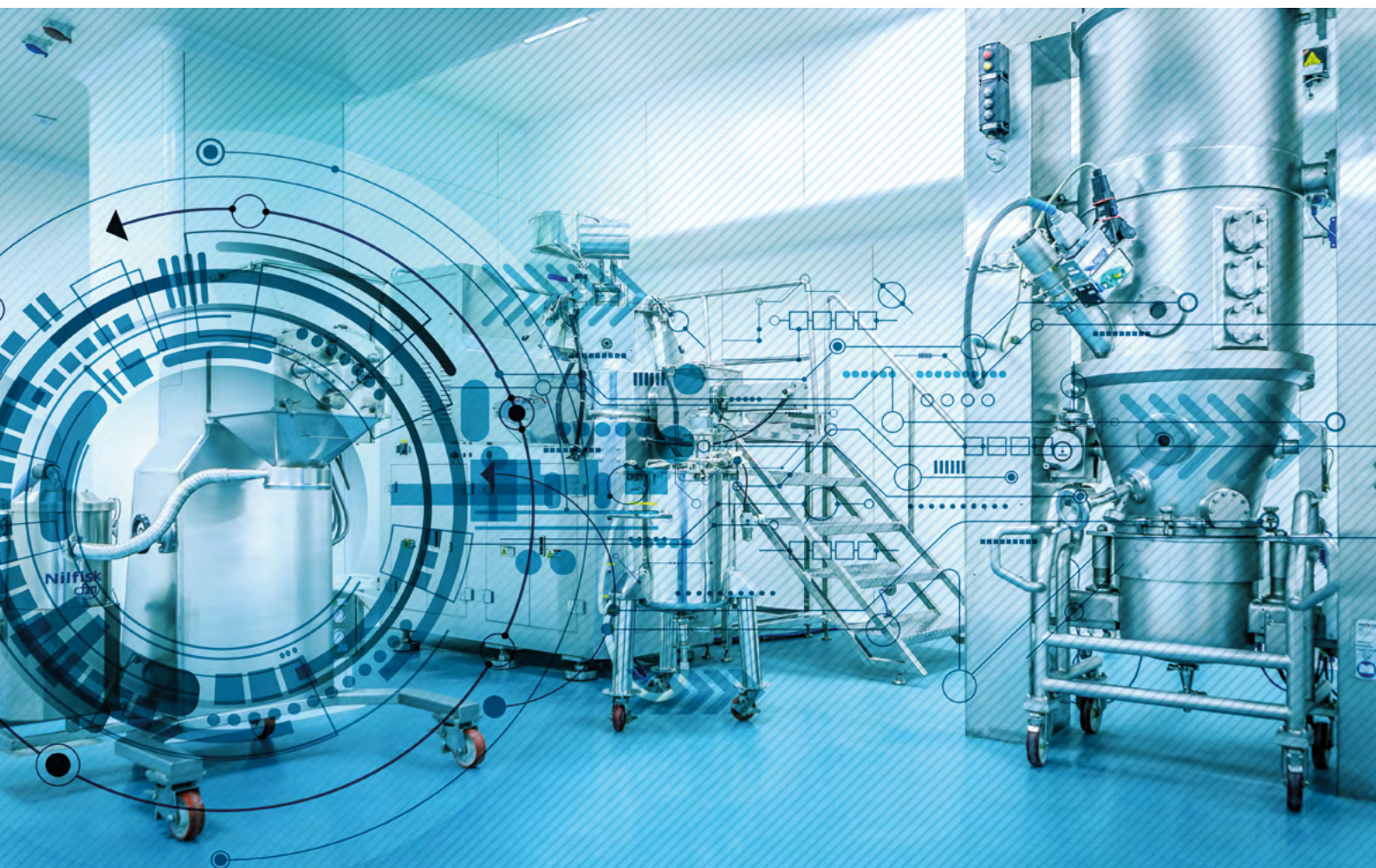




# PHARMACEUTICAL CHEMICALS AND PRODUCTION PLANTS

Recordati's pharmaceutical chemicals business focuses on:

- *satisfying the requirements of the pharmaceuticals business,*
- *striving for maximum product quality,*
- *strengthening its presence in highly regulated markets (the United States, Europe and Japan),*
- *safety of production processes,*
- *protection of the environment,*
- *health and safety in the workplace.*



*Recordati produces a number of active ingredients and intermediates for the pharmaceutical industry.*

#### **ITALY, CAMPOVERDE DI APRILIA**

The Campoverde plant mainly supplies the active ingredients used in the preparation of the various pharmaceutical specialties produced by the company, but is also an established independent producer of a number of active and intermediate ingredients for the pharmaceutical industry internationally. It is one of the most important producers in the world of verapamil HCl, phenytoin, papaverine HCl, dimenhydrinate, tribenoside and manidipine. Other pharmaceutical chemicals are produced on behalf of important pharmaceutical companies.

The facility was one of the first European plants to be inspected by the American Food and Drug Administration. The United States is one of the main markets for its production, second only to Europe.

The Campoverde site covers a surface area of around 380,000 sq. m. with an installed area of 35,000 sq. m., and produces approximately 650 metric tonnes per year of finished goods with approximately 5,000 metric tonnes of semifinished goods handled internally each year. High-tech systems are employed for the management of particularly delicate processes such as the reactions which employ cyanides, high pressure hydrogenations, methylations, chloromethylations or those which involve substances which require very stringent safety measures.

Investments have been made to enhance the technological and production capacity of the plant which over the years has resulted in the installation of 12 new reactors and a latest generation three stage

**Pharmaceutical chemical plants**

**2**

**Sites for pharmaceutical production**

**6**



distillation unit. To these, over the last two years, 9 more reactors were added, four for the production of lercanidipine, five for the production of tribenoside and in 2018 a new anti-acid filter was installed for the isolation of solid products.

A vast range of technologies, skills and expertise in the field of organic synthesis is employed which allow it to quickly and effectively study new processes for the production of active ingredients, from their synthesis to purification and finishing, through the various research stages, scale up and final industrialization.

The Research and Development laboratories are fitted with the latest equipment together with an extremely versatile pilot plant equipped for the small scale production, in accordance with cGMP (current Good Manufacturing Practices), of active ingredients.

In 2016 a high containment HP-API

pharmaceutical isolator (glove box) was installed in the plant's research laboratories.

The plant operates in compliance with current *Good Manufacturing Practices* (cGMP) and is regularly inspected by external verifying authorities such as AIFA (Agenzia Italiana del Farmaco), FDA (Food and Drug Administration), ANVISA (the Brazilian agency), PMDA (the Japanese ministry of health), KFDA (Korean Food and Drug Administration).

The plant's environmental management system is certified according to the UNI EN ISO 14001:2004:2015 standards by Det Norske Veritas Italia (DNV), an internationally accredited body, and is inspected on an annual basis.

#### IRELAND, CORK

In order to guarantee adequate and continuous supplies of the

active ingredient lercanidipine, an important original Recordati drug, in 2005 a dedicated plant was built in Cork in Ireland. The plant is certified according to cGMP (current *Good Manufacturing Practices*) standards and covers an area of around 44,000 sq. m. This facility boasts automated process control systems which ensure constant high quality production.

The continuous commitment to reduce and improve the use of energy was recognized in 2012 by the assignment of the National Energy Efficiency Award, which is promoted by the Sustainable Energy Authority of Ireland (SEAI), and in 2013 by the assignment of the European Energy Efficiency Award, promoted by the Chemical European Federation Industry Council (CEFIC).

In 2016 the site was extended, the two buildings housing the administration and the quality control laboratories were enlarged.



*Recordati has six pharmaceutical production facilities and a specialized packaging and distribution facility dedicated to rare disease products all of which operate with full respect for environmental protection regulations and in compliance with current Good Manufacturing Practices (cGMP).*

#### **ITALY**

The Milan site occupies a surface area of 21,000 sq. m. and produces 60 million packages per year. It is specialized in the manufacture and packaging of solid oral forms, liquids, injectables and products for topical use.

#### **FRANCE**

The plant at Saint Victor covers a surface area of 6,750 sq. m. and is specialized in the production and packaging of liquid, solid oral and spray formulations. It produces 33 million packages per year.

#### **TURKEY**

The Turkish site in Çerkezköy, built on 45,000 sq. m. of land, occupies a surface area of approximately 19,000 sq. m. and currently produces 57 million packages per year of solid oral and liquid formulations and products for topical use, of which 20% is dedicated to third party production. The plant was declared GMP compliant by the Turkish authorities in March 2016 and has a production capacity of 80 million packs per year.

It has substituted the production site in Esenyurt which was closed down in December 2016 after transferring all production to the new manufacturing site.

#### **SPAIN**

The Spanish plant is situated near Zaragoza covering a surface area of 8,800 sq. m. and is specialized in the production and packaging

of solid and liquid oral and topical formulations.

In particular, the plant manufactures a line of gastroenterological products. The plant produces around 12 million packs a year. Recently, a project was approved for the installation of a new line for the packaging of tablets in bottles which will increase the annual volumes by around 7-8 million packs.

#### **TUNISIA**

The Tunisian plant is situated near Tunis. It covers an area of around 7,500 sq. m. and produces liquid, semi-solid and oral solid forms for the local market and for some of the countries in the Arabian Peninsula. The plant produces around 17 million packs a year.

#### **CZECH REPUBLIC**

The plant in the Czech Republic, situated in Pardubice, produces creams, gels and ointments for a total of 2 million packages per year, some of which for third parties.

#### **PACKAGING AND DISTRIBUTION CENTER DEDICATED TO PRODUCTS FOR RARE DISEASES**

A new site in Nanterre (France) for the distribution of products for the treatment of rare diseases is operational. It occupies a surface area of 1,200 sq. m. and is entirely dedicated to the packaging, storage and shipping of rare disease products.

An area of 400 sq. m. is office space.

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## **PROJECTS FOR THE FUTURE**

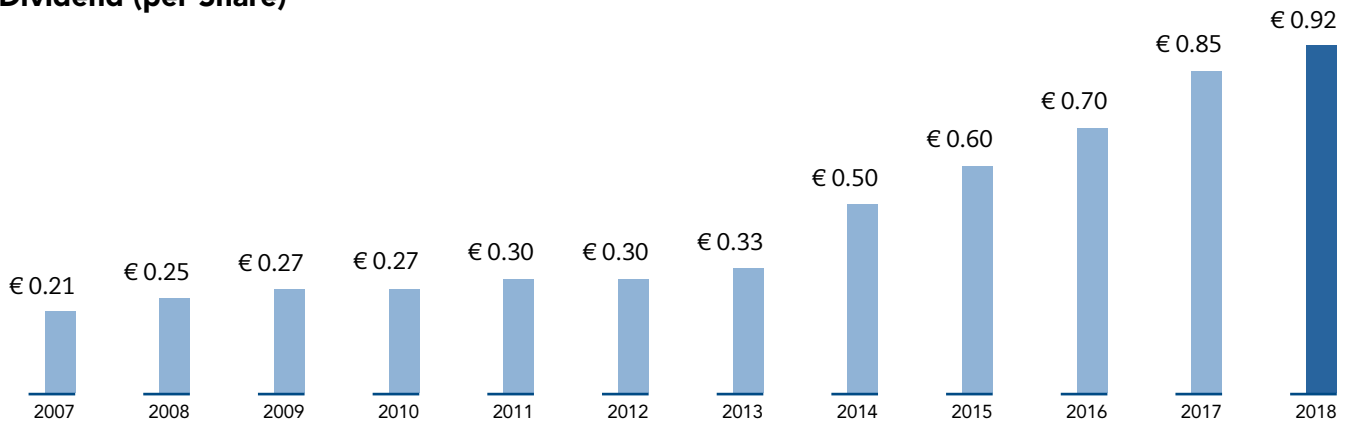
In compliance with the new directive which will regulate the traceability of pharmaceutical products in the various markets, known as the Serialization and Tamper Evidence measures, activities started in 2017 to implement the new legal requirements in our different plants.

The project, called WINGS FOR THE FUTURE, involves the plants in Milan, Saint Victor, Utebo and Nanterre, which, as from 2019, will be able to supply products packaged according to the directives in the various countries. With the objective of always ensuring increased efficiency in production plants already operating at high levels of production excellence, in 2017, starting with the plant in Milan, the application of the principles of Lean Manufacturing is being implemented. These manufacturing principles will be progressively extended to the other plants within the Group.



# THE RECORDATI SHARE

## Dividend (per Share)



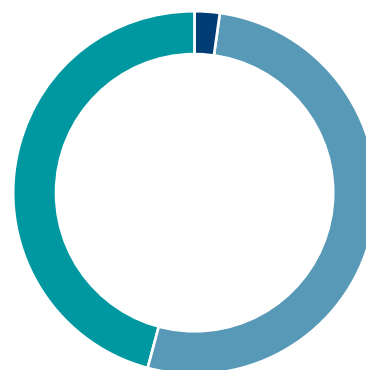


## The Recordati share at 31 December 2018

Listing:	Borsa Italiana, Blue Chip segment, healthcare
ISIN Code:	IT 0003828271
Ticker:	Bloomberg REC IM, Reuters RECI.MI
Index:	FTSE MIB FTSE Italia All-Share Pharmaceuticals & Biotechnology Index ICB Code 4570
Share Capital:	n. 209,125,156 common shares
Nominal value:	€ 0.125 per share
EPS (diluted):	€ 1.494
Dividend per share:	€ 0.92

## Principal shareholders at 31 December 2018

- 2.4% Treasury Stock
- 51.8% Consortium of investment funds controlled by CVC Capital Partners
- 45.8% Free float

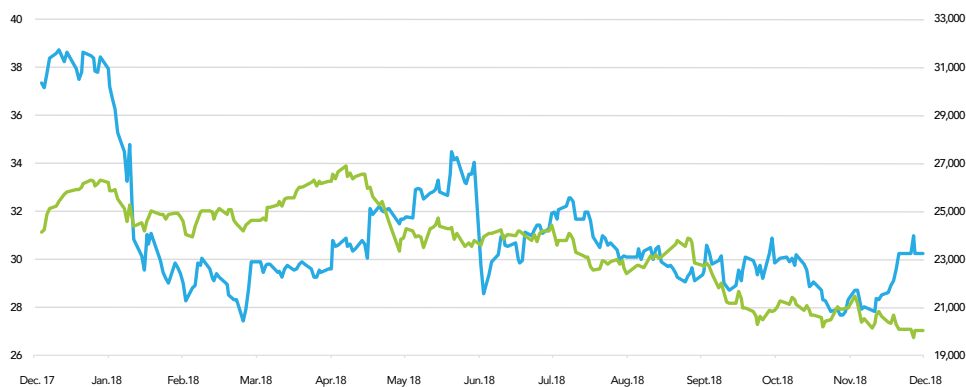


## Compared to FTSE Italia All-Share

Source: FactSet

Recordati S.p.A.  
(L)

FTSE Italia All Share (It)  
(R)

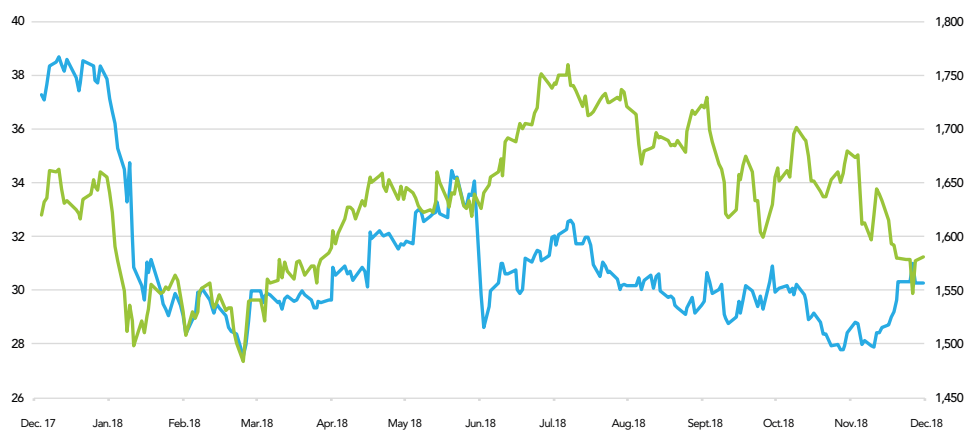


## Compared to STOXX 600/Healthcare

Source: FactSet

Recordati S.p.A.  
(L)

STOXX 600 / Health Care - ss  
(R)





# FINANCIAL HIGHLIGHTS

## REVENUE

€ (thousands)	2018	%	2017	%	Change 2018/2017	%
TOTAL REVENUE	1,352,235	100.0	1,288,123	100.0	64,112	5.0
Italy	273,197	20.2	258,551	20.1	14,646	5.7
International	1,079,038	79.9	1,029,572	79.9	49,446	4.8

## KEY CONSOLIDATED P&L DATA

€ (thousands)	2018	% of revenue	2017	% of revenue	Change 2018/2017	%
Revenue	1,352,235	100.0	1,288,123	100.0	64,112	5.0
EBITDA <sup>(1)</sup>	499,079	36.9	454,661	35.3	44,418	9.8
Operating income	442,219	32.7	406,492	31.6	35,727	8.8
Net income	312,422	23.1	288,799	22.4	23,623	8.2

(1) Operating income before depreciation, amortization and write down of both tangible and intangible assets.

## KEY CONSOLIDATED BALANCE SHEET DATA

€ (thousands)	31 December 2018	31 December 2017	Change 2018/2017	%
Net financial position <sup>(2)</sup>	(588,380)	(381,780)	(206,600)	54.1
Shareholders' equity	963,586	1,027,237	(63,651)	(6.2)

(2) Short-term financial investments, cash and cash equivalents, less bank overdrafts and loans which include the measurement at fair value of hedging derivatives.

## PER SHARE DATA

€	2018	2017	Change 2018/2017	%
Net income <sup>(3)</sup>	1.529	1.395	0.134	9.6
Shareholders' equity <sup>(3)</sup>	4.724	4.932	(0.208)	(4.2)
Dividend	0.92	0.85	0.07	8.2
<b>SHARES OUTSTANDING:</b>				
- average during the year	204,379,165	207,030,319		
- at December 31	203,971,585	208,261,894		

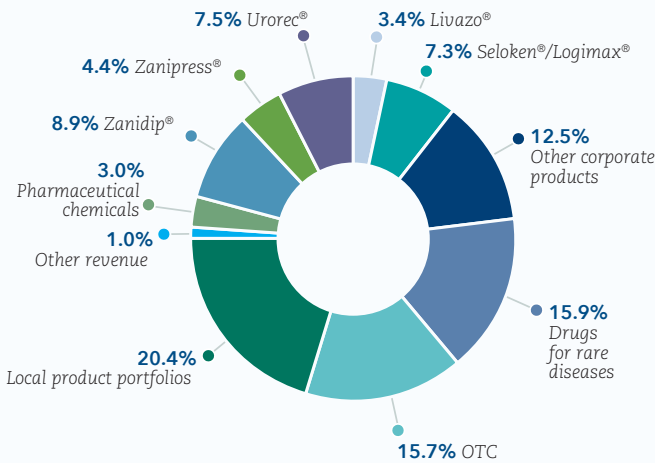
(3) Net income per share is based on average shares outstanding during the year net of average treasury stock. Shareholders' equity per share is based on total shares outstanding at year end. Shares outstanding are net of treasury stock. Treasury stock amounted to 5,153,571 shares at 31 December 2018 and 863,262 shares at 31 December 2017. Average treasury stock amounted to 4,745,991 shares in 2018 and 2,094,837 shares in 2017.

# 2018 OPERATIONAL AND FINANCIAL REVIEWS

## REVIEW OF OPERATIONS

Net revenue in 2018 is € 1,352.2 million, up 5.0% over the preceding year and includes the consolidation of the sales of Seloken®, Seloken® ZOK and Logimax® for an amount of € 50.1 million in the first half of 2018, the consolidation as from 1 July 2018 of sales amounting to € 7.7 million generated by Natural Point S.r.l., the Italian company acquired in June, as well as an estimated negative currency exchange rate effect of € 48.3 million. Excluding these items growth would have been of 4.2%. International sales grow by 4.8% to € 1,079.0 million, which represent 79.8% of total sales. Pharmaceutical sales are € 1,311.6 million, up by 5.2% while pharmaceutical chemicals sales are € 40.7 million, down by 0.7%, and represent 3.0% of total revenues.

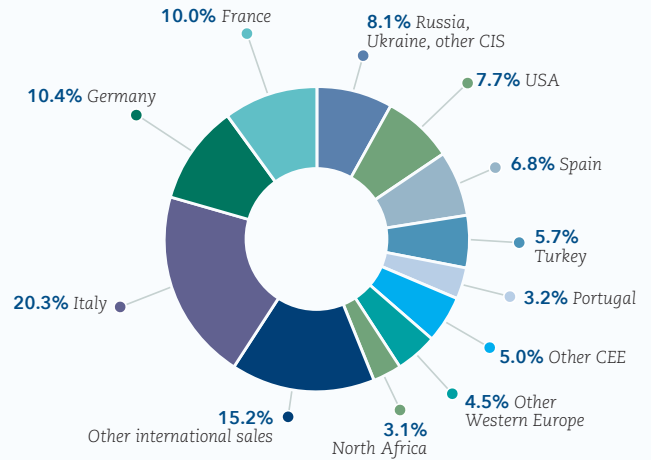
### SALES BY BUSINESS



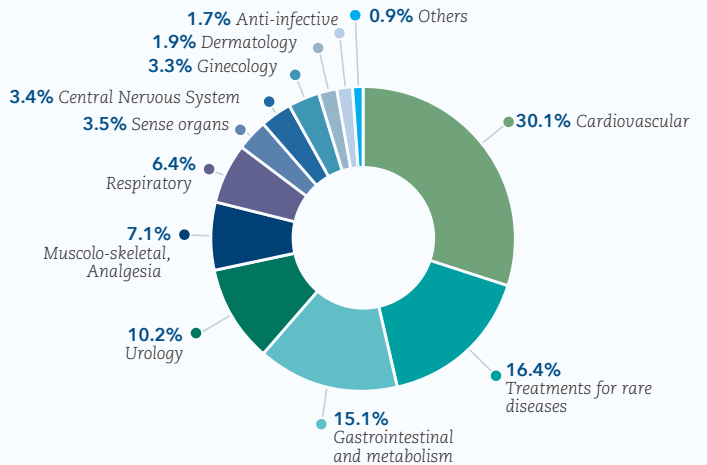
## PHARMACEUTICALS

The group's pharmaceutical business, which represents 97.0% of total revenue, is carried out in the main European markets, including Central and Eastern Europe, in Russia and other C.I.S., Ukraine, Turkey, Tunisia, and, concerning our rare disease business, also in the United States of America, Canada, Mexico, in some South American countries, in Japan and Australia, through our own subsidiaries and, in the rest of the world, mainly through licensing agreements with pharmaceutical companies of high standing. We have gradually extended our international presence through the acquisition of existing marketing organizations with the aim to add our proprietary products, and those obtained under multi-territorial licenses, to the local portfolios.

Pharmaceutical sales by geography in 2018 are shown below:



Pharmaceutical sales by therapeutic area in 2018 are shown below:



### Corporate products

The performance of products sold directly in more than one market (corporate products) during 2018 is shown in the table below.

€ (thousands)	2018	2017	Change 2018/2017	%
Zanidip® (lercanidipine)	120,762	120,633	129	0.1
Zanipress® (lercanidipine+enalapril)	59,366	69,213	(9,847)	(14.2)
Urorec® (silodosin)	101,090	92,756	8,334	9.0
Livazo® (pitavastatin)	46,416	39,224	7,192	18.3
Seloken®/Seloken® ZOK/ Logimax® (metoprololo/ metoprololo+felodipina)	98,877	46,984	51,893	n.s.
Other corporate products*	274,040	270,381	3,659	1.4
Drugs for rare diseases	214,832	211,241	3,591	1.7

\* Include the OTC corporate products for an amount of € 102.5 million in 2017 and € 84.3 million in 2016 (+21.5%).

**Zanidip® (lercanidipine)** is an antihypertensive calcium channel blocker discovered and developed entirely in the Recordati research laboratories and is available in more than 100 countries. Lercanidipine is effective in gradually lowering blood pressure values to optimal levels avoiding episodes of reflex tachycardia and reducing the risk of cardiovascular events and their related mortality. Its lipophilicity and high selectivity are properties which render lercanidipine effective with a superior tolerability profile. It ensures protection of the kidneys and the endothelium of the blood vessels. Thanks to this organ protection characteristic and its metabolic neutrality lercanidipine is well tolerated by patients suffering from other diseases such as diabetes and nephropathy. Our lercanidipine based products are sold directly to the market by our own marketing organizations in Western Europe as well as in Central and Eastern Europe, in Turkey and in North Africa. In the other markets they are sold by licensees, and in some of those aforementioned co-marketing agreements are in place.

€ (thousands)	2018	2017	Change 2018/2017	%
Direct sales	67,362	69,189	(1,827)	(2.6)
Sales to licensees	53,400	51,444	1,956	3.8
<b>Total lercanidipine sales</b>	<b>120,762</b>	<b>120,633</b>	<b>129</b>	<b>0.1</b>

The direct sales of lercanidipine based products are down by 2.6% mainly due to the negative impact of the exchange rate on sales in Turkey (up by 20.5% in local currency) and to the reduction of sales in Algeria, realized directly by our French subsidiary, following importation restrictions on products for which there is local production. Sales increase mainly in Greece and in Germany. Sales to licensees, which represent 44.2% of total lercanidipine sales, are up by 3.8%. Sales increase mainly in Australia, Israel, Russia and Thailand.

**Zanipress® (lercanidipine+enalapril)** is an antihypertensive drug developed by Recordati. It associates lercanidipine, a latest generation calcium channel blocker, with enalapril, a widely prescribed ACE inhibitor, allowing the simultaneous administration of two active ingredients and increasing treatment compliance by the patient. Combination therapy is considered as first line treatment for hypertensive patients at high risk for cardiovascular events. The benefits of the combination of these two active ingredients have been confirmed by the results of a number of clinical trials which have shown its significant antihypertensive efficacy, good tolerability in addition to renal and vascular protection from damage caused by hypertension. This product is marketed successfully by Recordati or by its licensees in 30 countries.

€ (thousands)	2018	2017	Change 2018/2017	%
Direct sales	47,991	55,036	(7,045)	(12.8)
Sales to licensees	11,375	14,177	(2,802)	(19.8)
<b>Total lercanidipine+enalapril sales</b>	<b>59,366</b>	<b>69,213</b>	<b>(9,847)</b>	<b>(14.2)</b>

Direct sales of Zanipress® in 2018 are down by 12.8% mainly due to competition from generic versions of the product mainly in Italy, Germany and France. Sales to licensees represent 19.2% of total Zanipress® sales and are down by 19.8% also due to the competition from generic versions of the product. Overall the fixed combination of lercanidipine and enalapril has a market share of 19.55% (*IQVIA/GERS Retail Sales Qtr 3 2018, C9B3, in the 12 main markets*) of which 87% consists of the Recordati branded products while 13% is generated by generic versions.

**Urorec® (silodosin)** is a drug indicated for the treatment of the symptoms of benign prostatic hyperplasia (BPH, enlargement of the prostate). BPH manifests with problems linked to urination, it is frequent in men over the age of fifty and its symptoms significantly reduce quality of life.

The prevalence of the disorder is increasing with the ageing of the population. Clinical evidence shows that patients receiving silodosin benefited from a significant reduction of symptoms associated with BPH and an improvement in quality of life within the first week of treatment. Symptom improvement is maintained during long term treatment. The safety and tolerability of silodosin has been widely assessed with positive results. The low incidence of orthostatic and vasodilatory side effects make it a well-tolerated treatment even in patients who take antihypertensive medication. Silodosin was originated by Kissei (Japan) and was obtained under license by Recordati for the development and marketing in Europe and a further 18 countries in the Middle East and Africa. Currently the product is successfully marketed in 39 countries and has achieved a share of 22.2% of the alpha blocker segment of the BPH market (*IQVIA/GERS Retail Sales Qtr 3 2018, G4C2, in the 15 main markets*). Silodosin based products are sold directly by our subsidiaries under the brand Urorec® and by licensees under the brand Silodyx™ and generated sales in 2018 of € 101.1 million, up by 9.0%. Urorec® is doing particularly well in Italy achieving sales in 2018 of € 28.6 million (+15.0%). The product is also well accepted by physicians in France and Spain where sales are € 17.3 million (+10.2%) and € 9.7 million (+10.1%) respectively. In local currency, sales of Urorec® in Turkey grow by 32.1%. Urorec® is also growing significantly in Russia and in Portugal where it generated sales of € 3.4 million (+12.4%) and € 3.1 million (+12.8%) respectively in 2018.

**Livazo® (pitavastatin)** is a latest generation statin indicated for the treatment of dyslipidaemia, a condition characterized by altered levels of blood cholesterol and other lipids and associated with an increased risk for heart disease and stroke. Controlled clinical trials show that pitavastatin induces a reduction in LDL-cholesterol (the "bad" cholesterol that contributes to formation of atherosclerotic plaques) and an increase in HDL-cholesterol (the "good" cholesterol that is removed from the arterial walls), a dual effect that should be regarded as highly relevant, since it appears to reduce the relative risk for cardiovascular complications. Furthermore, presents an excellent safety profile due to the lower likelihood of drug-drug interactions than that of most other statins. Thanks to these properties pitavastatin can be regarded as an effective and safe treatment of dyslipidemia. Pitavastatin was licensed by Recordati from the Japanese pharmaceutical company Kowa for the European market, Russia and the other C.I.S. countries and Turkey. The drug is sold by our marketing organizations in Spain, Portugal, Switzerland, Greece, Russia, Ukraine, other countries in the C.I.S and Turkey. Sales generated in 2018, including sales to co-marketers in Spain, Portugal and Greece, are € 46.4 million, up by 18.3%, and have achieved a share of 8.43% of the statins market in the six main countries (*IQVIA Retail Sales Qtr 3 2018, C10A1, in the 6 main markets*).

**Seloken®/Seloken® ZOK (metoprolol)** are metoprolol based medicines belonging to the beta-blocker class of drugs widely used in the treatment of angina pectoris, myocardial infarction and disturbances of cardiac rhythm, as well as hypertension and functional heart disorders. These drugs have been widely studied in large and important clinical trials such as MAPHY and MERIT-HF and are frequently used in primary care and by cardiologists to treat cardiac disturbances and hypertension. Long term mortality studies (Seloken®/Seloken® ZOK Core Data Sheet) have shown that the use of metoprolol reduces the rates of general mortality, cardiovascular mortality, sudden death and the progression of heart failure.

**Logimax® (metoprolol+felodipine)** is a fixed association of metoprolol with felodipine which over the years has shown high antihypertensive efficacy. The use of metoprolol together with felodipine enables the reduction of possible episodes of reflex tachycardia induced by the calcium channel blocker, while felodipine associated with metoprolol facilitates vasodilation by reducing peripheral vascular resistance. This mechanism of action explains why a therapy based on the association of a beta-blocker with a calcium channel blocker, administered to patients suffering from hypertension associated with ischemic cardiopathy, is one of the therapeutical combinations mostly mentioned and recommended by the European ESH/ESC guidelines.

The European rights to **Seloken®/Seloken® ZOK (metoprolol) and Logimax® (metoprolol+felodipine)** were acquired from AstraZeneca in June 2017 and the sales consolidated as from 1 July. The products are sold directly in Germany, Poland, France, Czech Republic, Romania, Switzerland, Italy, Spain, Greece and the United Kingdom and through distribution agreements in other European countries. Sales of these products in 2018 are € 98.9 million.

**Other corporate products** include specialties obtained from Recordati's original research, through the acquisition of product rights for various markets and through license agreements for multiple territories. The following paragraphs describe their characteristics and sales generated.

- Reagila® (cariprazine) is an innovative atypical antipsychotic for the treatment of schizophrenia. Cariprazine is an orally active and potent dopamine D3/D2 receptor partial agonist with preferential binding to D3 receptors and partial agonist at serotonin 5-HT1A receptors. The efficacy of cariprazine is shown by the positive results from three controlled trials in over 1,800 patients and one long-term trial, using the change from baseline in the scale, assessing the severity of schizophrenia symptoms, i.e. the Positive and Negative Syndrome Scale (PANSS) total score and the time to relapse as primary efficacy endpoints, respectively. A clinical trial with positive results was also carried out in patients suffering from predominant negative symptoms of schizophrenia. These results were the basis for a publication in *The Lancet (Cariprazine versus risperidone monotherapy for treatment of predominant negative symptoms in patients with schizophrenia: a randomised, double-blind, controlled trial; The Lancet Volume 389, No. 10074, p1103-1113, 18 March 2017)*. Reagila® was originated by Gedeon Richter and is sold under license by Recordati in Western Europe. During 2018 the product was launched in Germany, Switzerland, Italy, Benelux, United Kingdom and the Nordic countries where overall initial sales generated are of € 3.0 million.
- Tergynan® is a fixed combination of different active ingredients with antimicrobial, anti-inflammatory, antiprotozoal and antimycotic activity for the treatment and prevention of gynecological infections. Sales of this product in 2018 are € 26.0 million, down by 8.7%, and are generated mainly in Russia.
- CitraFleet® and PhosphoSoda®, are bowel cleansers used in preparation for any diagnostic procedure which requires emptying of the intestines, such as colonoscopy or X-rays. These products are sold mainly in Spain and in Germany. Thanks to the constant product portfolio integration process among the group's subsidiaries, the presence of CitraFleet® was extended to Italy, France, Ireland, Greece, Romania, Portugal, Poland, Switzerland, Tunisia and the Nordic countries while the presence of PhosphoSoda® was extended to France, Ireland, Russia, Turkey, Portugal, the Nordic countries and will soon be launched in Greece. In 2018 sales of CitraFleet® are € 24.9 million (+8.6%) and those of PhosphoSoda® are € 4.2 million (-11.7%). Fleet enema and Casenlax®, two other gastrointestinal products, generated sales of € 11.7 million (+8.1%) and € 9.8 million (+12.9%) respectively.
- Polydexa®, Isofra® and Otofa® are combination products for the treatment of ENT infections sold mainly in Russia. In 2018 sales of Polydexa® are € 31.2 million, those of Isofra® are € 17.5 million while Otofa® generated sales of € 4.5 million. Overall sales are up compared to the preceding year.
- The line of products under license from BioGaia comprises food supplements based on *Lactobacillus reuteri* protectis and includes the brand Reuflor® in Italy and the brands Casenbiotic®, Bioralsuero®, Reuteri® and Gastrus® in Spain and Portugal. Sales of these products in 2018 are € 27.5 million.
- Procto-Glyvenol® (tribenoside), leader in its class, is indicated for the treatment of internal and external hemorrhoids. It is marketed by Recordati in the following countries: Poland, Russia, Turkey, Romania, Czech Republic, Slovakia, Ukraine, Portugal, the Baltic states and Cyprus. Sales in the market of this product in 2018 are € 24.9 million, up by 12.6%.
- The Hexa line of products comprises biclotymol based antibacterial treatments of the oral cavity sold under the brands Hexaspray®, Hexalyse® and Hexapneumine®. The main brand of the line is Hexaspray®, a spray for sore throats which is a leader in its class in France. Overall sales of these products in 2018 are € 19.3 million, down by 6.6%, and are generated mainly in France, North Africa and Russia.
- Lomexin® (fenticonazole), an original Recordati product, is an internationally and widely used broad-spectrum antimycotic indicated for the treatment of dermatological and gynecological infections caused by fungi, mold, yeast and gram positive bacteria. Sales of this product for 2018 are € 16.6 million, down by 1.7% compared to the preceding year.
- TransAct® LAT, a transdermal patch containing 40 mg of flurbiprofen indicated for the symptomatic relief of localized pain involving the musculoskeletal system, obtained under license from Amdipharm, is sold on the Italian and Portuguese markets. Sales of this product are € 10.8 million (+4.9%) in 2018.
- Flavoxate, a Recordati original research product, is a muscle relaxant of the urinary tract. It is indicated for the symptomatic treatment of dysuria, urgency, nocturia, frequency and incontinency and the treatment of bladder and urethral spasms and is marketed under the brands Genurin® and Urispas®. Sales of this product in 2018 are € 8.2 million, down by 10.2%.
- Kentera® is an oxybutynin transdermal patch indicated for the symptomatic treatment of disorders of the lower urinary tract such as incontinence, increased urinary frequency and urgency, obtained under license from Allergan (previously Actavis and before that Watson Pharmaceuticals) and marketed in 18 countries. Sales of Kentera® are € 7.1 million (-13.4%) in 2018.
- Lopresor® (metoprolol) is a selective beta blocker for the treatment of different cardiovascular disorders, in particular hypertension and angina pectoris, marketed in Greece and in other European markets. Sales of this product in 2018 are € 6.2 million (-2.0%) and are generated mostly in Greece and in Germany.
- Lactigest® (tilactase) is an enzyme based preparation indicated in cases of lactose intolerance due to primary and secondary lactase deficiency. Sales of this product in 2018 are € 4.6 million (+6.5%) and are generated in Italy and in Switzerland.
- Rupatadine is a systemic antihistamine indicated for the treatment of allergies and in particular allergic rhinitis. Under license from Uriach, it is marketed in Italy and Germany as Rupafin® and in France as Wystamm®. Sales of all brands of rupatadine in 2018 total € 4.2 million, down by 43.7% following the entry of generic versions of the product on the market.
- Vitaros®/Virirec® (alprostadil) is the first topically applied cream formulation of alprostadil for the treatment of erectile dysfunction. The topical administration and local mechanism of action minimizes any systemic adverse reaction or interaction with other drugs, food or alcoholic beverages, and therefore Vitaros® can be considered an effective and safe alternative to existing orally administered products. It is sold under license from the US pharmaceutical company Apricus Biosciences. Launched successfully in Spain the product is now on the market in Portugal, Greece, Ireland, the Czech Republic, Slovakia and Romania. Sales generated in 2018 are € 2.9 million (+16.9%).
- Abufene® and Muvagyn® are gynaecological products indicated for menopausal symptoms. Sales of these products in 2018 are € 5.6 million (+1.2%) and € 2.7 million (-3.2%) respectively.
- Fortacin® (lidocaine+prilocaine) is an easy-to-use fast acting topical spray formulation of lidocaine and prilocaine for the treatment of premature ejaculation. The product, sold under license from Plethora Solutions, was launched during 2018 in Italy, Spain, Germany, Portugal and France. Initial sales of the product in 2018 are of € 0.8 million.

## Treatments for rare diseases

Rare diseases bring great suffering to millions of affected people worldwide. They are mostly genetic diseases that can affect patients of any age, sex or ethnic origin and involve any type of medical specialization. They are chronic, fatal or severely debilitating diseases which strongly impact patients, their families and the community as a whole. Very often sufferers are new-borns, children and young adults.

An orphan drug is a medicinal product developed for the treatment of a rare disease. A rare disease is defined as a condition that affects fewer than 5 per 10,000 inhabitants in Europe or fewer than 200,000 Americans in the U.S.A.. Over 30 million people are affected in Europe alone. There are over 7,000 known rare diseases but today approved treatment exists for fewer than 10% of these.

Due to the extensive spectrum of existing diseases and the scarcity of available information, it is possible that physicians may never see a patient with a rare disease in the whole of their career. For these reasons there's always a risk that when a baby is born with a rare disease a correct diagnosis may not be made and timely appropriate treatment may not be provided. To provide care for people with a rare disease and to encourage pharmaceutical and biotechnology companies to invest in treatments for rare diseases governments have created various legal and financial incentives. In 1983 the Orphan Drug Act was introduced in the U.S.A. and European legislation passed in 1999 explicitly recognized the unmet need for targeted treatments for orphan diseases and created regulatory pathways and incentives for manufacturers to develop orphan drugs. From April 2000, when the EU orphan drug regulation came into effect, many hundreds of drugs received orphan drug designation from the European Medicines Agency (EMA). Of those designated drugs, over 100 have received marketing authorization (MA). 40% of the orphan medicines were licensed for oncological and haematological conditions and about 30% of the orphan drug market consists of drugs for rare inborn errors of metabolism.

The Recordati group operates in the rare disease segment worldwide through its dedicated subsidiaries Orphan Europe and Recordati Rare Diseases who share the conviction that each person with a rare disease has the right to the best possible treatment. Our organizations work closely with specialists, healthcare professionals, patients' families and patient groups to spread knowledge, improve diagnosis and treatment, enable access to treatment by supporting patients and their needs.

Recordati operates directly in Europe, the Middle East and Africa through Orphan Europe, a pharmaceutical group dedicated to the research, development and marketing of treatments for rare diseases. It has worldwide coverage through its subsidiaries and highly qualified distributors. Furthermore, a direct distribution and packaging system is able to deliver very small numbers of specialist products to people around the world at short notice. Recordati has progressively and successfully intensified its commitment to treatments for rare diseases also in the U.S.A. where Recordati Rare Diseases Inc. offers a portfolio of products for the treatment of a number of rare diseases the most important of which is Panhematin® (haemin for injection) for the amelioration of recurrent attacks of acute intermittent porphyria. As from April 2017, the Group's presence in North America was reinforced with the establishment in Canada of Recordati Rare Diseases Canada, based in Toronto.

Furthermore, Recordati has consolidated its presence in Latin American countries in some of which such as in Mexico, Brazil and Colombia, it operates through its own subsidiaries. In Russia Recordati's organization guarantees access to treatments to patients living in the more remote areas of the country. In 2017 a representative office was opened in Malaysia with the intention of extending operations to the Asia-Pacific regions and in 2018 Recordati Rare Diseases subsidiaries were established in Japan and in Australia.

The main products in the segment dedicated to rare disease treatments are Panhematin®/Normosang® (human haemin) indicated for the treatment of acute attacks of hepatic porphyria; Carbaglu® (carglumic acid) indicated for the treatment of hyperammonaemia due to N-acetyl glutamate synthase deficiency (NAGS deficiency) and due to any of the three main organic acidaemias; Cosmegen® (dactinomycin) used mainly in the treatment of three rare cancers (Wilms' tumor, childhood rhabdomyosarcoma and choriocarcinoma); Cystadane® (betaine anhydrous) for the treatment of homocystinuria; Cystadrops® (cysteamine chlorhydrate), eye-drop solution for the treatment of corneal cystine crystal deposits in adults and children from 2 years of age with cystinosis; Cystagon® (cysteamine bitartrate) for the treatment of proven nephropathic cystinosis and Pedeas®/Neoprofen® (i.v. ibuprofen) used in the treatment of a serious congenital cardiac malformation, the persistence of patent ductus arteriosus (PDA).

Sales of these products in 2018 are of € 214.8 million, up by 1.7%. Sales in the United States of America are down by 7.8% due to competition from a generic version of Cosmegen® and to a negative currency exchange rate effect. Sales in the rest of the world grow by 12.0%.

## Pharmaceutical sales by geographical area

The pharmaceutical sales by geography of the Recordati subsidiaries are broken down as follows:

€ (thousands)	2018	2017	Change 2018/2017	%
Italy	265,705	251,040	14,665	5.8
Germany	136,764	122,426	14,338	11.7
France	131,772	124,704	7,068	5.7
Russia, other C.I.S. countries and Ukraine	105,611	107,028	(1,417)	(1.3)
U.S.A.	101,003	109,567	(8,564)	(7.8)
Spain	88,880	82,247	6,633	8.1
Turkey	74,968	86,022	(11,054)	(12.9)
Portugal	41,679	40,421	1,258	3.1
Other C.E.E. countries	65,328	46,979	18,349	39.1
Other Western European countries	59,021	52,859	6,162	11.7
North Africa	40,679	38,883	1,796	4.6
Other international sales	200,173	185,008	15,165	8.2
<b>Total pharmaceutical sales</b>	<b>1,311,583</b>	<b>1,247,184</b>	<b>64,399</b>	<b>5.2</b>

*Both years include sales as well as income from up-front payments, royalties and miscellaneous items.*

Sales in countries affected by currency exchange oscillations are shown hereunder in their relative local currencies.

Local currency (thousands)	2018	2017	Change 2018/2017	%
Russia (RUB)	6,166,623	5,916,581	250,043	4.2
Turkey (TRY)	402,459	333,979	68,480	20.5
United States of America (USD)	123,407	127,598	(4,191)	(3.3)

*Net revenues in Russia and in Turkey exclude sales of products for rare diseases.*



## ITALY

The Recordati group offers a broad range of medications in this country through its organizations Recordati S.p.A., Innova Pharma S.p.A., Orphan Europe Italy S.r.l., Italcimici S.p.A. and as from 2018 Natural Point S.r.l.. In addition to its historic and established presence in the cardio metabolic field, the Italian product portfolio also boasts quality medicines in urology, in gastroenterology and in pain control as well as treatments for rare diseases mainly of metabolic origin. Recordati also has an excellent reputation at the pharmacy level and continues to grow in the self-medication market, thanks to its large offering in a number of therapeutic areas such as oral hygiene, eye, nose and throat cure, and gastrointestinal disturbances.

The Italian pharmaceutical production site is situated in Milan, it occupies a surface area of 21,000 sq. m. and produces over 60 million packages per year. The plant is specialized in the manufacture and packaging of solid oral forms, liquids, injectables and products for topical use.

Pharmaceutical sales in Italy are up by 5.8% over the preceding year and include revenues generated by Natural Point S.r.l., consolidated as from 1 July 2018, for a total of € 7.7 million. The performance of the main products in Italy is the following:

€ (thousands)	2018	2017	Change 2018/2017	%
Prescription pharmaceuticals <sup>(a)</sup>	190,450	185,880	4,570	2.5
Self-medication pharmaceuticals <sup>(b)</sup>	75,255	65,160	10,095	15.5
<b>Pharmaceuticals, Italy</b>	<b>265,705</b>	<b>251,040</b>	<b>14,665</b>	<b>5.8</b>

(a) Prescription pharmaceuticals include both reimbursable and non-reimbursable drugs.

(b) Self-medication pharmaceuticals include OTC products and other pharmaceuticals not requiring a prescription.

€ (thousands)	Indication	2018	2017	Change 2018/2017	%
Urorec®	benign prostatic hyperplasia	28,622	24,890	3,732	15.0
Cardicor®	heart failure	27,195	25,005	2,190	8.8
Peptazol®	gastric ulcers	18,571	20,831	(2,260)	(10.8)
Zanedip®/Lercadip®	hypertension	18,194	18,224	(30)	(0.2)
Rextat®/Lovinacor®	hypercholesterolemia	14,345	13,719	626	4.6
Tora-Dol®	pain	12,594	12,259	335	2.7
Zanipril®/Lercaprel®	hypertension	12,085	14,927	(2,842)	(19.0)

Urorec®, Cardicor® (bisoprolol) and the statins Rextat® and Lovinacor® (lovastatin)® show sustained growth as well as the treatments for rare diseases which are up by 11.9%. Sales of Peptazol® (pantoprazole) and the lercanidipine based products have been affected by the competition from generic versions of the products.

Sales of self-medication products are € 75.3 million, significantly up compared to the preceding year, and have benefited from the consolidation of Natural Point's self-medication products, in particular of Magnesio Supremo®, a magnesium based food supplement. Alovex™, indicated for the treatment of oral cavity aphthae, is our best-selling self-medication product with sales of € 7.9 million, up by 5.7%, and remains market leader with a share of 32.2%. Proctolyn® (treatment of haemorrhoids) with sales of € 7.1 million also remains market leader with a share of more than 40%. TransAct® LAT (a transdermal patch containing 40 mg of flurbiprofen indicated for the symptomatic relief of localized pain involving the musculoskeletal system) generated sales of € 6.3 million. Dentosan®, a line of oral care products, generated sales of € 4.6 million. Sales of Eumill® (eye drops) at € 6.1 million are up by 9.2%. Sales of Imidazol® (eye drops) are down by 1.7%, mainly due to the performance of the overall market but has increased its market share to 32.4% thanks to the antihistamine formulation.

## GERMANY

In addition to its consolidated presence in the cardiovascular therapeutic area, Recordati Pharma GmbH is one of the most esteemed German pharmaceutical companies in the field of orthopedics. Over time it has developed a strong presence in orthopedics and offers first class product to specialists in this field. An important part of the Recordati Pharma operations is linked to its traditional presence in the gastroenterological area and in particular in the treatment of chronic inflammatory intestinal diseases.

The German subsidiary markets a line of self-medication products with a specific sales organization which operates in a growing market and is dedicated to the marketing of a number of well-known brands.

Operations in the segment dedicated to rare diseases in this country are carried out by Orphan Europe Germany GmbH.

Sales generated by our subsidiaries in Germany are € 136.8 million, an increase of 11.7% compared to the preceding year. The following table shows sales of the main products.

€ (thousands)	Indication	2018	2017	Change 2018/2017	%
Ortoton®	muscle relaxant	37,277	34,286	2,991	8.7
Seloken®/Seloken® ZOK/ Logimax®	Hypertension, cardiac disorders	21,235	10,392	10,843	n.s.
Claversal®	ulcerative colitis	11,164	11,653	(489)	(4.2)
Zanipress®	hypertension	10,788	13,200	(2,412)	(18.3)
Corifeo®/ lercanidipine	hypertension	9,639	8,826	813	9.2
Mirfulan®	healing ointment	7,901	6,569	1,332	20.3
Recosyn®	musculo-skeletal	6,355	6,601	(246)	(3.7)

The sales increase is to be attributed mainly to the sales of Seloken®, Seloken® ZOK and Logimax®, the metoprolol based products acquired from AstraZeneca and consolidated as from 1 July 2017. Worth mentioning is the growth of Ortoton® (methocarbamol) and the success of our own generic version of lercanidipine. The overall sales of self-medication products in Germany are € 18.8 million, up by 4.7% compared to the preceding year thanks mainly to the growth of Mirfulan® (+20.3%). Sales of the treatments for rare diseases in this country are up by 25.2%.

## FRANCE

Laboratoires Bouchara Recordati S.A.S. is solidly established in the French pharmaceutical market thanks to a number of prescription drugs and a historical presence in the market for self-medication products. Orphan Europe S.à R.L., the largest company in the Orphan Europe group dedicated exclusively to treatments for rare diseases, is based in France.

The French pharmaceutical production plant is in Saint Victor, it covers a surface area of 6,750 sq. m. and is specialized in the production and packaging of liquid, solid oral and spray formulations. The site produces 33 million packages per year. Furthermore, the group operates a new manufacturing site for the treatments for rare diseases in Nanterre. It occupies a surface area of 1,200 sq. m. and is entirely dedicated to the packaging, storage and shipping of rare disease products. An area of 400 sq. m. is office space.

The 2018 revenue realized by our subsidiaries in France is € 131.8 million, up by 5.7% compared to the preceding year. Below is the performance of the main products:

€ (thousands)	Indication	2018	2017	Change 2018/2017	%
Methadone	drug addiction	31,609	31,825	(216)	(0.7)
Urorec®	benign prostatic hyperplasia	17,320	15,719	1,601	10.2
Seloken®/Seloken® ZOK/ Logimax®	hypertension, cardiac disorders	9,716	4,583	5,133	n.s.
Zanextra®	hypertension	9,592	11,066	(1,474)	(13.3)
Lercan®/Zanidip®/ lercanidipine	hypertension	8,289	9,187	(898)	(9.8)
Hexa line	antibacterial	7,432	7,880	(448)	(5.7)

Methadone, a synthetic opioid analgesic used as a substitute for heroin in abstinence syndromes, in detoxification from opiates and in maintenance programs, is Laboratoires Bouchara Recordati's most important product. Highly specialized staff and dedicated resources lie behind the success of the detoxification programs. The benefits of treatment with methadone are universally recognized. The most important are the decrease in deaths resulting from the use of narcotics, the reduction of the diffusion of viral infections (HIV, HCV), reduced health, legal and social costs related to the use of drugs and improvements in the health and rehabilitation of addicts.

A new capsules formulation has contributed to expand its use. Sales of methadone in 2018 are € 31.6 million, substantially in line with those of the preceding year.

Worth mentioning is the significant growth of Urorec®. Sales include the metoprolol based products acquired from AstraZeneca and consolidated as from 1 July 2017, in addition to sales of Lercan® (lercanidipine) now sold directly by our subsidiary following the expiry of the license to Pierre Fabre, as well as the integration in the French portfolio of Transipeg® and Colopeg®, the gastrointestinal products acquired from Bayer in December 2017. Sales of the lercanidipine based products are down due to the competition from generic versions of the drug. Regarding the OTC portfolio, sales of the Hexa line of products are down due to weak seasonality. Sales of products for the treatment of rare diseases, up by 10.6%, are growing significantly.

## RUSSIA, OTHER C.I.S. COUNTRIES AND UKRAINE

Rusfic LLC, FIC Médical S.à R.L. and Recordati Ukraine LLC, are the Recordati group companies that operate in Russia and in other markets of the Commonwealth of Independent States (C.I.S.), in Ukraine and in Central Asia. The success of our organizations which operate in these territories, is largely based on the success of a line of anti-infective products, as well as to that of a well-known portfolio of self-medication products. Fic Médical, with its four representative offices in Kazakhstan, Belarus, Georgia and Armenia ensures the Group's direct presence in the C.I.S., in the Caucasian region and in Central Asia, territories in which the group's geographical coverage has significantly increased.

Revenue generated in Russia, Ukraine and in the countries within the Commonwealth of Independent States (C.I.S.) is € 105.6 million, down by 1.3% compared to the preceding year and include an estimated negative currency exchange effect of € 11.4 million. Sales in Russia, in local currency, are RUB 6,166.6 million, up by 4.2% over the preceding year.

The following table shows overall sales of the main products in Russia in local currency.

RUB (thousands)	Indication	2018	2017	Change 2018/2017	%
Polydexa®	ear infections	1,766,378	1,438,476	327,902	22.8
Tergynan®	gynaecological infections	1,258,320	1,260,209	(1,889)	(0.1)
Isofra®	nasal infections	1,081,030	1,044,854	36,176	3.5
Procto-Glyvenol®	hemorrhoids	529,471	409,611	119,860	29.3

Sales in Russia, in local currency, are in line with the growth of the market. The main product in the Russian portfolio is Polydexa® with continued increase of its market share. Isofra® is also growing and increased its market share while sales of Tergynan®, leader in its class, are substantially in line with those of the preceding year. Worth mentioning is the success of the corporate product Procto-Glyvenol® which has become one of the leading products in its class. Sales in Russia of the corporate products Urorec®, Zanidip® and Lomexin® record strong growth. Sales of the food supplement Alfavit®, on the other hand, are down due to the entry of competing brands. In 2018 the growth of the treatments for rare diseases is significant.

Sales generated in the other C.I.S. (Commonwealth of Independent States), mainly Belarus, Kazakhstan and Georgia and in Ukraine are growing significantly and have reached € 19.4 million.

## UNITED STATES OF AMERICA

The group's pharmaceutical business in the U.S.A. is dedicated exclusively to the marketing of products for the treatment of rare diseases through our subsidiary Recordati Rare Diseases Inc.. The main products are Panhematin® (haemin for injection) for the amelioration of recurrent attacks of acute intermittent porphyria, Carbaglu® (carglumic acid), indicated for the treatment of acute hyperammonaemia associated with NAGS deficiency, Cosmegen® (dactinomycin for injection) used mainly in the treatment of three rare cancers and Cystadane® (betaine anhydrous oral solution), used in the treatment of homocystinuria to reduce the high level of homocysteine in the blood. Sales in 2018 are € 101.0 million, down by 7.8% due to competition from a generic version of Cosmegen® and to estimated currency exchange rate losses of € 4.7 million.

## SPAIN

Casen Recordati S.L., the Spanish subsidiary of the Recordati group with headquarters in Madrid and production facilities in Utebo (Zaragoza), markets an extensive and substantial portfolio of products. It is particularly well-known for its products for bowel cleansing and oral rehydration which belong to markets in which the company is an undisputed leader. Among these, the main product is CitraFleet®, a bowel cleanser used in preparation for diagnostic procedures. In Spain, Orphan Europe Spain S.L. markets the portfolio of products for the treatment of rare diseases.

The Spanish production plant is situated near Zaragoza covering a surface area of 8,800 sq. m. and is specialized in the production and packaging of solid and liquid oral and topical formulations. In particular, it manufactures a line of gastroenterological products. The plant produces around 12 million packs a year.

Revenues in Spain are € 88.9 million, up by 8.1% compared to the preceding year. The following table shows sales of the main products.

€ (thousands)	Indication	2018	2017	Change 2018/2017	%
CitraFleet®	bowel cleansing	14,317	13,368	949	7.1
Livazo®	hypercholesterolemia	14,184	12,658	1,526	12.1
Urorec®	benign prostatic hyperplasia	9,724	8,834	890	10.1
Enema Casen	bowel cleansing	7,746	7,930	(184)	(2.3)
Bi-OralSuero	rehydrating solution	5,784	5,782	2	0.0
Cidine®	gastroprokinetic	5,377	5,414	(37)	(0.7)
Casenlax®	laxative	4,601	4,229	372	8.8
Zanipress®	hypertension	3,112	2,875	237	8.2

Sales of the main product in the portfolio, CitraFleet®, a preparation for colonoscopy grow by 7.1%. Livazo® and Urorec® are performing well and the treatments for rare diseases record a 16.6% growth. Sales of Cidine® (cinitapride) are slightly down due to the presence of generic competition in the market. Sales of Casenlax® and Zanipress® grow by 8.8% and 8.2% respectively. Sales of Virirec®, the product for erectile dysfunction, grow by 23.5%.

## TURKEY

Recordati Ilaç, the group's Turkish subsidiary, is one of the 25 leading pharmaceutical companies in Turkey and grows faster than the market. It continues to strengthen its position on the Turkish pharmaceutical market and has a strong consolidated presence in the fields of urology, cardiology, gynecology and in physical medicine and rehabilitation.

Recordati Ilaç has undertaken an important investment program for the construction of a new production plant in Çerkezköy, built on 45,000 sq. m. of land, it occupies a surface area of approximately 19,000 sq. m. and has a total production capacity of 80 million packs annually. It currently produces 57 million packages per year of solid oral and liquid formulations and products for topical use, of which 20% is dedicated to third party production. The new plant was declared GMP compliant by the Turkish authorities in 2016 and is now fully operational.

Sales in Turkey are € 75.0 million, down by 12.9%, and were impacted by the devaluation of the Turkish Lira which generated a negative currency exchange effect estimated at € 27.1 million. In local currency, sales in Turkey increase by 20.5%.

The following table shows sales of the main products in local currency.

TRY (thousands)	Indication	2018	2017	Change 2018/2017	%
Lercadip®	hypertension	68,553	56,876	11,677	20.5
Mictionorm®	urinary incontinence	67,272	56,282	10,990	19.5
Cabral®	muscle relaxant	55,411	54,242	1,169	2.2
Urorec®	benign prostatic hyperplasia	51,281	38,815	12,466	32.1
Zanipress®	hypertension	33,710	26,687	7,023	26.3
Kreval®	cough	33,351	30,652	2,699	8.8
Ciprasid®	anti-infective	31,446	24,543	6,903	28.1
Livazo®	hypercholesterolemia	28,163	11,636	16,527	n.s.
Procto-Glyvenol®	hemorrhoids	26,607	22,009	4,598	20.9

Worth mentioning is the good performance of the corporate products, mainly Lercadip®, Urorec®, Zanipress®, Procto-Glyvenol® e Livazo® (sold in Turkey under the brand Alipza®).

## PORTUGAL

Jaba Recordati S.A. is well positioned in the Portuguese pharmaceuticals market, mainly in the cardiovascular, urological, gastrointestinal and pain control fields and in the market for self-medication products.

Revenue generated by our subsidiaries in Portugal is € 41.7 million, up by 3.1%.

The performance of the main products is listed below.

€ (thousands)	Indication	2018	2017	Change 2018/2017	%
Livazo®	hypercholesterolemia	7,446	7,073	373	5.3
TransAct® LAT	anti-inflammatory	4,438	4,071	367	9.0
Microlax®	laxative	3,117	2,946	171	5.8
Urorec®	benign prostatic hyperplasia	3,057	2,710	347	12.8
Zanipress®	hypertension	2,915	3,360	(445)	(13.2)
Egostar®	vitamin D3	2,522	2,212	310	14.0

The decrease in the sales of Zanipress® is to be attributed to competition from generic versions of the product. Regarding the portfolio of self-medication products Procto-Glyvenol® is performing well and records growth of 12.8%. Furthermore, sales of the treatments for rare diseases are up by 5.6%.

## OTHER CENTRAL AND EASTERN EUROPEAN COUNTRIES

The acquisition in 2017 from AstraZeneca of the metoprolol based products, Seloken®, Seloken® ZOK and Logimax®, has had a significant impact on the sales of our subsidiaries in Central Europe and consequently increasing our presence in these countries.

The subsidiary in Poland, Recordati Polska Sp z o.o., markets a diversified product portfolio with an emphasis on the cardiovascular and urology therapeutic areas, in particular as regards benign prostatic hyperplasia. Sales in Poland in 2018 are € 26.5 million, up by 50.0% thanks mainly to the consolidation as from 1 July 2017 of the metoprolol based products acquired from AstraZeneca. Worth mentioning is the good performance of Lercan® (lercanidipine), up by 43.0% and of Lercaprel® (lercanidipine+enalapril), launched in 2017. Regarding the self-mediation portfolio, the Polish subsidiary's main product Procto-Glyvenol® generated sales of € 6.7 million, up by 63.1%.

Herbacos Recordati S.r.o., the group's subsidiary present in the Czech Republic and in Slovakia, successfully markets pharmaceutical products belonging to a number of therapeutic areas, including analgesic, anti-inflammatory and dermatological medicines. The subsidiary operates a small pharmaceutical production plant, situated in Pardubice, which produces creams, gels and ointments for a total of 2 million packages per year. Sales generated by Herbacos Recordati are € 23.8 million, up by 32.4% compared the preceding year, mainly thanks to the consolidation as from 1 July 2017 of the metoprolol based products acquired from AstraZeneca and to the launch of Mictonorm®, a propiverine based product for the treatment of urinary incontinence.

Recordati Romania S.R.L. promotes both prescription and self-mediation products successfully. Sales in Romania are € 12.0 million, up by 38.8%, also in this case thanks mainly to the consolidation as from 1 July 2017 of the metoprolol based products acquired from AstraZeneca.

Worth mentioning is the good performance of the product for hemorrhoids Procto-Glyvenol® and of Urorec®.

Sales in the Central and Eastern European markets of the specialty products indicated for the treatment of rare and orphan diseases amount to € 3.1 million, up by 13.3%.

## OTHER WESTERN EUROPEAN COUNTRIES

The Recordati group is also present with its own subsidiaries in the United Kingdom with Recordati Pharmaceuticals Ltd and Orphan Europe United Kingdom Ltd, in Ireland through its subsidiary Recordati Ireland Ltd, in Greece with Recordati Hellas Pharmaceuticals S.A., in Switzerland through Recordati AG (present also in Austria through Pro-Farma GmbH) and with Orphan Europe Switzerland GmbH, in the Nordic countries with Recordati AB and in Benelux with Recordati BVBA.

### Switzerland

Sales generated by Recordati AG in Switzerland are € 19.9 million and refer mainly to Zanidip®, Livazo®, Lacidigest® (tilattase) and Tretinac® (tretinoin) as well as the metoprolol based products acquired from AstraZeneca in 2017. During the year Reagila®, the new drug for the treatment of schizophrenia was launched in this country.

### Greece

Sales in Greece are € 17.3 million, up by 33.1% thanks to the good performance of Livazo®, Urorec® and Lopresor® as well as to the consolidation as from 1 July 2017 of the metoprolol based products acquired from AstraZeneca and the addition of sales of Zanidip® (lercanidipine) and Zaneril® (lercanidipine+enalapril) previously in the hands of a licensee.

### United Kingdom

Sales in the United Kingdom are € 7.7 million and relate mainly to products for the treatment of rare diseases which account for 74.2% of our revenues in this country. During the year Reagila® was also launched in the UK.

### Ireland

Sales in Ireland are € 1.5 million, mainly generated by Urorec®, Kentera® and Zanidip®.

### Nordic countries and Benelux

During 2018, the organizational structure of our subsidiaries Recordati AB in Sweden and Recordati BVBA in Belgium was reinforced to allow the promotion and sales of our specialty products, in addition to our products for the treatment of rare diseases, in the Nordic countries and in Benelux.

Sales of products for the treatment of rare diseases in these Western European countries (UK excluded) are of € 12.5 million.

## NORTH AFRICA

Recordati is present in North Africa with its subsidiary Opalia Pharma S.A. in Tunisia and through its export business from France, mainly towards Algeria. Opalia Pharma is one of the most important Tunisian pharmaceutical companies and it ranks high in the local pharmaceutical market. It markets branded generic drugs with leading products in dermatology and in the gastrointestinal and respiratory therapeutic areas. The company produces the majority of its products in its cGMP certified manufacturing plant. The Tunisian plant is situated near Tunis. It covers an area of around 7,500 sq. m. and produces liquid, semi-solid and oral solid forms for the local market and for some of the countries in the Arabian Peninsula. The plant produces around 17 million packs a year.

Overall, sales in North Africa are € 40.7 million, up by 4.6%, thanks to the significant increase in the sales of the products for the treatment of rare diseases in these territories. Sale in Tunisia in 2018 grew by 3.9% and by 18.3% in local currency.

## OTHER INTERNATIONAL SALES

Other international sales amount to € 200.2 million, up by 8.2%, and comprise the sales to, and other revenues from, our licensees for our corporate products, Laboratoires Bouchara Recordati's and Casen Recordati's export sales and Orphan Europe's sales in all other countries.

Sales to international licensees, including other revenues, are of € 145.8 million, growing by 9.8% due to the consolidation as from 1 July 2017 of the sales of the metoprolol based products acquired from AstraZeneca, Seloken®, Seloken® ZOK and Logimax®, in those countries where they are sold through distribution agreements.

Sales outside France by our French subsidiary Laboratoires Bouchara Recordati, excluding North Africa, are € 17.2 million, up by 7.1%, while sales outside Spain by our Spanish subsidiary Casen Recordati are € 4.9 million, up by 20.1%.

Revenue generated by our treatments for rare diseases in other countries, mainly in Canada, some countries in Latin America, the Middle East, Asia and Australia, mostly directly through our subsidiaries including the ones recently established in Japan and in Australia, are of € 32.3 million, up by 0.7%.

## PHARMACEUTICAL CHEMICALS

Recordati produces a number of active ingredients and intermediates for the pharmaceutical industry in its two pharmaceutical chemical production plants. Recordati's pharmaceutical chemicals business focuses on satisfying the requirements of the pharmaceutical business, striving for maximum product quality, strengthening its presence in highly regulated markets (the United States, Europe and Japan), and on constantly guaranteeing maximum safety of its production processes, protection of the environment and health and safety in the workplace.

The Campoverde di Aprilia plant in Italy mainly supplies the active ingredients used in the preparation of the various pharmaceutical specialties produced by the company, but is also an established independent producer of a number of active and intermediate ingredients for the pharmaceutical industry internationally. It is one of the most important producers in the world of verapamil HCl, phenytoin, papaverine HCl, dimenhydrinate, tribenoside and manidipine. Other pharmaceutical chemicals are produced on behalf of important pharmaceutical companies. In order to guarantee adequate and continuous supplies of the active ingredient lercanidipine, an important original Recordati drug, in 2005 a new and dedicated plant was constructed in Cork in Ireland. This facility boasts automated process control systems which ensure constant high quality production.

Sales of pharmaceutical chemicals, which comprise active substances produced in the Campoverde d'Aprilia plant for the international pharmaceutical industry, are substantially unchanged as compared to 2017. In particular, the products manidipine, tribenoside, dimenhydrinate, dobutamine, diphenhydramine and ketorolac performed well.

The sales of active ingredients by geographical area are shown below:

€ (thousands)	2018	%	2017	%	Change 2018/2017	%
Italy	2,950	7.3	2,997	7.3	(47)	(1.6)
Europe (Italy excluded)	13,663	33.6	15,407	37.6	(1,744)	(11.3)
United States of America	8,219	20.2	7,919	19.3	300	3.8
America (U.S. excluded)	3,881	9.5	3,821	9.3	60	1.6
Australasia	11,062	27.2	9,501	23.2	1,561	16.4
Africa	877	2.2	1,294	3.2	(417)	(32.2)
<b>Total</b>	<b>40,652</b>	<b>100.0</b>	<b>40,939</b>	<b>100.0</b>	<b>(287)</b>	<b>(0.7)</b>

## HEALTH, SAFETY AND ENVIRONMENT

The Recordati group recognizes the protection of the environment, safety in the workplace and prevention in general concerning all themes related to health, safety and the environment as one of its most important priorities.

Company policy is implemented through the careful organization of roles with regard to guaranteeing the safety and health of workers.

A well-defined corporate organization combined with a systemic approach to the management of safety at the workplace ensures continuous improvement in management with the object of constantly reducing work-related and environmental risks.

In order to define an organization model specifically designed to address health and safety at the workplace, as well as protect the environment, the Company has internal procedures in place to regulate these issues entitled "Procedures for Prevention Management, Accident Management and Medical Services" and "Procedures for environmental management". The application of these standards is periodically verified through internal audits.

The following common characteristics and measures for risk prevention are present within the system for the management of health, safety and the environment that the Recordati group employs in both its pharmaceutical chemicals and its pharmaceutical plants: risk assessment, training and information for workers, proper maintenance standards, environmental protection systems designed to minimize environmental impacts, appropriate emergency measures and compliance with local legislation on the subject. The group monitors and analyses injuries and accidents that occur at the various production sites as well as any work related illness. For every accident an action plan aimed at preventing similar episodes is prepared and implemented.

The results of these analyses of industrial accidents are periodically submitted to the Internal Audit Committee. Recordati employs a systematic approach to the management of health, safety and the environment, and sets itself the specific objective not only of compliance with the various national regulations in force at different production sites, but also of continuous improvement in the management of these matters.

Risk assessment is the principal tool used in the safety management system. It is used to define risk control factors along with the relative measures for prevention and protection to be adopted or monitored in order to reduce the risk to the health and safety of workers. The updating of the risk assessment document is a continuous activity, it records the sequence of the actions undertaken to improve the working environment and the activities in progress, and it also includes assessments of new activities or changes made to the work process.

Training, information and awareness of the workers are considered to be fundamental prevention tools in all matters related to health, safety and the environment. Health and safety training programs are implemented to ensure adequate competency of everyone within the whole company organization.

The goal is to increase the attention placed by personnel on risks and the prevention measures put in place in order to reduce accident rates caused by human error, which is the main cause of accidents at the company. Training and the dissemination of information on the organization of safety in the company is provided for all employees and, thanks to the use of remote training, the operational forces in the field are also systematically involved.

Maintenance is one of the key prevention activities. Equipment, plant and machinery are subject to regular maintenance programmes performed by both internal and external resources.

Out-sourcing to third party contractors is managed by special internal procedures which include the verification that the contractor is suitable and the sharing of the "Single Interference Risk Assessment Document" in order to reduce, and if possible eliminate, potential interferences between the work activities of external firms and the normal operations of the company.

Particular attention is placed on all aspects of an environmental nature, in order to protect the environment and to prevent any form of pollution.

The environmental factor is controlled and managed in the pharmaceutical chemicals plants by an environmental management system that is part of the general management system. It includes the organizational structure, planned activities, responsibilities, practices, procedures and resources to formulate, implement, review and maintain the company's environmental policies.

The environmental management system goes beyond carefully ensuring that laws and regulations for preventing potential incidents from occurring are complied with. It involves a programme of continuous improvement in corporate conduct towards the surrounding environment.

In the course of the restructuring activities during 2018 which involved the Milan site, as provided for by the building regulations for the city of Milan, a quality verification of the environmental matrices was carried out. Thirteen geognostic soundings were performed across the whole area and, overall, the analyses carried out showed concentrations significantly below the allowed levels of at least one order of magnitude and sometimes not even detectable by the analytic method used.

In 2018 the Campoverde di Aprilia plant underwent an inspection by DNV for the renewal of the ISO 14001 (Environmental) certification and the verification of the transition to the new standard ISO 14001:2015.

The accredited company DNV inspected the whole Environmental Management System and confirmed full compliance with the standards.

In 2018 the Turkish site of Cerkezkoy, which became fully operational in 2017, underwent an audit by the IFC (International Finance Corporation) officials of matters related to health, safety and the environment. No items of non-conformity were reported.

## FINANCIAL REVIEW

### INCOME STATEMENT

The following table shows the profit and loss accounts, including their expression as a percent of sales and change versus 2017:

€ (thousands)	2018	% revenue	2017	% revenue	Change 2018/2017	%
Revenue	1,352,235	100.0	1,288,123	100.0	64,112	5.0
Cost of sales	(395,569)	(29.3)	(382,754)	(29.7)	(12,815)	3.3
<b>Gross profit</b>	<b>956,666</b>	<b>70.7</b>	<b>905,369</b>	<b>70.3</b>	<b>51,297</b>	<b>5.7</b>
Selling expenses	(333,497)	(24.7)	(330,793)	(25.7)	(2,704)	0.8
R&D expenses	(109,693)	(8.1)	(100,256)	(7.8)	(9,437)	9.4
G&A expenses	(67,722)	(5.0)	(65,582)	(5.1)	(2,140)	3.3
Other income (expense), net	(3,535)	(0.3)	(2,246)	(0.2)	(1,289)	57.4
<b>Operating income</b>	<b>442,219</b>	<b>32.7</b>	<b>406,492</b>	<b>31.6</b>	<b>35,727</b>	<b>8.8</b>
Financial income (expense), net	(24,284)	(1.8)	(17,377)	(1.3)	(6,907)	39.7
<b>Pre-tax income</b>	<b>417,935</b>	<b>30.9</b>	<b>389,115</b>	<b>30.2</b>	<b>28,820</b>	<b>7.4</b>
Provision for income taxes	(105,513)	(7.8)	(100,316)	(7.8)	(5,197)	5.2
<b>Net income</b>	<b>312,422</b>	<b>23.1</b>	<b>288,799</b>	<b>22.4</b>	<b>23,623</b>	<b>8.2</b>
Attributable to:						
Equity holders of the parent	312,376	23.1	288,762	22.4	23,614	8.2
Minority interests	46	0.0	37	0.0	9	24.3

In 2018 international revenues went from € 1,029.6 million to € 1,079.0 million, an increase of 4.8%, and represent 79.8% of total revenue. Their breakdown by geographic area is shown in the table below:

€ (thousands)	2018	%	2017	%
Europe (Italy excluded)	828,728	76.8	774,255	75.2
United States of America	110,781	10.3	118,817	11.5
America (United States excluded)	25,970	2.4	24,116	2.3
Australasia	62,295	5.8	61,538	6.0
Africa	51,264	4.8	50,846	4.9
<b>Total</b>	<b>1,079,038</b>	<b>100.0</b>	<b>1,029,572</b>	<b>100.0</b>

Gross profit is € 956.7 million with a margin of 70.7% on sales, an increase over that of the preceding year due to the further growth of products with higher margins and to the positive effect of the metoprolol based products acquired from AstraZeneca.

Selling expenses increase less than sales and are therefore down as a percent of revenue compared to the preceding year thanks to the increased efficiency of the group's commercial organizations.

R&D expenses are € 109.7 million, up by 9.4% compared to those recorded in 2017 due to the initiation of new development programs and the amortization of the acquired rights to the metoprolol based products.

G&A expenses are up by 3.3% but decrease as percent of sales to 5.0%.

Overall, labor cost in 2018 is € 274.1 million, an increase of 1.0% over 2017, with the cost per employee up by 0.3%.

Personnel and other human resources data at 31 December 2018 and 2017 are shown in the following table:

	2018	2017
Employees at year-end	4,142	4,176
Average age	43	43
Average service (years)	8.3	7.9
<b>Labor productivity:</b>		
Labor cost on net sales	20.3%	21.1%
Sales per employee (€ thousands) <sup>(a)</sup>	330.7	317.2
Value added per employee (€ thousands) <sup>(a)</sup>	189.1	178.8

*Labor cost includes wages, related charges and additional costs.*

*(a) Data per employee for both years are computed on the average number of personnel, 4,061 in 2017 and 3,935 in 2016.*

In accordance with the international expansion process within the Group, the strengthening of our corporate organization continued in order to ensure the integration, monitoring and coordination of the foreign subsidiaries. Much effort was also dedicated to the creation of local organizational structures for the setting-up and development of the new international, both European and ex-European, subsidiaries' business. In general, personnel training and development represented a substantial portion of the Group's efforts to ensure the efficacy of the different work groups belonging to different business areas, maintaining at the same time continued attention towards the development of managerial competencies distinctive to Recordati.

Other expenses, net of other income, are € 3.5 million, up by € 1.3 million compared to the preceding year. They include ancillary expenses in association with the acquisition of the product Cystagon® and the companies Natural Point S.r.l. and Tonipharm S.A.S. for a total of € 2.7 million.

Net financial charges are € 24.3 million, an increase of € 6.9 million compared to the preceding year due mainly to the interest on the assessment with acceptance settled during the last quarter.

The effective tax rate during the period is 25.3%, slightly lower than that of the preceding year. During the year the settlement agreed with the internal revenue service was concluded. The agreement covers the complete definition

of all the disputes connected with the 2009-2015 fiscal period. The agreement also provides for a further cost (which also includes the 2016-2017 periods) of € 9.2 million on top of what was already accrued. Furthermore, tax credits were recognized in Turkey and in Italy for € 6.2 million and € 4.8 million respectively.

Net income at 23.1% of sales is € 312.4 million, an increase of 8.2% over the preceding year.

## FINANCIAL POSITION

The net financial position at 31 December 2018 records net debt of € 588.4 million compared to net debt of € 381.8 million at 31 December 2017.

€ (thousands)	31.12.2018	31.12.2017	Change 2018/2017	%
Cash and short-term financial investments	198,036	302,077	(104,041)	(34.4)
Bank overdrafts and short-term loans	(16,905)	(16,577)	(328)	2.0
Loans – due within one year	(135,278)	(51,710)	(83,568)	161.6
<b>Net liquid assets</b>	<b>45,853</b>	<b>233,790</b>	<b>(187,937)</b>	<b>(80.4)</b>
Loans – due after one year <sup>(1)</sup>	(634,233)	(615,570)	(18,663)	3.0
<b>Net financial position</b>	<b>(588,380)</b>	<b>(381,780)</b>	<b>(206,600)</b>	<b>54.1</b>

(1) Includes change in fair value of the relative currency risk hedging instruments (cash flow hedge).

During the year own shares were purchased for an overall amount of € 169.8 million and dividends were distributed for an amount of € 178.9 million. Furthermore, a € 15.0 million milestone was paid as per the license agreement with Gedeon Richter for the rights to Reagila® (cariprazine) and € 20.0 million were paid for the acquisition from Mylan of the rights to Cystagon® (cysteamine) for a number of territories including Europe. The Italian company Natural Point S.r.l. and the French company Tonipharm S.A.S. were acquired for an overall value of around € 148 million.

An amount of € 19.2 million was invested in property, plant and equipment, mainly involving the Parent company's Milan headquarters and production sites (€ 12.1 million).

Net working capital for operations at 31 December 2018 is € 162.0 million and is thus comprised:

€ (thousands)	31.12.2018	% revenue	31.12.2017	% revenue	Change 2018/2017	%
Trade receivables, net	245,742	18.2	244,117	19.0	1,625	0.7
Inventories	206,084	15.2	179,100	13.9	26,984	15.1
Other current assets	43,655	3.2	44,566	3.5	(911)	(2.0)
<b>Current assets</b>	<b>495,481</b>	<b>36.6</b>	<b>467,783</b>	<b>36.3</b>	<b>27,698</b>	<b>5.9</b>
Trade payables	165,020	12.2	141,740	11.0	23,280	16.4
Tax payable	42,149	3.1	24,373	1.9	17,776	72.9
Other current liabilities	126,339	9.3	131,587	10.2	(5,248)	(4.0)
<b>Current liabilities</b>	<b>333,508</b>	<b>24.7</b>	<b>297,700</b>	<b>23.1</b>	<b>35,808</b>	<b>12.0</b>
<b>Net working capital for operations</b>	<b>161,973</b>	<b>12.0</b>	<b>170,083</b>	<b>13.2</b>	<b>(8,110)</b>	<b>(4.8)</b>
Days of sales outstanding	61		62			
Inventories as % of cost of sales	50.7%		46.8%			

Details and comments relative to the different components are contained in the Notes to the financial statements.



## RELATED PARTY TRANSACTIONS

Tax liabilities include an amount of € 7.9 million, computed by Recordati S.p.A. based on estimated taxable income, payable to the controlling company Fimei S.p.A. consequent to the participation in a tax consolidation grouping under tax laws in Italy.

Except for the above, to our knowledge, no transactions or contracts have been entered into with related parties that can be considered significant, in value or conditions, or which could in any way materially affect the accounts.

## SUBSIDIARIES OUTSIDE THE EUROPEAN UNION

Pursuant to articles 15 (ex 36) and 18 (ex 39) of the Financial Markets Regulation (modified by Consob under Resolution n. 20249 on 28 December 2017) concerning the listing conditions of companies with subsidiaries of significant relevance in their consolidated accounts, established and regulated under the laws of countries outside the European Union, we point out that at 31 December 2018 the provisions of art. 15 (ex 36) of the Financial Markets Regulation apply to the subsidiaries Recordati İlaç, Recordati Rare Diseases Inc. and Rusfic LLC and that the conditions indicated in the abovementioned art. 15 (ex 36) are fulfilled.

## SIGNIFICANT OPERATIONS, PUBLICATION REQUIREMENTS DEROGATION

The company has decided to avail itself, as from 20 December 2012, of the faculty of derogation of the requirements to publish the information documents prescribed in the event of significant operations involving mergers, spin-offs, capital increases through contribution in kind, acquisitions and disposals, pursuant to article 70, paragraph 8 and article 71, paragraph 1-bis of the Issuers' Regulations enacted by Consob under Resolution n. 11971/1999 and following modifications.

## MAIN RISKS AND UNCERTAINTIES

The identification, valuation and management of company risk is based on an Enterprise Risk Management (ERM) approach, a structured risk management process, in line with international best practice prescriptions on the subject and in accordance with the main requisites of current rules and regulations. The criteria applied by the Group is that of evaluating its risks in terms of their occurrence probability and impact. When evaluating the impact of the risks on the Group, a number of dimensions, not only of economic or market related nature, but also of a reputational kind, are taken into consideration.

With the creation of a catalogue of company risks, which is subject to constant review, the objective of the Group is to classify the potential risks to which it is exposed, which could be both of an exogenous (e.g. evolution of the rules and regulations framework, competitive pressure, etc.) and of an endogenous kind connected with the management of the various company processes (pharmacovigilance, production process, patent expiry, launch of new products, etc.). Among the risks considered, are non financial risks referred to in Legislative Decree 254/2016. These relate to risks connected with environmental and health and safety management (damages caused by weather events and accidents, HSE – Health and Safety Executive related risks, industrial accidents), with workers' rights and supply chain subjects (size of the organizational structure, loss of key resources, inadequate selection of suppliers and commercial partners, interruption of critical supplies) as well as with corruption (compliance with international quality standards, compliance with medial information rules). These subjects and risks were analysed by the Group and classified as involving low to medium risk, in terms of residual risk, evaluated taking into account the probability of occurrence of a risky event and the impact of the event if it should occur.

### Results

The principal risk factors to which the Group is exposed are described below with an indication of the management strategies and policies pursued. They have been classified as follows:

- Risks associated with the external context
- Risks associated with strategy and operations
- Financial risks
- Legal and compliance risks

## RISKS ASSOCIATED WITH THE EXTERNAL CONTEXT

### *Risks associated with changes in legislation and regulations governing the pharmaceutical sector*

The pharmaceuticals sector is heavily regulated locally, nationally and internationally and this impacts activities at all levels. Group sales consist prevalently of products subject to medical prescription which are reimbursed by national healthcare services or other medical insurance schemes which are, however, prevalently of a public nature. While on the one hand this situation protects the Group from general economic trends, on the other it exposes it to changes in local legislation governing public spending on healthcare.

For many years the Group has pursued a policy of diversifying and expanding its sales on several geographical markets and in products not reimbursed by public healthcare schemes in order to mitigate dependency on decisions by single national governments to control spending on pharmaceuticals.

The pharmaceuticals sector is also characterised by the presence of national and international technical standards which regulate pharmaceutical research and development, production and promotion.

The Group implements a policy to constantly monitor changes in regulations on all the markets on which it operates, with dedicated organisational units in the Parent Company and in subsidiaries to implement efficient coordination mechanisms and information flows designed to identify and rapidly adopt the most appropriate response strategies.

### *Risks associated with business expansion into emerging markets*

The policies pursued by the Group include the expansion of operations in countries with the highest potential for development and the strongest growth rates (for example Central and Eastern Europe, the Middle East and North Africa). Operations in those countries could present risks associated with political, economic, currency, regulatory and fiscal instabilities or discontinuities.

Recordati carefully assesses all growth opportunities in all geographies in order to mitigate exposure to these uncertainties and where possible it prefers to acquire local companies with a smaller outlay of capital, rather than other companies that are more exposed to country risk. Evaluations of new business opportunities undergo analysis and monitoring by top management.

From an operational and organizational point of view, the International Primary and Specialty Care Business Unit (IPSC) is in charge of monitoring with the support of Regional Directors who are responsible for the overall supervision of the subsidiaries and for the coordination of the relative strategic activities, in collaboration with corporate structures.

### *Risks associated with market competition*

The Group, like any company operating in the pharmaceuticals sector, is subject to competition from products which could determine a contraction in its market share. These consist of both new pharmaceuticals launched by competitors in the same therapeutic classes in which the Group is present and also generic versions of pharmaceuticals coming to market when patents expire.

While the Group monitors the market continuously to detect the introduction of competing pharmaceuticals in advance, it also manages risk by pursuing a policy to progressively diversify and broaden the range of its product portfolio, in order to reduce dependency on a small number of strategic pharmaceuticals, and increase the presence in the product portfolio of OTC products and treatments for rare diseases.

## RISKS ASSOCIATED WITH STRATEGY AND OPERATIONS

### *Risks associated with the internationalization of the Group*

The Group currently operates in a growing number of countries and is therefore subject to risks arising from the complexity of conducting operations in delocalized areas.

In order to address this situation, the Group has put a management system in place with central units which integrate, monitor and co-ordinate the operations of local units on which operational and marketing powers are conferred to be exercised in compliance with guidelines and within limits indicated by the Group. Group policies and procedures have been formalized which provide corporate guidelines for the management of the main company processes which must be complied with by all subsidiaries.

### **Risks associated with the expiry of patents**

The pharmaceuticals industry makes large investments in research and development and as a consequence it enjoys a high degree of protection on its intellectual properties. Therefore, the expiry of patents covering important pharmaceuticals in product portfolios and the consequent introduction onto the market of generic versions exposes companies to reductions in revenues which can be large.

In order to counter the reduction in revenues as a result of competition from generic pharmaceuticals, the Group is pursuing a diversification strategy based on the reinforcement of its pipeline, the launch of new products in the therapeutic areas of major interest and the expansion of its operations onto new markets with high growth rates.

### **Risks associated with investments in research and development**

The competitive positioning of the Group depends on the continuous development of its product portfolio through the research and development of new molecules and pharmaceutical products in which it invests a substantial part of its resources. Given the complexity and long periods involved in these initiatives, it is not possible to be certain that investments in research and development will always produce the expected results, because the research conducted may fail or the necessary authorisations to market products may not be obtained or the pricing and reimbursement conditions may not be satisfactory.

In order to mitigate exposure to these risks, the Group constantly monitors the intermediate results generated at the various stages of the research and development process, in order to select and move forward only the most reliable initiatives that have the highest probability of an economic return and success. Furthermore, health technology evaluations have been introduced during the clinical development phases in order to effectively support the negotiations with the relevant authorities regarding reimbursement conditions for the products.

Additionally, prudentially, the costs for investments in research and development are fully expensed in the accounting period in which they are incurred.

### **Risks associated with the launch of new products**

A risk exists in the pharmaceuticals sector that delays in the development process, or in the issue of the necessary authorizations by regulatory authorities, may result in product launches occurring behind schedule with a consequent possible impact on the expected profitability of the product and/or delay in the achievement of growth targets.

In order to mitigate that risk Recordati pursues two policy lines.

One is to broaden and balance its pipeline of products, implemented by acquiring pharmaceuticals that are already registered or are about to be registered, or of new products at different stages of development.

The other is to pursue a plan of geographical diversification designed to limit dependence on the regulatory authorities of a single country.

### **Risks associated with pharmacovigilance**

The Group, as a holder of drug marketing authorizations, must comply with regulations on pharmacovigilance. These regulations require that holders of marketing authorizations submit to the regulatory bodies information regarding drug safety, within the time limits and in the manner established by these, with particular regard to adverse reactions. The ascertainment of

serious adverse drug reactions can expose the Group to the risk of restrictions being placed on the prescription of a drug, and in the most serious cases, authorization to market the product can be revoked.

In order to efficiently handle this risk and to comply with national regulations in the countries where the Group operates, Recordati has assigned specific pharmacovigilance responsibilities within its organizations and has put integrated systems in place to collect, assess, manage and submit the information required to the competent authorities. Following the introduction of even more stringent regulatory requirements internal organizations, instruments, training, procedures are constantly reinforced.

Coordination with subsidiaries and partners has improved and includes centralized evaluation of all information relating to pharmacovigilance.

### **Risks associated with the production process**

The Group has production plants which produce both intermediate products and active ingredients and also finished pharmaceutical products. Production activities are carried out in strict compliance with internationally established Good Manufacturing Practices (GMP) implemented through Standard Operating Procedures applicable to the pharmaceutical sector, and are submitted to monitoring and inspection by national and international relevant authorities. The Group's production sites are provided with adequate structures and qualified personnel, in accordance with the requirements of the sector's standards, to ensure that the production of medicinal specialties and active ingredients is carried out in compliance with good manufacturing practices (GMP) and with specific internal procedures and rules in force. In particular, the Group's main production site in Campoverde di Aprilia (Italy) regularly passes successfully inspections carried out by the Food and Drug Administration (FDA) and other national and international authorities.

### **Risks associated with interruption of the production process**

Production is by its nature exposed to potential risks of interruption which, if they were to have significant or long lasting effects - caused for example by natural disasters, fires, the revocation of production permits and licenses, malfunctioning of plant and equipment, interruptions in the supply of important raw materials or energy - could have adverse consequences on the continuity and regularity of sales.

In order to mitigate the effects of long lasting interruptions in production processes, the Group has an effective asset protection policy in place (through precise plant maintenance plans and adequate systems to automatically notice and put out fires) and has production plants with adequate capacity and flexibility to handle changed planning requirements.

Furthermore, the Group uses only reliable suppliers, approved as complying with the relevant technical standards. It also constantly monitors the availability of raw materials and strategic excipients, in order to promptly identify potential local or worldwide "out-of-stock" situations and to take the necessary action (supply and/or production backups) to guarantee production autonomy.

In addition, the company has reinforced its organization within the Procurement, Supply Chain and Contract manufacturing areas with the presence of dedicated professional staff. Furthermore, in order to reduce losses resulting from potential interruptions or damage to production cycles, the Group has taken out "All risk property" insurance policies which cover direct damages (such as damages to buildings, machines and goods) as well as indirect damages (such as loss of profit as a consequence of accidents).

### **Risks associated with health, safety and the environment**

Chemical and pharmaceutical production is subject to obligations to comply with environmental, health and safety rules and regulations. To ensure the correct application of these rules and regulations, the Group has in place organizational units specifically dedicated to prevention, verification and continuous monitoring as regards compliance with the structural technical standards (related to equipment, plant, the workplace, chemical, physical and biological agents) in addition to activities regarding health surveillance, security vigilance, workers training and information and the procurement of documents and certificates required by law. In particular, the environmental management system of the Group's main production plant, located at Campoverde di Aprilia, obtained certification from the accredited international body DNV (Det Norske Veritas, Italy) of compliance with the UNI EN ISO 14001:1996 standard in 2003, which was subsequently confirmed with certification for the UNI EN ISO 14001:2004 standard. Recordati Opalia's production plant in Tunisia also obtained UNI EN ISO 14001 (environment) and OHSAS 18001 (management of Health and Safety in the workplace) certification. The company's control and governing bodies are periodically informed by the responsible functions of accidents occurred and the activities undertaken to mitigate such accidents.

### **Risks associated with the management of information technology resources and data security**

Today's pervasiveness of information technology for the management of business and the necessary connection between company information systems and external information infrastructures (web and networks) exposes said systems to potential risks, both related to the availability, integrity and confidentiality of the data as well as to the availability and efficiency of the information systems.

In order to guarantee effective operational continuity, the Group has implemented a disaster recovery and business continuity system which ensures the immediate replication of the principal legacy systems' workstations. Furthermore, the active safety of the company's data and software is guaranteed by multiple protection levels of a physical and logic nature, of both servers and clients. Finally, the company is periodically submitted to VAPT (Vulnerability Assessment and Penetration Test) analysis and to additional IT security audits undertaken by independent technicians. The outcome of this analysis has always shown the company's information systems to be adequately protected.

As regards fraud through the use of information technology resources by external individuals, the company has introduced a training program for employees in order to create awareness as to the correct use of the resources and applications assigned to their use.

## **FINANCIAL RISKS**

### **Credit Risk**

Credit risk is exposure to potential losses resulting from commercial counterparties failing to meet their obligations. This risk is higher during long lasting periods of economic and financial hardship and as a result of exposure to geographical areas with specific dynamics and peculiarities (for example Russia and Tunisia).

The Group closely controls its credit exposure through the allocation of credit limits to each single customer and an internal reporting system.

### **Interest Rate Risk**

The Group raises funds using debt and invests excess cash in money market and other financial instruments. The fluctuation of market interest rates influences the cost and returns of the debt and investment instruments therefore affecting the Group's net financial charges. The significant expansion of the Group into countries with different economic dynamics from the Euro (for example Turkey, Russia and Tunisia) leads to an increase in risk.

The Group's policy is to limit the risk arising from interest rate fluctuations by establishing medium/long-term fixed interest loans or variable interest loans. Variable interest loans are covered with derivative financial instruments (for example interest rate swaps) for the sole purpose of minimizing such fluctuations and not for speculation. This hedging policy limits the Group's exposure to the risk of fluctuations in interest rates.

### **Foreign Currency Risk**

The Group operates in an international context and has assets and transactions denominated in foreign currency other than euro. It is therefore exposed to risks of foreign currency fluctuations which can affect its operating results and the value of its equity. The diversification strategy enacted by the Group results in a progressive higher exposure to trade transactions in foreign currency with respect to the Group's business volume. Many of the Recordati Group companies are exposed to a limited level of exchange risk linked to operations because in each country most of cash flows generated both by sales and by expenses are denominated in the currency of the relative country. For the sole purpose of hedging and not for speculation, the Group engages in forward contracts for the purchase and sale of currencies to cover amounts at risk.

### **Liquidity Risk**

The liquidity risk to which the Group may be exposed is represented by the inability to raise sufficient financial resources for its ongoing business and for the development of its industrial and commercial activities.

The two main factors which determine the Group's liquidity are, on the one hand, the cash generated or absorbed by operations and by investments, and on the other, the expiry and renewal terms of debt or the degree of liquidity of financial investments and market conditions. The Group has at its disposal liquidity readily available for its operations and plentiful lines of credit granted by a number of leading Italian and international financial institutions. The terms and conditions of the Group's loans and its financial assets are set out in Notes 18, 21 and 31 which address, respectively, short-term financial investments, cash and cash equivalents, loans and bank overdrafts.

The Group believes that the funds and credit lines currently available, in addition to those generated by operations and financing activities, are enough to satisfy investment needs, working capital requirements and the repayment of debts at their natural due dates.

## LEGAL AND COMPLIANCE RISKS

### ***Risks associated with product liability***

Despite careful compliance with standards and regulations, like any company operating in the pharmaceuticals sector, the Group could be exposed to risks of claims for damages caused by its pharmaceuticals. In order to meet those potential liabilities, the Group has taken out insurance policies to cover all the products marketed and under development.

The maximum liability limits are considered adequate and are constantly monitored with the help of analyses and market research conducted by leading insurance brokers.

### ***Risks associated with compliance***

All operating and marketing activities performed by the Group, both in Italy and abroad, are performed in compliance with the legislation and regulations that apply in the geographical areas in which it operates, including national and international technical standards that apply to the pharmaceuticals sector which regulate pharmaceutical research and development, production, distribution and promotion. As concerns the regulation of drug promotion activities, the Group has formulated a set of ethical rules of conduct.

All company personnel are continuously informed of those rules and monitoring, both internally and by independent certifiers, is performed constantly to ensure that they are properly observed. In compliance with Legislative Decree 231/2001 on the administrative liability of legal entities, the Italian companies in the Group have an "Organisation, Management and Control Model" that is continuously updated to comply with the latest amendments to the relevant legislation.

Analogous models are being adopted by other foreign subsidiaries in compliance with local regulations.

Regarding the risk of corruption, the Group has implemented a specific operational and behavioural plan for all its subsidiaries which defines the necessary measures to mitigate corruption risk.

Regarding anti-terrorism, the Group has implemented a Policy to monitor and handle transactions with counterparts residing in countries subject to sanctions or embargo.

### ***Risks associated with legal action***

It is always possible that the Group may be required to meet costs resulting from litigation of various types. In these cases, the Group may be called upon to pay extraordinary costs with consequences for operating and financial results. A detailed description of litigation in progress is given in Notes 27, 29 and 38 to the financial statements.

## BUSINESS OUTLOOK

On 21 December 2018 the company announced its financial targets for 2019. The objectives are to achieve sales ranging from € 1,430 million to € 1,450 million, an EBITDA of between € 520 and € 530 million, EBIT of between € 460 and € 470 million and net income of between € 330 and € 335 million.

Group consolidated sales during the first two months of 2019 are in line with our expectations.

Milan, 28 February 2019

Andrea Recordati  
Chief Executive Officer

# CONSOLIDATED FINANCIAL STATEMENTS

## RECORDATI S.P.A AND SUBSIDIARIES CONSOLIDATED FINANCIAL STATEMENTS AT AND FOR THE YEAR ENDED 31 DECEMBER 2018

The consolidated financial statements of the Recordati group have been prepared by Recordati Industria Chimica e Farmaceutica S.p.A. whose headquarters are situated in Via Matteo Civitali 1, Milan, Italy.

The consolidated financial statements are presented in accordance with the International Financial Reporting Standards (IFRS) issued or revised by the International Accounting Standards Board (IASB). The financial statements comply with the European Union's guidelines on the preparation of consolidated financial statements. Details regarding the accounting principles adopted by the Group are specified in Note 2. In order to better represent the Group's operations, the profit and loss accounts were classified by function while they are classified by nature in the financial statements of the Parent. The same accounting standards were used in the preparation of the financial statements at 31 December 2017.

These consolidated financial statements have been authorized for publication by the Board of Directors in their meeting of 28 February 2019 and are available at the company's head office.

## RECORDATI S.P.A. AND SUBSIDIARIES CONSOLIDATED INCOME STATEMENT FOR THE YEAR ENDED 31 DECEMBER 2018

### INCOME STATEMENT

€ (thousands)	Note	2018	2017
<b>Revenue</b>	3	1,352,235	1,288,123
Cost of sales	4	(395,569)	(382,754)
<b>Gross profit</b>		<b>956,666</b>	<b>905,369</b>
Selling expenses	4	(333,497)	(330,793)
R&D expenses	4	(109,693)	(100,256)
G&A expenses	4	(67,722)	(65,582)
Other income (expense), net	4	(3,535)	(2,246)
<b>Operating income</b>		<b>442,219</b>	<b>406,492</b>
Financial income (expense), net	5	(24,284)	(17,377)
<b>Pretax income</b>		<b>417,935</b>	<b>389,115</b>
Provision for income taxes	6	(105,513)	(100,316)
<b>Net income</b>		<b>312,422</b>	<b>288,799</b>
Attributable to:			
Equity holders of the parent		312,376	288,762
Minority interests		46	37
<b>Earnings per share</b>			
Basic		€ 1.529	€ 1.395
Diluted		€ 1.494	€ 1.381

Earnings per share (EPS) are based on average shares outstanding during each year, 204,379,165 in 2018 and 207,030,319 in 2017, net of average treasury stock which amounted to 4,745,991 shares in 2018 and 2,094,837 shares in 2017.

Diluted earnings per share is calculated taking into account stock options granted to company personnel.

The Notes are an integral part of the consolidated financial statements.

## RECORDATI S.P.A. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEET AT 31 DECEMBER 2018

### ASSETS

€ (thousands)	Note	31 December 2018	31 December 2017
<b>Non-current assets</b>			
Property, plant and equipment	7	103,582	103,009
Intangible assets	8	672,462	540,565
Goodwill	9	579,557	539,871
Other investments	10	20,773	24,171
Other non-current assets	11	5,860	5,944
Deferred tax assets	12	81,267	69,162
<b>Total non-current assets</b>		<b>1,463,501</b>	<b>1,282,722</b>
<b>Current assets</b>			
Inventories	13	206,084	179,100
Trade receivables	14	245,742	244,117
Other receivables	15	38,462	39,730
Other current assets	16	5,193	4,836
Fair value of hedging derivatives (cash flow hedge)	17	6,414	3,825
Short-term financial investments, cash and cash equivalents	18	198,036	302,077
<b>Total current assets</b>		<b>699,931</b>	<b>773,685</b>
<b>Total assets</b>		<b>2,163,432</b>	<b>2,056,407</b>

The Notes are an integral part of the consolidated financial statements.

### EQUITY AND LIABILITIES

€ (thousands)	Note	31 December 2018	31 December 2017
<b>Shareholders' equity</b>			
Share capital		26,141	26,141
Additional paid-in capital		83,719	83,719
Treasury stock		(145,608)	(17,029)
Hedging reserve (cash flow hedge)		(8,399)	(5,867)
Translation reserve		(154,146)	(124,004)
Other reserves		43,081	40,684
Retained earnings		897,990	822,154
Net income for the year		312,376	288,762
Interim dividend		(91,761)	(87,470)
<b>Group shareholders' equity</b>	<b>19</b>	<b>963,393</b>	<b>1,027,090</b>
Minority interest		193	147
<b>Shareholders' equity</b>	<b>20</b>	<b>963,586</b>	<b>1,027,237</b>
<b>Non-current liabilities</b>			
Loans - due after one year	21	640,647	612,462
Staff leaving indemnities	22	19,547	21,093
Deferred tax liabilities	23	45,653	17,554
Other non-current liabilities	24	3,257	2,515
<b>Total non-current liabilities</b>		<b>709,104</b>	<b>653,624</b>
<b>Current liabilities</b>			
Trade payables	25	165,020	141,740
Other payables	26	85,534	82,779
Tax liabilities	27	42,149	24,373
Other current liabilities	28	19,359	486
Provisions	29	21,446	48,322
Fair value of hedging derivatives (cash flow hedge)	30	9,746	9,559
Loans - due within one year	21	130,583	51,710
Bank overdrafts and short-term loans	30	16,905	16,577
<b>Total current liabilities</b>	<b>31</b>	<b>490,742</b>	<b>375,546</b>
<b>Total equity and liabilities</b>		<b>2,163,432</b>	<b>2,056,407</b>

The Notes are an integral part of the consolidated financial statements.



**RECORDATI S.P.A. AND SUBSIDIARIES**  
**STATEMENT OF COMPREHENSIVE INCOME FOR THE YEAR ENDED 31 DECEMBER 2018**

€ (thousands)	2018	2017
<b>Net income for the year</b>	<b>312,422</b>	<b>288,799</b>
Gains/(losses) on cash flow hedges, net of tax	(2,532)	1,553
Gains/(losses) on translation of foreign financial statements	(30,142)	(45,695)
Gains/(losses) on investments booked to equity, net of tax	(1,659)	4,264
Other gains/(losses), net of tax	944	(155)
<b>Income and expense for the year recognized directly in equity</b>	<b>(33,389)</b>	<b>(40,033)</b>
<b>Comprehensive income for the year</b>	<b>279,033</b>	<b>248,766</b>
Attributable to:		
Equity holders of the parent	278,987	248,729
Minority interests	46	37
Per share data		
Basic	€ 1,365	€ 1,202
Diluted	€ 1,334	€ 1,190

**RECORDATI S.P.A. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENT OF CHANGES IN GROUP SHAREHOLDERS' EQUITY**

€ (thousands)	Share capital	Add. paid-in capital	Treasury stock	Hedging reserve	Translation reserve	Other reserves	Retained earnings	Net income for the year	Interim dividend	Minority interest	Total
Balance at 31.12.2016	26,141	83,719	(76,761)	(7,420)	(78,309)	35,295	756,004	237,406	(72,245)	110	903,940
Allocation of 2016 net income:											
- Dividends							(34,280)	(110,102)	72,245		(72,137)
- Retained earnings							127,304	(127,304)			0
Change in the reserve for share based payments						1,280	2,682				3,962
Purchase of own shares											
Sale of own shares			59,732				(29,465)				30,267
Interim dividend									(87,470)		(87,470)
Other changes							(91)				(91)
Comprehensive income for the year				1,553	(45,695)	4,109		288,762		37	248,766
<b>Balance at 31.12.2017</b>	<b>26,141</b>	<b>83,719</b>	<b>(17,029)</b>	<b>(5,867)</b>	<b>(124,004)</b>	<b>40,684</b>	<b>822,154</b>	<b>288,762</b>	<b>(87,470)</b>	<b>147</b>	<b>1,027,237</b>
Change due to first application of IFRS 15							(18,759)				(18,759)
<b>Balance at 1.1.2018</b>	<b>26,141</b>	<b>83,719</b>	<b>(17,029)</b>	<b>(5,867)</b>	<b>(124,004)</b>	<b>40,684</b>	<b>803,395</b>	<b>288,762</b>	<b>(87,470)</b>	<b>147</b>	<b>1,008,748</b>
Allocation of 2017 net income:											
- Dividends							37,910	(212,506)	87,470		(87,126)
- Retained earnings							76,256	(76,256)			0
Change in the reserve for share based payments						3,112	1,908				5,020
Purchase of own shares			(169,769)								(169,769)
Sale of own shares			41,190				(20,973)				20,217
Interim dividend									(91,761)		(91,761)
Other changes							(506)				(506)
Comprehensive income for the year				(2,532)	(30,142)	(715)		312,376		46	279,033
<b>Balance at 31.12.2018</b>	<b>26,141</b>	<b>83,719</b>	<b>(145,608)</b>	<b>(8,399)</b>	<b>(154,146)</b>	<b>43,081</b>	<b>897,990</b>	<b>312,376</b>	<b>(91,761)</b>	<b>193</b>	<b>963,586</b>

The Notes are an integral part of the consolidated financial statements.

**RECORDATI S.P.A. AND SUBSIDIARIES**  
**CONSOLIDATED CASH FLOW STATEMENT FOR THE YEAR ENDED 31 DECEMBER 2018**

€ (thousands)	2018	2017
<b>Operating activities</b>		
<b>Cash flow</b>		
Net Income	312,422	288,799
Depreciation of property, plant and equipment	13,901	14,186
Amortization of intangible assets	42,959	33,967
Write-down of assets	0	16
<b>Total cash flow</b>	<b>369,282</b>	<b>336,968</b>
(Increase)/decrease in deferred tax assets	(10,773)	(32,422)
Increase/(decrease) in staff leaving indemnities	(1,660)	(582)
Increase/(decrease) in other non-current liabilities	1,337	(10,841)
	<b>358,186</b>	<b>293,123</b>
<b>Changes in working capital</b>		
Trade receivables	5,502	(38,129)
Inventories	(20,932)	(20,300)
Other receivables and other current assets	1,629	(8,111)
Trade payables	17,458	17,096
Tax liabilities	15,290	3,941
Other payables and other current liabilities	21,320	4,746
Provisions	(26,876)	20,345
<b>Changes in working capital</b>	<b>13,391</b>	<b>(20,412)</b>
<b>Net cash from operating activities</b>	<b>371,577</b>	<b>272,711</b>
<b>Investing activities</b>		
Net (investments)/disposals in property, plant and equipment	(19,362)	(14,588)
Net (investments)/disposals in intangible assets	(65,192)	(306,112)
Acquisition of equity	(83,597) <sup>(1)</sup>	0
Acquisition of equity	(72,636) <sup>(2)</sup>	0
Net (increase)/decrease in equity investments	0	28
Net (increase)/decrease in other non-current receivables	209	(516)
<b>Net cash used in investing activities</b>	<b>(240,578)</b>	<b>(321,188)</b>
<b>Financing activities</b>		
Short-term financial position of companies acquired or disposed of	8,800	0
Medium/long term loans	153,876	389,903
Re-payment of loans	(50,564)	(39,623)
Purchase of Treasury stock	(169,769)	0
Sale of Treasury stock	20,217	30,267
Other changes in equity	(13,300)	3,716
Dividends paid	(178,887)	(159,607)
<b>Net cash from/(used in) financing activities</b>	<b>(229,627)</b>	<b>224,656</b>
<b>Changes in short-term financial position</b>	<b>(98,628)</b>	<b>176,179</b>
Short-term financial position at beginning of year *	285,500	122,804
Change in translation reserve	(5,741)	(13,483)
<b>Short-term financial position at end of period *</b>	<b>181,131</b>	<b>285,500</b>

\* Includes cash and cash equivalents net of bank overdrafts and short-term loans.

(1) Acquisition of Natural Point S.r.l.: Working capital (1,628), short-term financial position\* (8,971), fixed assets (63,764), goodwill (27,892), personnel leaving indemnity 114, medium/long-term loans 1,351, deferred tax liabilities 17,193.

(2) Acquisition of Tonipharm S.A.S.: Working capital (3,653), short-term financial position\* 171, fixed assets (50,363), goodwill (30,186), deferred tax assets (800), deferred tax liabilities 12,320, non-current receivables (125).

The Notes are an integral part of the consolidated financial statements.

## RECORDATI S.P.A. AND SUBSIDIARIES

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2018

### 1. GENERAL

The consolidated financial statements at 31 December 2018 comprise Recordati S.p.A. (the Company) and subsidiaries controlled by the Company. The companies included in the consolidated accounts, the consolidation method applied, their percentage of ownership and a description of their activity are set out in attachment 1.

During the year the consolidation perimeter changed consequent to the following events:

- the acquisition, on June 11, of Natural Point S.r.l., an Italian company active in the food supplements market. The recognition of this company in the accounts is not yet definite, and could be subject to change, as allowed by IFRS 3, in view of the limited period of time elapsed and the need to assess the fair value of the assets and liabilities acquired. The profit and loss accounts of Natural Point S.r.l. were consolidated as from 1 July 2018 in view of the non significant financial value of the transactions between the date of acquisition and the 30th of June 2018. The consolidated cash flow statement and Note 34 include the effect of the balance sheet accounts at 30 June 2018;
- the acquisition, on 31 December, of Tonipharm S.A.S., a French company active in the self-medication market with over-the-counter products. The recognition of this company in the accounts is not yet definite, and could be subject to change, as allowed by IFRS 3, in view of the limited period of time elapsed and the need to assess the fair value of the assets and liabilities acquired. The profit and loss accounts of Tonipharm S.A.S. will be consolidated as from 1 January 2019. The consolidated cash flow statement and Note 34 include the effect of the balance sheet accounts at 31 December 2018;
- reorganization of the Group's presence in Switzerland through the incorporation of Recordati S.A. by Pro Farma AG, a company acquired in 2016 and redenominated Recordati AG;
- Recordati Rare Diseases Japan K.K. and Recordati Rare Diseases Australia Pty Ltd were established with the objective of expanding the Group's rare disease business in new markets;
- the companies Orphan Europe Nordic AB and Orphan Europe Benelux BVBA were respectively redenominated Recordati AB and Recordati BVBA.
- liquidation of the Portuguese company Orphan Europe Portugal Lda.

These financial statements are presented in euro (€) and all amounts are rounded to the nearest thousand euro unless otherwise stated.

### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) and in compliance with the European Union's guidelines on the preparation of consolidated financial statements. The same accounting policies used in the preparation of the financial statements at 31 December 2017.

The financial statements of the consolidated companies, prepared by the Board of Directors or the Sole Directors for submission to the respective Shareholders' meetings, have been reclassified and adjusted as required in accordance with international accounting principles.

The criteria applied is consistent with that of the consolidated financial statements at 31 December 2017.

The financial statements have been prepared on the historical cost basis, except for the financial assets available for sale included under the line "Other investments", hedging derivatives (and the relative underlying hedged financial liability) for which their fair value has been applied as prescribed by IFRS 9 and defined benefit plans for which the actuarial valuation was carried out as prescribed by IAS 19.

### APPLICATION OF NEW ACCOUNTING PRINCIPLES

As from 1 January 2018 the Group has applied two new accounting principles:

- IFRS 15 "Revenue from contracts with customers", which substitutes IAS 18 "Revenue", IAS 11 "Construction contracts" and their interpretations;
- IFRS 9 "Financial instruments", which substitutes IAS 39 "Financial instruments: Recognition and measurement".

IFRS 15, "Revenue from contracts with customers", introduces a single general rule to establish if, when and to what extent revenues should be recognized. In general, according to IFRS 15 revenues are recognized when the customer obtains control of the goods or services. The determination of when control is transferred, whether in a single moment or over the course of time, requires the evaluation of company management.

The main application area for the Group turned out to be the booking of the up-front payments established by license and distribution agreements.

The existing contracts were analyzed and the conclusion was that, based on the rules established by the new principle, the recognition of the milestones due from customers according to said contracts must, in some cases, be spread over the duration of the contract.

The Group applied IFRS 15 retroactively with cumulative effect at the date of first time application. Therefore, 2017 information was not restated but presented according to the principles and interpretations in place at the closing date of the previous year. Furthermore, in general, the mandatory reporting rules prescribed by IFRS 15 were not applied to the comparative information.

The re-calculation of the up-front payments received in previous years which, according to the new principle, must be recognized as revenues in 2018 and following years, determined a negative effect of € 18.8 million which was booked to equity and set-off by increasing Other liabilities by € 22.9 million and Deferred tax assets by € 4.1 million.

IFRS 9 "Financial instruments" introduces new requirements for the recognition and valuation of financial assets and liabilities and new rules for hedge accounting. The main area of application for the Group turned out to be the determination of the write-down of financial assets. IFRS 9 substitutes the

rule of realized loss with a rule of expected loss which takes into account past events, current conditions and the expectation of future economic conditions. The application of the new rules did not significantly impact net equity at 1 January 2018.

IFRS 16, "Leases", which will apply as from 1 January 2019, eliminates the classification of leases as operating or financial in the financial statements of the lessees. In substance, for all leases unless the lease term is 12 months or less or the underlying asset has a low value, the lessee is required to recognize a right-of-use asset and a lease liability representing the obligation of making the payments stipulated in the contract, as well as the effects on profit and loss of the amortization of the asset and the financial expense connected with the financial liability. The Group will apply IFRS 16 at the date of first time application (i.e. 1 January 2019) using the modified retroactive method. Therefore, the cumulative effect of the adoption of IFRS 16 will be recognized as an adjustment to retained earnings at 1 January 2019 without restating the comparative information. The effect of the application of the new principle are under evaluation. Based on currently available information the Group expects to identify further liabilities at the date of first time application for an amount of between € 25 million and € 30 million. The actual effect derived from the adoption of the abovementioned principle at 1 January 2019 may be different as the Group has not yet completed the testing and evaluation of the controls on its new information systems and the new evaluation criteria could be modified up until the presentation of the first consolidated Group financial statements of the year which includes the date of first time application.

## USE OF ESTIMATES

The preparation of the financial statements by management requires estimates and assumptions to be made, based on management's best judgment, that affect the reported amounts of revenues, expenses, assets, liabilities and disclosure of contingent assets and liabilities at the date of the financial statements. If in the future such estimates and assumptions deviate from the actual circumstances, the original estimates and assumptions will be modified as appropriate when circumstances change.

The balance sheet accounts which require, more than others, a higher degree of subjectivity on the part of management when making estimates, and for which a change in the conditions underlying the assumptions used could have a significant impact on financial data, are hereunder briefly described.

- **Goodwill:** according to the accounting principles applied by the Group, goodwill is subject to annual impairment testing in order to ascertain whether a reduction in value has occurred. These tests require on the part of management subjective evaluations based on available information within the Group and from the market, as well as historical experience. These also depend on factors that could change over time influencing the valuations and estimates made by management. Furthermore, when it has been determined that a potential reduction in value may have arisen, the Group proceeds to determine it by using the evaluation methods deemed to be most adequate.
- **Risk provisions:** the identification of the existence or not of a current obligation (legal or implicit) is in some cases not easy to determine. Management evaluates these events on a case by case basis, together with an estimate of the amount of financial resources required to comply with the obligation. When management considers that the generation of a liability is only possible, the risks are disclosed in the appropriate information section on risks and liabilities, and no accruals are made.
- **Deferred tax assets:** the recording is supported by a recovery plan based on hypotheses and assumptions which management considers to be reasonable.
- **Inventories:** inventories which appear to be obsolete or slow-moving are periodically tested and written-down if their recoverable value is less than their book value. The write-downs are based on assumptions and estimates which derive from experience and the historical results obtained.

- **Financial instruments:** trade receivables are reduced by their relative provision for bad debts in order to take into account their effective recoverable value.

The determination of the amounts to be written-down requires that management make subjective evaluations which take into account past events, current conditions and expectations of future economic conditions. In general, the methods for the calculation of the fair value of financial instruments, for accounting or disclosure purposes, are summarized below with regards to the main categories of financial instruments:

- **derivative financial instruments:** the pricing models are adopted based on the market values of the interest rates;
- **receivables and payables and non-listed financial assets and liabilities:** for the financial instruments with maturity greater than 1 year the discounted cash flow method was applied, therefore the discounting of expected cash flows in consideration of current interest rate conditions and credit ratings, for the determination of the Fair Value on first-time recognition. Further measurements are made based on the amortized cost method;
- **listed financial instruments:** the market value at the reporting date is utilized.

In relation to financial instruments measured at Fair Value, IFRS 13 requires the classification of these instruments according to the standard's hierarchy levels, which reflect the significance of the inputs utilized in establishing the fair value. The following levels are used:

- **Level 1:** unadjusted assets or liabilities subject to valuation on an active market;
- **Level 2:** inputs other than prices listed at the previous point, which are directly observable (prices) or indirectly (derivatives from the prices) on the market;
- **Level 3:** input which is not based on observable market data.

## BASIS OF CONSOLIDATION

The consolidated financial statements incorporate the financial statements of the Company and enterprises controlled by the Company (its subsidiaries) made up to 31 December each year. Control is achieved where the Company has the power to govern the financial and operating policies of an investee enterprise so as to obtain benefits from its activities.

The financial statements of the subsidiaries are prepared according to the same accounting policies adopted by the Company. Where necessary, adjustments are made to bring the accounting policies used in line with those used by the Company.

All intercompany transactions and balances between group enterprises, including unrealized gains, are eliminated on consolidation. Intragroup losses are also eliminated unless they indicate an impairment that requires recognition in the consolidated financial statements.

Subsidiaries are included in the consolidated financial statements from the effective date control is acquired up to the effective date control is transferred out of the group. When control is no longer exercised over a consolidated subsidiary, the results of the subsidiary are consolidated proportionally to the time period during which control was maintained.

The line-by-line consolidation method is applied using the following criteria:

- a. The book value of investments in consolidated subsidiaries is eliminated against the relevant shareholders' equity while the assets and liabilities are consolidated on a line-by-line basis.
- b. Intercompany payables and receivables and transactions, as well as intragroup profits and losses not yet realized, are eliminated.
- c. Any excess of the cost of acquisition over the value of equity at the date of acquisition is recognized as goodwill.

d. Minority interests in the equity of consolidated subsidiaries are shown separately under equity, while minority interests in the net income of such companies are shown separately in the consolidated income statement.

The financial statements of foreign subsidiaries expressed in currencies other than Euro are translated into Euro as follows:

- Assets and liabilities, at year-end exchange rates;
- Shareholders' equity at historical exchange rates;
- Income and expense items at the average exchange rates for the year;
- The goodwill resulting from the acquisition of a foreign company is recognized in the currency of the country in question and translated at year-end exchange rates.

Translation differences arising from this process are shown in the consolidated statement of comprehensive income.

## BALANCE SHEET

**Property, plant and equipment** - Property, plant and equipment is stated at purchase cost less accumulated depreciation and any recognized impairment loss. Reviews are performed when events or situations occur which indicate that the carrying amount of the assets can no longer be recovered (see paragraph on *Impairment*).

Depreciation is computed on a straight-line basis using rates which are deemed to be representative of the estimated useful life of the assets:

- Land and buildings 2.5% - 5.5%
- Plant and machinery 10% - 17.5%
- Other equipment 12% - 40%

The gain or loss arising on the disposal or retirement of an asset is determined as the difference between the sales proceeds and the carrying amount of the asset and is recognized in income.

**Leasing** - Leases are classified as finance leases whenever the terms of the lease transfer substantially all the risks and rewards of ownership to the lessee. Assets held under finance leases are recognized as assets of the Group at their fair value at the date of acquisition or, if lower, at the present value of the minimum lease payments, and depreciated over their estimated useful life. The corresponding liability to the lessor is included in the balance sheet as a financial liability. Lease payments are apportioned between finance charges and reduction of the financial liability. Finance charges are charged directly in the income statement.

All other leases are classified as operating leases and the rentals payable are charged to income as per the terms of the relevant lease.

**Intangible assets** - An intangible asset is recognized only if it can be identified, if it is probable that it will generate future economic benefits and its cost can be measured reliably. Intangible assets are valued at purchase cost, net of amortization calculated on a straight line basis and on the basis of their estimated useful life which, however, cannot exceed 20 years. Patents, licenses and know-how are amortized as from the year of the first sale of relevant products. Amortization of distribution and license rights is calculated over the duration of the contract. The following percentages are deemed to be representative of the estimated useful life of the intangible assets.

- Patent rights and marketing authorizations 5% - 33%
- Distribution, license, trademark and similar rights 5% - 25%

**Goodwill** - Goodwill arising on consolidation represents the excess of the cost of acquisition over the Group's interest in the fair value of the identifiable assets and liabilities of a subsidiary, associate or jointly controlled entity at the date of acquisition.

Transaction costs associated with the aggregation of companies are not considered acquisition costs and are recognized as expenses in the year they are incurred. Goodwill is recognized as an asset and reviewed annually in order to determine any impairment loss.

Goodwill arising on the acquisition of an associate is included within the carrying amount of the associate. Goodwill arising on the acquisition of subsidiaries and jointly controlled entities is presented separately in the balance sheet.

On disposal of a subsidiary, associate or jointly controlled entity, the attributable amount of remaining goodwill is included in the determination of the profit or loss on disposal.

**Impairment** - At each balance sheet date, the Group reviews the carrying amounts of its tangible and intangible assets to determine whether there is any indication that those assets have suffered an impairment loss.

If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss (if any). Where it is not possible to estimate the recoverable amount of an individual asset, the Group estimates the recoverable amount of the cash-generating unit to which the asset belongs.

Recoverable amount is the greater of net selling price and value in use.

In assessing value in use, the estimated future cash flows are discounted to their present value using an after-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

If the recoverable amount of an asset (or cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (cash-generating unit) is reduced to its recoverable amount. Impairment losses are recognized as an expense immediately.

Where an impairment loss subsequently reverses, the carrying amount of the asset (cash-generating unit) is increased to the revised estimate of its recoverable amount. However, the increased carrying amount cannot exceed the carrying amount that would have been determined had no impairment loss been recognized. A reversal of an impairment loss is recognized as income immediately. Losses resulting from the impairment of goodwill cannot be reversed.

**Investments in associates** - An associate is an enterprise over which the Group is in a position to exercise significant influence, but not control, through participation in the financial and operating policy decisions of the investee. The results and assets and liabilities of associates are incorporated in the consolidated financial statements using the equity method of accounting.

**Other investments** - They comprise equity instruments and are measured at fair value. If their market value is not available and their fair value cannot be reasonably determined, these investments are valued at cost and adjusted for loss of value (impairment) if required. The impairment cost is recognized in the income statement.

**Receivables (included in non-current assets)** - Receivables are stated at their nominal value and reduced by estimated irrecoverable amounts if and when necessary.

**Inventories** - Inventories are stated at the lower of cost or market, where the market value of raw materials and subsidiaries is their substitution cost while that related to finished goods and work-in-process is their net realizable value. Inventories of raw materials, supplies and promotional material are valued at their average acquisition cost including costs incurred in bringing the inventories to their location and condition at year end. Inventories of work-

in-process and finished goods are valued at their average manufacturing cost which includes the cost of raw materials, consumables, direct labour and indirect costs of production.

Inventories are written-down if market value is lower than cost as described above or in the case of obsolescence resulting from slow moving stocks.

**Trade receivables** - Trade receivables are stated at their nominal value as reduced by appropriate allowances for estimated irrecoverable amounts.

**Cash and cash equivalents** - Cash in banks on demand and highly liquid investments at fair value calculated by using their presumable realization value.

**Non-current assets held for sale and discontinued operations** - Comprise those components of an entity, whose operations and cash flows can be distinguished operationally and for financial reporting purposes, that either have been disposed of or that satisfy the criteria to be classified as held for sale.

A non-current asset (or disposal group) classified as held for sale is measured at the lower of fair value less costs to sell it and its carrying amount.

Non-current assets or disposal groups that are classified as held for sale are not depreciated.

**Equity** - Equity instruments issued by the Company are recorded at the proceeds received. Proposed dividend is recognized as a liability at the time of adoption of the dividend resolution at the annual shareholders' meeting. The cost and selling prices of treasury shares are recognized directly in equity and therefore gains and losses on sales are not recognized in the income statement.

**Loans** - Interest-bearing loans are recorded at the proceeds received, net of direct issue costs. Subsequently, loans are measured using the amortised cost method as prescribed by IFRS 9. The amortised cost of a financial asset or financial liability is the amount at which the financial asset or liability is measured at initial recognition minus principal repayments, plus or minus the cumulative amortisation using the effective interest method of any difference between that initial amount and the maturity amount.

If the loans are covered using derivative instruments qualifying as fair value hedges, in accordance with IFRS 9 these loans are measured at fair value as are their related derivative instruments.

**Staff leaving indemnities** - Employee benefits presented on the balance sheet are the result of valuations carried out as prescribed by IAS 19. The liability recognised in the balance sheet for post-employment benefit plans is the present value of the defined benefit obligation, as adjusted for unrecognised actuarial gains and losses and unrecognised past service cost. The present value of the defined benefit obligation is determined using the Projected Unit Credit Method.

**Trade payables** - Include payables arising from supply agreements and are stated at their nominal value.

**Other payables** - Include payables arising in the normal course of business (towards employees and third parties) and are stated at their nominal value.

**Bank overdrafts and loans** - Bank overdrafts and loans are recorded at the proceeds received, net of direct issue costs. Finance charges are accounted for on an accrual basis and are added to the

carrying amount of the instrument to the extent that they are not settled in the period in which they arise.

**Derivative financial instruments** - The Group uses derivative financial instruments to hedge its risks associated with interest rate and foreign currency fluctuations. Such derivatives are measured at fair value at the end of each reporting period.

Hedging relationships are of two types, "fair value hedge" or "cash flow hedge". A "fair value hedge" is a hedge of the exposure to changes in the fair value of an asset or liability that is already recognized in the balance sheet. A "cash flow hedge" is a hedge of the exposure to variability in cash flows relating to a recognized asset or liability or to a forecasted transaction.

The gain or loss from the change in fair value of a hedging instrument qualifying as a "fair value hedge" is recognized immediately in net profit or loss. At the same time, the carrying amount of the hedged item is adjusted for the corresponding gain or loss since the inception of the hedge, which also is recognized immediately in net profit or loss.

The gain or loss from the change in fair value of a hedging instrument qualifying as a "cash flow hedge" is recognized in the consolidated statement of comprehensive income.

The gain or loss from the change in fair value of a derivative financial instrument which does not qualify as a hedging instrument is recognized immediately in net profit or loss.

**Provisions** - Provisions are recognized when the Group has a present obligation as a result of past events, it is probable that an outflow of resources will be required to settle the obligation and a reliable estimate of the amount can be made.

**Foreign currencies** - Transactions in currencies other than the Euro are initially recorded at the rates of exchange prevailing on the dates of the transactions. Monetary assets and liabilities denominated in such currencies are retranslated at the rates prevailing on the balance sheet date. Profits and losses arising on exchange are included in net profit or loss for the period. Non-monetary assets and liabilities recorded at the rates of exchange prevailing on the dates of the transactions are not retranslated on the balance sheet date.

On consolidation, the assets and liabilities of the Group's foreign currency operations are translated at exchange rates prevailing on the balance sheet date. Income and expense items are translated at the average exchange rates for the period. Exchange differences arising, if any, are recognized in the consolidated statement of comprehensive income and included in the Group's translation reserve. Such translation differences are recognized as income or as expenses in the period in which the operation is disposed of.

## INCOME STATEMENT

**Revenues** - Revenues are recognized when it is probable that the economic benefits associated with the transaction will flow to the Group and that the amount of revenue can be measured reliably. Revenue arising from the sale of goods is recognized when the customer obtains their control. These are stated net of discounts, rebates and returns. Revenues include income from royalties due on licensed out products and up-front payments received under licensing agreements.

**Cost of Sales** - Represents the cost of goods sold and includes the cost of raw materials, supplies and consumables, finished goods, and direct and indirect production expenses.

**Selling expenses** - Include all expenses incurred in connection with the products sold during the year, such as payroll and other costs for sales and marketing personnel, promotional expenses and all distribution costs.

**Research and development expenses** - All research costs are expensed in the income statement in the year in which they are incurred in accordance with IAS 38. IAS 38 prescribes that development costs must be capitalized when technical and commercial feasibility is achieved. Regulatory and other uncertainties inherent in the development of new products are so high that the guidelines under IAS 38 are not met so that development costs are expensed as incurred. Research and development costs include amounts due under collaboration agreements with third parties.

**Non-reimbursable government grants** - Government grants towards investment in plant are recognized as income over the periods necessary to match them with the related costs and are stated in the balance sheet as deferred income. Research grants are booked on an accrual basis and are recognized in the income statement as other revenue.

**Transactions involving share based payments**

- As prescribed by IFRS 2 stock option plans for the benefit of group employees are considered part of their remuneration, the cost of which is the fair value of the stock options at the date they are granted. This cost is recognized in the profit and loss linearly distributed over the vesting period and booked directly to equity.

**Financial items** - Include interest income and expense, foreign exchange gains and losses, both realized and unrealized, and differences arising from the valuation of securities.

**Taxation** - Income tax expense represents the sum of the tax currently payable and deferred tax. The tax currently payable is based on taxable profit for the year and tax rates in force at the date of the balance sheet are applied.

Deferred tax is the tax expected to be payable or recoverable on temporary differences between the carrying amount of assets and liabilities in the financial statements and the corresponding tax basis used in the computation of taxable profit. Deferred tax liabilities are generally recognized for all taxable temporary differences and deferred tax assets are recognized to the extent that it is probable that taxable profits will be available against which deductible temporary differences can be utilized. Such assets and liabilities are not recognized if the temporary difference arises from goodwill.

Deferred tax is calculated at the tax rates that are expected to apply to the period when the liability is settled or the asset realized. Deferred tax is charged or credited in the income statement, except when it relates to items charged or credited directly to equity, in which case the deferred tax is also dealt with in equity.

Deferred tax assets and liabilities are offset when they relate to income taxes levied by the same taxation authority and the Group intends to settle its current tax assets and liabilities on a net basis.

**Earnings per share** - Earnings per share is the net profit for the period attributable to ordinary shareholders divided by the weighted average number of ordinary shares outstanding during the period.

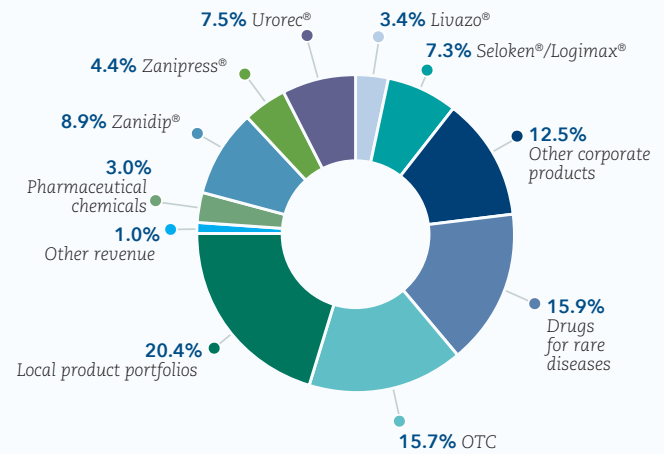
Diluted earnings per share is calculated by adjusting the number of shares for the effects of all dilutive potential ordinary shares.

**3. REVENUE**

Net revenue for the years 2018 and 2017 is € 1,352.2 million and € 1,288.1 million respectively and can be broken down as follows:

€ (thousands)	2018	2017	Change 2018/2017
Net sales	1,334,124	1,272,973	61,151
Royalties	6,248	4,106	2,142
Up-front payments	6,491	5,604	887
Miscellaneous items	5,372	5,440	(68)
<b>Total revenue</b>	<b>1,352,235</b>	<b>1,288,123</b>	<b>64,112</b>

The following pie chart illustrates the composition of 2018 sales by product or product class.



Please refer to the Review of Operations for further sales analysis.

Revenue from up-front payments refers to the licensing and distribution of corporate products and in 2018 are mainly relative to agreements for the licensing out of the lercanidipine-enalapril combination (€ 1.7 million), of lercanidipine (€ 1.5 million), pitavastatin (€ 1.3 million), Cystadrops® (cysteamine hydrochloride) (€ 0.7 million) and silodosin (€ 0.5 million). The first time application of the new accounting principle IFRS 15 generated revenues of € 5.9 million resulting from up-front payments received in previous years (see Note 2).

## 4. OPERATING EXPENSES

Total operating expenses for the years 2018 and 2017 are € 910.0 million and € 881.6 million respectively and are analyzed by function as follows:

€ (thousands)	2018	2017	Change 2018/2017
Cost of sales	395,569	382,754	12,815
Selling expenses	333,497	330,793	2,704
Research and development expenses	109,693	100,256	9,437
General and administrative expenses	67,722	65,582	2,140
Other (income) expense, net	3,535	2,246	1,289
<b>Total operating expenses</b>	<b>910,016</b>	<b>881,631</b>	<b>28,385</b>

Research and development expenses include the amortization of intangible assets, classified as licenses, brands and patents, referable to acquired products for an overall amount of € 42.6 million.

The following table summarizes the more significant components of the line "Other (income) expense, net" which refer mainly to non-recurrent events, transactions and items which do not occur frequently in the ordinary course of business.

€ (thousands)	2018	2017	Change 2018/2017
Ancillary costs related to acquisitions	2,694	769	1,925
Write-downs of intangible assets	0	16	(16)
Others	841	1,461	(620)
<b>Total other (income) expense, net</b>	<b>3,535</b>	<b>2,246</b>	<b>1,289</b>

The ancillary costs related to acquisitions refer to the process for the transfer of control of the companies Natural Point S.r.l. and Tonipharm S.A.S. and of the rights to products classified as intangible assets.

In compliance with Consob's communication dated 28 July 2006 it is hereby stated that during 2018 no atypical or unusual operations, as defined by the communication itself, were put in place.

Total operating expenses are analyzed by nature as follows:

€ (thousands)	2018	2017	Change 2018/2017
Material consumption	307,778	295,540	12,238
Payroll cost	234,494	231,896	2,598
Other employee costs	39,615	39,500	115
Variable sales expenses	66,935	67,084	(149)
Depreciation and amortization	56,860	48,153	8,707
Utilities and consumables	29,776	29,297	479
Other expenses	174,558	170,161	4,397
<b>Total operating expenses</b>	<b>910,016</b>	<b>881,631</b>	<b>28,385</b>

Payroll cost includes charges of € 5.0 million related to stock option plans, up by € 1.0 million over the preceding year. The average number of employees in 2018 is of 4,089.

Depreciation and amortization charges are € 56.9 million. Depreciation of property, plant and equipment is € 13.9 million, down by € 0.3 million

compared to 2017. Amortization of intangibles is € 43.0 million, an increase of € 9.0 million as compared to the preceding year mainly due to the metoprolol based product rights acquired from AstraZeneca in June 2017. The useful life of the intangible assets owned by the subsidiary Recordati Rare Diseases Inc. was re-assessed from 15 to 20 years which resulted in lower amortization charges for the period for an amount of € 1.8 million.

## 5. FINANCIAL INCOME AND EXPENSE

In 2018 and 2017 financial items recorded a net expense of € 24.3 million and € 17.4 million respectively which are comprised as follows:

€ (thousands)	2018	2017	Change 2018/2017
Exchange (gains) losses	1,731	3,623	(1,892)
Interest expense on loans	12,675	10,495	2,180
Interest expense related to tax audits	6,034	0	6,034
Net interest (income) expense on s/t financial position	3,571	3,030	541
Interest cost in respect of defined benefit plans	273	229	44
<b>Total financial (income) expense, net</b>	<b>24,284</b>	<b>17,377</b>	<b>6,907</b>

The net exchange losses in 2018 are mainly determined by the devaluation of some currencies, mainly the Turkish Lira and the Russian Ruble.

The increase in interest expense on loans is to be attributed mainly to new loans raised (see Note 21).

The interest expense related to tax audits is attributable to the assessments with acceptance which took place in the last quarter related to the years 2009 to 2015 (see Note 38).

## 6. PROVISION FOR INCOME TAXES

The provision for income taxes amounts to € 105.5 million and includes income taxes levied on all consolidated companies as well as the Italian regional tax on production activities (IRAP) which is levied on all Italian companies.

The current standard corporate income tax rate in Italy can be reconciled with the tax rate effectively incurred on consolidated pre-tax income, as follows:

	2018 %	2017 %
Standard income tax rate on pre-tax income of the parent company	24.0	24.0
Dividends from foreign subsidiaries	0.4	0.5
Consolidation effect	(2.3)	(0.5)
Franking of the difference between book values and recognized fiscal values	0	(4.5)
Provisions for risks deriving from ongoing tax audits	2.2	5.7
Other differences, net	(1.0)	(0.7)
<b>Effective tax rate on income</b>	<b>23.3</b>	<b>24.5</b>
IRAP	2.0	1.3
<b>Effective tax rate, including IRAP</b>	<b>25.3</b>	<b>25.8</b>



During the year the settlement agreed with the internal revenue service was concluded. The agreement covers the complete settlement of all the disputes connected with the 2009-2015 fiscal period (see Note 38). The agreement also provides for a further cost (which also includes the years 2016 and 2017) of € 9.2 million. Furthermore, tax credits were recognized in Turkey and in Italy for € 6.2 million and € 4.8 million respectively.

In 2017 the Parent and the subsidiary Italcimici S.p.A. took advantage of the faculty, allowed by tax law, to frank the differences between the higher book value of the goodwill and intangible assets determined by extraordinary transactions and the corresponding recognized fiscal values. Tax law provides for the payment of an IRES and IRAP substitute tax of 16% and the subsequent deductibility of the franked values in the amount of one fifth per year starting, as the case may be, from the first or the second fiscal year subsequent to that in which the substitute tax was paid. The exercise of the franking option entailed, overall, the payment of substitute tax in the amount of € 23.0 million, the booking of deferred tax assets for an amount of € 30.8 million related to future tax benefits and the reversal of deferred tax liabilities previously booked for an amount of € 9.7 million.

IRAP is levied only on the Italian companies and is computed applying a 5.35% rate to a broader taxable base calculated before the deduction of interest.

## 7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment, net of accumulated depreciation, amounts to € 103.6 million and € 103.0 million at 31 December 2018 and 2017 respectively. The composition and variation of property, plant and equipment are shown in the following table:

€ (thousands)	Land & buildings	Plant & machinery	Other equipment	Advances/ construction in progress	Total
<b>Cost</b>					
Balance at 31.12.17	76,513	225,772	66,105	8,309	376,699
Additions	603	3,428	2,526	12,633	19,190
Disposals	(27)	(261)	(1,731)	(31)	(2,050)
Changes in reporting entities	3,605	0	225	0	3,830
Other changes	(3,490)	(1,069)	908	(6,160)	(9,811)
<b>Balance at 31.12.18</b>	<b>77,204</b>	<b>227,870</b>	<b>68,033</b>	<b>14,751</b>	<b>387,858</b>
<b>Accumulated depreciation</b>					
Balance at 31.12.17	41,000	180,717	51,973	0	273,690
Depreciation for the year	2,255	7,596	4,050	0	13,901
Disposals	(19)	(191)	(1,678)	0	(1,888)
Changes in reporting entities	1,078	0	148	0	1,226
Other changes	(547)	(1,757)	(349)	0	(2,653)
<b>Balance at 31.12.18</b>	<b>43,767</b>	<b>186,365</b>	<b>54,144</b>	<b>0</b>	<b>284,276</b>
<b>Carrying amount at</b>					
<b>31 December 2018</b>	<b>33,437</b>	<b>41,505</b>	<b>13,889</b>	<b>14,751</b>	<b>103,582</b>
31 December 2017	35,513	45,055	14,132	8,309	103,009

Additions during the year of € 19.2 million refer mainly to investments made by the Parent in the Milan production plant and headquarters for an amount of € 12.1 million.

The intangible assets belonging to the recently acquired company Natural Point S.r.l. as of the date of first consolidation are classified under "Changes in reporting entities" for a net overall value of € 2.6 million. They refer mainly to the net book value of the company's headquarters building held under financial lease determined as prescribed by IAS 17.

The conversion into Euros of property, plant and equipment booked in different currencies resulted in a net decrease of € 7.5 million compared to their value at 31 December 2017, of which € 6.8 million is due to the devaluation of the Turkish Lira and € 0.7 million is due to the devaluation of the Tunisian Dinar.

At 31 December 2018 property, plant and equipment held under financial leases amount to € 2.5 million of which € 2.2 million referable to Natural Point S.r.l. and € 0.3 million to the company in Tunisia Opalia Pharma.

## 8. INTANGIBLE ASSETS

Intangible assets, net of accumulated amortization, at 31 December 2018 and 2017 amount to € 672.5 million and € 540.6 million respectively. Their composition and variation are shown in the following table:

€ (thousands)	Patent rights and marketing authorizations	Distribution, license, trademark and similar rights	Other	Advance payments	Total
<b>Cost</b>					
Balance at 31.12.17	584,105	197,421	18,354	46,680	846,560
Additions	113	35,046	1,498	29,022	65,679
Disposals	(151)	(1,346)	(6)	(9)	(1,512)
Changes in reporting entities	18	137,078	23	357	137,476
Other changes	(1,624)	45,311	(921)	(45,483)	(2,717)
<b>Balance at 31.12.18</b>	<b>582,461</b>	<b>413,510</b>	<b>18,948</b>	<b>30,567</b>	<b>1,045,486</b>
<b>Accumulated amortization</b>					
Balance at 31.12.17	160,169	129,269	16,557	0	305,995
Amortization for the year	27,370	15,205	384	0	42,959
Disposals	0	(1,346)	(11)	0	(1,357)
Changes in reporting entities	0	25,931	23	0	25,954
Other changes	(121)	(141)	(265)	0	(527)
<b>Balance at 31.12.18</b>	<b>187,418</b>	<b>168,918</b>	<b>16,688</b>	<b>0</b>	<b>373,024</b>
<b>Carrying amount at</b>					
<b>31 December 2018</b>	<b>395,043</b>	<b>244,592</b>	<b>2,260</b>	<b>30,567</b>	<b>672,462</b>
31 December 2017	423,936	68,152	1,797	46,680	540,565

The additions during the period include:

- € 20.0 million for the acquisition from Helsinn of the exclusive commercialization rights to Ledaga® (chlormethine), indicated for the topical treatment of mycosis fungoides-type cutaneous T-cell lymphoma, in all the world excluding the U.S.A., China, Hong Kong and Israel.

- € 19,0 million for the acquisition from Mylan of the rights to Cystagon® (cysteamine bitartrate), indicated for the treatment of proven nephropathic cystinosis in children and adults, for certain territories, including Europe.
- € 15,0 million paid to Gedeon Richter in accordance with the terms of the license agreement for the rights of Reagila® (cariprazine), an innovative atypical antipsychotic drug for the treatment of schizophrenia in Western Europe, Algeria, Tunisia and Turkey.
- € 4,0 million in accordance with the terms of the license agreement signed in 2014 with Plethora Solutions Limited and Plethora Solutions Holdings Plc for the commercialization of Fortacin®, a topical spray formulation of lidocaine and pilocaine for the treatment of premature ejaculation.

“Changes in reporting entities” include:

- A value of € 61.2 million which has been preliminarily allocated to Magnesio Supremo®, a food supplement and the main product sold by Natural Point S.r.l., as calculated during the acquired assets and liabilities fair value identification process. Based on knowledge of the market in which the acquired company operates and considering the historical trend of the product’s sales, a useful life of 20 years has been estimated for this asset.
- The intangible assets of the recently acquired French company Tonipharm S.A.S. for a net overall value of € 50.3 million. The value refers mainly to the brands Ginkor® (€ 44.4 million) and Alodont® (€ 5.0 million) which identify the company’s main products, and includes the added value preliminarily allocated during the acquired assets and liabilities fair value identification process for an overall amount of € 38.5 million.

The conversion into Euros of intangible assets booked in different currencies resulted in a net decrease of € 1.9 million compared to their value at 31 December 2017, mainly attributable to the opposite effects determined by the revaluation of the U.S. Dollar for an amount of € 2.5 million and by the devaluation of the Russian Ruble for an amount of € 2.7 million and of the Turkish Lira for an amount of € 1.7 million.

## 9. GOODWILL

Goodwill at 31 December 2018 and 2017 amounted to € 579.6 million and € 539.9 million respectively and changed as follows:

€ (thousands)	Goodwill
<b>Cost</b>	
Balance at 31.12.17	577,535
Change in reporting entities (Natural Point S.r.l.)	27,892
Change in reporting entities (Tonipharm S.A.S.)	30,186
Exchange rate adjustments	(18,392)
<b>Balance at 31.12.18</b>	<b>617,221</b>
<b>Accumulated amortization</b>	
Balance at 31.12.17	37,664
Changes during the year	0
<b>Balance at 31.12.18</b>	<b>37,664</b>
<b>Carrying amount at</b>	
<b>31 December 2018</b>	<b>579,557</b>
31 December 2017	539,871

The values associated with the companies acquired in 2018, the Italian company Natural Point S.r.l. and the French company Tonipharm S.A.S., were allocated as prescribed by IFRS 3.

The acquisition of Natural Point S.r.l. determined an increase of € 27.9 million. The preliminary process for the measurement of the fair value of the assets and liabilities at the date of acquisition resulted in the identification of added value for the intangible asset Magnesio Supremo®. Therefore, an amount of € 61.2 million of the difference between the amount paid and the book value of the assets and liabilities acquired was allocated to this asset and € 17.1 million to the relative deferred tax liabilities, while € 27.9 million were allocated to goodwill. The allocation is to be considered not yet definite, as allowed by IFRS 3.

The acquisition of Tonipharm S.A.S. determined an increase of € 30.2 million. The preliminary process for the measurement of the fair value of the assets and liabilities at the date of acquisition resulted in the identification of added value for the intangible assets Ginkor® and Alodont®. Therefore, an amount of € 38.5 million of the difference between the amount paid and the book value of the assets and liabilities acquired was allocated to these assets and € 12.3 million to the relative deferred tax liabilities, while € 30.2 million were allocated to goodwill. The allocation is to be considered not yet definite, as allowed by IFRS 3.

The exchange rate adjustments are related to the goodwill associated with the acquisitions made in countries having currencies different from the euro: goodwill calculated in local currency is translated into euros for the preparation of the consolidated financial accounts using the year-end exchange rates. An overall decrease of € 18.4 million as compared to 31 December 2017 resulted. In particular, the goodwill associated with the acquisitions in Turkey, Tunisia, Russia, Poland and the Czech Republic decreased respectively by € 13.7 million, € 2.4 million, € 2.0 million, € 0.5 million and € 0.1 million, while the goodwill associated with the acquisition in Switzerland increased by € 0.3 million.

Net goodwill at 31 December 2018, amounting to € 579.6 million, relates to the following operational areas, which represent the same number of cash generating units:

- France: € 76.0 million;
- Russia: € 25.7 million;
- Germany: € 48.8 million;
- Portugal: € 32.8 million;
- Treatments for rare diseases business: € 110.6 million;
- Turkey: € 41.1 million;
- Czech Republic: € 13.8 million;
- Romania: € 0.2 million;
- Poland: € 15.3 million;
- Spain: € 58.1 million;
- Tunisia: € 15.8 million;
- Italy: € 133.2 million;
- Switzerland: € 8.2 million.

As reported in the preceding note 2 - Summary of significant accounting policies and as required by IFRS 3, goodwill is not amortized systematically but is subject to impairment tests to determine its recoverable value. Goodwill is allocated to the individual cash generating units identified on the basis of the business segments and the markets on which the companies acquired operate. A cash generating unit to which goodwill has been allocated shall be tested for impairment annually, and when there is any indication that it may be impaired, by comparing the carrying amount of the unit, including goodwill, with the recoverable amount of the unit. If the recoverable amount of the unit exceeds the carrying amount of the unit, the unit and the goodwill allocated to that unit is not impaired. If the carrying amount of the unit exceeds the recoverable amount of the unit, the entity must recognize an impairment loss.

The recoverable amount was determined by calculating the value in use of the individual cash generating units.

The main hypotheses used for calculating the value in use concern the expected operating cash flows during the period assumed for the calculation, the discount rate and the growth rate.

Operating cash flow forecasts for the explicit period assumed for the calculation (2019-2021) are derived from the 2019 budget approved by the Board of Directors of the Parent on 18 December 2018 and, for the years 2020 and 2021, from specific forecasts prepared for the cash generating units subject to impairment testing approved by the Board of Directors of the Parent on 28 February 2019.

The discount rate used is the after-tax average weighted cost of capital which reflects current market valuations of the cost of money and the specific risk associated with the cash generating units. The growth rates used for the period subsequent to the explicit forecast period were prudently estimated and take into account the peculiarities of each country involved.

The following table shows the discount rates used for the impairment test for each of the main cash generating units.

Cash generating unit	Discount rate
France	5.24%
Russia	12.39%
Germany	4.76%
Portugal	6.87%
Business dedicated to treatments for rare diseases	7.52%
Turkey	20.38%
Czech Republic	6.79%
Poland	7.88%
Spain	6.45%
Tunisia	14.09%
Italy	8.58%
Switzerland	5.02%

The value in use, calculated according to the procedures described for each cash generating unit, was examined and approved by the Board of Directors. In all cases it was greater than the book value recognised in the financial statements at 31 December 2018 and therefore no loss in the value of goodwill was recognised.

## 10. OTHER INVESTMENTS

Investments in equity instruments of non-consolidated companies are as follows:

€ (thousands)	Balance sheet value		Percentage of equity owned	
	31.12.18	31.12.17	31.12.18	31.12.17
PureTech Health p.l.c., United Kingdom	17,997	16,153	3.4%	4.0%
Erytech Pharma S.A., France	2,694	7,974	2.4%	2.4%
Codexis Inc., U.S.A.	72	36	n.s.	n.s.
Fluidigm Corp., U.S.A.	7	5	n.s.	n.s.
Others	3	3	n.s.	n.s.
<b>Total equity investments</b>	<b>20,773</b>	<b>24,171</b>		

The main investment is that made in the U.K. company PureTech Health plc, specialized in investment in start-up companies dedicated to innovative therapies, medical devices and new research technologies. Starting 19 June 2015 the shares of the company were admitted to trading on the London Stock Exchange. At 31 December 2018 the overall fair value of the 9,554,140 shares held is of € 18.0 million. The € 1.8 million increase in value compared to that at 31 December 2017 is booked as a gain for the period recognized directly in equity, net of the relative tax effect, and shown on the statement of comprehensive income, in line with the accounting treatment applied in previous years.

Erytech Pharma S.A. is a French biopharmaceutical company focused on orphan oncology and rare diseases. The original investment of € 5.0 million consisted of a non-interest bearing loan which was converted into 431,034 shares in May 2013. The value of the investment was decreased by € 5.3 million as compared to that at 31 December 2017 to take into account its fair value. The after-tax difference was booked to equity and recognized in the statement of comprehensive income, in line with the accounting treatment applied in previous years.

## 11. OTHER NON CURRENT ASSETS

Receivables included in non-current assets at 31 December 2018 are € 5.9 million and refer mainly to guarantee deposits on rental and service contracts.

## 12. DEFERRED TAX ASSETS

Deferred tax assets at 31 December 2018 and 2017 amount to € 81.3 million and € 69.2 million respectively. The main deferred tax assets and their change are analyzed below.

€ (thousands)	2018	2017
Balance at 1 January	73,297	37,231
Additions	16,968	38,777
Utilizations	(9,798)	(6,846)
Changes in reporting entities	800	0
<b>Balance at 31 December</b>	<b>81,267</b>	<b>69,162</b>

€ (thousands)	Previous years' losses	Profit and loss temporary differences	Franking	Tax credits	Other	Total
Balance at 1 January	4,305	8,896	30,816	0	29,280	73,297
Additions	0	3,771	0	5,849	7,348	16,968
Utilization	(1,529)	(4,622)	(1,724)	0	(1,923)	(9,798)
Changes in reporting entities	0	800	0	0	0	800
<b>Balance at 31 December</b>	<b>2,776</b>	<b>8,845</b>	<b>29,092</b>	<b>5,849</b>	<b>34,705</b>	<b>81,267</b>

The balance at 1 January 2018 includes an amount of € 4.1 million determined by the first time application of IFRS 15 which was classified as "Other" (see Note 2). During the period an amount of € 1.0 million were booked to Profit and Loss.

The tax credit refers to tax incentives associated with the construction of the new manufacturing plant in Turkey which will be recognized in the following years.

During 2017 the Parent and the subsidiary Italcimici S.p.A. took advantage of the faculty, allowed by tax law, to frank the differences between the higher book value of the goodwill and intangible assets determined by extraordinary transactions and the corresponding recognized fiscal values. Tax law provides for the payment of an IRES and IRAP substitute tax of 16% and the subsequent deductibility of the franked values in the amount of one fifth per year starting, as the case may be, from the first or the second fiscal year subsequent to that in which the substitute tax was paid.

Regarding the Parent, the amounts franked relate to the goodwill, determined according to fiscal rules, arising from the acquisition of Italcimici S.p.A. and Pro Farma AG, both in 2016. The benefit deriving from the future fiscal deductibility of the franked amounts resulted in the recognition of deferred tax assets for an amount of € 22.2 million. The amount franked by Italcimici S.p.A. relates to the goodwill, determined according to fiscal rules, arising from a merger operation independently realized before their entry into the Recordati group. The benefit deriving from the future fiscal deductibility resulted in the recognition of deferred tax assets for an amount of € 8.6 million. In 2018 the deferred tax assets corresponding to Italcimici's recognized tax benefits were utilized for an amount of € 1.7 million.

"Other" deferred tax assets refers mainly to temporary differences arising from the elimination of unrealized gains on intercompany transactions.

## 13. INVENTORIES

Inventories at 31 December 2018 and 2017 amount to € 206.1 million and € 179.1 million respectively, net of their respective obsolescence provisions for slow moving or expiring pharmaceutical products of € 3.8 million and € 4.8 million. Composition of inventories is as follows:

€ (thousands)	31.12.2018	31.12.2017	Change 2018/2017
Raw materials and supplies	54,403	50,828	3,575
Intermediates and work-in-process	27,546	27,405	141
Finished goods	124,135	100,867	23,268
<b>Total inventories</b>	<b>206,084</b>	<b>179,100</b>	<b>26,984</b>

The values at 31 December 2018 corresponding to the acquired companies Natural Point S.r.l. and Tonipharm S.A.S. amount to € 1.1 million and € 5.3 million respectively.

## 14. TRADE RECEIVABLES

Trade accounts receivable at 31 December 2018 and 2017 amount to € 245.7 million and € 244.1 million respectively. These are shown net of the allowance for doubtful accounts which at 31 December 2018 is € 14.6 million (€ 15.4 million at 31 December 2017) and is considered to be sufficient to cover potential losses of certain receivables which, due to the nature of the customers in question or the destination markets, may be difficult to collect. Average days of sales outstanding are 61, compared to 62 at 31 December 2017.

Trade receivables at 31 December 2018 include those of the companies acquired during the year for an overall amount of € 6.4 million.

## 15. OTHER RECEIVABLES

Other receivables amount to € 38.5 million, a decrease of € 1.3 million compared to those at 31 December 2017, and their breakdown is as follows:

€ (thousands)	31.12.2018	31.12.2017	Change 2018/2017
Tax receivable	30,375	29,464	911
Balances due from employees and agents	2,928	1,369	1,559
Other	5,159	8,897	(3,738)
<b>Total other receivables</b>	<b>38,462</b>	<b>39,730</b>	<b>(1,268)</b>

Tax receivable comprises value added tax (VAT) receivable (€ 15.7 million) and advance payments of income tax. Receivables from employees and agents comprise advances on expense accounts and other credits. Under "Other" are included advances paid to suppliers and other parties and to computed credits under licensing-in agreements.

## 16. OTHER CURRENT ASSETS

At 31 December 2018 other current assets amount to € 5.2 million (€ 4.8 million at 31 December 2017) and relate mainly to prepaid expenses.

## 17. FAIR VALUE OF HEDGING DERIVATIVES

At 31 December 2018 the value of hedging derivatives included under this account is of € 6.4 million.

The cross currency swaps covering the cash flows related to the notes issued and privately placed on 30 September 2014, for an amount of \$ 75 million, measured at fair value at 31 December 2017 give rise to a € 6.4 million asset which represents the potential benefit of a lower value in euros of the future dollar denominated capital and interest flows, in view of the revaluation of the foreign currency subsequent to the moment in which the loan and hedging instrument were negotiated. In particular, the change in fair value of the hedging instrument covering the \$ 50 million tranche of the loan, provided by Mediobanca, was positive for an amount of € 4.4 million, and that covering the \$ 25 million tranche of the loan, provided by UniCredit, yielded a € 2.0 million positive value change.

## 18. SHORT TERM FINANCIAL INVESTMENTS, CASH AND CASH EQUIVALENTS

A break down is shown in the following table.

Short term time deposits have maturities of three months or less.

€ (thousands)	31.12.2018	31.12.2017	Change 2018/2017
Short term time deposits	25,615	28,734	(3,119)
Deposits in bank current accounts	172,350	273,309	(100,959)
Cash on hand	71	34	37
<b>Total short term financial investments, cash and cash equivalents</b>	<b>198,036</b>	<b>302,077</b>	<b>(104,041)</b>

At 31 December 2018 cash and cash equivalents are mainly denominated in Euros (70.4 million), in Pounds Sterling (15.2 million, mainly in the U.K. subsidiaries) and in U.S. Dollars (106.4 million, mainly in the U.S. subsidiary Recordati Rare Diseases Inc.).

## 19. SHAREHOLDERS' EQUITY

**Share capital** – At 31 December 2018 the issued and fully paid share capital consists of 209,125,156 ordinary shares with a par value of € 0.125 each for a total of € 26,140,644.50 and remains unchanged compared to the preceding year.

At 31 December 2018 the Company has three stock option plans in favor of certain group employees in place, the 2010-2013 plan, under which options were granted on 9 February 2011, on 8 May 2012, on 17 April 2013 and on 30 October 2013, the 2014-2018, plan under which options were granted on 29 July 2014 and on 13 April 2016 and the 2018-2022 plan, under which options were granted on 3 August 2018. The strike price of the options is the average of the parent company's listed share price during the 30 days prior to the grant date. Stock options are vested over a period of five years and those not exercised within the eighth year of the date of grant expire. Options cannot be exercised if the employee leaves the company before they are vested.

Stock options outstanding at 31 December 2018 are analyzed in the following table.

	Strike price outstanding (€) at 1.1.2018	Options outstanding during 2018	Options granted during 2018	Options exercised during 2018	Options cancelled or expired	Options outstanding at 31.12.2018
<b>Date of grant</b>						
9 February 2011	6.7505	171,500	-	(98,000)	-	73,500
8 May 2012	5.3070	566,500	-	(139,000)	-	427,500
17 April 2013	7.1600	37,500	-	(12,500)	-	25,000
30 October 2013	8.9300	65,000	-	(50,000)	-	15,000
29 July 2014	12.2900	2,991,000	-	(780,000)	(40,000)	2,171,000
13 April 2016	21.9300	3,523,000	-	(396,500)	(165,000)	2,961,500
3 August 2018	30.7300	-	4,818,000	-	-	4,818,000
<b>Total</b>		<b>7,354,500</b>	<b>4,818,000</b>	<b>(1,476,000)</b>	<b>(205,000)</b>	<b>10,491,500</b>

**Additional paid-in capital** – At 31 December 2018 additional paid-in capital is € 83.7 million, unchanged compared to the preceding year.

**Treasury stock** – At 31 December 2018, 5,153,571 shares are held as treasury stock, an increase of 4,290,309 shares compared to those held at 31 December 2017. The change is due to the sale of 1,476,000 shares, for an amount of € 20.2 million, to service the exercise of options granted to company employees under the stock option plans and to the purchase of 5,766,309 shares for an amount of € 169.8 million. The total cost incurred for the purchase of current treasury stock is € 145.6 million and the average purchase price per share is € 28.25.

**Hedging reserve** – In accordance with IFRS 9, the assets resulting from the measurement at market value of the cross currency swaps qualifying as cash flow hedges, the counterpart of the recognition in the income statement offsetting the valuation at year-end exchange rates of the covered foreign exchange loan, and the liabilities resulting from the measurement at market value of the interest rate swaps qualifying as cash flow hedges are recognized directly in equity as a hedging reserve. At 31 December 2018 this fair value measurement gives rise to a net liability, after-tax, of € 8.4 million.

**Other reserves** – These amount to € 43.1 million at 31 December 2018, an increase of € 2.4 million compared to those at 31 December 2017. Other reserves include the statutory reserve of the parent company in the amount of € 5.2 million, reserves for grants received for a total of € 15.5 million and reserves for amounts booked directly to equity in application of international accounting and reporting standards. The application of IFRS 2 and IAS 19 resulted in positive recordings of € 12.3 million and € 1.3 million respectively. The recognition of the gains associated with the investment in Puretech Health determined a positive after-tax effect of € 10.4 million while the recognition of the reduced value of the investment in Erytech Pharma determined an after-tax negative effect of € 1.6 million.

### Retained earnings and net income for the year

– These amount to € 898.0 million at 31 December 2018 and increase by € 75.8 million as compared to 31 December 2017. Net income for the year is € 312.4 million, an increase of 8.2% compared to the € 288.8 million 2017 net income. Retained earnings includes an amount of € 18.8 million generated by the first time application of the IFRS 15 at 1 January 2018 (see Note 2). The shareholders' equity of the Italian companies includes untaxed reserves of € 101.1 million, net of € 16.6 million withholding tax already paid, and their distribution is subject to taxation under fiscal law. In accordance with IAS 12 deferred taxes are not recognized on these reserves until their distribution is resolved.

**Interim dividend** – During the year the Board of Directors of Recordati S.p.A. resolved to distribute an interim dividend for 2018 of € 0.45 per share, for a total amount of € 91.8 million.

## 20. MINORITY INTEREST

All consolidated companies are 100% owned except for the Italian subsidiary of Orphan Europe which is 99% owned and the Tunisian company Opalia Pharma which is 90% owned. The latter has however been 100% consolidated by applying the anticipated acquisition method allowed by IAS 32. Consequently, the amount estimated for the acquisition of the remaining 10% (€ 3.3 million at 31 December 2018, up by € 0.7 million compared to the preceding year) was recognized as a liability since the transfer of this quota is covered by contractual agreements which provide for reciprocal put and call options between the parties which have a high probability of being exercised. Subsequent variations of this estimate will be recognized in a shareholders' equity reserve. This accounting method is not detrimental to the rights of the minority shareholders during the period until all capital shares are transferred.

## 21. LOANS

At 31 December 2018 medium and long-term loans total € 771.2 million. The net increase of € 107.1 million compared to 31 December 2017 was determined by the granting of new loans for an amount of € 153.9 million, reimbursements during the year of € 50.6 million and the effect of the conversion of loans in foreign currency which generated an increase of € 2.4 million. Furthermore, during the year the acquired company Natural Point S.r.l. was consolidated determining an effect of € 1.4 million relative to the liability associated with the financial lease on the building where the company has its headquarters.

The composition of medium and long-term loans at 31 December 2018 and 2017 is shown in the following table:

€ (thousands)	31.12.2018	31.12.2017
<b>Loans granted to Recordati S.p.A.:</b>		
Guaranteed senior notes issued by Recordati S.p.A. privately placed with international institutional investors in 2014 in two tranches: \$ 50 million at a fixed interest rate of 4.28% repayable semi-annually starting 2022 through 2026, transformed with cross currency swap into a € 37.3 million loan at a fixed interest rate of 2.895%, \$ 25 million at a fixed interest rate of 4.51% repayable semi-annually starting 2023 through 2029, transformed with cross currency swap into a € 18.7 million loan at a fixed interest rate of 3.15%.	*65,266	*62,272
Loan granted by Centrobanca, at variable interest rate covered by an interest rate swap, repayable in semi-annual installments starting 2012 through 2022	*27,186	*33,982
Loan granted by UniCredit, at variable interest rate partly covered by an interest rate swap, repayable in semi-annual installments starting 2015 through 2020	*14,893	*24,781
Loan granted by Banca Nazionale del Lavoro, at variable interest rate covered by an interest rate swap, repaid in 2018	-	*12,406
Loan granted by ING Bank, at variable interest rate covered by an interest rate swap, repayable in semi-annual installments starting 2016 through 2020	*11,220	*18,690
Loan granted by Banca Nazionale del Lavoro, at variable interest rate covered by an interest rate swap, repayable in semi-annual installments starting 2019 through 2020	*24,977	*24,963
Loan granted by Intesa Sanpaolo, at variable interest rate covered by an interest rate swap, repayable in semi-annual installments starting 2019 through 2021	*24,955	*24,940
Guaranteed senior notes issued by Recordati S.p.A. privately placed with international institutional investors in 2017 at a fixed interest rate of 2.07% repayable in annual installments starting 2025 through 2032	*124,888	*124,880
Loan granted by Mediobanca, at variable interest rate covered by an interest rate swap, repayable in annual installments starting 2018 through 2024	64,500	75,000
Loan granted by UbiBanca, at variable interest rate covered by an interest rate swap, repayable in 2022	*49,962	*49,952
Loan granted by Unicredit, at variable interest rate covered by an interest rate swap, repayable in 2021	*49,948	*49,930
Loan granted by Intesa Sanpaolo, at variable interest rate covered by an interest rate swap, repayable in semi-annual installments starting 2019 through 2025	*74,808	*74,780
Loan granted by Banca Passadore, at variable interest rate - 3 months' Euribor plus spread of 65 basis points - repayable in annual installments starting 2020 through 2022	*14,994	*14,993
Loan granted by Medio Credito Centrale, at a reduced interest rate of 0.5%, repayable in semi-annual installments starting 2019 through 2021	*4,268	-
Loan granted by Mediobanca, at variable interest rate covered by an interest rate swap, repayable in semi-annual installments starting 2020 through 2023	*149,337	-
<b>Loans granted to other Group companies:</b>		
Guaranteed senior notes issued by Recordati Rare Diseases Inc. (U.S.) privately placed with international institutional investors in 2013: \$ 40 million at a fixed interest rate of 4.55% due 2023 (10 year bullet)		
\$ 30 million at a fixed interest rate of 4.70% due 2025 (12 year bullet)	*60,776	*57,971
Loan granted by IFC-World Bank to Recordati İlaç for an amount of TRY 71.6 million, at variable interest rate, repayable in quarterly installments starting 2016 through 2022	*7,190	*12,223
Loan granted by ING Bank to Recordati İlaç for an amount of TRY 5.9 million, at a fixed interest rate of 13.25%, repaid in 2018	-	1,293
Financial leases granted to Opalia Pharma S.A. due within 2022	335	602
Various interest-free loans granted to Casen Recordati S.L. due within 2029	395	496
Loan granted to Opalia Recordati S. à R.L. due within 2021	12	18
Financial lease on Natural Point S.r.l. building, repayable within 2027	1,300	-
<b>Total amortized cost of loans</b>	<b>771,230</b>	<b>664,172</b>
Portion due within one year	130,583	51,710
Portion due after one year	640,647	612,462

\* Net of direct issue costs for a total of € 2.2 million, amortized using the effective interest method, mainly relative to the private placements by Recordati S.p.A. in 2014 and 2017 (€ 0.4 million) and by Recordati Rare Diseases Ltd (€ 0.4 million), and to the loans granted by UniCredit (€ 0.2 million), Intesa Sanpaolo (€ 0.2 million), IFC-World Bank (€ 0.2 million), Mediobanca (€ 0.7 million) and Centrobanca (€ 0.1 million),

At 31 December 2018, the repayment schedule of long-term debt due after 31 December 2019 is as follows:

€ (thousands)	
2020	87,533
2021	138,085
2022	134,680
2023	74,422
2024 and subsequent years	205,927
<b>Total</b>	<b>640,647</b>

The average effective interest rate at 31 December 2018, applying the rates resulting from the hedging instruments, is 1.90%.

In November the Parent stipulated a loan agreement with Mediobanca for an amount of € 150.0 million. The main terms and conditions provide for variable interest rate fixed at the six months' Euribor plus a spread of 130 basis points with semi-annual repayments of capital from 23 November 2020 through 22 November 2023. The loan is entirely covered with an interest rate swap, qualifying as a cash flow hedge, effectively converting the interest charges from variable to a fixed rate of 1.619%. The measurement at fair value at 31 December 2018 of the swap generated a liability of € 1.6 million which is recognized directly as a decrease in equity and stated as an increase of the 'Fair value of hedging derivatives (cash flow hedge)' under current liabilities (see Note 30). The loan agreement includes covenants which, if not met, could lead to a request for immediate repayment of the loan. The financial covenants are the following:

- the ratio of consolidated net debt to consolidated EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;
- the ratio of consolidated operating income to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions were amply fulfilled during the period.

In July the Parent received a loan of € 4.3 million to fund investments in research and development from the Banca del Mezzogiorno-Mediocredito Centrale, of which € 3.9 million at a reduced fixed interest rate of 0.50% to be repaid in six semi-annual installments starting 30 June 2019 through 31 December 2021, and € 0.4 million at a variable interest rate equal to the 6 months' Euribor plus a spread of 220 basis points, to be repaid in two installments on 30 June and 31 December 2021.

During the period two loans were fully repaid: the € 50,0 million loan received by the Parent company on 30 September 2013 from Banca Nazionale del Lavoro, with the payment of the last two installments for a total of € 12.5 million, and the loan received by subsidiary Recordati Ilac on 30 November 2015 from ING Bank, with the payment of the 5.9 million Turkish Lira bullet, equivalent to € 1.3 million.

The main other long-term loans outstanding are:

- a) A loan agreement with Banca Passadore undersigned by the Parent in November 2017 for an amount of € 15.0 million, disbursed net of up-front commissions of 0.05%. The main terms and conditions provide for variable interest rate fixed at the three months' Euribor plus a spread of 65 basis points with quarterly payments of interest and a duration of 5 years with annual repayments of capital from November 2020 through November 2022. The loan agreement includes covenants which, if not met, could lead to a request for immediate repayment of the loan. The financial covenants are the following:
- the ratio of consolidated net debt to consolidated EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;

- the ratio of consolidated operating income to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions were amply fulfilled during the period.

- b) A loan agreement with Intesa Sanpaolo undersigned by the Parent in October 2017 for an amount of € 75.0 million, disbursed net of up-front commissions of 0.30%. The main terms and conditions provide for variable interest rate fixed at the six months' Euribor plus a spread of 95 basis points, semi-annual payments of interest and a duration of 8 years with semi-annual repayments of capital from June 2019 through October 2025. The loan is entirely covered with an interest rate swap, qualifying as a cash flow hedge, effectively converting the interest charges from variable to a fixed rate of 1.305%. The measurement at fair value at 31 December 2018 of the swap generated a liability of € 0.5 million which is recognized directly as a decrease in equity and stated as an increase of the 'Fair value of hedging derivatives (cash flow hedge)' under current liabilities (see Note 30). The loan agreement includes covenants which, if not met, could lead to a request for immediate repayment of the loan. The financial covenants are the following:

- the ratio of consolidated net debt to consolidated EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;
- the ratio of consolidated operating income to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions were amply fulfilled during the period.

- c) A loan agreement with UniCredit undersigned by the Parent in September 2017 for an amount of € 50.0 million, disbursed net of up-front commissions of 0.15%. The main terms and conditions provide for variable interest rate fixed at the six months Euribor plus a spread of 55 basis points with semi-annual payments of interest and the repayment of capital on 29 September 2021. The loan is entirely covered with an interest rate swap, qualifying as a cash flow hedge, effectively converting the interest charges from variable to a fixed rate of 0.698%. The measurement at fair value at 31 December 2018 of the swap generated a liability of € 0.4 million which is recognized directly as a decrease in equity and stated as an increase of the 'Fair value of hedging derivatives (cash flow hedge)' under current liabilities (see Note 30). The loan agreement includes covenants which, if not met, could lead to a request for immediate repayment of the loan. The financial covenants are the following:

- the ratio of consolidated net debt to consolidated EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;
- the ratio of consolidated operating income to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions were amply fulfilled during the period.

- d) A loan agreement with UBI Banca undersigned by the Parent in September 2017 for an amount of € 50.0 million, disbursed net of up-front commissions of 0.10%. The main terms and conditions provide for variable interest rate fixed at the six months Euribor plus a spread of 50 basis points with semi-annual payments of interest and the repayment of capital on 7 September 2022. The loan is entirely covered with an interest rate swap, qualifying as a cash flow hedge, effectively converting the interest charges from variable to a fixed rate of 0.714%. The measurement at fair value at 31 December 2018 of the swap generated a liability of € 0.4 million which is recognized directly as a decrease in equity and stated as an increase of the 'Fair value of hedging derivatives (cash flow hedge)' under current liabilities (see Note 30). The loan agreement includes covenants which, if not met, could lead to a request for immediate repayment of the loan. The financial covenants are the following:

- the ratio of consolidated net debt to consolidated EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;

- the ratio of consolidated operating income to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions were amply fulfilled during the period.

- e) A loan agreement with Mediobanca undersigned by the Parent in July 2017 for an amount of € 75.0 million. The main terms and conditions provide for variable interest rate fixed at the six months Euribor plus a spread of 95 basis points and a duration of 7 years with annual repayments of capital from July 2018 through July 2024. The debt outstanding at 31 December 2018 is of € 64.5 million. The loan is entirely covered with an interest rate swap, qualifying as a cash flow hedge, effectively converting the interest charges from variable to a fixed rate of 1.29%. The measurement at fair value at 31 December 2018 of the swap generated a liability of € 0.7 million which is recognized directly as a decrease in equity and stated as an increase of the 'Fair value of hedging derivatives (cash flow hedge)' under current liabilities (see Note 30). The loan agreement includes covenants which, if not met, could lead to a request for immediate repayment of the loan. The financial covenants are the following:
- the ratio of consolidated net debt to consolidated EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;
  - the ratio of consolidated operating income to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions were amply fulfilled during the period.

- f) Privately placed guaranteed senior notes by the Parent in May 2017 for an overall amount of € 125.0 million at 2.07% fixed interest rate with repayment in annual instalments starting on 31 May 2025 through 31 May 2032. The note purchase agreement covering the notes includes covenants which, if not met, could lead to a request for immediate repayment of the loan. The financial covenants are the following:
- the ratio of consolidated net debt to consolidated EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;
  - the ratio of consolidated operating income to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions were amply fulfilled during the period.

- g) A loan agreement with Banca Nazionale del Lavoro undersigned by the Parent company in December 2016 for an amount of € 25.0 million, disbursed net of expenses and commissions of € 0.1 million. The main terms and conditions provide for variable interest rate fixed at the six months Euribor plus a spread of 40 basis points and a duration of 4 years with semi-annual repayments of capital from March 2019 through September 2020. The loan is entirely covered with an interest rate swap, qualifying as a cash flow hedge, effectively converting the interest charges from variable to a fixed rate of 0.41%. The measurement at fair value at 31 December 2018 of the swap generated a liability of € 0.1 million which is recognized directly as a decrease in equity and stated as an increase of the 'Fair value of hedging derivatives (cash flow hedge)' under current liabilities (see Note 30). The loan agreement includes covenants which, if not met, could lead to a request for immediate repayment of the loan. The financial covenants are the following:
- the ratio of consolidated net debt to consolidated EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;
  - the ratio of consolidated operating income to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions are amply fulfilled.

- h) A loan agreement with Intesa Sanpaolo undersigned by the Parent company in December 2016 for an amount of € 25.0 million, disbursed net of expenses and commissions of € 0.1 million.

The main terms and conditions provide for variable interest rate fixed at the six months Euribor plus a spread of 60 basis points and a duration of 5 years with semi-annual repayments of capital from June 2019 through December 2021. The loan is entirely covered with an interest rate swap, qualifying as a cash flow hedge, effectively converting the interest charges from variable to a fixed rate of 0.68%. The measurement at fair value at 31 December 2018 of the swap generated a liability of € 0.1 million which is recognized directly as a decrease in equity and stated as an increase of the 'Fair value of hedging derivatives (cash flow hedge)' under current liabilities (see Note 30). The loan agreement includes covenants which, if not met, could lead to a request for immediate repayment of the loan.

The financial covenants are:

- the ratio of consolidated net debt to EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;
- the ratio of consolidated operating income to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions are amply fulfilled.

- i) A loan agreement with UniCredit undersigned by the Parent company in May 2015 for an amount of € 50.0 million. The main terms and conditions provide for variable interest rate fixed at the six months Euribor plus a spread of 80 basis points and a duration of 5 years with semi-annual repayments of capital from November 2015 through May 2020. The debt outstanding at 31 December 2018 is of € 14.9 million. The loan is partly covered with an interest rate swap, qualifying as a cash flow hedge, effectively converting the interest charges on a portion of the debt from variable to a fixed rate of 1.734%. The measurement at fair value at 31 December 2018 of the swap covering € 8.3 million generated a liability of € 0.1 million which is recognized directly as a decrease in equity and stated as an increase of the 'Fair value of hedging derivatives (cash flow hedge)' under current liabilities (see Note 30). The loan agreement includes covenants which, if not met, could lead to a request for immediate repayment of the loan. The financial covenants are:
- the ratio of consolidated net debt to EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;
  - the ratio of consolidated operating income to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions are amply fulfilled.

- j) A loan agreement with ING Bank for an amount of € 30.0 million, originally undersigned by the Parent company on 8 January 2014, was re-negotiated on 12 June 2015 with only the interest rate being changed. Main terms are: variable interest rate equivalent to the six months' Euribor plus a spread of 85 basis points (as opposed to the 190 basis points in the previous agreement), and reimbursement of principal at the end of every six months starting July 2016 through January 2020. The debt outstanding at 31 December 2018 is of € 11.2 million. The loan was simultaneously covered with an interest rate swap qualifying as a cash flow hedge transforming the interest payable on the entire debt to a fixed interest rate of 1.913% following the above mentioned re-negotiation. The fair value measurement of the swap at 31 December 2018 generated a liability of € 0.2 million which is recognized directly as a decrease in equity and stated as an increase of the 'Fair value of hedging derivatives (cash flow hedge)' under current liabilities (see Note 30). The ING Bank loan agreement contains covenants which, if not met, could lead to a request for immediate repayment of the loan. The financial covenants are the following:
- the ratio of consolidated net debt to consolidated EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;
  - the ratio of consolidated operating income to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions are amply fulfilled.



k) A loan agreement with IFC-World Bank undersigned by the subsidiary Recordati Ilaç on 16 October 2014 for an amount of 71.6 million Turkish lira to finance the construction of a new production plant. Main terms are: variable interest rate equivalent to the three months' trlibor plus a spread of 162 basis points, 8-year duration and reimbursement of principal at the end of every three months starting November 2016 through August 2022. The value in euros of the outstanding loan at 31 December 2018 is of € 7.2 million, resulting in a reduction of the liability by € 5.0 million as compared to that at 31 December 2017, of which € 3.0 million was due to the devaluation of the Turkish lira and € 2.0 million to repayments during the period. The loan agreement includes covenants which, if not met, could lead to a request for immediate repayment of the loan.

The financial covenants are:

- the ratio of consolidated net debt to consolidated shareholders' equity must be less than 0.75;
- the ratio of consolidated net debt to consolidated EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;
- the ratio of consolidated operating income to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions were amply fulfilled.

l) Privately placed guaranteed senior notes by the Parent company on 30 September 2014 for an amount of \$ 75 million in two tranches: \$ 50 million at a fixed interest rate of 4,28% to be reimbursed bi-annually as from 30 March 2022 through 30 September 2026, and \$ 25 million at a fixed interest rate of 4.51% to be reimbursed bi-annually as from 30 March 2023 through 30 September 2029. The conversion of the loan into euros at 31 December 2018 resulted in an increase of the liability by € 3.0 million as compared to that at 31 December 2017 due to the revaluation of the U.S. dollar. The loan was simultaneously covered with two currency rate swaps transforming the overall debt to € 56.0 million, of which € 37.3 million at a fixed interest rate of 2.895% on the 12-year tranche and € 18.7 million at a fixed interest rate of 3.15% on the 15-year tranche. At 31 December 2018 the measurement at fair value of the hedging instruments generated an overall positive amount of € 6.4 million recognized directly to equity and stated as an increase of the 'Fair value of hedging derivatives (cash flow hedge)' under current assets (see Note 17).

The note purchase agreement covering the senior guaranteed notes issued by Recordati S.p.A. includes covenants which, if not met, could lead to a request for immediate repayment of the loan. The financial covenants are the following:

- the ratio of consolidated net debt to consolidated EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;
- the ratio of consolidated operating income to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions were amply fulfilled during the period.

m) Senior guaranteed notes issued by Recordati Rare Diseases Inc. privately placed with U.S. investors on 13 June 2013 to fund the acquisition of a portfolio of products for the treatment of rare and other diseases sold mainly in the United States of America. The loan comprises two series of notes for a total of \$ 70 million, of which \$ 40 million ten-year bullet and 4.55% coupon and \$ 30 million twelve-year bullet and 4.70% coupon. Following the acquisition of FIMEI S.p.A., the controlling shareholder of the Parent, by a consortium of investment funds controlled by CVC Capital Partners, in the fourth quarter of 2018, the notes will be redeemed in advance during the first quarter of 2019. The conversion of the loan into euros at 31 December 2018 resulted in an increase of the liability by € 2.8 million as compared to that at 31 December 2017 due to the revaluation of the U.S. dollar. The note purchase agreement covering the senior guaranteed notes issued by Recordati Rare Diseases Inc. includes covenants which, if not met, could lead to a request for immediate repayment of the loan.

The financial covenants are the following:

- the ratio of consolidated net debt to consolidated EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;
- the ratio of consolidated operating income to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions were amply fulfilled during the period.

n) A loan agreement with Centrobanca undersigned by the Parent company on 30 November 2010 to fund a three-year research and investment program. The loan, for which Centrobanca received funding from the European Investment Bank, amounts to € 75.0 million of which € 30.0 million were cashed in during 2010 and € 45.0 million in the first quarter of 2011, net of the € 0.3 million expenses. The main terms and conditions provide for a variable interest rate and a duration of 12 years with semi-annual repayments of capital from June 2012 through December 2022.

At 31 December 2018 the outstanding amount of the loan is € 27.2 million. During the month of June 2012 interest on the whole loan was covered with an interest rate swap qualifying as a cash flow hedge. The current interest rate on the loan is 2.575%. The measurement at fair value of the hedging instrument at 31 December 2018 generated a liability of € 1.0 million which is recognized directly as a decrease in equity and stated as an increase of the 'Fair value of hedging derivatives (cash flow hedge)' under current liabilities (see Note 30). The loan agreement includes covenants which, if not met, could lead to a request for immediate repayment of the loan. The financial covenants are the following:

- the ratio of consolidated net debt to consolidated net equity must be less than 0.75;
- the ratio of consolidated net debt to consolidated EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;
- the ratio of consolidated EBITDA to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions were amply fulfilled during the period.

## 22. STAFF LEAVING INDEMNITIES

This provision at 31 December 2018 and 2017 is € 19.5 million and € 21.1 million respectively and reflects the Group's obligation towards its employees determined in accordance with IAS 19.

The roll forward of this fund is as follows:

€ (thousands)	2018	2017
Balance at 1 January	21,093	21,675
Additions	1,899	965
Utilization	(2,106)	(1,698)
Change in reporting entities	114	0
Change in fair value	(1,453)	151
<b>Balance at 31 December</b>	<b>19,547</b>	<b>21,093</b>

The main part of this liability is to be attributed to the staff leaving indemnity fund (TFR, trattamento fine rapporto) in the Italian companies. The value of this fund as measured in accordance with IAS 19 amounts to € 11.1 million. The remaining part of this provision comprises employee benefit plans in the French subsidiary Laboratoires Bouchara Recordati (€ 4.0 million), in the U.S. subsidiary Recordati Rare Diseases (€ 1.6 million), in the German subsidiary Recordati Pharma (€ 1.2 million) and in the Orphan Europe group companies (€ 1.0 million). The fair value calculation made using actuarial parameters updated at 31 December 2018 determined a reduction of € 1.5 million compared to the value of the funds at 31 December 2017 which is recognized in the statement of comprehensive income, net of the tax effect, as prescribed by the relevant accounting principle.

## 23. DEFERRED TAX LIABILITIES

Deferred tax liabilities at 31 December 2018 are € 45.7 million, a net increase of € 28.1 million over the balance at 31 December 2017. The roll forward of this account is as follows:

€ (thousands)	2018	2017
Balance at 1 January	17,554	27,659
Additions	1,417	1,222
Utilization	(2,831)	(11,327)
Changes in reporting entities	29,513	0
<b>Balance at 31 December</b>	<b>45,653</b>	<b>17,554</b>

The net increase of € 28.1 million is almost entirely attributable to the change in reporting entities following the acquisition of the companies Natural Point S.r.l. and Tonipharm S.A.S.. Regarding Natural Point, an amount of € 17.1 million refer to deferred tax liabilities calculated on the € 61.2 million allocated to Magnesio Supremo®. Regarding Tonipharm an amount of € 12.3 million refer to deferred tax liabilities calculated on the total of € 38.5 million allocated to Ginkor® and Alodont®.

At 31 December 2018 no deferred tax liabilities were calculated on subsidiaries' undistributed earnings because no significant additional tax would have to be paid by the group in the event of these dividend distributions as they are essentially exempt from dual income taxation.

## 24. OTHER NON-CURRENT LIABILITIES

Other non-current liabilities as at 31 December 2018 are € 3.3 million which refer to the amount due for the acquisition of a further 10% of the share capital of Opalia Pharma which, based on the put and call options in place contractually, should occur not before 2020.

## 25. TRADE PAYABLES

Trade accounts payable, which are entirely of a commercial nature and include allocations for invoices to be received, at 31 December 2018 and 2017 amount to € 165.0 million and € 141.7 million respectively. Trade payables at 31 December 2018 reported by the companies acquired during the year total € 5.8 million.

## 26. OTHER PAYABLES

Other accounts payable at 31 December 2018 and 2017 amount to € 85.5 million and € 82.8 million respectively. Their composition is as follows:

€ (thousands)	31.12.2018	31.12.2017	Change 2018/2017
Personnel	27,336	28,924	(1,588)
Social security	14,953	14,756	197
Agents	716	746	(30)
Other	42,529	38,353	4,176
<b>Total other payables</b>	<b>85,534</b>	<b>82,779</b>	<b>2,755</b>

The line "Other" includes:

- € 6.6 million due by Recordati Rare Diseases Inc. to the U.S. healthcare insurance schemes;
- € 5.4 million to be paid to the "Krankenkassen" (German healthcare schemes) by Recordati Pharma GmbH;
- € 5.2 million which results from a mandatory discount of 1.83% on the retail selling price of reimbursed medicines and the contribution in substitution of a 5% price reduction on selected products to be paid by the Italian companies to the Italian regional healthcare systems.

## 27. TAX LIABILITIES

Tax liabilities at 31 December 2018 and 2017 amount to € 42.1 million and € 24.4 million respectively and include tax provisions computed by the companies on the basis of estimated taxable income, net of tax advances already paid, and withholding taxes payable. In early application of the interpretation IFRIC 23, also included is an accrual of around € 5 million, which results from the intention to apply the same criteria used by the Italian internal revenue service (Agenzia delle Entrate) for the settlement of the assessment with acceptance relative to the years 2009 to 2015 to the years 2016 and 2017 to be settled in 2019 (see Note 38).

## 28. OTHER CURRENT LIABILITIES

At 31 December 2018 other current liabilities amount to € 19.4 million, an increase of € 18.9 million as compared to those at 31 December 2017.

The increase is almost entirely attributable to the adoption of the new accounting principle IFRS 15 (see Note 2) of which the first time application on 1 January 2018 is worth € 22.9 million. The liability will be recognized in the income statement over the following years in variable installments based on the realization of the conditions for the revenue recognition.

## 29. PROVISIONS

Provisions in place at 31 December 2018 amount to € 21.4 million and include tax provisions and other provisions for future contingencies which are uncertain as to timing and value. The following tables contain their composition and changes.

€ (thousands)	31.12.2018	31.12.2017	Change 2018/2017
Tax	644	26,559	(25,915)
Other	20,802	21,763	(961)
<b>Total provisions</b>	<b>21,446</b>	<b>48,322</b>	<b>(26,876)</b>

€ (thousands)	2018	2017
Balance at 1 January	48,322	27,977
Additions	3,183	24,988
Utilization	(30,059)	(4,643)
<b>Balance at 31 December</b>	<b>21,446</b>	<b>48,322</b>

The reduction during the year are mainly related to the utilization of the tax provision accrued in preceding years following the agreement with the Italian internal revenue service (Agenzia delle Entrate) for the definition of the dispute related to the fiscal periods 2009 to 2015 (see Note 38).

Total provisions at year end are mainly comprised by those booked by the Parent and the other Italian companies (€ 11.3 million), by the Spanish company (€ 3.2 million), by the companies in France (€ 2.8 million) and in Germany (€ 1.8 million).

### 30. FAIR VALUE OF HEDGING DERIVATIVES

The interest rate swaps covering the cash flows related to medium and long-term loans measured at fair value at 31 December 2018 give rise to a € 5.1 million liability which represents the unrealized benefit of paying the current expected future rates instead of the rates agreed for the duration of the loans. The liability refers to the interest rate swaps covering the interest rate risk on loans granted by Centrobanca (€ 1.0 million), ING Bank (€ 0.2 million), Mediobanca (€ 0.7 million), UniCredit (€ 0.5 million), Banca Nazionale del Lavoro (€ 0.1 million), Intesa Sanpaolo (€ 0.6 million), UBI Banca (€ 0.4 million) and by Mediobanca on the loan granted in 2018 (€ 1.6 million).

In November 2016, following two loan agreements undersigned by the U.S. company Recordati Rare Diseases and the Parent for a nominal total of \$ 70 million, two cross currency swaps were provided by Unicredit which effectively convert the loan into a total of € 62.9 million, of which € 35.9 million at a fixed interest rate of 1.56% per year corresponding to the tranche expiring in 2023 and € 27.0 million at a fixed interest rate of 1.76% per year for the tranche expiring in 2025. At 31 December 2018 the fair value of the hedging instruments resulted in a liability of € 4.7 million, recognized directly in equity.

### 31. BANK OVERDRAFTS AND SHORT-TERM LOANS

Bank overdrafts and short-term loans at 31 December 2018 are € 16.9 million and comprise mainly, temporary use of lines of credit, overdrafts by foreign subsidiaries and by interest due on existing loans. At 31 December 2018, a total of 20 million Turkish Lira, for an equivalent amount of € 3.3 million, were drawn down on the revolving line of credit renewed in July 2017 by Recordati İlaç, the subsidiary in Turkey, for a maximum amount of 40 million Turkish Lira. This short-term financing instrument, which has 24 months' maximum duration, provides flexibility by combining the fact that it's non-revocable with the variability of the draw-downs based on specific financial needs. The agreement contains financial covenants in line with those already in place for other loans.

### 32. FAIR VALUE OF FINANCIAL INSTRUMENTS

As prescribed by IFRS 7 hereunder are stated the balance sheet values and fair values at 31 December 2018 of financial assets and liabilities:

€ (thousands)	Book value	Fair value
<b>Financial assets</b>		
Short-term financial investments, cash and cash equivalents	198,036	198,036
Trade receivables	245,742	245,742
Equity investments	20,773	20,773
Other receivables	38,462	38,462
Fair value of hedging derivatives (cash flow hedge)	6,414	6,414
<b>Financial liabilities</b>		
<b>Borrowings</b>		
- loans at variable interest rates	7,190	7,190
- loans at variable interest rates covered with interest rate swaps	511,048	511,048
- loans at fixed interest rates	126,950	128,946
- loans at fixed interest rates covered with cross currency swaps	126,042	117,759
Trade payables	165,020	165,020
Other payables	127,683	127,683
Fair value of hedging derivatives (cash flow hedge)	9,746	9,746
Bank overdrafts and short-term loans	16,905	16,905

### 33. DISCLOSURE OF FINANCIAL RISKS

The Group aims at achieving a balanced and prudent financial structure as a basic condition for funding internal and external growth, minimizing financing costs and maximizing yields. Speculative investments in equities, funds or financial assets which could impair the value of the company are forbidden. The only admitted financial investments are investments in risk free assets and/or funds issued by major financial institutions.

The Group monitors the financial risks to which it is exposed in order to take immediate mitigating actions, whenever necessary, in compliance with the applicable legislations and regulations. All companies belonging to the Group shall operate only with investment grade banks.

On the basis of the above and considering that the related effects would be not significant no sensitivity analysis has been performed.

As prescribed by IFRS 7 the main financial risks to which the Group is exposed are hereby disclosed.

**Credit Risk** – The Group closely controls its credit exposure through the allocation of credit limits to each single customer and an internal reporting system. At 31 December 2018 the credit exposure is not critical due to the large number of customers, their geographical distribution and the average amount of each account receivable. In particular, at 31 December 2018, total trade receivables of € 260.4 million include € 21.9 million of receivables overdue by more than 90 days.

Of these, € 6.7 million are receivables from public hospitals which, despite their very long payment times, do not represent a significant risk situation. An allowance for doubtful accounts of € 14.6 million, which is considered to be sufficient to cover potential losses on collection, is in place.

**Interest Rate Risk** – The Group raises funds using debt and invests excess cash in money market and other financial instruments. The fluctuation of market interest rates influences the cost and returns of the debt and investment instruments therefore affecting the Group's net financial charges. The Group's policy is to limit the risk arising from interest rate fluctuations by establishing fixed interest loans or variable interest loans covered by derivative financial instruments, which are used to hedge risk and are never of a speculative nature, to minimize such fluctuations, as described in Note 21. As a result of this policy and considering the current amount of net debt, it is believed that the change in current interest rates would not have a significant impact on net financial expenses.

**Foreign Currency Risk** – The Group is exposed to foreign currency exchange rate fluctuations which can affect its operating results and the value of its equity. All companies are subject to exchange rate fluctuations affecting trade and financial balances in currencies different from their own. In order to limit this risk, in some cases non speculative hedging instruments are negotiated.

As at 31 December 2018 positions in currencies different from the euro in companies in countries belonging to the European Monetary Union, not covered by hedging instruments, are the following:

net receivables of 1,112.6 million Russian Rubles;  
net receivables of 3.8 million U.S. Dollars;  
net receivables of 7.0 million Romanian Ron;  
net receivables of 41.3 million Czech Crowns;  
net receivables of 1.4 million Canadian Dollars;  
net receivables of 10.3 million Polish Zloty.

Among the companies in countries outside the European Monetary Union, at 31 December 2018 the main net exposure in currencies different from their own, and not covered by hedging instruments, is in Euros and is referred to the companies in the Czech Republic (net receivables of 2.0 million), Sweden (net receivables of 0.7 million), Canada (net payables of 0.8 million), Turkey (net payables of 8.1 million), Ukraine (net payables of 3.4 million) and Romania (net payables of 0.3 million).

For consolidation purposes the income statements and balance sheets of the group companies located outside the European Monetary Union are converted from their local currencies into Euros.

At 31 December 2018 the net equity values of these companies are denominated mainly in U.S. Dollars (184.8 million), in Pounds Sterling (16.4 million), in Swiss Francs (14.6 million), in Turkish Lira (322.4 million), in Czech Crowns (317.0 million), in Romanian Ron (31.2 million), in Russian Rubles (2,821.9 million), in Polish Zloty (12.3 million) and in Tunisian Dinars (43.2 million). The effect of exchange rate variations on the conversion of these values is recognized in the consolidated statement of comprehensive income and booked to the translation reserve in shareholders' equity which, at 31 December 2018, is negative by € 154.1 million.

**Liquidity Risk** – The liquidity risk to which the Group may be exposed is the inability to raise sufficient financial resources for its ongoing business and for the development of its industrial and commercial activities.

The two main factors which determine the Group's liquidity are, on the one hand, the cash generated or absorbed by operations and by investments, and on the other, the expiry and renewal terms of debt or the degree of liquidity of financial investments and market conditions.

At 31 December 2018 the Group has at its disposal a supply of liquidity readily available for its operations and plentiful lines of credit granted by a number of leading Italian and international financial institutions.

The terms and conditions of the Group's financial assets and its loans are set out in notes 18, 21 and 31 which address, respectively, short-term financial investments, cash and cash equivalents, loans and bank overdrafts.

The Group believes that the funds and credit lines currently available, in addition to those generated by operations and financing activities, are enough to satisfy investment needs, working capital requirements and the repayment of loans at their contractual due dates.

### 34. ACQUISITION OF COMPANIES

The Group acquired 100% of the share capital of Natural Point S.r.l. on 11 June 2018. The following table summarizes the effects of the first time consolidation of the acquired company.

€ (thousands)	Book value	Fair value adjustments	Fair value of assets and liabilities acquired
<b>Non-current assets</b>			
Property, plant and equipment	2,564	0	2,564
Intangible assets	0	61,200	61,200
<b>Current assets</b>			
Inventories	769	0	769
Trade receivables	3,865	0	3,865
Other receivables	7	0	7
Tax receivable	1	0	1
Other current assets	47	0	47
Short-term financial investments, cash and cash equivalents	8,971	0	8,971
<b>Non-current liabilities</b>			
Loans – due after one year	(1,248)	0	(1,248)
Staff leaving indemnities	(114)	0	(114)
Deferred tax liabilities	(118)	(17,075)	(17,193)
<b>Current liabilities</b>			
Trade payables	(1,329)	0	(1,329)
Other payables	(133)	0	(133)
Tax liabilities	(1,599)	0	(1,599)
Loans – portion due within one year	(103)	0	(103)
	<b>11,580</b>	<b>44,125</b>	<b>55,705</b>
Goodwill			27,892
<b>Cost of the acquisition</b>			<b>83,597</b>

An amount of € 61.2 million from the difference between the amount paid and the book value of the assets and liabilities acquired was allocated to Magnesio Supremo®, the company's main product consisting of a particular formulation of magnesium carbonate and citric acid that has the characteristic of being easily assimilated into the body. The remainder of the cost of the acquisition for an amount of € 27.9 million, after having calculated the taxes of € 17.1 million on the added value allocated to intangible assets in the amount, was allocated to goodwill. The allocation of the cost of the acquisition is however not yet definite, as allowed by IFRS 3, in view of the limited period of time elapsed and the need to obtain further information.

The Group acquired 100% of the share capital of Tonipharm S.A.S. on 31 December 2018. The following table summarizes the effects of the first time consolidation of the acquired company.

€ (thousands)	Book value	Fair value adjustments	Fair value of assets and liabilities acquired
<b>Non-current assets</b>			
Property, plant and equipment	40	0	40
Intangible assets	11,823	38,500	50,323
Non-current receivables	125	0	125
Deferred tax assets	800	0	800
<b>Current assets</b>			
Inventories	5,283	0	5,283
Trade receivables	3,262	0	3,262
Other receivables	32	0	32
Tax receivable	555	0	555
Other current assets	77	0	77
Short-term financial investments, cash and cash equivalents	90	0	90
<b>Non-current liabilities</b>			
Deferred tax liabilities	0	(12,320)	(12,320)
<b>Current liabilities</b>			
Trade payables	(4,493)	0	(4,493)
Other payables	(176)	0	(176)
Tax liabilities	(887)	0	(887)
Bank overdrafts and short-term loans	(261)	0	(261)
	<b>16,270</b>	<b>26,180</b>	<b>42,450</b>
Goodwill			30,186
<b>Cost of the acquisition</b>			<b>72,636</b>

An amount of € 38.5 million from the difference between the amount paid and the book value of the assets and liabilities acquired was allocated to the products Ginkor® and Alodont®, € 36.0 million to the first and € 2.5 million to the second. The remainder of the cost of the acquisition in the amount of € 30.2 million, after having calculated taxes of € 12.3 million on the added value allocated to intangible assets, was allocated to goodwill. The allocation of the cost of the acquisition is however not yet definite, as allowed by IFRS 3, in view of the limited period of time elapsed and the need to obtain further information.

### 35. OPERATING SEGMENTS

The financial information reported by line of business and by geographical area, in compliance with IFRS 8 – Operating segments, is prepared using the same accounting principles and reporting standards used for the preparation and disclosure of the Group consolidated financial statements.

Based on the characteristics of their business, operational and strategic models two main business segments can be identified, the specialty and primary care segment and the segment dedicated to treatments for rare diseases.

The identification took into account the different management and marketing strategies applied to the products belonging to the two segments. As a consequence, well identified and separate business models and organizational structures were developed. All economic and financial data derive from precise accounting and do not discount allocation criteria.

The geographical footprint of the Group's specialty and primary care business is focused mainly on Europe. The Group operates in the main European markets, including Central and Eastern Europe, Russia and the other C.I.S. countries, Ukraine, Turkey and Tunisia, where it has established its own subsidiaries. In the rest of the world sales of specialty and primary care products are carried out mainly through licensing agreements with pharmaceutical companies of high standing. The Group has gradually extended its international presence through the acquisition of existing marketing organizations with the aim to add our proprietary products, and those obtained under multi-territorial licenses, to the local portfolios.

The Group's segment dedicated to treatments for rare diseases is a worldwide business. The Group operates through its dedicated subsidiaries Orphan Europe and Recordati Rare Diseases who share the conviction that each person with a rare disease has the right to the best possible treatment. Our organizations work closely with specialists, healthcare professionals, patients' families and patient groups to spread knowledge, improve diagnosis and treatment, enable access to treatment by supporting patients and their needs.

The Group operates directly in Europe, the Middle East, Africa, the U.S.A. and Canada through its subsidiaries and highly qualified distributors. Furthermore, the Group has consolidated its presence in Latin American countries in some of which such as in Mexico, Brazil and Colombia, it operates through its own subsidiaries. In Russia Recordati's organization guarantees access to treatments to patients living in the more remote areas of the country. In 2017 a representative office was opened in Malaysia with the intention of extending operations to the Asia-Pacific regions and in 2018 Recordati Rare Diseases subsidiaries were established in Japan and in Australia.

The following table shows financial information for these two business segments as at 31 December 2018 and includes comparative data.

€ (thousands)	Specialty & primary care segment*	Orphan drugs segment	Non-allocated	Consolidated accounts
<b>2018</b>				
Revenues	1,137,403	214,832	-	1,352,235
Expenses	(798,465)	(111,551)	-	(910,016)
<b>Operating income</b>	<b>338,938</b>	<b>103,281</b>	-	<b>442,219</b>
EBITDA <sup>(1)</sup>	390,571	108,508	-	499,079
<b>2017</b>				
Revenues	1,076,882	211,241	-	1,288,123
Expenses	(768,256)	(113,375)	-	(881,631)
<b>Operating income</b>	<b>308,626</b>	<b>97,866</b>	-	<b>406,492</b>
EBITDA <sup>(1)</sup>	350,247	104,414	-	454,661

\* Includes the pharmaceutical chemicals operations

<sup>(1)</sup> Operating income before depreciation, amortization and write down of both tangible and intangible assets.

€ (thousands)	Specialty & primary care segment*	Rare diseases segment	Non-allocated**	Consolidated accounts
<b>31 December 2018</b>				
Non-current assets	1,216,263	226,466	20,772	1,463,501
Inventories	188,988	17,096	-	206,084
Trade receivables	206,389	39,353	-	245,742
Other current assets	38,371	5,284	6,414	50,069
Short-term investments, cash and cash equivalents	-	-	198,036	198,036
<b>Total assets</b>	<b>1,650,011</b>	<b>288,199</b>	<b>225,222</b>	<b>2,163,432</b>
Non-current liabilities	65,805	2,652	640,647	709,104
Current liabilities	264,813	68,694	157,235	490,742
<b>Total liabilities</b>	<b>330,618</b>	<b>71,346</b>	<b>797,882</b>	<b>1,199,846</b>
<b>Net capital employed</b>	<b>1,319,393</b>	<b>216,853</b>		
<b>31 December 2017</b>				
Non-current assets	1,075,356	183,195	24,171	1,282,722
Inventories	161,561	17,539	-	179,100
Trade receivables	210,114	34,003	-	244,117
Other current assets	32,343	12,223	3,825	48,391
Short-term investments, cash and cash equivalents	-	-	302,077	302,077
<b>Total assets</b>	<b>1,479,374</b>	<b>246,960</b>	<b>330,073</b>	<b>2,056,407</b>
Non-current liabilities	37,591	2,546	613,487	653,624
Current liabilities	262,572	35,128	77,846	375,546
<b>Total liabilities</b>	<b>300,163</b>	<b>37,674</b>	<b>691,333</b>	<b>1,029,170</b>
<b>Net capital employed</b>	<b>1,179,211</b>	<b>209,286</b>		

\* Includes the pharmaceutical chemicals operations.

\*\* Non-allocated amounts include: other equity investments, short-term investments, cash and cash equivalents, loans, hedging instruments, bank overdrafts and short-term loans.

The pharmaceutical chemicals operations are considered part of the specialty and primary care segment as they are prevalently dedicated to the production of active ingredients for this business, both from a strategic and organizational point of view.

The following table presents net revenues by geographic area:

€ (thousands)	2018	2017	Change 2018/2017
Europe	1,101,925	1,032,806	69,119
of which Italy	273,197	258,551	14,646
Australasia	62,295	61,538	757
America	136,751	142,933	(6,182)
Africa	51,264	50,846	418
<b>Total revenue</b>	<b>1,352,235</b>	<b>1,288,123</b>	<b>64,112</b>

The Group's production facilities are located almost exclusively in Europe and therefore non-current assets and Group investments are located for the most part in this area.

## 36. NET FINANCIAL POSITION

The following table summarizes the Company's net financial position:

€ (thousands)	2018	2017	Change 2018/2017
Deposits in bank current accounts and cash on hand	172,421	273,343	(100,922)
Short-term time deposits	25,615	28,734	(3,119)
<b>Liquid assets</b>	<b>198,036</b>	<b>302,077</b>	<b>(104,041)</b>
Bank overdrafts and short-term loans	(16,905)	(16,577)	(328)
Loans - due within one year	(69,807)	(51,710)	(18,097)
Loan notes issued <sup>(1)</sup>	(65,471)	-	(65,471)
<b>Short term borrowings</b>	<b>(152,183)</b>	<b>(68,287)</b>	<b>(83,896)</b>
<b>Net current financial position</b>	<b>45,853</b>	<b>233,790</b>	<b>(187,937)</b>
Loans - due after one year	(450,493)	(367,340)	(83,153)
Loan notes issued <sup>(1)</sup>	(183,740)	(248,230)	64,490
<b>Non-current loans</b>	<b>(634,233)</b>	<b>(615,570)</b>	<b>(18,663)</b>
<b>Net financial position</b>	<b>(588,380)</b>	<b>(381,780)</b>	<b>(206,600)</b>

(1) Includes change in fair value of the relative currency risk hedging instruments (cash flow hedge).

## 37. RECONCILIATION BETWEEN THE PARENT COMPANY'S SHAREHOLDERS' EQUITY AND NET INCOME AND GROUP CONSOLIDATED SHAREHOLDERS' EQUITY AND NET INCOME

The reconciliation between the parent company's shareholders' equity and net income and the Group consolidated shareholders' equity and net income is as follows:

€ (thousands)	Shareholders' equity		Net income for the year	
	31.12.2018	31.12.2017	2018	2017
Recordati S.p.A.	336,058	444,499	217,330	212,506
Consolidation adjustments:				
Margin in inventories	(58,411)	(35,050)	(23,361)	(7,336)
Related deferred tax	16,296	9,719	6,577	2,014
Other adjustments	(10,802)	(8,217)	(2,463)	(1,946)
Retained earnings of consolidated subsidiaries at beginning of the year, net of amounts already booked by Recordati S.p.A.	591,143	496,569	-	-
Net income for the year of consolidated subsidiaries, net of amounts already booked by Recordati S.p.A.	243,255	243,574	243,255	243,574
Dividends received from consolidated subsidiaries	-	-	(135,162)	(160,050)
Write-down of holdings in controlled companies	-	-	6,200	-
Translation adjustments	(154,146)	(124,004)	-	-
<b>Consolidated financial statements</b>	<b>963,393</b>	<b>1,027,090</b>	<b>312,376</b>	<b>288,762</b>

### 38. LITIGATION AND CONTINGENT LIABILITIES

In December 2015, the Italian Tax Police (Guardia di Finanza) notified the Company of their intention to commence a general income tax inspection covering the years 2009 through 2014 involving the Group companies which reside in Ireland and in Luxembourg, Recordati Ireland Ltd and Recordati S.A. Chemical and Pharmaceutical Company respectively. The declared intention of the inspection is to evaluate the operational context of the foreign companies in order to verify whether said companies are in reality only formally localized abroad but are substantially managed/administered from Italy. On 28th February 2017 the Italian Tax Police (Guardia di Finanza) prescribed the extension of the income tax inspection to include the year 2015. After having analysed the documents and completed the investigation process, the Italian Tax Police finally revealed to Recordati Ireland Ltd., on 6th September 2017, their reasons for considering the Irish company subject to tax in Italy for corporate tax purposes in the reference period, resulting in an assessment of taxes allegedly owed to Italy, in the amount of € 109,4 million, against taxes of € 51,8 million already paid in Ireland. Similarly, the Italian Tax Police finally revealed to Recordati S.A. Chemical and Pharmaceutical Company, on 6th September 2017, their reasons for considering the Luxembourg company subject to tax in Italy for corporate tax purposes in the reference period, resulting in an assessment of taxes allegedly owed to Italy, in the amount of € 7.2 million. Recordati Ireland Ltd. and Recordati S.p.A. (as acquiring company by way of merger of Recordati S.A. Chemical & Pharmaceutical Company) filed their comments and observations on the findings reported in the above mentioned Tax Audits Reports within the legal deadlines.

During 2018, the Lombardy Regional Directorate of the Italian Revenue Agency, in charge of Recordati SpA, reviewed the claims raised in the aforementioned audit report and carried out an in-depth analysis on the relations between Recordati SpA and the Irish subsidiary in the tax periods from 2009 to 2015. Following that analysis, the Agency concluded - confirming the soundness of the Company's thesis - that, in the tax periods from 2009 to 2015, the Irish company cannot be deemed a fictitious foreign resident company. However, according to the Agency, part of the profit made by the Irish subsidiary in the aforementioned financial years was attributable to Recordati S.p.A, due to an alleged "management support" provided by the Italian parent company to the Irish subsidiary.

Based on those assumptions, the Agency has made a proposal of tax settlement for Ires and Irap purposes with respect to the tax years from 2009 to 2015, wherein it required the payment of further taxes equal to a total of € 21.0 million, over € 4.9 million of interest and € 2.5 million for penalties, which Recordati S.p.A. accepted, with a view to avoid litigation. The Company will apply the same criteria to the subsequent years, from 2016 to 2017, with the intention to settle the tax claim in 2019 for which the related provision has been recognized in the income statement for an amount of around € 5 million. During 2018 the same criteria defined by the Agency for the preceding years was applied and set out in a Commercial and Management Service Agreement. Following the audit report drawn up by the Tax Police for the periods from 2009 to 2015 with respect to Recordati S.A. Chemical & Pharmaceutical Company, wound-up and cancelled from the Luxembourg commercial register on 21 June 2017 as a result of the merger into Recordati S.p.A, the Provincial Directorate II of Milan - Audit Office made a proposal of tax settlement related to the aforementioned tax periods, containing a tax claim equal to € 4.6 million, over € 1.1 million of interest and € 1.9 million for penalties. Recordati S.p.A. has accepted that proposal in light of the substantial reduction of the taxable income previously claimed and with a view to avoid litigation. The amounts subject to tax settlement are almost entirely attributable to the taxation of the dividends received by the Luxembourg company and always paid in full to the parent company Recordati S.p.A., and therefore already subject to the Italian taxation.

### 39. RELATED PARTY TRANSACTIONS

Tax liabilities shown in the consolidated balance sheet at 31 December 2018 include those payable to the controlling company FIMEI S.p.A. for an amount of € 7.9 million. This amount refers to tax liabilities computed by the parent Recordati S.p.A. based on estimated taxable income and transferred to the controlling company consequent to the participation in a tax consolidation grouping under tax laws in Italy.

In compliance with the information required by article 38 of legislative decree 127/91, it is hereby specified that the overall compensation of the Directors and Statutory Auditors of the Parent for the performance of their functions, including those in other Group companies, during 2018 amount to € 0.6 million and € 0.1 million respectively.

Except for the above, to our knowledge, no transactions or contracts have been entered into with related parties that can be considered significant, in value or conditions, or which could in any way materially affect the accounts.



## 40. SUBSEQUENT EVENTS

On 6 December 2018, as a result of the transfer by the shareholders of FIMEI S.p.A. (controller of Recordati S.p.A.) of the total ownership in FIMEI S.p.A. itself to Rossini Investimenti S.p.A., company designated by a consortium of investment funds controlled by CVC Capital Partners VII, the legal requirements were met for the promotion by Rossini Investimenti S.p.A. of a mandatory takeover bid, pursuant to and for the purposes of articles 102 and 106, paragraph 1-bis, of the TUF concerning a maximum of 97,735,180 ordinary shares of Recordati S.p.A., representing 46.735% of the share capital of the company, excluded the 5,172,571 Issuer's treasury shares, equal to 2.473%, and included a maximum of 2,091,500 ordinary shares in the event that all stock options deriving from the existing Stock Option Plans are exercised.

On 21 December 2018, the Mandatory Takeover Bid was authorised by Consob and on 2 January 2019 the subscription period began. On 1 February 2019, the subscription period for the Mandatory Takeover Bid was completed: 59,816 ordinary shares of Recordati S.p.A. were subscribed, equal to 0.061% of the shares that were object of the Bid and, therefore, equal to approximately 0.029% of the Company's share capital. Therefore, on 8 February 2019, the date of payment of the transfer price owed to the holders of the subscribed shares and the contemporaneous transfer of these shares to the bidder, the shareholding held by FIMEI S.p.A. (as the actual buyer designated in the Bid) in Recordati S.p.A. was equal to 51.820% of the share capital. In consideration of the final results of the Mandatory Takeover Bid, the conditions for the exercise of the Commitment and the Right to Squeeze-out pursuant to article 108, paragraphs 1 and 2, and article 111 of the TUF were not met.

Except for the above, no significant events occurred subsequent to 31 December 2018.

## RECORDATI S.P.A. AND SUBSIDIARIES

### SUBSIDIARIES INCLUDED IN THE CONSOLIDATED ACCOUNTS AT 31 DECEMBER 2018

#### ATTACHMENT 1.

Consolidated Companies	Head Office	Share Capital	Currency	Consolidation Method
<b>RECORDATI S.P.A.</b> Development, production, marketing and sales of pharmaceuticals and pharmaceutical chemicals	Italy	26,140,644.50	EUR	Line-by-line
<b>INNOVA PHARMA S.P.A.</b> Marketing and sales of pharmaceuticals	Italy	1,920,000.00	EUR	Line-by-line
<b>CASEN RECORDATI S.L.</b> Development, production, marketing and sales of pharmaceuticals	Spain	238,966,000.00	EUR	Line-by-line
<b>BOUCHARA RECORDATI S.A.S.</b> Development, production, marketing and sales of pharmaceuticals	France	4,600,000.00	EUR	Line-by-line
<b>RECORDATI RARE DISEASES COMERCIO DE MEDICAMENTOS LTDA</b> Dormant, holds pharmaceutical marketing rights in Brazil	Brazil	166.00	BRL	Line-by-line
<b>RECORDATI RARE DISEASES INC.</b> Development, production, marketing and sales of pharmaceuticals	U.S.A.	11,979,138.00	USD	Line-by-line
<b>RECORDATI IRELAND LTD</b> Development, production, marketing and sales of pharmaceuticals	Ireland	200,000.00	EUR	Line-by-line
<b>LABORATOIRES BOUCHARA RECORDATI S.A.S.</b> Development, production, marketing and sales of pharmaceuticals	France	14,000,000.00	EUR	Line-by-line
<b>RECORDATI PHARMA GmbH</b> Marketing and sales of pharmaceuticals	Germany	600,000.00	EUR	Line-by-line
<b>RECORDATI PHARMACEUTICALS LTD</b> Marketing and sales of pharmaceuticals	United Kingdom	15,000,000.00	GBP	Line-by-line
<b>RECORDATI HELLAS PHARMACEUTICALS S.A.</b> Marketing and sales of pharmaceuticals	Greece	10,050,000.00	EUR	Line-by-line
<b>JABA RECORDATI S.A.</b> Marketing and sales of pharmaceuticals	Portugal	2,000,000.00	EUR	Line-by-line
<b>JABAFARMA PRODUTOS FARMACÊUTICOS S.A.</b> Marketing of pharmaceuticals	Portugal	50,000.00	EUR	Line-by-line
<b>BONAFARMA PRODUTOS FARMACÊUTICOS S.A.</b> Marketing of pharmaceuticals	Portugal	50,000.00	EUR	Line-by-line
<b>RECORDATI ORPHAN DRUGS S.A.S.</b> Holding company	France	57,000,000.00	EUR	Line-by-line
<b>ORPHAN EUROPE SWITZERLAND GmbH</b> Marketing and sales of pharmaceuticals	Switzerland	20,000.00	CHF	Line-by-line
<b>ORPHAN EUROPE MIDDLE EAST FZ LLC</b> Marketing and sales of pharmaceuticals	United Arab Emirates	100,000.00	AED	Line-by-line
<b>RECORDATI AB</b> Marketing and sales of pharmaceuticals	Sweden	100,000.00	SEK	Line-by-line
<b>ORPHAN EUROPE S.à.R.L.</b> Development, production, marketing and sales of pharmaceuticals	France	320,000.00	EUR	Line-by-line
<b>ORPHAN EUROPE UNITED KINGDOM LTD</b> Marketing and sales of pharmaceuticals	United Kingdom	50,000.00	GBP	Line-by-line
<b>ORPHAN EUROPE GERMANY GmbH</b> Marketing and sales of pharmaceuticals	Germany	25,600.00	EUR	Line-by-line
<b>ORPHAN EUROPE SPAIN S.L.</b> Marketing and sales of pharmaceuticals	Spain	1,775,065.49	EUR	Line-by-line
<b>ORPHAN EUROPE ITALY S.R.L.</b> Marketing and sales of pharmaceuticals	Italy	40,000.00	EUR	Line-by-line
<b>RECORDATI BVBA</b> Marketing and sales of pharmaceuticals	Belgium	18,600.00	EUR	Line-by-line

Consolidated Companies	Head Office	Share Capital	Currency	Consolidation Method
FIC MEDICAL S.à.R.L. Marketing of pharmaceuticals	France	173,700.00	EUR	Line-by-line
HERBACOS RECORDATI s.r.o. Development, production, marketing and sales of pharmaceuticals	Czech Republic	25,600,000.00	CZK	Line-by-line
RECORDATI SK s.r.o. Marketing of pharmaceuticals	Slovakia	33,193.92	EUR	Line-by-line
RUSFIC LLC Marketing and sales of pharmaceuticals	Russian Federation	3,560,000.00	RUB	Line-by-line
RECOFARMA İLAÇ Ve Hammaddeleri Sanayi Ve Ticaret L.Ş. Marketing of pharmaceuticals	Turkey	10,000.00	TRY	Line-by-line
RECORDATI ROMÂNIA S.R.L. Marketing and sales of pharmaceuticals	Romania	5,000,000.00	RON	Line-by-line
RECORDATI İLAÇ Sanayi Ve Ticaret A.Ş. Development, production, marketing and sales of pharmaceuticals	Turkey	180,000,000.00	TRY	Line-by-line
RECORDATI-POLSKA Sp. z o.o. Marketing and sales of pharmaceuticals	Poland	4,500,000.00	PLN	Line-by-line
ACCENT LLC Holds pharmaceutical marketing rights	Russian Federation	20,000.00	RUB	Line-by-line
RECORDATI UKRAINE LLC Marketing and sales of pharmaceuticals	Ukraine	1,031,896.30	UAH	Line-by-line
CASEN RECORDATI PORTUGAL Unipessoal Lda Marketing and sales of pharmaceuticals	Portugal	100,000.00	EUR	Line-by-line
OPALIA PHARMA S.A. Development, production, marketing and sales of pharmaceuticals	Tunisia	9,656,000.00	TND	Line-by-line
OPALIA RECORDATI S.A.R.L. Marketing of pharmaceuticals	Tunisia	20,000.00	TND	Line-by-line
RECORDATI RARE DISEASES S.A. DE C.V. Marketing and sales of pharmaceuticals	Mexico	16,250,000.00	MXN	Line-by-line
RECORDATI RARE DISEASES COLOMBIA S.A.S. Marketing and sales of pharmaceuticals	Colombia	150,000,000.00	COP	Line-by-line
ITALCHIMICI S.p.A. <sup>(1)</sup> Marketing and sales of pharmaceuticals	Italy	7,646,000.00	EUR	Line-by-line
RECORDATI AG Marketing and sales of pharmaceuticals	Switzerland	3,000,000.00	CHF	Line-by-line
PRO FARMA GmbH Marketing and sales of pharmaceuticals	Austria	35,000.00	EUR	Line-by-line
RECORDATI RARE DISEASES CANADA Inc. <sup>(1)</sup> Marketing and sales of pharmaceuticals	Canada	350,000.00	CAD	Line-by-line
RECORDATI RARE DISEASES JAPAN K.K. <sup>(2)</sup> Marketing of pharmaceuticals	Japan	10,000,000.00	JPY	Line-by-line
NATURAL POINT S.r.l. <sup>(3)</sup> Marketing of pharmaceuticals	Italy	10,400.00	EUR	Line-by-line
RECORDATI RARE DISEASES AUSTRALIA Pty Ltd <sup>(2)</sup> Marketing of pharmaceuticals	Australia	200,000.00	AUD	Line-by-line
TONIPHARM S.A.S. <sup>(3)</sup> Marketing of pharmaceuticals	France	257,700.00	EUR	Line-by-line

(1) Established in 2017

(2) Established in 2018

(3) Acquired in 2018



Consolidated companies	PERCENTAGE OF OWNERSHIP										
	Recordati S.p.A. (Parent)	Recordati Pharma GmbH	Bouchara Recordati S.A.S.	Casen Recordati S.L.	Recordati Orphan Drugs S.A.S.	Orphan Europe S.A.R.L.	Herbacos Recordati s.r.o.	Recordati İlaç A.Ş.	Opalia Pharma S.A.	Pro Farma AG	Total
HERBACOS RECORDATI s.r.o.	100.00										100.00
RECORDATI SK s.r.o.							100.00				100.00
RUSFIC LLC			100.00								100.00
RECOFARMA İLAÇ Ve Hammaddeleri Sanayi Ve Ticaret L.Ş.								100.00			100.00
RECORDATI ROMÂNIA S.R.L.	100.00										100.00
RECORDATI İLAÇ Sanayi Ve Ticaret A.Ş.				100.00							100.00
RECORDATI POLSKA Sp. z o.o	100.00										100.00
ACCENT LLC	100.00										100.00
RECORDATI UKRAINE LLC	0.01		99.99								100.00
CASEN RECORDATI PORTUGAL Unipessoal Lda				100.00							100.00
OPALIA PHARMA S.A.	90.00										90.00
OPALIA RECORDATI S.à R.L.			1.00					99.00			100.00
RECORDATI RARE DISEASES S.A. DE C.V.	99.998					0.002					100.00
RECORDATI RARE DISEASES COLOMBIA S.A.S.				100.00							100.00
ITALCHIMICI S.p.A.	100.00										100.00
RECORDATI AG	100.00										100.00
PRO FARMA GmbH									100.00		100.00
RECORDATI RARE DISEASES CANADA Inc <sup>(1)</sup>	100.00										100.00
RECORDATI RARE DISEASES JAPAN K.K. <sup>(2)</sup>						100.00					100.00
NATURAL POINT S.r.l. <sup>(3)</sup>	100.00										100.00
RECORDATI RARE DISEASES AUSTRALIA Pty Ltd <sup>(2)</sup>						100.00					100.00
TONIPHARM S.A.S. <sup>(3)</sup>	100.00										100.00

(1) Established in 2017

(2) Established in 2018

(3) Acquired in 2018

**RECORDATI S.P.A. AND SUBSIDIARIES**  
**DISCLOSURE OF AUDITORS' FEES FOR ACCOUNTING AUDITS AND OTHER SERVICES**

**ATTACHMENT 2.**

Type of service	Provider of the service	Recipient	Fees Amounts in €
Accounting audit	Auditor of Parent Company	Parent Company	130,200
Accounting audit	Auditor of Parent Company	Subsidiaries	58,100
Accounting audit	Network of auditor of Parent Company	Subsidiaries	600,904
Due diligence	Auditor of Parent Company	Parent Company	223,000
Tax compliance	Network of auditor of Parent Company	Subsidiaries	4,913
Signature on returns and attestations	Auditor of Parent Company	Parent Company	44,000
Signature on returns and attestations	Network of auditor of Parent Company	Subsidiaries	22,416
Other services	Auditor of Parent Company	Parent Company	30,000
Other services	Network of auditor of Parent Company	Subsidiaries	935

## RECORDATI S.P.A. AND SUBSIDIARIES

# ATTESTATION IN RESPECT OF THE CONSOLIDATED FINANCIAL STATEMENTS UNDER ARTICLE 154-BIS OF LEGISLATIVE DECREE 58/98

1. The undersigned, Andrea Recordati, in his capacity as the Chief Executive Officer of the Company, and Fritz Squindo, as the Manager responsible for the preparation of the Company's financial statements, pursuant to the provisions of Article 154-bis, clauses 3 and 4, of Legislative Decree no. 58 of 1998, hereby attest:

- the adequacy with respect to the Company structure,
- and the effective application,

of the administrative and accounting procedures applied in the preparation of the Company's consolidated financial statements at and for the year ended 31 December 2018.

2. The undersigned moreover attest that:

2.1 The consolidated financial statements at 31 December 2018:

- have been prepared in accordance with the International Financial Reporting Standards, as endorsed by the European Union through Regulation (EC) 1606/2002 of the European Parliament and Council, dated 19 July 2002;
- correspond to the amounts shown in the Company's accounts, books and records; and
- provide a fair and correct representation of the financial conditions, results of operations and cash flows of the Company and its consolidated subsidiaries.

2.2 The report on operations includes a reliable operating and financial review of the Company and of the Group as well as a description of the main risks and uncertainties to which they are exposed.

Milan, 28 February 2019

Signed by  
Andrea Recordati  
Chief Executive Officer

Signed by  
Fritz Squindo  
Manager responsible for preparing  
the company's financial reports





# AUDITORS' REPORT



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 Telefono +39 02 6763.1  
 Email it-fmauditaly@kpmg.it  
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(Translation from the Italian original which remains the definitive version)

## Independent auditors' report pursuant to article 14 of Legislative decree no. 39 of 27 January 2010 and article 10 of Regulation (EU) no. 537 of 16 April 2014

To the shareholders of  
 Recordati Industria Chimica e Farmaceutica S.p.A.

### Report on the audit of the consolidated financial statements

#### Opinion

We have audited the consolidated financial statements of the Recordati Group (the "group"), which comprise the statement of financial position as at 31 December 2018, the income statement and the statements of other comprehensive income, changes in equity and cash flows for the year then ended and notes thereto, which include a summary of the significant accounting policies.

In our opinion, the consolidated financial statements give a true and fair view of the financial position of the Recordati Group as at 31 December 2018 and of its financial performance and cash flows for the year then ended in accordance with the International Financial Reporting Standards endorsed by the European Union and the Italian regulations implementing article 9 of Legislative decree no. 38/05.

#### Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (ISA Italia). Our responsibilities under those standards are further described in the "Auditors' responsibilities for the audit of the consolidated financial statements" section of our report. We are independent of Recordati Industria Chimica e Farmaceutica S.p.A. (the "parent") in accordance with the ethics and independence rules and standards applicable in Italy to audits of financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

KPMG S.p.A. è una società per azioni di diritto italiano e fa parte del network KPMG di entità indipendenti affiliate a KPMG International Cooperative ("KPMG International"), entità di diritto svizzero.

Società per azioni  
 Capitale sociale  
 Euro 10.345.200,00 i.v.  
 Registro Imprese Milano e  
 Codice Fiscale N. 00709600159  
 R.E.A. Milano N. 512967  
 Partita IVA 00709600159  
 VAT number IT00709600159  
 Sede legale: Via Vittor Pisani, 25  
 20124 Milano MI ITALIA

Ancona Aosta Bari Bergamo  
 Bologna Bolzano Brescia  
 Catania Como Firenze Genova  
 Lecce Milano Napoli Novara  
 Padova Palermo Parma Perugia  
 Pescara Roma Torino Treviso  
 Trieste Varese Verona



**Recordati Group**  
Independent auditors' report  
31 December 2018

### **Key audit matters**

Key audit matters are those matters that, in our professional judgement, were of most significance in the audit of the consolidated financial statements of the current year. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

### **Measurement of goodwill**

*Notes to the consolidated financial statements: paragraphs 2 "Summary of significant accounting policies" and 9 "Goodwill"*

<b>Key audit matter</b>	<b>Audit procedures addressing the key audit matter</b>
<p>The consolidated financial statements at 31 December 2018 include goodwill of €579.6 million.</p> <p>Annually or more frequently, if necessary, the directors check the recoverable amount of the goodwill by comparing its carrying amount to its value in use, calculated using a method that discounts expected cash flows.</p> <p>The key assumptions used to calculate value in use relate to the operating cash flows' forecasts over the calculation period and the discount and growth rates of those flows.</p> <p>The directors have forecast the operating cash flows for the explicit projection period (2019-2021) used for impairment testing on the basis of the 2019 budget approved by the parent's board of directors on 18 December 2018 and of the specific forecasts for 2020 and 2021, which were approved by the parent's board of directors on 28 February 2019.</p> <p>Impairment testing entails a high level of judgement by the directors, especially forecasting the operating cash flows, which takes into account the general economic performance and that of group's sector. Accordingly, the recoverability of goodwill was a key audit matter.</p>	<p>Our audit procedures, which also involved our own valuation specialists, included:</p> <ul style="list-style-type: none"> <li>— understanding the process adopted for impairment testing approved by the parent's board of directors;</li> <li>— understanding the process adopted to prepare the 2019-2021 business plan from which the expected cash flows used for impairment testing have been derived;</li> <li>— analysing the reasonableness of the assumptions used by the directors to determine the recoverable amount of goodwill, including the operating cash flows of the 2019-2021 plan used by the parent. Our analyses included comparing the key assumptions used to the historical data and external information, where available;</li> <li>— analysing the reasonableness of the assumptions underlying the valuation model used by the company to calculate the recoverable amount of goodwill;</li> <li>— assessing the appropriateness of the disclosures provided in the notes.</li> </ul>



**Recordati Group**  
*Independent auditors' report*  
 31 December 2018

***Responsibilities of the parent's directors and board of statutory auditors ("Collegio Sindacale") for the consolidated financial statements***

The directors are responsible for the preparation of consolidated financial statements that give a true and fair view in accordance with the International Financial Reporting Standards endorsed by the European Union and the Italian regulations implementing article 9 of Legislative decree no. 38/05 and, within the terms established by the Italian law, for such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

The directors are responsible for assessing the group's ability to continue as a going concern and for the appropriate use of the going concern basis in the preparation of the consolidated financial statements and for the adequacy of the related disclosures. The use of this basis of accounting is appropriate unless the directors believe that the conditions for liquidating the parent or ceasing operations exist, or have no realistic alternative but to do so.

The *Collegio Sindacale* is responsible for overseeing, within the terms established by the Italian law, the group's financial reporting process.

***Auditors' responsibilities for the audit of the consolidated financial statements***

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditors' report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISA Italia will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

As part of an audit in accordance with ISA Italia, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control;
- obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the group's internal control;
- evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors;
- conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the group's ability to continue as a going concern. If we conclude that a material



**Recordati Group**  
*Independent auditors' report*  
 31 December 2018

uncertainty exists, we are required to draw attention in our auditors' report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditors' report. However, future events or conditions may cause the group to cease to continue as a going concern;

- evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation;
- obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with those charged with governance, identified at the appropriate level required by ISA Italia, regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide those charged with governance with a statement that we have complied with the ethics and independence rules and standards applicable in Italy and communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with those charged with governance, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current year and are, therefore, the key audit matters. We describe these matters in this report.

***Other information required by article 10 of Regulation (EU) no. 537/14***

On 13 April 2011, the parent's shareholders appointed us to perform the statutory audit of its separate and consolidated financial statements as at and for the years ending from 31 December 2011 to 31 December 2019.

We declare that we did not provide the prohibited non-audit services referred to in article 5.1 of Regulation (EU) no. 537/14 and that we remained independent of the parent in conducting the statutory audit.

We confirm that the opinion on the consolidated financial statements expressed herein is consistent with the additional report to the *Collegio Sindacale*, in its capacity as audit committee, prepared in accordance with article 11 of the Regulation mentioned above.



Recordati Group  
Independent auditors' report  
31 December 2018

## Report on other legal and regulatory requirements

### ***Opinion pursuant to article 14.2.e) of Legislative decree no. 39/10 and article 123-bis.4 of Legislative decree no. 58/98***

The parent's directors are responsible for the preparation of the group's directors' report and report on corporate governance and ownership structure at 31 December 2018 and for the consistency of such reports with the related consolidated financial statements and their compliance with the applicable law.

We have performed the procedures required by Standard on Auditing (SA Italia) 720B in order to express an opinion on the consistency of the directors' report and the specific information presented in the report on corporate governance and ownership structure indicated by article 123-bis.4 of Legislative decree no. 58/98 with the group's consolidated financial statements at 31 December 2018 and their compliance with the applicable law and to state whether we have identified material misstatements.

In our opinion, the directors' report and the specific information presented in the report on corporate governance and ownership structure referred to above are consistent with the group's consolidated financial statements at 31 December 2018 and have been prepared in compliance with the applicable law.

With reference to the above statement required by article 14.2.e) of Legislative decree no. 39/10, based on our knowledge and understanding of the entity and its environment obtained through our audit, we have nothing to report.

### ***Statement pursuant to article 4 of the Consob regulation implementing Legislative decree no. 254/16***

The directors of Recordati Industria Chimica e Farmaceutica S.p.A. are responsible for the preparation of a non-financial statement pursuant to Legislative decree no. 254/16. We have checked that the directors had approved such non-financial statement. In accordance with article 3.10 of Legislative decree no. 254/16, we attested the compliance of the non-financial statement separately.

Milan, 20 March 2019

KPMG S.p.A.

(signed on the original)

Claudio Mariani  
Director of Audit



RECORDATI S.P.A AND SUBSIDIARIES

# DISCLOSURE OF CONSOLIDATED NON-FINANCIAL STATEMENT 2018

PREPARED PURSUANT TO ARTICLE 4  
OF ITALIAN LEGISLATIVE DECREE NO. 254/2016

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# NOTE ON METHODOLOGY

In recent years, the Recordati Group (hereinafter also "Recordati" or the "Group") has decided to take a structured and organic approach to sustainability, considering the economic, social and environmental aspects of sustainability in a manner that is in line with its organisational structure. In order to provide a clear understanding of the business' activities, its development, its results and its impacts on sustainability, in 2018 the Group's commitment to sustainability was reiterated with the preparation of the second Consolidated Non-Financial Statement (also the "Non-Financial Statement" or "Statement") for the purposes of compliance with the obligations provided by Articles 3 and 4 of Legislative Decree no. 254/16. As such, presented in this Statement are the principle policies adopted by the Group, its management models and the principle activities carried out by the Group in 2018 with respect to the matters expressly specified by Italian Legislative Decree no. 254/16 (environmental, social, staff, human rights and anti-corruption), as well as the principle identified risks related to these themes.

In line with the one of the two options provided by Article 5 of Italian Legislative Decree no. 254/16, this Statement is a separate report. However, it is noted that, as stated in specific notes contained in this document, further details relative to certain non-financial information, as well as the relative management models and main identified risks, are also included in the Annual Report and the Corporate Governance Report and Ownership Structure.

This document represents the second Consolidated Non-Financial Statement produced in compliance with Italian Legislative Decree no. 254 of 30 December 2016 in implementation of Directive 2014/95/EU, of the Companies belonging to Recordati S.p.A. and its subsidiaries, describing the initiatives and principle results in terms of the Group's performance on the subject of sustainability in 2018 (reporting period: 1 January to 31 December 2018).

The Non-Financial Statement 2018 has been prepared in accordance with the new GRI Sustainability Reporting Standards published in 2016 by the Global Reporting Initiative (GRI), in line with the "Core" option. The table of GRI reporting indicators is attached for reference in the annex of this document. The report was prepared based on the results of the materiality analysis conducted in 2017, also deemed valid and consistent with the characteristics of the Group's business for the Non-Financial Statement 2018, which identified the key material aspects for the Recordati Group and its stakeholders and considered the topics referred to in Italian Legislative Decree no. 254/2016.

The scope of the financial data referred to in this document corresponds to the data considered in the Consolidated Financial Statement 2018 of the Recordati Group. The scope of the social and environmental data and information extends to Companies belonging to the Recordati Group as of 31 December 2018, consolidated with the comprehensive approach in the Group's Consolidated Financial Statement<sup>1</sup>. However, while ensuring the correct understanding of the company's business, it should be noted that:

- in line with the 2017 report, the information and data regarding environmental aspects (energy use, emissions, water use and waste) refer exclusively to the Group's production plants as such aspects are not deemed significant at other sites (with the exception of the Milan plant, where the offices at said site are also considered);
- compared to the information reported in the Non-Financial Statement 2017, the scope of information relative to health and safety and the principle accident indicators includes employees of the following production plants: Italy - Campoverde di Aprilia (Recordati S.p.A.), Ireland (Recordati Ireland Ltd), Czech Republic (Herbacos Recordati S.R.O.), Turkey (Recordati İLAÇ ve Hammaddeleri Sanayi ve Ticaret A.S.) and France - Nanterre (Orphan Europe S.A.R.L); while for the following sites in Italy - Milan (Recordati S.p.A. and Innova Pharma S.p.A.), Spain (Casen Recordati S.L.), Tunisia (Opalia Pharma) and France - Bouchara (Laboratoires Bouchara Recordati S.a.s.) both office, plant and commercial staff are included. In fact, a reporting system is currently being developed to process data regarding the workforce at all of the Group's offices and commercial sites.

In compliance with the reporting standards used and the Legislative Decree no. 254/16, these exceptions and any other minor limitations are expressly indicated in the text. Furthermore, in order to provide a correct representation of performance and guarantee the reliability of the data provided, estimates have been kept to a minimum and, where unavoidable, are based on the best available methods, duly indicated.

<sup>1</sup> The scope of social and environmental data also includes the company Natural Point S.r.l., acquired in June 2018. However, in line with the scope of the financial data of the Consolidated Financial Statement, the French company Tonipharm S.A.S, acquired at the end of 2018, shall be consolidated as of the start of the 2019 reporting period.



For more information regarding significant changes to the scope and share ownership of the Group during the reporting period, reference should be made to the sections "Introduction" and "Ownership structure" in the Corporate Governance Report and Ownership Structure of the Recordati Group as of 31 December 2018.

The Non-Financial Statement is published on an annual basis. The Non-Financial Statement is also available online at Group's website [www.recordati.it](http://www.recordati.it).

This Statement was presented for evaluation and approval to the Risk, Control and Sustainability Committee on 25 February 2019 and was approved by the Board of Directors of Recordati S.p.A. on 28 February 2019.

This Statement was subject to a compliance review by an independent auditing company, which issued a separate report confirming the compliance of the information contained herein pursuant to Article 3, paragraph 10 of Italian Legislative Decree no. 254/16. The audit was carried out according to the procedures indicated in the "Report of the Independent Auditing Company".

Finally, it is noted that, in the context of continuous improvement, the Group renews its commitment to continue its sustainability path towards a progressive formalisation of the commitments and operating practices in implementation of the principles of the Code of Ethics adopted by the Group and Legislative Decree no. 254/16.

In particular, in the course of 2018 the Recordati Group has formalised a reporting procedure aimed at defining the operating process for the preparation of the Non-Financial Statement, describing the activities, time frames, roles and responsibilities of the company departments/structures involved in the reporting process.

The company Recordati S.p.A., and therefore its new Board of Directors appointed on 5 February 2019 following the change of the share ownership of the Group in 2018, will continue to pursue the development of sustainability policies, including by way of the progressive enforcement of the Group Code of Ethics with specific reference to the principles, commitments and management methods implemented by the Group in relation to the principle topics of sustainability, and with reference to the topics expressly referred to by Legislative Decree no. 254/16.

## Contacts

For all information regarding the Non-Financial Statement of the Recordati Group, please refer to the following contacts:

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# 1. PROFILE OF THE RECORDATI GROUP

## 1.1. THE RECORDATI GROUP

Established in 1926, the Recordati Group is based in Milan and is one of Italy's oldest pharmaceutical companies. Since its foundation, the Group has grown consistently to become a leading international pharmaceutical group and has been listed on Borsa Italiana (now part of the London Stock Exchange) since 1984. The Group has numerous branches both in and outside Europe in the pharmaceutical and chemical-pharmaceutical sectors.

The growth of the Recordati Group is the result of the quality of its products and services, as well as the implementation of the policy aimed at internationalisation and diversification, based on a focused strategy of acquisitions and targeted licensing agreements. As well as its presence in Western Europe (France, Germany, Greece, Ireland, Italy, Portugal, Spain and Switzerland) Recordati also operates directly in countries of central Europe, Russia and in other countries of the Commonwealth of Independent States (CIS), Ukraine, Turkey, Tunisia, the United States, Canada, Mexico, certain South American countries, Japan and Australia. Although the Group's principle reference market is the European Market, which turns out to be the second largest pharmaceutical market in the world, Recordati sells its products on over 150 markets, including through various licensing agreements, and markets pharmaceutical products under licence from primary pharmaceutical companies.

Recordati has six pharmaceutical manufacturing plants and one packaging and distribution plant dedicated to pharmaceuticals for rare diseases, and two chemical-pharmaceutical sites where it produces numerous active substances and intermediates. Recordati produces and promotes a wide range of innovative pharmaceuticals and its product portfolio includes general medicines as well as specialist pharmaceuticals for the treatment of rare diseases. The Group's pharmaceutical activities extend across all phases of the process and include research and development, production, packaging, storage and commercialisation. Furthermore, thanks to licensing agreements with leading pharmaceutical companies Recordati products are distributed in more than 100 countries. The chemical-pharmaceutical activities of the Recordati Group focus on the chemical production of intermediates and active substances both for Recordati's pharmaceutical products and for the international pharmaceutical industry.

The Group's most important products include lercanidipine-based pharmaceuticals, a latest-generation antihypertensive calcium channel blocker, and products containing a combination of lercanidipine and enalapril, an ACE inhibitor. Both substances are used to treat cardiovascular conditions; the Group has strengthened its presence in this sector with the acquisition in 2017 of pharmaceuticals based on the beta-blocker metoprolol. For over forty years the Group has operated in the genito-urinary area, acquiring specific expertise and becoming the European partner of established international pharmaceutical companies.

With a view to innovation and growth, the Group has enhanced its therapeutic offering, developing its own pipeline of products and entering into the rare diseases sector. In fact, Recordati develops, produces and markets pharmaceuticals for the treatment of rare diseases through Orphan Europe and Recordati Rare Diseases. Orphan Europe is a leading European pharmaceutical company entirely devoted to the research, development and commercialisation of pharmaceuticals for the treatment of rare diseases. It is one of the leading companies in Europe in terms of number of products launched on the market developed specifically to treat a rare disease. Since 2013, the Group's US branch Recordati Rare Diseases Inc. has offered a portfolio of products dedicated to the treatment of various rare diseases, with a particular focus on genetic metabolic disorders. In recent years, the Group's activities to develop pharmaceuticals to treat rare diseases have extended to various countries in North and South America, as well as the Middle East, Japan and Australia.

With a commitment to the discovery, development and sale of innovative products with high added-value and the objective of improving health and quality of life, the Recordati Group has defined its mission as a commitment to research, innovation, quality and the creation of value for its stakeholders, all of which are distinctive elements of the Group's corporate social responsibility.

For more information on the main business activities of the Group, its products and its markets, please refer to the *"Recordati, an International Group"* and *"Review of Operation"* sections of the Annual Report.

## 1.2. ORGANISATIONAL AND MANAGEMENT MODEL

The Group's business model for the management of the main sustainability themes is described in the Organisational, Management and Control Model pursuant to Italian Legislative Decree no. 231/2001 (the "Model") adopted by all Italian Companies of the Recordati Group. While the Parent Company updated its Model in 2017, in 2018 the subsidiaries Innova Pharma S.p.A. and Orphan Europe Italia S.r.l. updated their own Model, the Company Italcimici S.p.A. adopted a model and, in addition, a plan for the adoption of a Model by the Company Natural Point S.r.l. acquired by Recordati in June 2018 was drawn up, due to come into effect in the first six months of 2019.

For Companies in other countries, if required by local legislation, policies have been or are in the process of being implemented which serve similar functions to those of the Organisational Model pursuant to Legislative Decree no. 231/2001. In particular, on 14 March 2018 the Spanish branch Casen Recordati S.L. adopted an Organisational, Management and Control Model in compliance with the *Ley Organica 2015/1* of 30 March 2015, which introduced into Spanish criminal law certain new criteria of criminal liability of legal persons.

The Models adopted by Group Companies comply with the guidelines issued by Confindustria and are dynamic and effective tools thanks to a constant control and review process promoted by the Supervisory Bodies. The Organisational Models pursuant to Legislative Decree no. 231/2001 envisage dedicated channels for reports of irregularities or breaches by employees and regular staff training on the contents of Decree no. 231/2001 and the Organisational Model pursuant to Legislative Decree no. 231/2001 itself. The Supervisory Bodies appointed in the Group's Italian Companies are represented by boards comprised of the Internal Audit Department Manager and external professionals. Each Supervisory Body is internally regulated and operates according to a specific programme. The Supervisory Bodies periodically refer to the Board of Directors and the Board of Statutory Auditors, where present. The Organisational Models are constantly monitored and updated, with particular attention to crime prevention and risk assessment following the introduction of new legislation.

As envisaged by the best practices, a board-style Supervisory Body has been appointed and is in operation at the Group's Spanish branch. In 2018, the Supervisory Body of the Spanish branch adopted its own code of operations, prepared a business and audit plan, and delivered training sessions on the Model (including, in particular, sessions relating to the principles of the Recordati Group Code of Ethics and anti-corruption) to all branch staff.

Further information regarding the Organisational Models pursuant to Legislative Decree no. 231/2001, the relative procedures and the training provided on the same is available in the "Internal Control and Risk Management System" section of the Corporate Governance Report and Ownership Structure.

The systematic approach of the Organisational, Management and Control Model pursuant to Legislative Decree no. 231/2001 is reinforced through additional models dedicated to specific company departments, such as in the context of health and safety in the workplace, environmental management and privacy.

In terms of data processing and privacy, the Recordati Group has adopted the new General Data Protection Regulation (GDPR no. 2016/679). The project has enabled all Group Companies to adopt the measures envisaged by the European regulation. More specifically, compliance with the GDPR has led to the definition and implementation of a privacy management model with new regulations and company procedures both at Group and local level with Recordati's European branches. In terms of organisation, the most significant event was the appointment of a Data Protection Officer (in the person of the Group Auditing Manager) and a Key Privacy Person in each branch affected by the Regulation. As regards the operational procedures and regulations, a set of Group policies has been adopted, forming the basis for local procedures that have already been adopted by the various branches. Activities to promote the adoption of an IT tool designed to enable improved and more efficient operational activities when implementing company procedures are in progress and will continue in 2019.

### **The Recordati Group Code of Ethics**

The Code of Ethics adopted by all Group Companies provides a concrete and clear representation of the Groups values, including: protection of employees, fairness and equality, ethical and lawful behaviour, loyalty, privacy of information, respect of the interests of all parties, professionalism, health and environmental protection.

The Code of Ethics also provides the rules of conduct for all recipients of the Code, particularly with regard to the subject of the prevention of active and passive corruption (e.g. the prohibition of engaging in corrupt practices). On this issue, the Group has also adopted an Anti-Bribery Model that applies to all Group Companies and envisages the periodic assessment of the status of internal controls in compliance with the main international and national anti-bribery regulations in the countries in which the Group has an active presence. These tools represent the firm commitment of the Group to conduct its business in line with the principles of transparency, honesty and ethics in all of the countries in which it operates, and to refuse all forms of corruption, demonstrating its awareness of the potential risks relating to the various relations with the Public Administration typical in the business areas in which the Group operates.

For Italian Companies, the distribution and diffusion of the Code of Ethics is carried out directly by the Parent Company: all new employees are provided with a copy of the Code of Ethics, which is also available on the company website. In 2018, the Code of Ethics was distributed to the Group's international branches. In total, in 2018 the Code of Ethics was delivered to 1,325 employees. Furthermore, Recordati offers continuous training to all employees: in 2018 training on the Code of Ethics and the Organisational Model pursuant to Italian Legislative Decree no. 231/2001 in Italy was delivered to around 300 employees of the Group's Italian Companies in lecture theatres and through remote learning.

As well as Group employees, all providers and commercial partners of the Recordati Group are required to comply with the Code of Ethics within its relevant scope of application, through:

- the supplier approval process, which requires all new suppliers to accept the Code of Ethics during the selection phase. This process is an integral part of the ATTITUDE project concerning the implementation of a new procurement management policy, currently in force in Italy and expected to be extended to all Group Companies by 2021
- the presence of a specific clause regarding the compliance with the Code of Ethics in the contracts with the Group's commercial partners. The process of integrating the existing contracts with this clause, launched in 2015 for the major Group Companies, was extended in 2018 to all Group Companies.

The current version of the Recordati Group Code of Ethics will be subject to a general review in 2019. Without prejudice to the principles set forth in the Code, the document will be reviewed with a view to improving its legibility and usability and will be updated with additional conduct guidelines.

### The Anti-Bribery Model of the Recordati Group

The Recordati Group is deeply committed to conducting its business in line with the principles of transparency, honesty and ethics in all of the countries in which it operates, and to refuse all forms of corruption, demonstrating its awareness of the potential risks relating to the various relations with the Public Administration typical of the business areas in which the Group operates. To this end, since 2009 the Group has conducted an assessment on its internal controls in line with international and national Anti-Bribery legislation in the countries in which the Group has an active presence. Furthermore, the Group has developed an Anti-Bribery programme that involves the staff of the Parent Company and branch staff in four key stages:

1. assessment of local and national legislation;
2. assessment of local systems, procedures and models to control corruptive behaviour;
3. analysis of existing risks and controls to identify any residual risks;
4. definition and publication of the Group's Anti-Bribery Model.

From the analysis of the documentation and information collected, 13 business areas potentially exposed to the risk of corruption were identified, upon which the conduct guidelines to avoid corruptive behaviour were based. On the basis of this analysis, the Group implemented an Anti-Bribery Manual.

The 13 areas potentially exposed to corruption risk are: Research and Development, Production, Relations with the medical community and healthcare facilities, regulatory activities, transactions with public authorities, consultancy, medical samples, courses and conferences, promotional material, contributions and donations, financial transactions, human resources and relations with politicians or political parties.

The Manual has been distributed to Recordati branches in Spain, France, Russia, Turkey, Portugal and Germany and is currently being rolled out to the remaining branches.

The current version of the Anti-Bribery Manual is currently being reviewed and an updated version of the Manual is expected to be distributed to all Group Companies in 2019.

In order to improve communication, coordination and control activities between the Parent Company and the various branches, in 2018 specific data streams on the subject of anti-corruption and anti-terrorism were defined which would enable, through dedicated channels managed by the Group Audit Department, the identification and management of potential risk situations. This data stream system will be implemented in 2019.

In terms of communication and training on the subjects of anti-corruption and the principles ratified by the Recordati Group Code of Ethics, in 2017 all members of the Board of Directors of Recordati S.p.A. were informed of the policies and procedures adopted. Furthermore, in 2018 anti-corruption training was given to 933 employees, 292 of which were in Italian branches with the remaining 641 located in the Group's foreign branches.

For some time now, the Company has provided for dedicated *whistleblowing* channels in its Organisational Models pursuant to Legislative Decree no. 231/2001 for Italian Companies and the Group Anti-Bribery system<sup>2</sup>. In 2018 these whistleblowing channels were strengthened with the introduction of other communication tools: in the Group's French branches a new procedure was implemented and new reporting channels were introduced in compliance with new local legislation (*Loi Sapin 2*) while in Italian branches - which were already in compliance with Law no. 179/2017 concerning "Provisions for the protection of whistleblowers of offences or irregularities which come to their knowledge in the context of a public or private working relationship" (so-called "Whistleblowing Law") - improvements are being made to the reporting system.

In addition, it should be noted that in 2018 an employee of the Belarus representative office was investigated in a criminal proceeding in which the alleged offense was that of corruption. The investigation by the Belarusian authorities is under way. The company is conducting its own internal audits.

These tools and additional information regarding the fight against corruption are described in more detail in the "*Internal Control and Risk Management System*" section of the Corporate Governance Report and Ownership Structure.

### 1.3. INTERNAL AUDIT AND RISK MANAGEMENT SYSTEM

The Internal Audit and Risk Management System is a structured and organic set of procedures and organisational structures aimed at preventing or limiting the consequences of unforeseen results and enabling the achievement of company objectives, compliance to legislation and regulations, and the correct and transparent disclosure of information both internally and to the market. Furthermore, this System enables the identification, measurement, management and monitoring of the main risks in order to promote the efficiency and efficacy of company processes, protect the value of the Group's activities, ensure the reliability and integrity of accounting and management information and ensure that transactions comply with all existing legislative measures.

The Internal Audit and Risk Management System is based on an Enterprise Risk Management (ERM) approach and consists of a structured risk management process, in line with the provisions of international best practices on the subject and in compliance with current legislation. The aim of this System is to facilitate activities consistent with the company goals, promoting informed decisions and ensuring the efficiency and efficacy of internal processes, as well as the reliability of financial information. By cataloguing company risks, the System enables the identification, measurement and control of the level of exposure of all Group Companies to various risk factors, as well as the management of overall exposure, and envisages the implementation of control measures and procedures able to flag any anomalies. As described in more detail in the "*Principle Risks and Uncertainties*" section of the Consolidated Financial Statement and the "*Internal Control and Risk Management System*" section of the Corporate Governance Report and Ownership Structure, the main risk factors to which the Group is exposed relate to the external context, strategic and operational risks (including risks related to Research and Development, the environment, health and safety, and pharmacovigilance risks), financial risks, legal risks and compliance risks.

The Group subjects its Risk Catalogue to a periodic interim review, implementing a bottom-up approach to critical risk assessment to coincide with significant company activities, such as the definition of the budget, the review of the organisational structure and other events that could have a potential impact on the risks to which the Company is exposed. In particular, the Board of Directors examined the update to the Risk Catalogue in relation to the 2018 financial year, created with the support of the consultancy company, in order to provide an up-to-date and formalised framework of the principle internal and external risks of the Recordati Group and the various existing tools and processes for the management of such risks.

The Board of Directors, including on the basis of this review, has evaluated whether the level and nature of the risks identified by the Group Risk Catalogue, presented to the Board at the meeting of 28 February 2019, are compatible with the Group's strategic objectives.

<sup>2</sup> *Corporate Governance Code, comment to Article 7: "The Committee deems that, at least for companies belonging to the FTSE MiB index, an adequate internal control and risk management system must include an internal whistleblowing system for employees to report any irregularities or breaches to applicable legislation and internal procedures (so-called whistleblowing system) in line with national and international best practices, which guarantees a specific and confidential informational channel as well as the anonymity of the whistleblower."*

### The principle non-financial risks

The identification, assessment and management of corporate risks is based on an Enterprise Risk Management (ERM) approach and includes the principle non-financial risks related to the topics expressly specified by Italian Legislative Decree no. 254/2016.

In particular, the principle non-financial risks identified by Recordati relate to:

- environmental management and safety in the workplace (e.g. damage caused by meteorological events and incidents, risks covered by the Health and Safety Executive (HSE), industrial incidents);
- the rights of employees and collaborators along the supply chain (e.g. change in dimension of the organisational structure, loss of key resources, inappropriate selection of suppliers and commercial partners, interruption of supply by critical partners);
- corruption (e.g. non-compliance with international quality standards, with legislation pertaining to the scientific information of the pharmaceutical).

The aforementioned risks were identified by the Group and classified as medium-low risk, in terms of residual risk, assessed in terms of the likelihood of an at-risk event and the impact of such an occurrence. In fact, in relation to such risks, the Group has adopted specific policies, management models and activities aimed at the mitigation of the same.

A brief description of the principle non-financial risks identified by the Group and related to the material topics of the Recordati Group, as well as the procedures in place for their management and mitigation, is given below:

- Environmental topics: the risks in this context predominantly relate to the production process. In particular, such risks concern those deriving from industrial incidents that may have serious consequences for people and the environment, with resulting impacts in terms of economics and corporate image. The management of these risk is above all required by the quality standards provided for by the sector in which the Group operates, compliance with which is represented by the environmental certificates obtained by the Group's main production sites. Specific measures are represented by a preventative risk analysis carried out by specific and qualified personnel, an audit plan and plant maintenance activities to which significant financial resources are allocated on an annual basis. These measures enable the Group to drastically reduce its exposure to risks of this nature.
- Topics linked to HR management: these risks concern the rights, health and safety of workers as well as their professional development. In relation to health and safety in the workplace, compliance with legislation is guaranteed by the respect for technical-structural standards relative to equipment, plants, work places and chemical, physical and biological substances, as well as organisational activities such as emergency management, first aid, tendering processes and periodic safety meetings, and consultations with workers' safety representatives. Finally, health checks, information sessions and training activities for works as well as an internal audit plan enable the Group to minimise risks in this context. In relation to workers' rights, the principle risk identified concerns the size of the organisational structure in terms of the adequacy of resources and skills, as well as the risk of losing key resources. To confront these risks, the Human Resources Department constantly monitors the size of the workforce within the various departments and units of the Group. Furthermore, the Company employs a specific skills mapping process (the Group Performance Appraisal System), mapping both managerial and technical skills and enabling the identification at Group level of key resources, with an initial focus on Managers and then considering lower levels within the company.

- Topics linked to the supply chain: although the Group operates in a highly regulated sector, certain risks relating to the procurement chain have been identified, including the risk of being unable to source adequate commercial partners and the lack of control of outsourcing contracts. The Group confronts these risks through contractual clauses that define the mutual responsibilities of the parties, the use of consolidated and qualified suppliers in line with applicable technical standards, document audit activities and on-site inspections carried out by qualified personnel. In order to protect the rights of workers in the supply chain, termination clauses are included in company contracts for failure to comply with the company Code of Ethics. Furthermore, the use of an IT platform for supplier approval, an advantage of which is the organic collection of relevant documentation such as certificates and declarations, further reduces the risk of partnerships with suppliers with unsuitable technical profiles, ethics and conduct.
- Topics linked to the compliance: compliance risks refer to the risk of offences against the Public Administration as well as risks related to non-compliance with international quality standards and legislation regulating the scientific information of the pharmaceutical product. To prevent non-compliance with the quality standards (Good Manufacturing Standards - GMP) that regulate chemical and pharmaceutical production activities, the Group has adopted a consolidated Management Model that provides for the implementation of Standard Operating Procedures and a dedicated quality control department. The Model is periodically subject to inspection by national and international authorities, as well as commercial partners. As regards the medical scientific information, compliance is ensured by appropriate company procedures, by control activities carried out by dedicated organisational departments and by the continuous training of personnel on compliance with ethical standards and industry legislation. In order to promote increasingly transparent relations with the medical community, the Group's branches publicly disclose Value Transfers in relation to business meetings, consultancy and donations. Finally, the Anti-Bribery Manual aims to promote correct conduct in the various activities relating to scientific information and more generally to relations with the medical community and areas exposed to corruption risk.
- Topics relating to product responsibility: these refer to Product Liability risks with the potential need for product recalls, impacts on patient health and consequent economic or reputational impacts for the company (including the risk of demands for compensation as a result of side effects caused by its products). For this reason, the Group has appointed specific quality control personnel that carry out specific product analyses in order to identify the "robustness" and reliability of the production processes. These professional figures, required by industry legislation, such as the "Qualified Person", the "Quality Assurance Officer" and the "Quality Manager" are responsible for ensuring compliance with Good Manufacturing Practices envisaged by specific internal procedures and existing legislation. Further control measures related to the topics outlined above include inspections of the Group's production units by third party bodies, as well as the constant increase in authorisations held by the Group's pharmaceutical laboratories.

This information is described in more detail in the "Focus on the Environment", "The Recordati Group's Employees" and "The Supply Chain" sections of the Non-Financial Statement and the "Health, Safety and the Environment" section of the Annual Report 2018. For a more detailed description of the management system of company risks, including the aforementioned non-financial risks, as well as the relative management methods, please refer to the "Principle Risks and Uncertainties" section of the Annual Report.

## 2. THE RECORDATI GROUP'S APPROACH TO SUSTAINABILITY

### 2.1. SUSTAINABILITY IN FIGURES

#### MORE THAN € 1 BILLION

*of economic value generated and distributed by the Group in 2018*

#### APPROXIMATELY € 2 MILLION<sup>3</sup>

*of donations and contributions disbursed in 2018*

#### 151 AUDITS

*carried out on suppliers to ensure product quality and security*

#### 45%

*of the Group's workforce represented by women*

#### 94%

*of employees hired on permanent contracts*

#### MORE THAN 85,000 HOURS

*of training provided to employees*

#### - 3%

*reduction in water consumption at production facilities compared to 2017*

#### APPROXIMATELY 30 GWH

*self-generated electricity produced at the Campoverde di Aprilia plant*

#### ALMOST 17%

*of the water used in the Group's production facilities in 2018 was recycled and reused*

### 2.2. THE RECORDATI GROUP'S COMMITMENT TO SUSTAINABILITY

As noted by the Chief Executive Officer in the Letter to Shareholders of the Annual Report, in 2018 the Recordati Group launched various initiatives regarding sustainability, in line with its strategic, organisational and operational characteristics. When defining the Group's management strategies and policies, in addition to ensuring the Group's development at an international level and focusing on the treatment of rare diseases, one of the Group's current priorities is to consider the interests of all stakeholders, taking into account the economic, social and environmental impacts of our work. Recordati's success as a pharmaceutical firm has brought, and must continue to bring, advantages both to patients and all those who collaborate with the Group: employees, clients, consumers, patients, associations, investors and the financial community, suppliers and strategic partners.

In order to transform the values and principles of sustainability into operational decisions and managerial activities, the internal engagement initiative launched in 2017 has been continued, aiming to:

- identify key stakeholders with whom to establish a positive dialogue and collaboration;
- identify and assess significant issues of economic, environmental and social sustainability relating to the Group's activities and its stakeholders;
- share the values, mission and processes involved in order to develop sustainability reporting procedures.

### 2.3. THE RECORDATI GROUP'S STAKEHOLDERS

Integrating corporate responsibility into a business approach means focusing on creating value for all relevant parties and uniting economic, social and environmental aspects.

In this context, the Recordati Group has identified its own key stakeholders by focusing on its understanding of how the Group's corporate role relates to company activities, with the aim of identifying their expectations and setting significant targets to be achieved.

<sup>3</sup> In 2018, as well as € 1.3 million disbursed in donations and contributions to foundations, associations, non-profit organisations and medical institutions, the Recordati Group also paid out € 657 thousand of the amount allocated in 2017 to the "V. Buzzi" Children's Hospital in Milan, equating to total donations of approximately € 2 million.

## THE RECORDATI GROUP'S STAKEHOLDERS



**INVESTORS  
AND THE FINANCIAL  
COMMUNITY**



**EMPLOYEES**



**GOVERNMENT  
AGENCIES,  
REGULATORS, PA**



**SUPPLIERS  
AND STRATEGIC  
PARTNERS**



**PHARMACIES  
AND DISTRIBUTORS**



**LOCAL  
COMMUNITIES**



**PATIENTS  
AND THEIR  
ASSOCIATION**



**HEALTHCARE  
OPERATORS**



**SCIENTIFIC  
ORGANISATIONS  
AND UNIVERSITIES**



**CLIENTS AND  
CONSUMERS**

In order to increase the engagement of all of our stakeholders in their activities, optimising their roles and potential and monitoring the possible direct and indirect impacts of the Group's activities on the relevant parties, the Recordati Group has launched a number of stakeholder engagement initiatives, including:

- the creation of a department focused on managing Investor Relations. This department, within the company's organisation, manages relations with financial analysts and institutional investors and organises periodic meetings focused on providing economic and financial information;
- the organisation of awareness-raising initiatives and scientific research projects through conferences and training courses on specific themes relating to the treatment of rare diseases. Aimed at health professionals, doctors

and researchers, these initiatives are designed to intensify the sharing of knowledge about the treatment of rare diseases;

- promotion of support initiatives aimed at the families of patients affected by rare diseases, with the aim of improving quality of life for both patients and their families.

Furthermore, given the strictly regulated nature of the pharmaceutical sector, industrial associations operating in this area represent one of the most important stakeholders with whom the Recordati Group interacts. These organisations coordinate, protect and promote the interests of the pharmaceutical sector and its associated companies. In 2018, the Recordati Group collaborated with 65 industry associations located throughout its global business network, ensuring a constant and continuous flow of information.

## THE RECORDATI GROUP'S INDUSTRIAL ASSOCIATIONS, 2018

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### ITALY

- Pharmaceutical Industry
- EFPIA
- ASSONIME

### FRANCE

- LEEM (Les Entreprises du Médicament)
- AFIPA (Association Française de l'Industrie Pharmaceutique pour l'Automédication)
- Club Léonard de Vinci
- CRIP (Cercle de réflexion de l'industrie pharmaceutique)

### BELGIUM

- Pharma.be (General national association of the pharmaceutical industry).

### GERMANY

- BAH - Bundesverband der Arzneimittel-Hersteller e.V.
- AGV Chemie- Arbeitgeberverband der Chemischen Industrie
- IHK Ulm - Industrie- und Handelskammer Ulm
- AKG e.V. - Arzneimittel und Kooperation im Gesundheitswesen e.V.
- Camera di Commercio Italo-Tedesca (Deutsch-Italienische Handelskammer)
- Pharma-Lizenz Club
- Wirtschaftsrat der CDU
- Senat der Wirtschaft
- BPI - Bundesverband der Pharmazeutischen Industrie e.V. (The German Pharmaceutical Industry Association)

### SWITZERLAND

- Swiss Association of the Pharmaceutical Industry
- Business Association Chemistry, Pharma, Biotech
- Swiss Healthcare Licensing Group
- Swiss Health Quality Association

### AUSTRIA

- PHARMIG - Verband der pharmazeutischen Industrie Österreichs

### SPAIN

- Farmaindustria
- Anefp (National Association of OTC products)
- AINFA

### IRELAND

- Bio Pharmachemical Ireland (BPPCI)
- IPHA (Irish Pharmaceutical and Healthcare Association)
- National Irish Safety Organization
- IBEC (Irish Business Employers' Confederation)
- Cork Chamber of Commerce
- Institute of Environmental Management and Assessment (IEMA) – Production
- Irish Exporters Membership - Logistics
- PMI (Pharmaceutical Managers of Ireland)
- MMRI (Medical Reps Institute of Ireland)
- TOPRA (The Organization for Professionals in Regulatory Affairs)

### PORTUGAL

- APIFARMA - Portuguese Pharmaceutical
- GROQUIFAR

### POLAND

- Commercial Chamber "Farmacja Polska"

### CZECH REPUBLIC

- SARAP – Slovenská asociácia spoločností v oblasti liekovej regulácie
- CASP – česká asociace pro speciální potraviny

### RUSSIA

- GIM-Unimpresa

### UKRAINE

- EBA - European Business Association

### TURKEY

- Pharmaceutical Manufacturers Association of Turkey
- ICC - The Istanbul Chamber of Commerce
- Camera di Commercio Italo-Turca
- Çerkezköy Organized Industrial Zone
- Çerkezköy Chamber of Commerce and Industry
- Istanbul Chemicals and Chemical Products Exporters' Association
- The Union of Chambers and Commodity Exchanges of Turkey
- YASED (International Investors Association)

### GREECE

- Camera di Commercio Italo-Ellenica
- SFEE - Member of Hellenic association of Pharmaceutical Companies

### TUNISIA

- CNIP - The National Chamber of Pharmaceutical Industry
- The Council of the Pharmacists Association.

### UNITED KINGDOM

- ABPI - Association of the British Pharmaceutical Industry

### UNITED STATES

- American Association of Pharmaceutical Scientists
- American Chemical Society
- BIO - Biotechnology Innovation Organization
- DIA - The Drug Information Association
- Global Genes
- Healthcare Distribution Association
- International Society of Pharmaceutical Engineers
- Parenteral Drug Association
- RAPS - Regulatory Affairs Professional Society

### CANADA

- LSO - Life Sciences Ontario



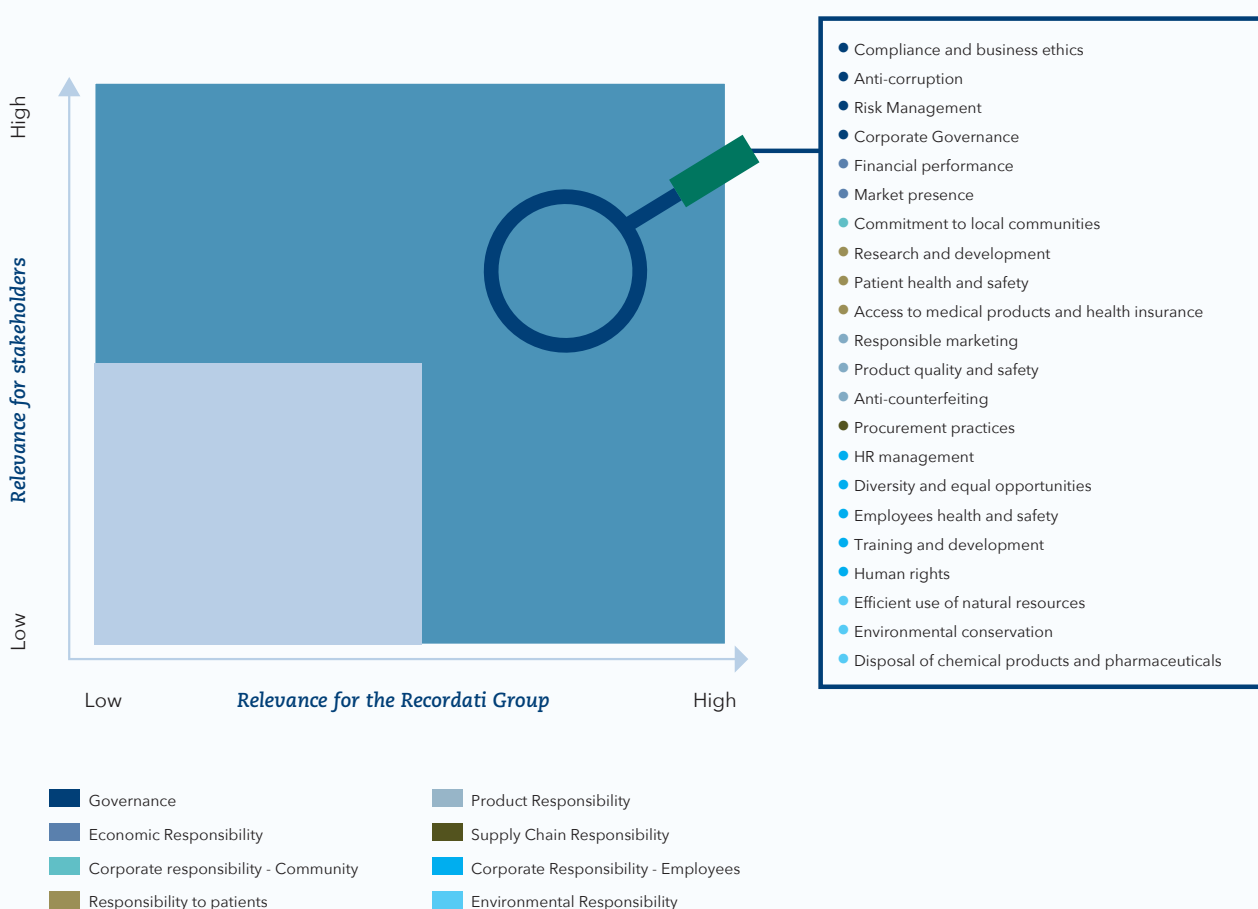
## 2.4. MATERIALITY ANALYSIS

In order to identify the main sustainability issues that relate to its business, in 2017 the Recordati Group launched an internal stakeholder engagement initiative in collaboration with senior management. The initiative promoted the discussion and debate of a range of economic, social, environmental, governance and product issues deemed significant for the industry and specifically required by Italian Legislative Decree, no. 254/2016. Given the continuity of the Group's business, the materiality analysis and the

relative results obtained were deemed valid for 2018 and consistent with the indications of the reporting standards and macro trends observed in the sector.

The materiality index represents the 22 issues selected according to their economic, social and environmental relevance both for the Recordati Group and for the relevant stakeholders.

### THE RECORDATI GROUP'S MATERIALITY INDEX



The 22 topics highlighted by the materiality analysis are covered in this Statement in line with the reporting standards and the provisions of Italian Legislative Decree no. 254/2016. It is noted that the issue of human rights, one of the significant themes highlighted by the materiality analysis, is expressed by the Group through its management of relations with employees, collaborators and supply chain operators in a manner that respects the principles and values of the Group's Code of Ethics.

In fact, the Group is committed to respecting basic human rights in accordance with the Conventions of the International Labour Organisation in all of the countries in which it operates.

For more detail on the policies adopted relative to this topic, please refer to the relevant sections (e.g. "Supply chain", "Diversity and equal opportunities", "Health and safety in the workplace") of the Non-Financial Statement.

## 2.5. DIRECT AND INDIRECT ECONOMIC BENEFITS

During 2018, the activities of the Recordati Group in the field of the research and sale of medicines represented an important profitability factor for the Group and generated various economic advantages, including direct benefits for stakeholders through the distributed economic value as well as indirect benefits for the various associations or third-party organisations which receive donations and contributions from the Group.

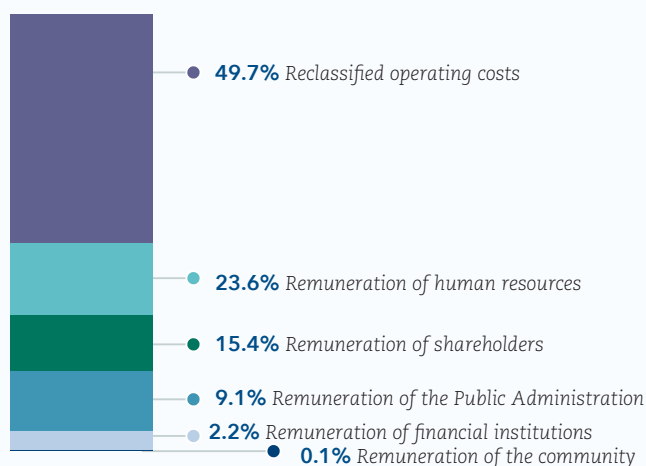
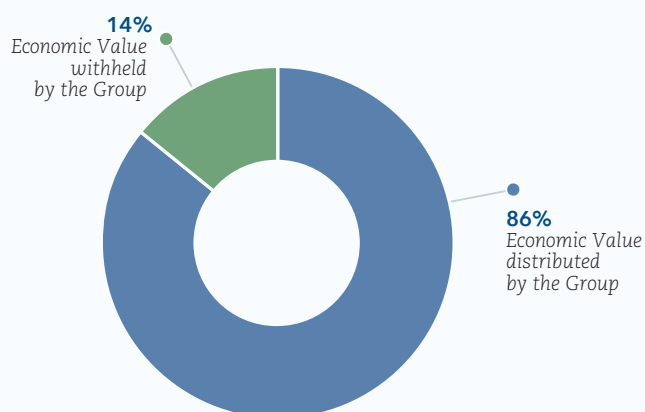
### Economic value generated and distributed by the Group

The Economic Value represents the wealth generated by the Recordati Group which is then distributed in various forms to stakeholders. Data regarding the creation and distribution of the economic value provides a basic indication of how the Group has generated wealth for its stakeholders, highlighting the economic benefits produced by the Group's entrepreneurial management which are directly shared with the main categories of stakeholders with whom the Group interacts and maintains medium to long-term relations: suppliers (reclassified operating costs), human resources (remuneration of human resources; staff costs); shareholders (remuneration of shareholders: profit distribution), financial institutions (remuneration of financial institutions: financial charges) and the Public Administration (remuneration of Public Administration: taxes and duties).

In 2018, of the € 1,353 million of Economic Value generated by the Recordati Group, approximately 86% (equal to € 1,162.9 million) was distributed as follows:

- reclassified operating costs of € 577.7 million, represented predominantly by the costs of raw materials, consumables and services;
- remuneration of human resources for a total of € 274.1 million, represented predominantly by the salaries and wages of Group personnel;
- remuneration of shareholders for a total of € 178.9 million, attributable to the distribution of dividends to shareholders<sup>4</sup>;
- remuneration of the Public Administration, in the form of taxes, for € 105.5 million;
- remuneration of financial institutions for € 25.4 million, primarily formed of borrowing costs;
- Community donations allocated and disbursed during the year, sponsorships and community contributions, for € 1.3 million.

### DISTRIBUTION OF THE ECONOMIC VALUE GENERATED AND DISTRIBUTED BY THE RECORDATI GROUP IN 2018<sup>5</sup>



<sup>4</sup> The value of the dividends distributed to shareholders refers to the balance for the 2017 financial year resolved in April 2018 for € 87.1 million, and the account for the 2018 financial year resolved in November 2018 for € 91.8 million.

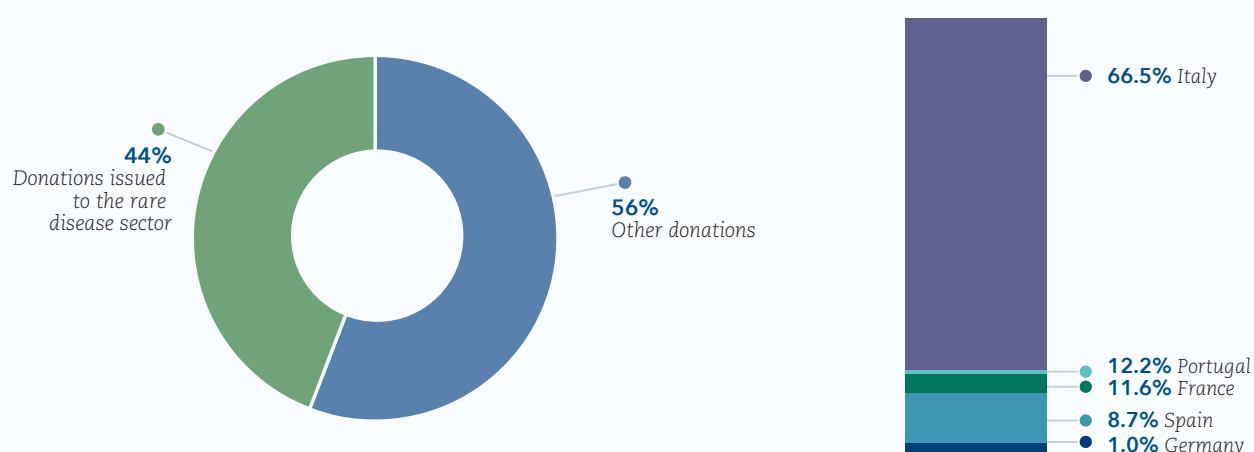
<sup>5</sup> The distribution of the Economic Value generated and distributed to various categories of stakeholders represents a quantifiable indicator for the calculation of the economic value, processed according to the GRI Sustainability Reporting Standards.

## Donations and contributions

Our commitment to providing support to patients is an intrinsic value of the Recordati Group and is evidenced in the development of social projects and initiatives to support organisations operating in the field of health and medication. These include activities implemented by the Group each year to support the numerous associations that focus on the treatment of diseases and improving the quality of life of patients and their families, and research projects and initiatives by supporting social and cultural institutions which carry out their work diligently and passionately every day. In 2018, as well

as € 1.3 million disbursed in donations and contributions to foundations, associations, non-profit organisations and medical institutions, the Recordati Group also paid out € 657 thousand of the amount allocated in 2017 to the "V. Buzzi" Children's Hospital in Milan, equating to total donations of approximately € 2 million. 44% of the total was allocated to activities aimed at the treatment of rare diseases while the remaining 56% refers to contributions and donations awarded to social and cultural organisations and institutions in various countries: Italy (66.5%), Portugal (12.2%), France (11.6%), Spain (8.7%) and Germany (1%).

### SUBDIVISION OF DONATIONS AND CONTRIBUTIONS ALLOCATED BY THE RECORDATI GROUP IN 2018



The donation of € 657 donated in 2018 to the "V.Buzzi" Children's Hospital in Milan represents approximately 33% of the funds allocated in 2017 (€ 2 million), used to further the redevelopment of the paediatric wards and the neurological outpatient unit. This initiative aimed to facilitate the redevelopment of the new Paediatric Ward and the construction of a new Neurology Department, representing the first important step in implementing the project at Milan's Children's Healthcare Centre. This contribution demonstrates the Recordati Group's desire to continue its key investment role in a project that will enable the community of Milan to achieve important targets and provide an increasingly high level of care in the paediatric sector.

## Social initiatives and activities

As well as monetary donations, the Recordati Group provides a constant and significant contribution in the countries where its Companies are located by developing and implementing social and community initiatives, events and projects aimed at vulnerable groups, foreigners, people with disabilities and, more generally, people experiencing any kind of disadvantaged or difficult situation. The type of contribution offered depends on the people to whom it is directed and the characteristics of the association in question.

In particular, the following initiatives are worthy of note:

- The donation of material assets or working hours to promote the redevelopment of primary schools in Tunisia and the preparation of medical kits for people in need in France;
- the assignment of corporate services for organisations for the disabled, such as the fleet management service provided to Donau-Iller-Werkstätten and the laundry service offered to Grüner Zweig, both in Germany;
- direct support for Recordati employees in the organisation and management of social initiatives, such as the Diakonie Neu-Ulm project in Germany which organises events for homeless or disadvantaged people or the commitment to environmental conservation and clean-up operations in Ireland.

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## THE RECORDATI GROUP'S COMMITMENT TO IMPROVING ACCESS TO MEDICAL PRODUCTS AND HEALTH INSURANCE

Rare diseases are predominantly genetic disorders that can affect patients of any age, gender and ethnicity, and involve every category of medical specialisation. These are chronic, often fatal or severely debilitating diseases which have a great impact on patients, their families and on society. A disease is defined as rare when its prevalence, understood as the number of cases in a given population, does not exceed a predefined threshold; in Europe this is 0.05% of the population, or 5 cases per 10,000 people. In order to treat these diseases, specialist medical products known as “orphan drugs” are developed.

The Group companies operating in the rare diseases sector, Orphan Europe S.a.r.l. and Recordati Rare Diseases Inc., share the principle that every person affected by a rare disease has the right to the best treatment possible. For this reason, the activities carried out by Orphan Europe S.a.r.l. and other Group Companies include support for patient associations for people affected by rare diseases, which help patients and their families by facilitating access to orphan drugs and treatment centres. Furthermore, Recordati's orphan drug specialists (ODS) actively collaborate with the medical community to facilitate dialogue between hospitals with limited expertise of rare diseases and specialist medical centres able to diagnose and treat rare conditions in an appropriate manner.

The US Company Recordati Rare Diseases Inc. (RRD) has developed two distinctive programmes to provide assistance to patients eligible for financial support for their products: the Patient Assistance Program (PAP), valid for all products, and the Co-Pay Assistance Program (CAP) available for three drugs (Carbaglu, Cystadane and Panhematin):

- Patient Assistance Program (PAP): this programme enables Recordati Rare Diseases Inc. to supply products to medical professionals or hospitals which require free products to treat their patients, who (i) do not have adequate medical insurance to cover the cost of the drug; (ii) are able to show financial hardship that meets the criteria of Recordati Rare Diseases Inc.; and (iii) meet the eligibility requirements. To determine whether patients are eligible for the programme, including from a financial point of view, a case-by-case assessment is carried out by a third party appointed by RRD. Once the eligibility requirements have been met, the patient is registered to the PAP for a period of up to six months, at the end of which a new assessment is carried out to confirm eligibility for continued participation in the programme.
- Co-Pay Assistance (CPA): this support programme offered by RRD by a third party provides financial support to insured patients, for all or part of their financial responsibilities, for certain RRD products up to a predefined maximum limit. In order to benefit from this assistance, patients must fulfil certain requirements such as being in possession of a valid medical prescription for the product and being insured by an insurance plan that does not cover the full cost of the prescription, etc.

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## LA COURSE DES HÉROS

The “Course des Héros”, one of the most important charitable events in France, is an annual appointment organised by the Group Company Orphan Europe. Over the last four years the Orphan Europe team has collaborated with the L'Envol Association to raise funds for “Recreational Therapies” organised for seriously ill children hospitalised in the association's dedicated facilities. At the event in Paris on 17 June, ten Orphan Europe team members raised a total of € 2,640 to be donated to L'Envol. The race, which raised a total of € 2 million, is an opportunity to demonstrate our engagement in providing care for patients and their families. In its 20 years of operation, L'Envol has welcomed 7,500 children aged between 7 and 17 in its facilities managed by medical experts and volunteers.



### 3.

# PRODUCT QUALITY AND SAFETY

In order to guarantee the highest possible levels of health and safety for patients, the Group is committed to guaranteeing product quality and safety throughout the Recordati supply chain, from the research and development phase for new products to the procurement of raw materials and the production and commercialisation of registered medicines.

During the research phase, specific clinical studies are carried out in order to ensure the efficacy and safety of the products and confirm the absence of any possible dangerous side effects. Furthermore, the results of these studies are assessed by national and European regulatory bodies before authorisation is given to commercialise the medicines on the market.

Throughout the supply chain, our suppliers are selected and regularly assessed according to audit schedules in order to verify compliance with certain criteria, from environmental factors to the quality of the ingredients.

During manufacture, all medicinal products are produced in accordance with Good Manufacturing Practices in plants authorised by the relative local regulatory bodies. Our plants are constantly subject to inspections and checks to ascertain compliance with current legislation and internal regulations.

In the product commercialisation phase, the Recordati Group has implemented a system to guarantee compliance with European Directives regarding anti-counterfeiting, respecting the requirements of the European Union with regard to product serialisation and the use of quality seals on product packaging. Furthermore, when handling all complaints made regarding its products, the Group investigates any possibility of counterfeiting.

Finally, the Recordati Group operates a post-sale pharmacovigilance policy, enabling doctors and patients to promptly notify the Group of any significant events or adverse reactions experienced during the use of Recordati medicines.

#### **Compliance with legislation and regulations**

The Recordati Group operates in full compliance with legislation and regulations in different fields thanks to dedicated and qualified employees. The Group's Code of Ethics states: *"ensuring the compliance of all conduct with applicable legislation and ethical regulations is a mandatory prerequisite for Recordati and our collaborators in every country in which we operate"*.

Important company figures in this regard include the managers of the Pharmacovigilance Department, the Scientific Department, the Clinical and Manufacturing Quality Assurance Departments and the Regulatory Affairs Department, as well as the Qualified Person, the Health, Safety and Environment Manager and the Compliance Officer.

Activities aimed at ensuring compliance with legislation and regulations are undertaken in compliance with international best practices and are constantly examined through inspections conducted by commercial partners, authorities or certification bodies.

In this regard, the Recordati Group complies with the regulations issued by industry certification bodies and has been awarded the GMP (Good Manufacturing Practice) certification for product quality and safety at its plant in Cork, which is valid until 11/01/2020.

The Campoverde di Aprilia site is regularly inspected by the Italian Medicines Agency, the US Food and Drug Administration, the Brazilian *Agência Nacional de Vigilância Sanitária* and the Korean Food and Drug Administration and is certified by the Japanese Ministry of Health.

As regards cases of non-compliance, in 2018 the Group recorded a limited number of episodes: in fact, only a small number of Group branches recorded breaches and/or disputes reported by local authorities:

- the Turkish branch Recordati İlaç Sanayi ve Ticaret Anonim Şirketi was awarded an administrative fine of € 29,000 by Turkey's Social Security Institution. The Institution claimed to have sustained damages due to the branch's failure to promptly announce price variations of certain products in the reference countries. As the appeal presented before the competent governing authorities was not accepted, the Company brought legal action - which is still ongoing - against the local Social Security Institution;
- due to a manufacturing defect regarding the packaging of a product, the Russian company RUSFIC LLC voluntarily recalled - without the application of penalties - the product batches already in circulation;
- in 2018 the Portuguese branch Jaba Recordati S.A received a warning from the National Authority of Medicines and Sanitary Products ("INFARMED") for failure to monitor the online information of its products. Following an inspection carried out by INFARMED, and with the application of a warning without further consequences, Jaba Recordati S.A resolved to appeal to the Administrative Court to obtain greater clarity on the circumstances.

Finally, it is noted that in relation to the information provided in the Non-Financial Statement 2017, in 2018 the Portuguese branch completed the action plan drawn up by the Parent Company regarding the consolidated processing of information relative to pharmacovigilance activities. This action plan was launched in response to a specific request issued by the Portuguese authorities following a branch inspection.

### 3.1. RESEARCH & DEVELOPMENT AND INTELLECTUAL PROPERTY

The Group is constantly committed to Research & Development activities, implemented through the development and launch of pipeline pharmaceuticals and the acquisition of new specialities. In particular, in recent years Recordati has focused its efforts on the research and development of pharmaceuticals to treat rare diseases and urological conditions.

Over the last few years, the development of new pharmaceuticals, both through internal research programmes and through R&D opportunities in partnership with external companies and research institutions, has been a fundamental element in enriching the pipeline and ensuring the Group's future growth.

The Group's intellectual property is protected by its patents, which enable Recordati to transform its R&D investments into a profitable activity. Following a positive outcome of the patent criteria assessment (principally relating to new products and innovative development phases) according to local laws and legislation, the award of European and international patents provides for patent protection in a great number of companies.

This protection, which varies from country to country, depends on the type of patent application and the intended objective. The patent application may be formulated to protect new compounds, manufacturing processes, medical indications, devices and the composition of materials. In countries where the Group files an application to gain patent protection, the duration of the same is generally twenty years, beginning from the date of filing. This period may be extended for a maximum of five years in certain countries, particularly in Europe and the United States, following the approval of the pharmaceutical product by the local Health Authorities.

The patent portfolio is regularly monitored in collaboration with the operational units involved, in order to identify potential breaches and take any necessary legal action. The Group also benefits from the protection of international intellectual property rights through licensing agreements for products and compounds that have been patented by other companies.

As at 31 December 2018 the Group held 563 patents, of which 12 were granted in 2018.

Trademarks also protect the Group's intellectual property. This protection, which varies from country to country, refers principally to their use and registration. Trademark rights are obtained based on national, international and EU registrations, and are generally granted for renewable periods of 10 years. The Group holds around 7,300 registrations for 900 trademarks filed in the name of various companies. Approximately 50% of the trademarks are currently in use.

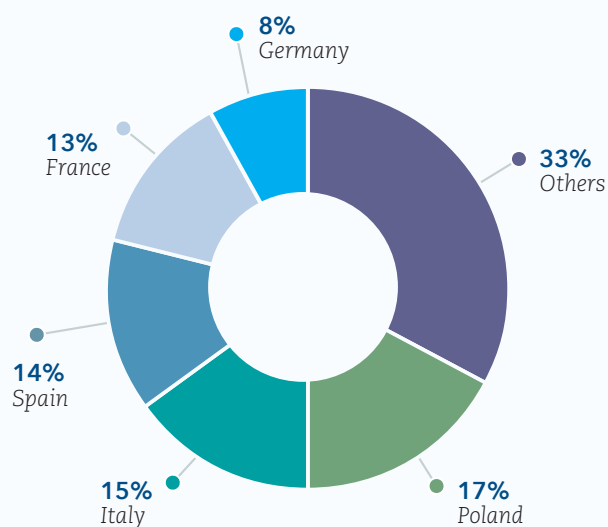
For more information on the Group's research and development activities please refer to the "Research and Development" section of the Annual Report.

### 3.2. SUPPLY CHAIN

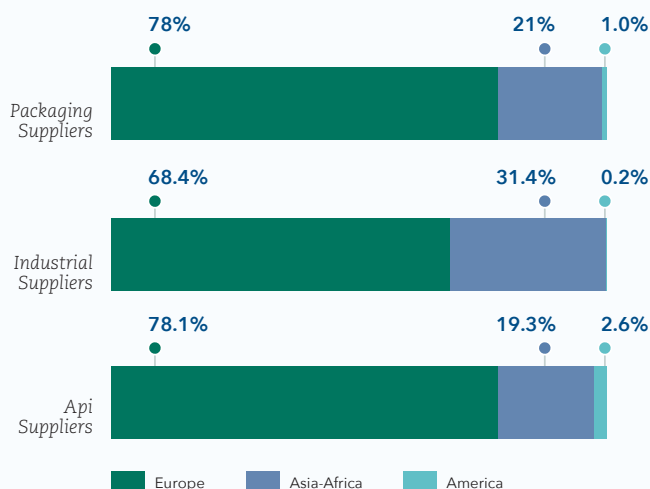
The supply chain of the Recordati Group operates within a highly regulated market and is characterised by the search for efficiency both in terms of financial viability and the maintenance of the supply chain. The Recordati Group is served by approximately 14,500 suppliers, predominantly located in the countries in which the Group operates manufacturing plants or has a commercial presence. The supply chain is characterised by the purchase of direct ingredients (active substance, packaging material, excipients and chemical intermediates), finished products and indirect services required for regular operation (consultancy services, marketing, supplies, licensing, etc.). In this regard, the main purchase categories are represented by APIs (Active Pharmaceutical Ingredients), packaging, industrial products and services and finished products.

In 2018 the Recordati Group interacted with around 450 certified API suppliers principally located in Europe and India. Approved suppliers for the packaging of medicinal products produced directly in the Group's plants numbered approximately 200, located principally in the countries in which the Group has a manufacturing site (of these, approximately 10% are approved suppliers for two or more factories). Suppliers of industrial materials and services for use in the Group's plants numbered approximately 1,400, with a pronounced local presence due to the type of goods and services. Finally, it should be noted that there are approximately 130 suppliers of finished products at Group level, with a pronounced predominance of European producers.

**PERCENTAGE BREAKDOWN OF SUPPLIERS OF THE RECORDATI GROUP BY LOCATION, 2018**



**PERCENTAGE SUBDIVISION OF THE THREE SUPPLIER CATEGORIES OF THE RECORDATI GROUP BY LOCATION, 2018**



In order to operate within the Recordati Group, our suppliers are selected and approved according to two different methods for direct and indirect products. For the purchase of indirect materials and services, information regarding the suppliers' economic and financial position is collected through documental evidence and research. For the purchase of direct materials, potential suppliers are subjected to financial checks and are required to follow a regulated documentation collection procedure in line with GMPs and GDPs (Good Manufacturing Practices and Good Distribution Practices) before undergoing a strict monitoring and auditing process.

In order to standardise the selection process, in 2015 the ATTITUDE project was launched, aimed at implementing a new purchase management policy at Group level using an eProcurement platform. The project aims to promote transparency in the procurement process in terms of supplier assessment and effective negotiation in line with the distribution of procedures and tools at a centralised and local level. Our supplier selection criteria include:

- focus on the environment and the laws that regulate it;
- compliance with the Group's Code of Ethics which includes respect of the basic Human Rights of all employees, the prevention of child exploitation and the prohibition of forced or enslaved labour, in accordance with the International Labour Organisation. These selection criteria are binding and all suppliers must declare their commitment to the Code of Ethics and the practices contained therein.

This management process was successfully implemented in Italy in 2016. Recordati has set itself the target of extending the initiative to all Group Companies by the end of 2021, in order to create a unique and shared supplier database.

**3.3. AUDITS AND INSPECTIONS**

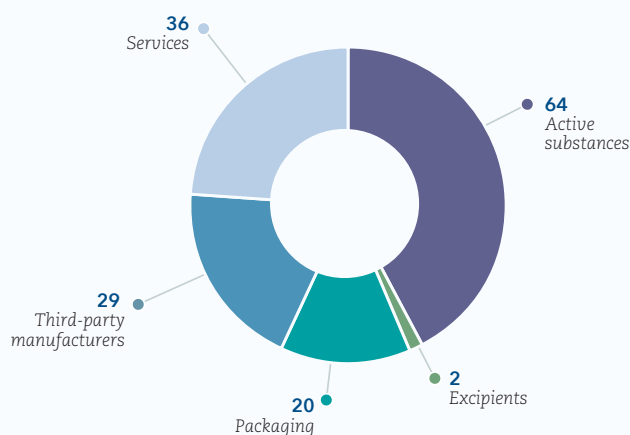
In order to ensure the safety of its products and verify the compliance of its suppliers with quality, environmental, health and safety legislation and regulations, the policies implemented by the Recordati Group include periodic audits of the supply chain, as well as continuous inspections and self-inspections within its own manufacturing plants.

**Supplier audits**

One of the main control measures implemented in the supply chain are the audits carried out by the Group at third-party pharmaceutical companies which produce medicines, as well as suppliers of APIs, excipients and packaging. As well as assessments at the supplier approval stage, the supplies provided by suppliers are constantly monitored for quality assurance purposes.

In line with the current procedures for supplier approval, all suppliers, particularly those supplying active substances, excipients and services, are subjected to periodic audits as defined by a risk assessment rating. In fact, in 2018 the Pharmaceutical Division of the Recordati Group conducted 151 supplier audits, of which 20% related to third-party manufacturers, 42% to suppliers of active substances, 13% to suppliers of packaging, 24% to service suppliers and 1% to suppliers of excipients.

**SUBDIVISION OF SUPPLIER AUDITS CONDUCTED BY THE PHARMACEUTICAL DIVISION BY PRODUCT CATEGORY, 2018**



Regarding supplier inspections carried out by the Chemical and Pharmaceutical Division, it should be noted that in the course of 2018 the Campoverde di Aprilia plant conducted ten audits of suppliers of raw materials.

### Production plant inspections

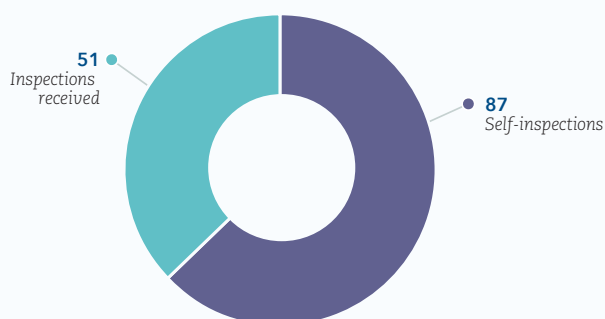
The production plants of the Recordati Group are regularly subjected to internal or external inspections (the latter by competent authorities, third-party companies and clients) in order to verify compliance with product quality regulations.

During the production phase, every single batch of Recordati medicines is produced in accordance with the dossiers approved by the relative health authorities and is subject to controls designed to ensure their quality.

Within its own pharmaceutical plants, the Group is committed to maintaining a quality control system that fulfils all national and international requirements, guidelines and standards for the production of finished pharmaceutical products. In particular, the manufacturing plants operate in line with GMPs (Good Manufacturing Practices) and are regularly verified by inspections conducted by national and international competent authorities. The Quality Control departments are responsible for the control of procured raw materials and the finished products in accordance with the relative procedures, approved methods and the pharmacopoeial monographs.

In 2018, a total of 138 inspections and audits were carried out at the Group's pharmaceutical plants in order to assess product quality and safety. Of these, 87 (63%) were self-inspections carried out by the Group at its own plants while the remaining 51 were carried out by competent authorities (Health Ministries, Agencies, Certification Bodies, FDA and AIFA) and third-party companies.

#### SUBDIVISION OF QUALITY AND SAFETY INSPECTIONS/AUDITS CARRIED OUT AT GROUP PHARMACEUTICAL PLANTS IN 2018



Among the inspections received in 2018, the pharmaceutical plants received inspection from regulatory bodies in order to review/grant manufacturing authorisations. In this regard, the inspections conducted by the Russian authorities at the plants in Utebo (Spain), Nanterre (France) and Cerkezkoj (Turkey) and by the Danish authorities in Cerkezkoj (Turkey), were of particular

note. While those carried out in Utebo and Nanterre were predominantly aimed at renewing existing authorisations, those carried out in Cerkezkoj were aimed at authorising the site to produce certain specialist pharmaceutical products for the Russian and European market, ensuring the presence of a back-up site for said products/markets. While in the case of Utebo the existing authorisations had already been renewed, post-inspection procedures are currently in progress at Nanterre and Cerkezkoj (e.g. the presentation of a corrective action plan) in order to bring the process to a successful conclusion.

With a view to constantly improving production, in the course of 2018 inspections were carried out at the plant in Kalaat El Andalous (Tunisia) to obtain the ISO 9001:2015, ISO 14001:2015 and OHSAS 18001:2017 certifications. The outcome of these inspections was positive and the certificates were issued in May 2018.

As well as the inspections conducted by external bodies since 2018, the pharmaceutical production plants were subject to internal audits carried out by the Group's internal Quality Assurance department on an annual basis (not all sites were subject to these controls in the first year but will be from 2019).

With regard to the inspections carried out at the two chemical pharmaceutical plants, it should be noted that an external inspection of the Quality Management System was carried out at the Campoverde di Aprilia plant in 2018 by the US Food and Drug Administration (FDA), the US pharmaceuticals control body. The inspection concerned compliance with GMPs in relation to the production, control and storage of 14 products distributed in the United States, and a positive outcome was obtained with no observations made by the inspecting body. Furthermore, the internal Quality Assurance department conducted 14 internal audits at the plant in Campoverde di Aprilia in the production, quality control and maintenance departments, and was subjected to 26 customer audits.

With regard to the plant in Cork, the following inspections were carried out:

- an inspection was carried out by the Health Products Regulatory Authority (HPRA) of the Irish Health Ministry in May 2018, as part of the three-year renewal of the plant's Certificate of Compliance with Good Manufacturing Practices for the production of active substances. This inspection aimed to verify the progress and effective efficacy of the control measures identified following the recommendations issued by the Authority in 2017. The inspection was passed and enabled the renewal of the GMP certificate for a further three years.
- during the year the plant was also inspected and approved by a client who buys an active substance manufactured on the site;
- during the year the internal audit plan consisting of various inspections in different sectors (Production, Quality, Maintenance) was carried out, resulting in the identification of measures and improvements to strengthen the various activities.



### 3.4. PRODUCT SERIALISATION

Since 2006, the European Federation of Pharmaceutical Industries and Associations (EFPIA) has been developing a standardised medicinal products traceability system as part of the fight against counterfeiting. Working in collaboration with three other European organisations, EFPIA has been involved in the creation of an ambitious coding and serialisation system known as the European Stakeholder Model (ESM). In conjunction with this project, ESM members worked to implement the European Medicines Verification System (EMVS) which aims to regulate the dispensation of medicines to ensure product authenticity.

In this context, in February 2016 the European Parliament issued a regulation dictating the technical requirements for all prescription medicines in order to combat medicines being counterfeited. This regulation will come into force in February 2019. However, certain member states, Italy included, are exempt from implementing this regulation for a further six years due to the adoption of internal anti-counterfeiting systems at national level. After this date, medicinal products that do not comply with the safety requirements established by this regulation may no longer be commercialised.

In this regard, in 2015 the Recordati Group launched a project to ensure that all medicinal products produced at its own production plants or those of third-party companies comply with this regulation. The process is continuing in line with the implementation deadlines provided for by legislation and the packs produced for the Group will comply with legislative requirements by January 2019. In order to prevent unforeseen circumstances and/or delays, reserve stocks have been established according to a risk assessment plan, so as to ensure continuity of supply for all products. All equipment was successfully installed according to the envisaged deadlines in the four pharmaceutical plants involved in the project. All information generated in regard to the serialisation of individual packs shall be collated in a database designed to enable the in-out management of all third-parties of the Group as part of a European data collection system.

Similar initiatives aimed at combating the counterfeiting of medicinal products have been launched or are currently being implemented in various countries in which the Group operates. In particular, in Turkey, China, the USA and Korea, the medicinal products commercialised by the Recordati Group already comply with these safety requirements, while the Group's sites in Russia will conform in the course of 2019, as provided for by local legislation.

## 4. THE RECORDATI GROUP'S EMPLOYEES

### 4.1. THE IMPORTANCE OF OUR EMPLOYEES

The Recordati Group operates in highly specialised sectors including traditional pharmaceuticals, the treatment of rare diseases and chemical pharmaceuticals. In order to operate effectively in these fields, it is essential to collaborate with increasingly highly qualified employees able to bring professionalism and added value to the Group and enable us to confront and overcome market challenges.

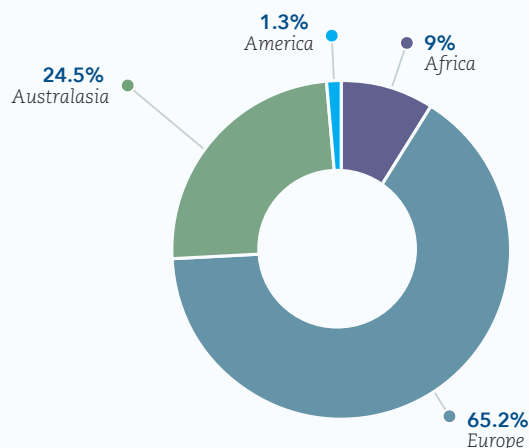
For this reason, the Group policy for the development and optimisation of human resources aims to incentivise professional growth and career development. This policy has been developed through our belief that the Group's results are closely linked to the ability of our employees to engage their own commitment and talent to reach targets. Furthermore, optimisation of human resources is a key priority when fulfilling company roles. The recruitment process is aimed at selecting the candidates that best respond to the profiles required by company departments in accordance with the given time frames and market cost criteria.

As of 31 December 2018, the Group's workforce was formed of 4,142 employees, with a gender division of 55% and 45% of men and women respectively. The workforce in 2018 was substantially in line with that recorded at the end of 2017 (4,176 employees). At present, the Group's workforce is also supplemented by some 100 resources who collaborate with the Group at various levels; approximately one third of these collaborators is represented by women.

#### SUBDIVISION OF EMPLOYEES AND COLLABORATORS BY GENDER, AS OF 31 DECEMBER 2018

Number of employees	2018			2017		
	Men	Women	Total	Men	Women	Total
Employees	2,276	1,866	4,142	2,297	1,879	4,176
Collaborators	74	34	108	103	97	200
<b>Total</b>	<b>2,350</b>	<b>1,900</b>	<b>4,250</b>	<b>2,400</b>	<b>1,976</b>	<b>4,376</b>

#### PERCENTAGE BREAKDOWN OF EMPLOYEES BY GEOGRAPHIC AREA, AS OF 31 DECEMBER 2018<sup>6</sup>



#### SUBDIVISION OF EMPLOYEES BY COUNTRY, AS OF 31 DECEMBER 2018 (NO. PEOPLE)

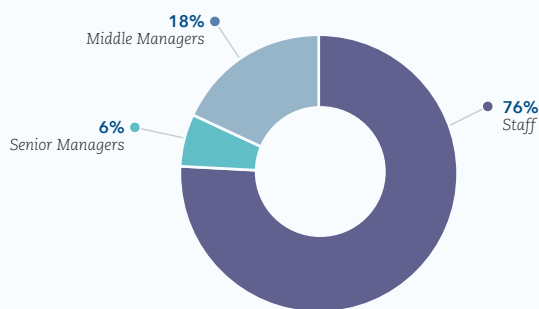
Total	4,142
Italy (28%)	1,189
Turkey (18%)	672
France (9%)	387
Tunisia (9%)	371
Spain (7%)	307
Russia (7%)	287
Germany (5%)	203
Portugal (3%)	121
Poland (3%)	117
Czech Republic (2%)	95
Ukraine (2%)	84
Ireland (1.4%)	61
Greece (1%)	44
Romania (1%)	30
United States (1%)	30
Switzerland (0.4%)	18
Kazakhstan (0.4%)	18
Belarus (0.3%)	16
Colombia (0.2%)	12
Georgia (0.2%)	11
Other Countries* (1.1%)	69

(\*) The item "Other Countries" includes employees who work in Armenia, Benelux, Brazil, United Arab Emirates, Mexico, United Kingdom, Sweden, Hungary, Canada, Australia, Japan and Malaysia.

<sup>6</sup> Australasia includes the Turkish branch (Recordati İLAÇ ve Hammaddeleri Sanayi ve Ticaret A.S.) and the Russian branch (RUSFIC LLC).

As regards the breakdown of the Recordati Group's workforce by professional category, 239 employees are Senior Managers (6% of the total), 741 are Middle Managers (almost 18%) while the remaining 3,162 people are ordinary employees (76%). In line with 2017, all Senior Managers, men and women, were recruited locally<sup>7</sup>.

**PERCENTAGE BREAKDOWN OF GROUP EMPLOYEES BY PROFESSIONAL LEVEL, AS OF 31 DECEMBER 2018**



Approximately 64% of the workforce is comprised of employees aged between 30 and 50, around 25% are over 50 and approximately 11% are under 30.

**SUBDIVISION OF GROUP EMPLOYEES BY PROFESSIONAL LEVEL AND AGE, AS OF 31 DECEMBER 2018**

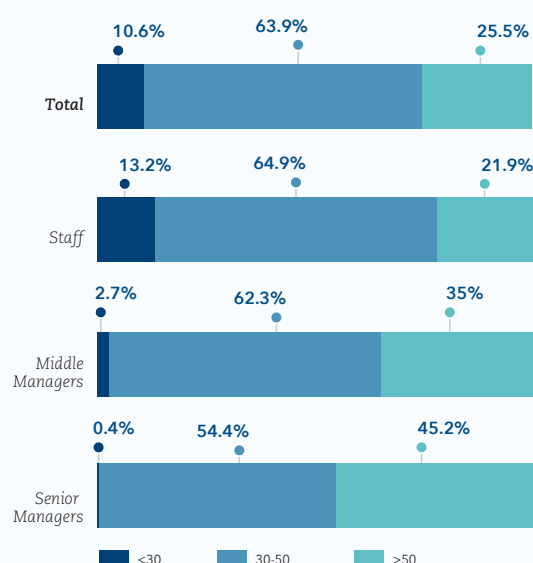
**2018**

Number of employees	<30	30-50	>50	Total
Senior Managers	1	130	108	239
Middle Managers	20	462	259	741
Staff	418	2,053	691	3,162
<b>Total</b>	<b>439</b>	<b>2,645</b>	<b>1,058</b>	<b>4,142</b>

**2017**

Senior Managers	1	138	98	237
Middle Managers	18	405	175	598
Staff	455	2,167	719	3,341
<b>Total</b>	<b>474</b>	<b>2,710</b>	<b>992</b>	<b>4,176</b>

**PERCENTAGE BREAKDOWN OF GROUP EMPLOYEES BY PROFESSIONAL LEVEL AND AGE, AS OF 31 DECEMBER 2018**



The selection process outlined by the recruitment policy can take place internally, through the development of horizontal and vertical career paths designed to develop the technical and professional skills of employees already operating within the Group through the self-application system, or externally through recruitment campaigns conducted directly or through the use of approved recruitment agencies.

In order to optimise the development of human resources, in the case of suitable vacancies and candidates the Group prioritises the recruitment of internal employees. For junior positions, the recruitment process begins at university level, focusing on undergraduates in their final year or new graduates who have been selected according to their university or Master's specialisation. This policy offers young people the opportunity to embark on a professional development programme within the Group through placements and apprenticeships, in particular in the areas of Finance, Research and Development, Marketing and Industry. To select the best candidates, the Group uses an internal Assessment Centre that aims to assess the transferable skills and communication abilities of the young candidates.

With a view to standardising the selection of candidates, a "Recruiting Grid" has been implemented in the HR departments of the various Group Companies, aimed at supporting line managers involved in the selection of a new employee during the candidate interviewing process. In a nutshell, this initiative provides a series of prompts aimed at exploring if, and to what extent, the candidate possesses the managerial skills that characterise employees of the Recordati Group.

<sup>7</sup> Senior Managers recruited locally include those born, or with the legal permanent right to reside (as naturalised citizens or permanent visa holders) in the country in which they were hired.

During the interview, the manager draws on a series of suggestions on how to engage with the interviewee, such as how to pose questions and which aspects to develop further. Furthermore, the "Recruiting Grid" offers various positive and negative indicators to indicate whether a candidate possesses a certain skill.

In 2018, 653 new employees joined the Recordati Group, with an inbound turnover rate (the ratio between the number of new employees and the total Group workforce as at 31 December 2018) of approximately 16%, while the number of employees who left the company was 687 (with an outbound turnover rate - the ratio of number of people leaving the Group to total Group workforce as of 31 December 2018 - of around 17%).

#### SUBDIVISION OF TOTAL EMPLOYEES ENTERING AND LEAVING THE COMPANY BY GENDER AND AGE, AS OF 31 DECEMBER 2018

Number of employees	2018					2017				
	<30	30-50	>50	Total	Turnover %	<30	30-50	>50	Total	Turnover %
<b>New employees entering the Group</b>										
Men	84	209	32	325	14%	92	183	26	301	13%
Women	101	208	19	328	18%	97	212	21	330	18%
Total	185	417	51	653	16%	189	395	47	631	15%
Turnover %	42%	16%	5%	16%		40%	15%	5%	15%	
<b>Employees leaving the Group</b>										
Men	50	245	51	346	15%	55	207	25	287	12%
Women	70	238	33	341	18%	76	173	35	284	15%
Total	120	483	84	687	17%	131	380	60	571	14%
Turnover %	27%	18%	8%	17%		28%	14%	6%	14%	

#### SUBDIVISION OF EMPLOYEES ENTERING AND LEAVING THE COMPANY BY GENDER, AGE AND LOCATION, AS OF 31 DECEMBER 2018

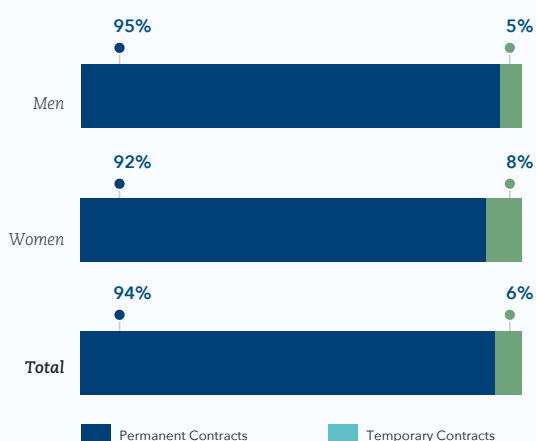
Number of employees	2018									
	<30	30-50	>50	Total	Turnover %	<30	30-50	>50	Total	Turnover %
<b>Employees joining the Group - Europe</b>					<b>Employees leaving the Group - Europe</b>					
Men	42	104	21	167	11%	17	73	40	130	9%
Women	43	117	19	179	15%	30	123	29	182	15%
Total	85	221	40	346	13%	47	196	69	312	12%
Turnover %	47%	14%	4%	13%		26%	13%	7%	12%	
<b>Employees joining the Group - Australasia</b>					<b>Employees leaving the Group - Australasia</b>					
Men	25	81	9	115	20%	24	140	7	171	30%
Women	27	69	0	96	22%	21	90	1	112	26%
Total	52	150	9	211	21%	45	230	8	283	28%
Turnover %	37%	18%	22%	21%		32%	28%	20%	28%	
<b>Employees joining the Group - Africa</b>					<b>Employees leaving the Group - Africa</b>					
Men	17	22	0	39	24%	9	32	4	45	27%
Women	30	18	0	48	23%	19	22	1	42	20%
Total	47	40	0	87	23%	28	54	5	87	23%
Turnover %	41%	17%	0%	23%		25%	23%	29%	23%	
<b>Employees joining the Group - America</b>					<b>Employees leaving the Group - America</b>					
Men	0	2	2	4	14%	0	0	0	0	0%
Women	1	4	0	5	18%	0	3	2	5	18%
Total	1	6	2	9	16%	0	3	2	5	9%
Turnover %	33%	24%	7%	16%		0%	12%	7%	9%	

The Recordati Group believes that offering a stable and long-lasting working relationship is an important factor to promoting employee motivation and represents an essential element of the Group's growth and economic development. For this reason, 94% of all resources are recruited on permanent contracts while 6% are on temporary contracts, in line with the data for 2017.

**SUBDIVISION OF EMPLOYEES BY CONTRACT TYPE (PERMANENT OR TEMPORARY) AND GENDER, AS OF 31 DECEMBER 2018**

Number of employees	2018			2017		
	Men	Women	Total	Men	Women	Total
Permanent Contracts	2,165	1,718	3,883	2,189	1,733	3,922
Temporary Contracts	111	148	259	108	146	254
<b>Total</b>	<b>2,276</b>	<b>1,866</b>	<b>4,142</b>	<b>2,297</b>	<b>1,879</b>	<b>4,176</b>

**PERCENTAGE SUBDIVISION OF EMPLOYEES BY CONTRACT TYPE (PERMANENT OR TEMPORARY) AND GENDER, AS OF 31 DECEMBER 2018**



In order to promote continuous improvement aimed at optimising the sharing of information regarding human resources, in 2017 a feasibility study was launched to assess the possibility of creating a centralised database, with the aim of collating the information (name, contract, wage) of all Group employees and implementing initiatives aimed at promoting maximum intra-group cooperation. In 2018, assessment activities were continued with the selected partner, a leading multinational HR service provider, prioritising the installation of the HR Administration platform for the Parent Company, with the aim of using it as a basis for the construction of a Group database.

**4.2. DIVERSITY AND EQUAL OPPORTUNITIES**

As stated in the Code of Ethics, the Recordati Group is committed to offering equal working opportunities without any discrimination based on ethnic background, age, sexual orientation, physical or mental disability, nationality, religious beliefs or membership of political parties or unions, and guarantees all employees equal and meritocratic treatment. Furthermore, the Code of Ethics states the Group's commitment to "the respect for basic human rights, the prevention of child exploitation and the prohibition of forced or enslaved labour" in compliance with the Conventions of the International Labour Organisation.

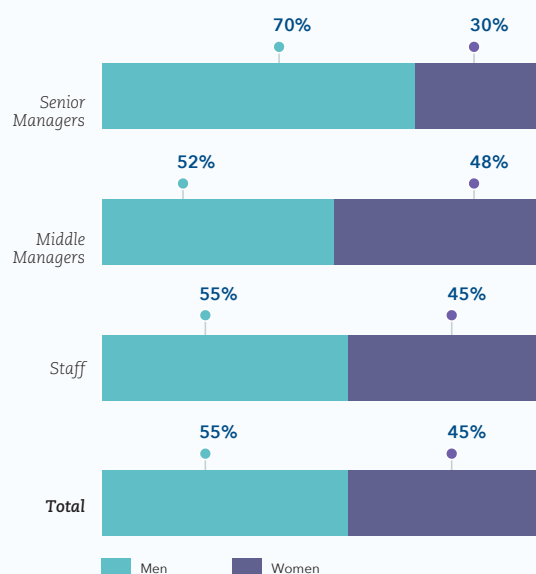
As such, all Group departments are committed to: adopting criteria based on merit, skills and professionalism; selecting, recruiting, training, rewarding and managing employees without discrimination; promoting the integration of employees from other countries.

The Group has a good gender balance, with 55% of employees represented by men and 45% represented by women. The workforce is evenly divided by professional category and the gender balance remains broadly in line with the previous year.

**SUBDIVISION OF GROUP EMPLOYEES BY PROFESSIONAL LEVEL AND GENDER, AS OF 31 DECEMBER 2018**

Number of employees	2018			2017		
	Men	Women	Total	Men	Women	Total
Senior managers	167	72	239	160	77	237
Middle managers	382	359	741	320	278	598
Staff	1,727	1,435	3,162	1,817	1,524	3,341
<b>Total</b>	<b>2,276</b>	<b>1,866</b>	<b>4,142</b>	<b>2,297</b>	<b>1,879</b>	<b>4,176</b>

**PERCENTAGE BREAKDOWN OF GROUP EMPLOYEES BY PROFESSIONAL LEVEL AND GENDER, AS OF 31 DECEMBER 2018**



The Recordati Group always aims to ensure the maximum respect for the human rights of its employees. In this context, the Group's Code of Ethics states that a constant commitment to promoting and consolidating the culture of a safe working environment is one of the fundamental principles of the human resources management policy, aimed at implementing practices and preventative measures to protect the physical and psychological health and safety all Group employees.

All company departments of the Group are committed to creating a working environment where the personal characteristics of individual employees do not form the basis for discrimination of any kind. As such, in compliance with the Conventions of the International Labour Organisation, the Group is committed to respecting basic human rights such as the prevention of child exploitation and the prohibition of forced or enslaved labour. Furthermore, the Group is committed to ensuring a healthy, clean and pollution-free environment in all of its sites and plants. In its internal and external working relations, the Group prohibits all cases of subjugation by violence, threat, deceit, abuse of authority, harassment of any kind, or exploration of a physical or psychological vulnerability or vulnerable situation.

Managers across all company departments constantly monitor compliance with the provisions of the Code of Ethics and are committed to intervening promptly in the event of any situation that could potentially result in breaches to the conduct required and promoted by the Group. With reference to the management models adopted by the Group to protect the human rights of its employees, the Group has integrated a management policy which promotes the concept of inclusion, respects diversity and gives all employees a voice in order that every contribution be heard and considered.

As regards industrial relations, the Recordati Group protects the right of employees to join and form unions, supports alternative methods of union representation and collective labour agreements and ensures that union representatives are not discriminated against at their place of work and are free to communicate with their members. The industrial relations model implemented by the Companies of the Recordati Group is based on continuous dialogue and debate, characterised by proper and transparent relations and is aimed at increasing the firm's competitiveness and promoting responsible employment. Approximately 60% of the Group workforce, predominantly located in western Europe, is covered by a collective labour agreement.

### 4.3. EMPLOYEE WELFARE

The Recordati Group believes that the welfare of its employees is a key element to achieving company targets. In general terms, welfare initiatives vary between countries due to the specific characteristics of different states (regulatory framework, availability of public services etc.) and the existence of previous agreements developed by the various corporate entities before they became part of the Group. The promotion of corporate welfare is part of a wider strategy aimed at managerial innovation and corporate social responsibility and represents a tool to improve relations with employees and internal stakeholders while also developing human, social and relational capital.

Regardless of format, every welfare initiative implemented by the Recordati Group aims to achieve both tangible and intangible results relating to the management of employee relations. In particular, these initiatives aim to promote:

- the maintenance of a healthy and positive working environment and life for all employees;
- the increase in engagement of human resources in the context of corporate activities and, more generally, an improvement in the quality of internal relations;
- a positive level of motivation resulting in a consistent professional contribution to individual and Group productivity;
- stable relations and a strong sense of belonging among employees;
- the reduction in turnover and, in terms of Employer Branding, an increasingly attractive and visible corporate profile on the employment market, particularly within the highly selective and competitive contexts within which the Recordati Group operates.

In its approach to employee welfare initiatives, the Recordati Group has always retained a strong belief in the importance of closely supporting employees and their families, offering concrete and proactive assistance particularly in the case of serious health concerns.

To this end, the increased focus on employee welfare at a corporate level in recent months led the Group to commission an external consultancy firm to produce a report on the various welfare systems in Italy's pharmaceutical sector. This report highlighted that the welfare package offered by the Recordati Group is in line with the other companies in the sample for its wide range of additional benefits; these include technical and specialist training programmes, language courses, preventive medicine initiatives (such as flu vaccines and in-house specialist appointments), membership of professional institutions, agreements with suppliers (such as public transport operators), company canteens, company vehicles and various health insurance packages. Based on these findings, the short-term goal is to develop a benefits scheme that further broadens the current welfare system, ensuring constant alignment with the needs of the Group's workforce while also achieving the expected results.

In 2018, the Parent Group launched a flexible benefits system: this system represents an alternative remuneration method for employed work consisting of a range of goods, services and non-financial benefits offered by the Group to its employees in addition to their "standard" wage package, in order to increase employees' buying power and improve their quality of life. More specifically, this system replaces a percentage of the overall remuneration package with goods and/or services which are usually purchased externally by the employee to meet their personal or family requirements, ranging from grocery or fuel vouchers and the reimbursement of medical or school fees for the employee or their family members, to membership to recreational initiatives and support for the care of elderly relatives.

The term "flexible benefits" refers to a fixed allowance allocated to employees that can be "spent" freely on the goods and services which best correspond to their individual requirements.

This package has been designed to offer the broadest possible variety of options, meeting the different needs of a population characterised by diverse ages and requirements. After consolidation at corporate level, the aim is to evaluate the possible extension of the package to other Group companies, in line with the individual characteristics of local legislation, with a view to further standardisation.

At a contractual level and in line with 2017, 98 people opted for part-time contracts. 80% of employees on part-time contracts are women. Compared to 2017, it is noted that the number of men opting for part-time contracts has risen by approximately 20%.

#### SUBDIVISION OF EMPLOYEES BY PROFESSIONAL TYPE (FULL OR PART TIME) AND GENDER, AS OF 31 DECEMBERER

Number of employees	2018			2017 <sup>8</sup>		
	Men	Women	Total	Men	Women	Total
Part-time	18	80	98	15	81	96
Full-time	2,258	1,786	4,044	2,282	1,798	4,080
<b>Total</b>	<b>2,276</b>	<b>1,866</b>	<b>4,142</b>	<b>2,297</b>	<b>1,879</b>	<b>4,176</b>

#### Remuneration system

The remuneration system of the Recordati Group is based on the meritocratic "Pay for performance" principle and has been designed to encourage and reward high levels of performance, aligning managers' interests with those of our shareholders. The remuneration strategy aims to ensure that pay corresponds to the responsibilities of each role and individual performance, optimising and retaining key resources while remaining in line with national employment legislation. The remuneration system is composed of basic pay, variable short-term compensation (variable annual bonus), additional benefits (pension contributions, reimbursement of medical expenses, etc.) and variable mid-to-long term compensation (principally represented by stock option plans). The variable short and mid-to-long term payments are subject to the achievement of financial results which are measurable, quantifiable and made known to beneficiaries.

The Group's remuneration policy aims to guarantee equal conditions for men and women across all professional levels, rewarding merit and the ability to fulfil the assigned role and meet defined objectives. In terms of remuneration, the ratio between the average basic salary of female employees and male employees is 75% at Senior Management level, 92% at Middle Management level and 96% for all other employee categories. The ratio in terms of total remuneration is 73% for Senior Managers, 88% for Middle Managers and 93% for all other employee categories.

#### RATIO BETWEEN BASIC SALARY AND TOTAL REMUNERATION<sup>9</sup> FOR MEN AND WOMEN BY PROFESSIONAL LEVEL, FOR ITALIAN AND FOREIGN COMPANIES OF THE RECORDATI GROUP, AS AT 31 DECEMBER 2018

Ratio between women and men	2018		2017	
	Basic Salary	Total Remuneration	Basic Salary	Total Remuneration
Senior managers	75%	73%	70%	71%
Middle managers	92%	88%	94%	87%
Staff	96%	93%	98%	90%

#### Principle internal engagement initiatives

The MBO system plays a key role in the definition of internal engagement and sharing initiatives, aimed at directing the Group's results and the energies and efforts of senior managers and middle managers towards a common goal through the definition of clear, challenging and shared objectives.

In terms of "soft" initiatives, significant importance is placed on the Recordati style of management. Developed through the identification of the distinctive managerial skills that have characterised the Group's evolution over the years and which will continue to overcome future challenges, this managerial approach is implemented through the skills appraisal process which promotes the sharing and discussion of assessments between the "assessor" and the "assessee" (manager and collaborator) in order to optimise and promote Recordati's distinctive managerial style.

Through the combination of MBOs and appraisals, managers are assessed in terms of their achievements (individual targets assigned by the Group) and the way in which these achievements are reached (conduct which displays the use of managerial skills).

More generally, the principle internal engagement initiative is the Management Meeting of the Recordati Group, held each year in Milan. This meeting represents an opportunity for debate and discussion between Managers from all Group Companies and features a series of presentations given by Senior Managers or important figures in the pharmaceutical industry about the Group's results, the advancement of activities, the development of the business and its products and, more generally, any new initiatives which have been launched or are in development.

<sup>8</sup> The data for 2017 have been revised in line with the new requirements of the GRI Standards that provide for the breakdown in full-time and part-time for the total workforce, as a substitute for the GRI G4, which required the breakdown only for permanent employees.

<sup>9</sup> The variable component of total remuneration differs between Italian and foreign companies. In Italy, this variable component is predominantly composed of MBO programmes (available for all senior managers and around half of all middle managers) and the participation bonus offered to all middle managers and employees except senior managers. Foreign Companies manage the variable component independently through packages similar to MBO programmes which are offered to all employees in line with local regulations.

Achieved targets are discussed and future strategies and developments are defined and reinforced. At the end of the day, a much anticipated and appreciated Awards Ceremony is held to reward the best scientific contributors from each branch. Furthermore, the sector meetings held by each company department with representatives of foreign branches are a smaller-scale but equally important method of the sharing of methods and tools. Developed as part of the launch of new projects, these events now represent an essential opportunity for debate and orientation, aiming to promote a shared approach and develop the sense of Group belonging in an increasingly complex and multicultural context. At a local level, conventions are organised for local management teams and staff operating in commercial facilities "in the field" (scientific consultants and area managers), representing important opportunities for sharing best practices and discussing commercial themes and products.

One of the most important initiatives of an informative nature is the "Inside Recordati" magazine. Presenting the Group's activities and distributed to all employees, the publication features news articles and describes the events and initiatives that have characterised the Group during the given period.

As regards the most recent hires in the Recordati Group, an induction process is now carried out at corporate level. For employees of the Parent Company, this programme consists of a day-long course for new hires which takes place within six months of recruitment, enabling resources to have developed direct knowledge of the company structure before being guided by HR to receive a comprehensive overview of the organisation of the Recordati Group.

The day course is usually introduced by the Human Resources Manager who explains the Group policies, after which presentations are given to provide background information on the organisational structure, history and characteristics of the company. The morning is brought to a close by a session centred around the Communications and Investor Relations department. The rest of the day consists of talks given by managers of various departments to illustrate the activities and processes of the various business areas. This provides an ideal opportunity for new hires to ask questions or seek clarifications on the business model and the company's adopted policies.

In the second half of the day, a visit is made to the Milan plant, offering a constructive method of learning about the organisation and its processes.

For new resources recruited to sites outside Italy, an individual induction process is carried out at corporate level each time a new employee is appointed to the local Management Team; shortly after hiring, the new member is invited to the head offices to meet the managers of the main departments with whom they will interact as a result of their role, giving both parties an opportunity to get to know one another and also providing an overview of the department's key activities and priorities.

#### 4.4. TRAINING AND DEVELOPMENT OF HUMAN CAPITAL

The Group considers the development of human capital as an important professional and personal process that enables employees to understand the key skills required by their role and develop their personal growth through individual training, on-the-job training, coaching, mentoring and one-to-one counselling.

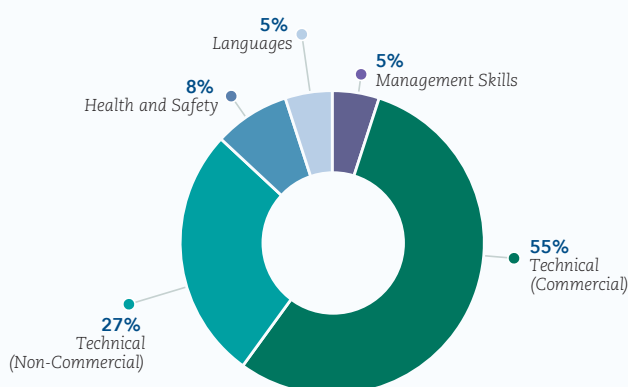
In this respect, the main initiatives promoted by the Group throughout the year have aimed to define and develop the technical, managerial and linguistic skills of managers, as well as offer training programmes to develop specialised and professional skills.

In line with the previous year, in 2018 the Recordati Group provided over 85,000 hours of training to its employees, equating to 20.6 hours of training pro capita. In particular, 77% of all training hours was provided to staff, 18% to Middle Managers and 5% to Senior Managers. Various types of training courses were offered including management skills, technical commercial skills, technical non-commercial skills, languages and health and safety.

##### SUBDIVISION OF PRO CAPITA TRAINING TIMES PROVIDED TO EMPLOYEES BY PROFESSIONAL LEVEL AND GENDER

Average number of hours	2018			2017		
	Average number of hours Men	Average number of hours Women	Average number of hours Total	Average number of hours Men	Average number of hours Women	Average number of hours Total
Senior Managers	16.8	25.9	19.6	16.7	26.6	19.9
Middle Managers	21.7	18.8	20.3	23.9	25.7	24.8
Staff	23.4	17.6	20.8	23.0	23.5	23.2
<b>Total</b>	<b>22.7</b>	<b>18.2</b>	<b>20.6</b>	<b>22.7</b>	<b>23.9</b>	<b>23.2</b>

##### PERCENTAGE BREAKDOWN OF TRAINING HOURS PROVIDED TO EMPLOYEES BY TRAINING TYPE, 2018





The intense expansion and internationalisation project of the Recordati Group has led to the need to develop a system to better understand, evaluate and optimise the Group's human capital. In this regard, in the last few years the Recordati Group has launched a skills evaluation project which is currently being consolidated in Italy and throughout the Group's international branches. The initiative aims to identify, evaluate, optimise and promote the key skills that have characterised the Group's evolution over the years and which will continue to contribute to the Group's success as it confronts new challenges. This is not a simple assessment of performance, which could result in attitudes not in line with the spirit of the project but is an assessment of skills aimed at promoting the continuous development of the Group and the professional growth of each employee. To manage the individual evaluation process, the Recordati Group has implemented a cloud-based platform (which in 2018 was replaced with a new, more user-friendly platform with more comprehensive and effective reporting capabilities) in order to ensure standardised procedures, ease of use and the possibility of carrying out assessments involving numerous assessors (but nonetheless respecting the corporate hierarchy) and personalising forms, fields and messages at a global Group level. The project's aim is to promote the professional growth of each employee and ensure the continued development of the Group. Managers assess their collaborators based on skills observed during their working activities. The initial assessment is then reviewed by the manager's superior or the department manager at corporate level. At the end of the assessment period, an internal committee analyses the results and mitigates any elements of subjectivity (calibration phase). The appraisal process is concluded by a meeting between the assessor and the assessed employee in order to share and discuss the results. The Recordati Group has also constructed a *Competency Model* that links the observed behaviour with a soft skill. Based on these evaluations, the system automatically generates a development programme (accessible on the cloud platform) for each employee to develop any skills that fall below a certain threshold. Finally, the system automatically forwards these proposals to the assessor who is then free to make amendments, additions or alternatives to the plan. This is the truly innovative aspect of the system and has been deemed highly effective by the HR Innovation Practice Observatory of Milan Polytechnic University.

For "top performers", career and retention plans are defined while "poor performers" are offered programmes to improve their managerial skills. In the future, the same assessment approach will be extended to technical skills as defined by the analysis of the roles in each country. The appraisal system enables all employees to gain a better understanding of their role and helps to construct a development plan. Employees with the required skills and experience may be offered opportunities to develop their role and enhance their performance. Specific tools to assess soft and transversal skills are used to evaluate whether a change of role is appropriate and identify any training that may be required to best encourage professional development.

In 2018, training continued in the same vein as in 2017, with individual training courses (ad hoc courses designed around an individual's needs) and departmental initiatives (ITIL - Information Technology Infrastructure Library - and Prince - Projects in Controlled Environments - for the entire IT team, Project Management for the Auditing team, promotion of best practices and insights on opportunities of the future market scenario for the sales force in terms of Products for Consumers), as well as initiatives aimed at broader areas of the company workforce ("lean organisation" techniques, waste-free culture, IT security training delivered to all employees at the Milan branch in 2018 and then rolled out to the entire External Sales Force).

Following the assessments made, in 2018 various training and professional development initiatives were implemented. Many of these involved individual initiatives, such as the management coaching tool aimed at professionals operating in Italy and abroad.

In most cases these initiatives were aimed at valued resources whose commitment to the Group has been recognised, offering the opportunity to further improve their performance by developing certain management skills such as assertiveness, leadership abilities or organisational skills. All of the projects are implemented with the involvement - from the planning stage onwards - of the manager concerned, the line manager and the HR department at corporate or branch level.

The management coaching initiatives are sometimes combined with technical training delivering one-to-one or in small groups, such as the courses held for certain managers of the Orphan Drugs business which focused on the Life Cycle of the pharmaceutical product.

This year, focus was given in particular to Pharmaceutical Research and Development at corporate level and the corresponding operational branches of the Orphan Drugs business, defining a structured plan of activities and projects to effectively support interaction between branches and the Parent Company. After an initial meeting held in Paris in February to launch the project and define its requirements, all resources involved in the project took part in an outdoor training event. At the event, attended by representatives of top management such as the CEO, R&D Manager and HR Manager, the foundations were laid for a business approach inspired by a matrix model. This model revolves around project management skills and aims to guarantee increasing levels of efficiency and efficacy in Research and Development departments.

After the necessary orientation period, employees became increasingly engaged and involved: a further two meetings were held in April and September to strengthen the technical project management skills gained, to promote the sense of team spirit and to share the results achieved in the first few months of work. Employee satisfaction and motivation was very high, while the success of the project was confirmed by a visibly different approach to everyday work.

A second, very technical project focused on the Risk Environment was extended to all employees with a scientific background: the course was custom-designed by a specialist consultancy firm and featured a modular structure with various levels of detail: all resources in the R&D departments were involved, participating in different modules depending on their level of interest.

Another development-oriented project concerned the HR Department, with the design and implementation of a 360° feedback system during the appraisal process aimed at providing employees with feedback from their line Manager, colleagues in their own department and in other business units, and collaborators for comparison with their own self-appraisal, with the entire process managed by a cloud-based platform. The questions were defined by constructing a skills system consistent with, yet not identical to, the management skills appraisal system, identifying areas and practices that best relate to the Group's culture.

Activities aimed at transversal areas of the workforce sharing similar training requirements include the decision to continue the use of the previously adopted online language training platform in 2018. A training package was put together with the previously selected training provider that combines online and telephone lessons with a considerable increase in the number of one-to-one lessons, aiming at teaching grammatical structures, fluency and full comprehension of the course content. Individual one-to-one lessons on a weekly or intensive basis are still used in the case of specific professional requirements.

Finally, the "lean" training project continues to be provided, aimed at increasing and consolidating existing expertise within the organisation and promoting the top-down distribution of specific skills aimed at reducing everyday operational inefficiencies.

## 4.5. HEALTH AND SAFETY IN THE WORKPLACE<sup>10</sup>

The Recordati Group recognises that the protection of the health and safety of its workers is a key priority and responsibility. The Group is committed to implementing a policy to promote initiatives aimed at preventing work-related accidents and diseases, minimising the risks that may impact the health and safety of employees and other workers and providing appropriate technical, financial, human and professional resources.

As stated in the Code of Ethics, the Group is committed to *“promoting and consolidating a culture of safety, raising awareness of risks, promoting responsible behaviour among all Recipients and working to protect the health and safety of those operating for the Company, including by preventive measures. All company activities are carried out in compliance with current legislation regarding risk prevention and protection, with a constant focus on the improvement of workplace health and safety conditions”*.

At the Group's production sites, independently of the nature and purpose of the activities carried out, the prevention measures provided for by local legislation apply, aimed at ensuring the constant improvement of workplace health and safety conditions. To this end, technical and organisational measures are implemented, such as:

- the introduction of an integrated risk management and security system;
- continuous assessment of the risks and critical issues and the resources to be protected;
- the continuous maintenance and adoption of advanced technologies to prevent the emergence of risks relating to workers' health and safety;
- the review and updating of working practices;
- the provision of training and communications initiatives;
- the adoption of appropriate emergency procedures and health check protocols.

All Recordati employees, particularly department Managers, are constantly reminded to employ the maximum care in performing their activities, strictly observing any safety and prevention measures established and avoiding any possible risks to themselves or their collaborators and colleagues.

In this respect, the Group aims to promote responsibility among the management team through the definition of health and safety roles and responsibilities, and each production plant has a level of autonomy over its health and safety budget. In particular, the person in charge of health and safety oversees working activities and ensures compliance with any received directives, verifying their correct implementation by workers and using personal initiative to carry out their role. In this regard, the Recordati Group complies with the regulations issued by industry certification bodies. In fact, the Tunisian pharmaceutical production plant employs an OHSAS 18001-certified Management System.

Activities at each production site are controlled and monitored through inspections and audits.

In particular, in 2018 the production plant in Cork, Ireland received an inspection from the company Ramboll regarding the health and safety procedures in place at the site. The inspection did not reveal any irregularities and the report to certify the plant's compliance with health and safety regulations is currently being produced.

In 2018 the Campoverde di Aprilia plant was inspected by the Commission established pursuant to Article 27, paragraph 6 of Legislative Decree no. 105 of 26 June 2015, in order to ascertain the adequacy of the Fire Prevention Policy adopted by the Manager. This led to the scheduled and systematic control of the technical, organisational and management systems pursuant to Legislative Decree no. 105/15. In particular, the Safety Management System and its compliance to Legislative Decree no. 105/2015 (Seveso) were assessed.

At the Campoverde di Aprilia plant, in order to prevent the occurrence of accidents a series of preventive measures relating to equipment, operating processes, management systems and procedures has been implemented, including a computerised control system for various devices, the installation of locking devices on certain equipment, safety valves for exhaust devices, air pollution control devices and systems to detect the presence of dangerous substances in the atmosphere. Moreover, dedicated fire prevention systems are available on site such as fire-fighting vehicles and portable fire extinguishers. Standardised procedures regulate the unloading of tank vehicles, the preparation of warehouse stock, the transportation of components, pre-loading controls and all cleaning, sampling, analysis and shipping operations. In addition, an internal Emergency Plan which described the procedures and measures to be adopted in the case of an incident was approved for the same production plant. An internal Emergency Team ensures a constant presence during each shift to offer the highest possible levels of safety for internal and external personnel.

<sup>10</sup> The scope of data relative to health and safety and the principle accident indicators for 2018 include:

- employees at the Group's production plants in Italy - Campoverde di Aprilia (Recordati S.p.A.), Ireland (Recordati Ireland Ltd), Czech Republic (Herbacos Recordati S.R.O.), Turkey (Recordati İLAÇ ve Hammaddeleri Sanayi ve Ticaret A.S.) and France - Nanterre (Orphan Europe S.A.R.L)

- employees at production plants and commercial offices in the following sites: Italia - Milan (Recordati S.p.A. and Innova Pharma S.p.A.), Spain (Casen Recordati S.L.), Tunisia (Opalia Pharma) and France - Bouchara (Laboratoires Bouchara Recordati S.a.s.).

However, a reporting system is currently being developed to process data regarding the workforce at all of the Group's offices and commercial sites.

In the Group's chemical-pharmaceutical and pharmaceutical plants, various health and safety risk assessment activities were carried out in 2018:

- at the Milan plant the machinery used on the blister pack production lines was inspected, with the aim of ensuring continued compliance with the Machines Directive. This specific control was then used to update the General Risk Assessment Document of the department;
- at the Campoverde di Aprilia plant, a seismic risk assessment is currently being carried out for the entire site, based on a geological, geomorphological and hydro-geological study and a seismic model. Launched in 2017, the study involves a dynamic analysis aimed at determining any structural deformations or strains in the tanks containing the most hazardous or critical substances. The same study was rolled out across all departments at the plant in 2018;
- at the same chemical-pharmaceutical plant at Campoverde di Aprilia, the project to install two tanks (S-8626 and S-8627) containing benzoyl chloride, which may be alternated and used independently of each other, was concluded. This operating method offers maximum system security. A risk limitation study was carried out and a request for approval by the Latina Fire Department was submitted. Additionally, a feasibility study was carried out to assess the possibility of expanding the acetone storage facilities at the site. The analysis did not find any factors determining the aggravation of the current risk level pursuant to Legislative Decree no. 105/2005 and approval was granted by the Fire Department;
- at the Cork plant, a study of the entire thionyl chloride transportation line was concluded, leading to the identification of certain areas for improvement in terms of site equipment and procedures for the transportation phase of the chemical substance from its arrival on site until its deposit in its dedicated storage tank, in order to further strengthen the protection against chemical risk for employees and the public. The implementation of these measures has been scheduled for the first half of 2019, supported by training for the persons involved in the process.

During the year, the Group also implemented initiatives involving various production plants:

- at the Saint Victor site in France, a management system to regulate the management of workplace health and safety documentation was implemented, including training, safety procedures, risk assessments, operational instructions and the management of safety data sheets. Furthermore, in 2018 the plant-based chemical products inventory, the corresponding safety data sheets and the specific chemical risk assessment software (SEIRICH) were updated. The software consolidates all of the data provided on the substance safety data sheets in order to assess the relative chemical risk. The assessment highlighted a lower risk level at the chemical laboratory than the Occupational Exposure Limit Value ("OELV");
- at the Italian sites in Milan and Campoverde di Aprilia, specialist software (SIMPLEDO) was installed in 2017 to manage workplace health and safety

aspects in accordance with the provisions of Italian Legislative Decree no. 81/08 and Italian Legislative Decree no. 106/2009. The software enables the management of all company data, the supply and expiry date of PPE (Personal Protective Equipment), staff training courses and their expiry dates, risk assessments, health inspections, management of cases of non-compliance and the implementation of corrective actions, the management of audits and control checklists, contract management and the Consolidated Inference Risk Assessment Document. In particular, at the galenic production department at the Milan plant, a project is in progress to enhance the ergonomics for operators during working activities, improving access to work decks. Also in the galenic production department, to improve the transition of the pharmaceutical product from the mixers to the storage tanks, flexible polyurethane connectors have been installed to enable a continuous, closed-cycle connection with resulting benefits in terms of the reduction of airborne dust. In this regard, in 2017 a "zero gravity" handler was installed to handle heavy bags/crates/boxes without any effort by the operator, while systems are due to be installed to reduce the manual handling of loads without any effort by the operator.

This project was originally planned exclusively for the preparation areas but was later extended to the previous and subsequent processes, prolonging the time required for installation. Furthermore, the Milan plant has obtained a renewal of the Fire Prevention Certificate issued by the Italian Fire Department which extends its validity until 12/04/2022. To this end, various initiatives were carried out such as the installation of three fire suffocation extinguishing systems in the solvent warehouse, the oil warehouse and the alcohol distillation department. In 2018 an additional inert gas fire suppression system was installed for the counter-sample room on the third floor. Other work has been carried out at the Milan plant to ensure an increasingly high level of workplace safety, including the installation of five oxygen sensors in five production areas which use nitrogen (wash room and preparation areas for vials, ointments and drops), a gas which is otherwise difficult to detect;

- the Group's focus on terms of health and safety is also consolidated through the regular use and review of its assets at its production sites. At the Milan plant, assessments were carried out in 2018 aimed at obtaining the Static Stability Certificate (Certificato di Idoneità Statica - CIS). The Buildings Regulation of the Municipality of Milan, in force from 26 November 2014, introduced new provisions concerning the "Maintenance and periodic review of buildings" and consisting of the granting of the CIS, a document certifying the structural resistance of the building's supporting structure to the loads to which it is currently subjected, accompanied by an assessment of the condition of certain elements such as parapets, façades, walls, etc. On the basis of the results achieved, it is possible to determine the "supporting capacity" of the construction against the measures provided for by legislative measures at the time of construction, identifying any critical issues. In response to the above, at the Milan site the first phase of the evaluation was launched in 2018, consisting of a qualitative analysis of the production plant (first level assessment): document retrieval, geometric and typological surveys, load resistance assessments, crack surveys, temporal evolution analysis, maintenance assessment, assessment of interaction with external elements.

In 2018 the first assessment phase was completed and the second phase is due to continue in the coming months, consisting of an analysis based on experimental and/or analytical surveys (second level assessment) according to the legislation in force at the time of construction.

The Recordati Group believes that training and educating its employees is essential to ensuring the prevention of health and safety risks. For this reason, each production plant implements training plans aimed at workers exposed to specific risks.

All personnel who work within the two chemical pharmaceutical plants (plant in Campoverde di Aprilia and plant in Cork) receive ongoing training in the application of GMPs, environmental protection procedures and workplace health and safety. New employees undergo a training period supported by experienced operators and theoretical lessons delivered by qualified personnel. The training activities at the plants are carried out according to the integrated Quality, Environmental and Safety Training Plan. The main health and safety training and educational activities focus on safety issues relating to the operational activities of managers, safety officers, the RLSSA (Work, Health and Safety and the Environment Representatives), vehicle operators, the emergency team, chemical operators and new employees.

The internal training and education programme was continued at the two chemical pharmaceutical plants in 2018. At the Campoverde di Aprilia factory, more than 1,500 hours of health and safety training was provided to all employees at all levels, in addition to 860 hours of specialist training dedicated to the internal emergency team. In particular, in the Campoverde di Aprilia plant in 2018, 350 people attended internal training courses, in line with the 352 employees who attended in 2017. In line with 2017, the number of people taking part in external training courses remained stable at approximately 250.

Specifically, at the Italian chemical-pharmaceutical plant the following training initiatives were carried out:

- refresher courses and practical exercises for the internal emergency team;
- training and education course for the use of industrial self-propelled trucks with on-board driver - retractable category;
- Machine Risk training courses with a particular focus on hydraulic machine and seal risks;
- "Chemical Risk" and "Machine Risk" training courses for employees hired in the last three years;
- three-year first aid refresher course;
- training and education course on "Category III Personal Protective Equipment (PPE) - APVR TR82 Spasciani";
- annual training course on critical incident risks (Legislative Decree no. 105/15) with particular focus on materials and distillations;
- training and educational course on the 3M Series 6000 half mask; qualitative face-fit test to monitor correct use.

In 2018 the plant in Cork, Ireland recorded 200 training hours on the following topics: first aid, fire prevention and the manual handling of loads. The fire prevention course takes place each year. In 2018, 12 members of the Production Team and one member of the Maintenance Team completed the course and received the necessary training on this subject. Training courses on chemical hazards and first aid are structured differently and the training provided will be brought to conclusion in 2019.

Furthermore, in 2018 various pharmaceutical plants implemented numerous health and safety training programmes:

- at the Utebo site in Spain, in 2018 training sessions on noise risk, repetitive strain and activities in hyperbaric chambers were delivered;
- at the Cerkezkoj site in Turkey, various training sessions were provided on the following topics: waste management, waste classification, the correct use of absorbent materials, waste water treatment and correct environmental management;
- at the Milan site, approximately 650 hours of health and safety training were provided involving the entire workforce, focusing on the following themes: training of new staff, coaching and practical tests for the emergency and first aid team, correct use of PPE in the packaging department, correct use of equipment in the dispensing department, correct use of PPE in laboratories, refresher courses for Safety Officers and Managers.

All work-related accidents and illnesses regarding the Group's production plants are recorded and managed through the quarterly report prepared by the Risk and Sustainability Control Committee.

This system monitors key accident indicators and analyses the causes and circumstances of any incidents. Moreover, health and safety incidents are brought to the attention of the Group's senior management team at least once a year.

**NUMBER OF ACCIDENTS AND HEALTH AND SAFETY INDICATORS OF GROUP EMPLOYEES BY GENDER, COUNTRY OR PRODUCTION SITE IN 2018**
**Italy (Campoverde di Aprilia) - Chemical pharmaceutical production plant**

Injuries and Injury Index <sup>11</sup>	2018			2017		
	Men	Women	Total	Men	Women	Total
<i>Accidents in the workplace (No.)</i>	9	0	9	6	0	6
<i>Accidents during travel (No.)</i>	3	0	3	2	0	2
Cases of work-related diseases (No.)	0	0	0	0	0	0
Severity Index (Lost Day Rate LDR)	81.0	0	74.0	82.4	0	75.5
Frequency Index/Injury Rate (IR)	4.7	0	4.3	3.2	0	2.9
Occupational Disease Rate (ODR)	0	0	0	0	0	0
Absentee Rate (AR) (%)	5.0%	1.8%	4.7%	4.6%	1.9%	4.4%

**Ireland (Cork) - chemical pharmaceutical plant**

Injuries and Injury Index	2018			2017		
	Men	Women	Total	Men	Women	Total
<i>Accidents in the workplace (No.)</i>	0	1	1	0	0	0
<i>Accidents during travel (No.)</i>	0	0	0	0	0	0
Cases of work-related diseases (No.)	0	0	0	0	0	0
Severity Index (Lost Day Rate LDR)	0	390.5	175.7	0	0	0
Frequency Index/Injury Rate (IR)	0	4.3	1.9	0	0	0
Occupational Disease Rate (ODR)	0	0	0	0	0	0
Absentee Rate (AR) (%)	5.7%	5.4%	5.6%	0.8%	3%	1.8%

**Italy (Milan) - Pharmaceutical production plant and offices**

Injuries and Injury Index	2018			2017		
	Men	Women	Total	Men	Women	Total
<i>Accidents in the workplace (No.)</i>	6	2	8	2	5	7
<i>Accidents during travel (No.)</i>	2	4	6	1	0	1
Cases of work-related diseases (No.)	0	0	0	0	0	0
Severity Index (Lost Day Rate LDR)	33.6	86.7	51.9	16.5	76.1	37
Frequency Index/Injury Rate (IR)	3.1	4.4	3.6	1.1	3.6	2
Occupational Disease Rate (ODR)	0	0	0	0	0	0
Absentee Rate (AR) (%)	2.7%	2.7%	2.7%	2.6%	2.6%	2.6%

<sup>11</sup> The severity index represents the ratio between the number of days lost due to professional injury/disease and the total number of working hours in the same period, multiplied by 200,000 (Source: Sustainability Reporting Guidelines - Version GRI Standards, Global Reporting Initiative).

The frequency index represents the ratio between the total number of injuries and the total number of hours worked in the same period, multiplied by 200,000 (Source: Sustainability Reporting Guidelines - Version GRI Standards, Global Reporting Initiative).

The occupational disease rate represents the ratio between the number of cases of work-related diseases and the number of hours worked in the same period, multiplied by 200,000 (Source: Sustainability Reporting Guidelines - Version GRI Standards, Global Reporting Initiative).

The absenteeism rate is the percentage of daily absences against the total number of working days in the same period (Source: Sustainability Reporting Guidelines - Version GRI Standards, Global Reporting Initiative).

**Czech Republic - Pharmaceutical production plant**

Injuries and Injury Index	2018			2017		
	Men	Women	Total	Men	Women	Total
<i>Accidents in the workplace (No.)</i>	0	0	0	0	0	0
<i>Accidents during travel (No.)</i>	0	0	0	0	0	0
Cases of work-related diseases (No.)	0	0	0	0	0	0
Severity Index (Lost Day Rate LDR)	0	0	0	0	0	0
Frequency Index/Injury Rate (IR)	0	0	0	0	0	0
Occupational Disease Rate (ODR)	0	0	0	0	0	0
Absentee Rate (AR) (%)	2.7%	6.5%	5.4%	0%	0%	0%

**Spain <sup>12</sup>**

Injuries and Injury Index	2018			2017		
	Men	Women	Total	Men	Women	Total
<i>Accidents in the workplace (No.)</i>	2	4	6	3	0	3
<i>Accidents during travel (No.)</i>	0	0	0	0	1	1
Cases of work-related diseases (No.)	0	0	0	0	0	0
Severity Index (Lost Day Rate LDR)	14.3	9.1	11.7	9.5	193.4	119.8
Frequency Index/Injury Rate (IR)	1.5	3.2	2.4	14.9	3.4	8.1
Occupational Disease Rate (ODR)	0.0	0.0	0.0	0	0	0
Absentee Rate (AR) (%)	2.2%	5.6%	3.9%	4.3%	5.5%	5.0%

**Tunisia<sup>13</sup>**

Injuries and Injury Index	2018			2017		
	Men	Women	Total	Men	Women	Total
<i>Accidents in the workplace (No.)</i>	5	2	7	4	3	7
<i>Accidents during travel (No.)</i>	0	0	0	0	0	0
Cases of work-related diseases (No.)	0	0	0	0	0	0
Severity Index (Lost Day Rate LDR)	21.2	3.8	11.5	23.6	6.1	18.8
Frequency Index/Injury Rate (IR)	2.7	0.91	1.7	2.4	1.7	2
Occupational Disease Rate (ODR)	0.0	0.0	0.0	0	0	0
Absentee Rate (AR) (%)	2.6%	6.6%	4.8%	2.4%	3.9%	3.2%

12 Unlike the 2017 data for the Spanish site which extended only to production plant staff, the data for 2018 includes production plant and office staff.

13 Unlike the 2017 data for the Tunisian site which extended only to production plant staff, the data for 2018 includes production plant and office staff.

**Turkey - Pharmaceutical production plant**

Injuries and Injury Index	2018			2017		
	Men	Women	Total	Men	Women	Total
<i>Accidents in the workplace (No.)</i>	7	2	9	4	0	4
<i>Accidents during travel (No.)</i>	0	0	0	0	0	0
Cases of work-related diseases (No.)	0	0	0	0	0	0
Severity Index (Lost Day Rate LDR)	24.7	6.8	19.3	12.2	0	8.7
Frequency Index/Injury Rate (IR)	4.8	3.2	4.3	2.4	0	1.7
Occupational Disease Rate (ODR)	0.0	0.0	0.0	0	0	0
Absentee Rate (AR) (%)	0.3%	0.2%	0.3%	0.4%	0.4%	0.4%

**France (Bouchara)<sup>14</sup>**

Injuries and Injury Index	2018			2017		
	Men	Women	Total	Men	Women	Total
<i>Accidents in the workplace (No.)</i>	1	4	5	4	1	5
<i>Accidents during travel (No.)</i>	0	0	0	0	0	0
Cases of work-related diseases (No.)	0	1	1	0	0	0
Severity Index (Lost Day Rate LDR)	63.3	250.2	175.5	573.9	8.3	309.1
Frequency Index/Injury Rate (IR)	3.8	3.8	3.8	9.9	2.8	6.5
Occupational Disease Rate (ODR)	0.0	0.0	0.0	0	0	0
Absentee Rate (AR) (%)	7.9%	6.0%	6.7%	6.4%	3.2%	4.9%

**France (Nanterre) - Distribution Centre (Orphan Europe)**

Injuries and Injury Index	2018			2017		
	Men	Women	Total	Men	Women	Total
<i>Accidents in the workplace (No.)</i>	0	0	0	0	0	0
<i>Accidents during travel (No.)</i>	0	0	0	0	1	1
Cases of work-related diseases (No.)	0	0	0	0	0	0
Severity Index (Lost Day Rate LDR)	0	0	0	0	0	0
Frequency Index/Injury Rate (IR)	0	0	0	0	20.5	11.1
Occupational Disease Rate (ODR)	0	0	0	0	0	0
Absentee Rate (AR) (%)	0.9%	0.5%	0.7%	4.0%	4.4%	4.2%

14 Unlike the 2017 data for the French branch Laboratoires Bouchara Recordati S.a.s. which extended only to production plant staff, the data for 2018 includes production plant and office staff.

## 5. FOCUS ON THE ENVIRONMENT<sup>15</sup>

### 5.1. COMMITMENT TO ENVIRONMENTAL PROTECTION

As stated in the Code of Ethics, the Recordati Group considers environmental protection to be a vital component of its general approach to company activities aimed at supporting the sustainable development of the regions in which it operates. To this end, in the course of its operational management and activities the Group has adopted a policy aimed at reducing the negative impact that company activities may have on the environment and complying with all related legislative and regulatory requirements, including:

- the promotion of environmentally sustainable processes and procedures through the use of advanced environmental technology, energy efficiency and the sustainable use of resources;
- evaluation of the environmental impact of all company activities and processes;
- collaboration with stakeholders both internally (employees) and externally (institutions) to optimise the management of environmental issues;
- active employee participation through regular environmental training plans and the adoption of environmentally sustainable principles in the course of operational activities;
- compliance with environmental protection standards through the implementation of appropriate management and monitoring systems.

The Group is committed to ensuring environmental sustainability at its production plants and all branches are required to comply with local legislation, minimising energy use and effectively managing water resources. Environmental sustainability compliance officers, whose roles include formal responsibilities with precise operational powers, are particularly important in this regard.

All of the Group's production sites hold the necessary environmental authorisations and ensuring compliance with said authorisations is an important part of the responsibilities of the management team at each site. The Recordati Group responds to any cases of increased environmental risk by implementing a series of internal inspections. The sites of Campoverde di Aprilia and Cork, where active pharmaceutical ingredients are manufactured, are included in the European Pollutant Release and Transfer Register (E-PRTR), set up on the basis of EU Regulation 166/2006. Furthermore, the Campoverde di Aprilia site is included in the national inventory of plants capable of causing potential environmental accidents, pursuant to Legislative Decree no. 334/99, replaced by Legislative Decree no. 105/2015, which implemented the directive 2012/18/EU. All the duties deriving from such inclusions are regularly fulfilled.

Furthermore, the Campoverde di Aprilia site – following a communication of voluntary disclosure to competent authorities made in 2001 based on art. 9 of Ministerial Decree no. 471/99, in respect of the potential contamination of soils and waters of the site deriving from past industrial manufacturings – was included in 2001 in the temporary register of contaminated sites of the Lazio Region. The administrative proceeding commenced in 2004 by the Company following such communication is still pending, the Company is waiting feedback from local authorities; in the meantime the Company has continued implementing, in respect to such historical contamination, the necessary containment measures and monitoring activities, in compliance with applicable laws.

In this regard, in 2018 the Campoverde di Aprilia plant received an environmental audit by a consultancy firm and carried out five audits of intermediaries and waste disposal plants. Furthermore, the inspection aimed at renewing the environmental certificate ISO 14001 and monitoring the transition to the new ISO 14001:2015 regulation carried out in May 2018 by the accredited company DNV GL was particularly significant. During the visits of the Lead Auditor of DNV GL, accompanied at various times by four inspectors specialising in different areas, the entire Environmental Management System of the Campoverde di Aprilia plant was inspected.

The high level of control was necessary in order to renew the three-year certificate and monitor transition to the ISO 14001:2015 standard that presents various differences to the previous standard (ISO 14001:2004).

The audit considered all areas of the new system: policy, planning, legal compliance, implementation and operation, monitoring, corrective action and review. The result was considered highly satisfactory and confirmed the implementation by all Recordati personnel of the management system, which conforms to the required standards and is able to provide a high level of environmental protection and safety. In the inspection's final report, no cases of non-compliance were noted and only six formal observations were made.

In particular, the new edition of the Environmental Analysis pursuant to standard ISO 14001:2015 was issued, accompanied by an environmental risk assessment document based on the concept of the life cycle of all plant processes and the relative activities that may result in a lesser or greater environmental impact.

The Campoverde di Aprilia plant also supplemented its training and information programme with specific training for the changes to the Environmental Management System associated with the application of the new standard ISO 14001:2015, informing employees at all levels of the plant's environmental policies, projects and objectives as well as the environmental risks associated with the plant's activities.

The analysis conducted previously enabled the definition of the Risk Management procedure associated with the Site's Environmental Management, and thus the measures to be implemented in order to identify and assess the risks associated with the context and the interested parties, defining, if necessary, the mitigation actions to reduce the risk factors to an acceptable level.

<sup>15</sup> The information and data regarding environmental aspects (energy use, emissions, water use and waste) refer exclusively to the Group's production plants as such aspects are not deemed significant at other sites (with the exception of the Milan plant, where the offices at the same site are also considered).



These measures enable the organisation to gain:

- a better impression of the medical community and the market, and thus a potential increase in market competitiveness;
- a reduction in the costs related to production shut-offs following accidents and/or emergencies and associated with any remediation activities or the management of fires or other emergencies;
- a reduction in direct and indirect costs linked to disputes and/or complaints by Clients or the external Community, Environmental Associations, Supervisory Bodies, etc., relating to non-compliant atmospheric emissions, non-compliance waste, odour and noise emissions over the permitted limits, environmental remediation;
- a positive image to Customers and the medical community as a result of the reduction in environmental risks associated with its activities and compliance with legislation.

At environmental level, in 2018 the site in Cork received an unannounced inspection from the Environmental Protection Agency (EPA), focusing on the environmental management system and the traceability of waste and waste materials - no cases of non-compliance were observed by the Authority. Effluent discharged from the site was monitored on two occasions during the year and all chemical samples analysed were below current discharge limits.

In addition to the environmental inspections, it is noted that:

- in the course of recent years, the chemical pharmaceutical plant in Cork has joined the Responsible Care initiative which aims to promote the continuous improvement in the chemical and pharmaceutical industry of all aspects that have a direct or indirect aspect on the environment, employees or the community. In this regard, in 2013 the site received the *“Responsible Care Award”* for SMEs from the European Chemical Industry Council (CEFIC) in recognition of the continuous improvements achieved by the site in the last five years. The plant’s environmental system was developed to ensure full compliance with environmental legislation, regulated in Ireland by the Environmental Protection Agency (EPA), and is subject to regular inspections by EPA officers;

- in January 2016, the pharmaceutical plant in Milan obtained the AUA (Autorizzazione Unica Ambientale) environmental authorisation from the Metropolitan City of Milan for atmospheric emissions, discharges into the water grid of water from the geothermal heat pump system and discharges into the sewers of industrial waste water and rainwater used to clean areas of the site. Waste water sampling and analysis activities are carried out regularly to confirm compliance with the limits provided by Italian Legislative Decree no. 152/06. Furthermore, in summer 2017, daytime and night-time phonometric surveys were carried out at the production plant in Milan to assess the impact on the local population of extending production to include a third shift. Following this assessment, with a view to continuous improvement in 2018 acoustic absorption panels were installed close to the plant to reduce noise pollution caused by the machinery;
- as well as the Campoverde di Aprilia plant, it is noted that the production plant in Tunisia is also certified according to standard ISO 14001:2015;
- At the Milan site, during the 2018 construction works to redevelop the third and fourth floors, controls were carried out pursuant to Article 10 of the Buildings Regulation of the Municipality of Milan to assess the quality of the environmental matrices and identify any cases of contamination. Thirteen geognostic surveys were carried out across the site, of which three penetrated to a maximum depth of 3.0 m below ground level and ten penetrated to a maximum depth of 5.0 m below ground level, while two excavations by suction excavator penetrated to a depth of 1.5 m below ground level. The soil samples were subject to analytical investigations to assess possible contamination and identify the scale of the volume of contaminated soil or the possible migration of the contaminant to groundwater reserves. The analyses carried out revealed concentrations which were significantly lower than legal limits, by an order of magnitude of at least one compared to legal limits, and at times undetectable by the analytical method applied.

## 5.2. ENERGY USE AND EMISSIONS

### Energy use

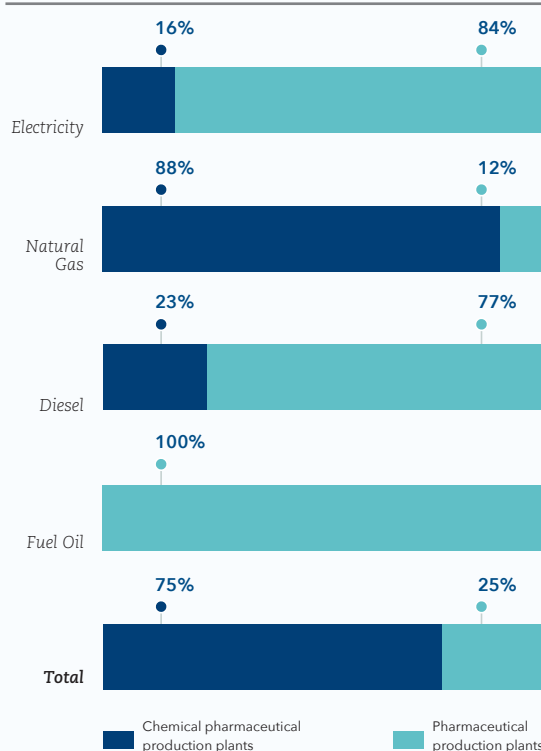
The Recordati Group manages the general use of energy resources through a range of initiatives to reduce energy use, with the aim of improving energy efficiency in all of the Group's industrial and commercial operations. The main energy resources used at the Group's production plants are electricity, natural gas, diesel and fuel oil. In 2018, the Group's plants consumed approximately 614 TJ, a slight increase of 1% compared to the previous year due to the overall increase in production volume.

In consideration of this, thanks to continuous efforts to improve energy efficiency the increase in energy use is negligible and is not proportional to the increase in the Group's industrial production. Furthermore, it is noted that the percentage in electricity obtained from renewable energy sources relates solely to the supply of electricity to the Milan and Cork plants, while the use of fuel oil is attributable to the distribution plant of Orphan Europe in France. In this regard, it is noted that the significant percentage increase in the use of fuel oil is predominantly linked to a power outage at the Nanterre plant, in response to which an emergency fuel oil generator was used.

### ENERGY USE AT THE PRODUCTION PLANTS OF THE RECORDATI GROUP BY SOURCE<sup>16</sup>

Type of fuel	Unit of measurement	2018	2017	Variation %
Purchased electricity	kWh	31,671,271	29,124,233	9%
	GJ	114,017	104,847	
<i>originating from renewable sources<sup>17</sup></i>	kWh	1,498,981	1,545,565	-3%
	GJ	5,396	5,564	
Natural Gas	m <sup>3</sup>	14,135,292	14,227,325	-0.3%
	GJ	498,269	499,863	
Diesel	Litres	67,912.62	48,942	39%
	GJ	2,431	1,752	
Fuel oil	Litres	658	389	69%
	GJ	27	16	
<b>Total</b>	<b>GJ</b>	<b>614,744</b>	<b>606,478</b>	<b>1%</b>

### PERCENTAGE SUBDIVISION OF ELECTRICITY USE BY PRODUCTION PLANTS, SUBDIVIDED BY USAGE AND TYPE OF PLANT, 2018



Energy use at pharmaceutical production plants totalled approximately 155 TJ (equal to 25% of the total), a 1% increase on the previous year. In particular, compared to chemical pharmaceutical plants, pharmaceutical plants used higher quantities of diesel to produce electricity and more electricity was bought from the national grid. However, in 2018 energy use by the Group's chemical pharmaceutical production plants was 459 TJ (75% of the total), a slight increase on the previous year.

<sup>16</sup> Lower Calorific Value (LCV) of natural gas: 0.035 GJ/m<sup>3</sup>; average density of diesel: 0.835 kg/ltr; LCV of diesel: 42.87 GJ/ltr; average density of fuel oil: 0.98 kg/ltr; LCV of fuel oil: 41.02 GJ/ltr (Source: Italian Ministry of the Environment and the Protection of Land and Sea, Table of National Standard Limits, 2018).

<sup>17</sup> The proportion of electricity obtained from renewable sources originates from a combination of national energy providers and the Guarantee of Origin is not certified. As such, this quota is included in the calculation of Scope 2 Emissions (Market-based approach).

#### ENERGY USE AT PHARMACEUTICAL PRODUCTION PLANTS BY FUEL SOURCE

Type of fuel	Unit of measurement	2018	2017	Variation %
Purchased electricity	kWh	26,565,569	25,500,470	4%
	GJ	95,636	91,802	
<i>originating from renewable sources</i>	kWh	1,136,854	1,111,565	2%
	GJ	4,093	4,002	
Natural Gas	m <sup>3</sup>	1,647,294	1,730,744	-5%
	GJ	58,067	60,808	
Diesel	Litres	52,521	36,142	45%
	GJ	1,880	1,294	
Fuel oil	Litres	658	389	69%
	GJ	27	16	
<b>Total</b>	<b>GJ</b>	<b>155,610</b>	<b>153,919</b>	<b>1%</b>

#### ENERGY USE AT CHEMICAL PHARMACEUTICAL PRODUCTION PLANTS BY FUEL SOURCE

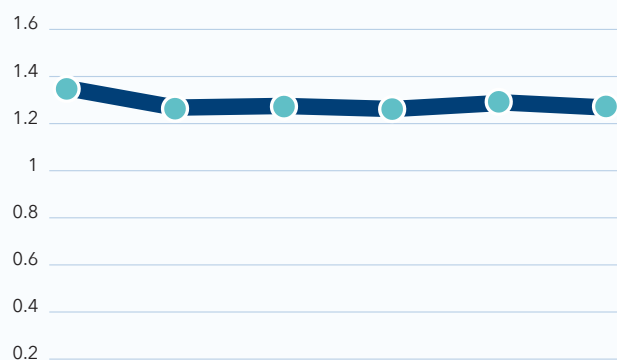
Type of fuel	Unit of measurement	2018	2017	Variation %
Purchased electricity	kWh	5,105,702	3,623,763	41%
	GJ	18,381	13,045	
<i>originating from renewable sources</i>	kWh	362,127	434,000	-17%
	GJ	1,303	1,562	
Natural Gas	m <sup>3</sup>	12,487,998	12,496,581	-0.3%
	GJ	440,202	439,055	
Diesel	Litres	15,388	12,800	20%
	GJ	551	458	
<b>Total</b>	<b>GJ</b>	<b>459,134</b>	<b>452,558</b>	<b>1%</b>

The chemical pharmaceutical plants consume higher quantities of natural gas than the pharmaceutical plants: a high proportion of this gas usage derives from the electricity generation system at the Campoverde di Aprilia plant, where a self-generation policy for electricity and thermal energy has been in place for over 20 years thanks to the installation of a co-generation system (for more details, see the "Co-Generation System of the Campoverde di Aprilia" information box). Through the use of a single fuel source (natural gas), the co-generation system enables the plant to generate enough electricity to meet its needs, sell any excess to the national grid and produce all of the steam used in the plant without the use of any additional gas or resources. In 2018, the proportion of self-generated electricity used internally fell by 5% compared to 2017, while the amount of electricity sold back to the grid decreased by approximately 23%. The reduction in energy production at the Campoverde di Aprilia plant relates predominantly to the malfunction of the co-generation plant in March and December 2018 which also led to the need to buy in a higher percentage of electricity. It should also be noted that while the usage of methane per kilogram of material (chemical intermediates, solvents and finished products) at the plant remained consistent, the use of methane per turnover unit (in thousands of Euro) fell in 2018 by approximately 7%, demonstrating a consistent trend of the co-generation system's energy efficiency.

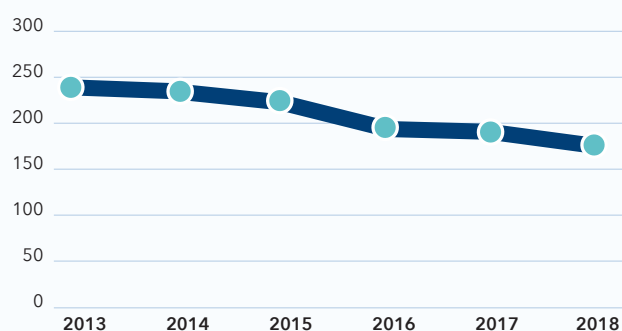
#### ELECTRICITY AND THERMAL ENERGY GENERATED AND SOLD BY THE CAMPOVERDE DI APRILIA CO-GENERATION PLANT

Type of fuel	Unit of measurement	2018	2017	Variation %
Self-generated electricity	kWh	29,685,824	31,242,481	-5%
<i>Consumed internally</i>	kWh	25,829,795	26,207,618	-1%
<i>Sold externally</i>	kWh	3,856,029	5,034,863	-23%
Self-generated and consumed thermal energy	Kg of steam	65,795,000	66,794,000	-1%

#### RATIO OF CUBIC METRES OF METHANE ACQUIRED AGAINST KILOGRAMS OF PRODUCT PROCESSED BY THE CAMPOVERDE DI APRILIA PLANT, 2018



#### RATIO OF CUBIC METRES OF METHANE ACQUIRED AGAINST TURNOVER (IN THOUSANDS OF EURO) GENERATED BY THE CAMPOVERDE DI APRILIA PLANT, 2018



## THE CO-GENERATION SYSTEM AT THE CAMPOVERDE DI APRILIA PLANT

In 1994, following the increased demand for electricity and thermal energy determined by the production facilities at the time, a feasibility study was launched and concluded to assess the installation of a steam and electricity co-generation production system at the Recordati chemical plant in Campoverde di Aprilia. Following the completion of the feasibility study, a co-generation system was installed at the site, entering into service in September 1996 and in operation ever since.

Co-generation is defined as the combined generation of electricity and heat based upon a cascade process where electricity is produced using a high temperature thermo-dynamic cycle which, in turn, releases heat and produces thermal energy. In the industrial sector, co-generation is also produced using gas-powered turbines.

The co-generation system at the Campoverde di Aprilia plant is equipped with a 15-bar methane gas turbine. In its current configuration and with an air temperature of 9°C, the system is able to generate a maximum output of approximately 4.3 MW of electricity.

Gas turbines operate by burning the fuel source in a special combustion chamber and expanding it with compressed air inside the turbine itself. During expansion, the mixture of air and fuel interacts with the blades of the turbines and activates the rotational motion of the rotor to generate mechanical energy.

This mechanical energy is then converted into electricity by an alternator.

The fumes produced by the gases expanded in the turbine are emitted at very high temperatures (450-500°C) and consequently specialist heat exchangers or boilers may be used (the Recordati plant at Campoverde di Aprilia uses a steam recovery boiler - Figure 1) to produce hot water or steam.

The use of the steam recovery boilers prevents exclusive use of methane gas to meet the plant's demand for steam for use in chemical processes and as a heating fluid.



Figure 1  
Exhaust gases vent and recovery boiler - Co-Generation System - Campoverde di Aprilia Plant

The steam recovery boiler installed in the co-generation system, which recovers the gases expanded in the turbine, enables the production of 15-bar saturated steam up to a capacity of 16 tons per hour.

Without the steam produced using the gas turbine fumes in the recovery boiler, it is estimated that in 2018 approximately 4 million cubic metres of gas would have been required.

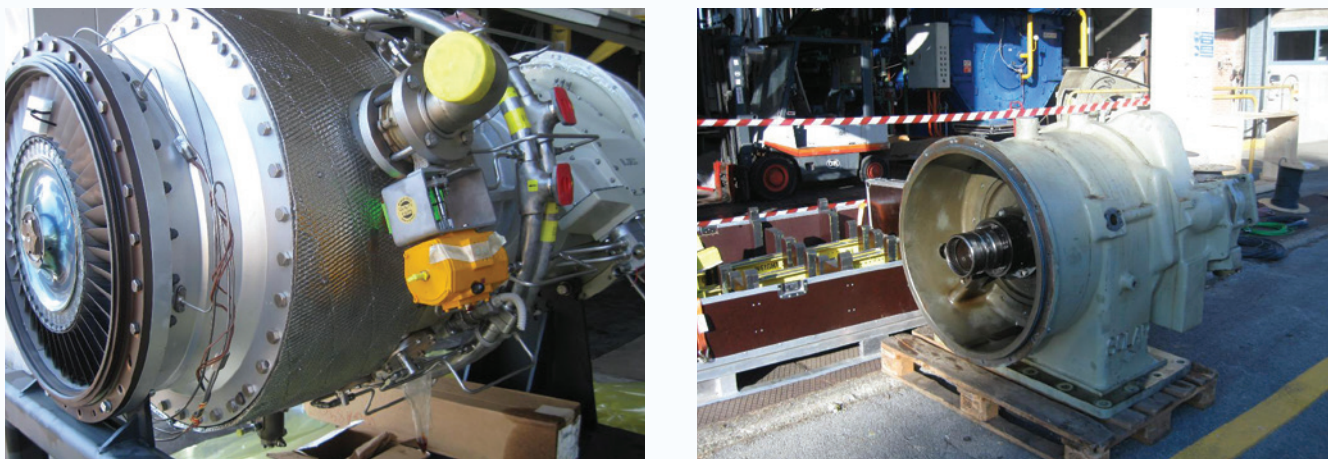
As described above, the co-generation system at the Campoverde di Aprilia plant features a gas turbine (Figure 2) fuelled by methane gas at a pressure of 15 bar and above constructed by the company SOLAR (model TBM-T50), coupled by a reduction gearbox to a GEC Alsthom alternator.

In its current configuration and with an air temperature of 9°C, the system is able to generate a maximum output of approximately 4.3 MW of electricity.

The gas turbine is composed of three main pieces of machinery: the compressor, the combustion unit and the power turbine. The compressor draws in air from the environment through filters, compressing it in the combustion chamber (combuster). The sparks generated by the spark plugs in the ignition chamber light the flame in the combustion chamber. The expansion of the discharged gases causes the power turbine to rotate, enabling the transmission of mechanical energy to the rotator shaft to which it is keyed.

The final conical cog of the compressor shaft is connected to the gearbox.

The reduction gearbox, which is a coupling mechanism with a rotating body able to vary the torque and the angular speed, enables the reduction in rotation speed of the power turbine from 15,000 g/min to 1,500 g/min, the correct rotation speed for the generation of electricity at a voltage of 6300 V and a frequency of 50 HZ.



*Figure 2*  
The gas turbine during its replacement (left); the dismantled reduction gearbox during installation (right) (August 2016)

The gas turbine and reduction gearbox continue to operate 24 hours a day year-round, except for the scheduled site closures in August (at least three weeks), in the last eight days of December and at Easter (except in the last three years).

The manufacturer of the two machines, Turbomach, recommends a full service at its offices at least every 32,000 hours of operation, which in the Recordati plant is the equivalent of four years. This service requires the gas turbine and the reduction gearbox to be completely dismantled, replacing the machines with equivalent newly serviced systems with operating times reset to zero.

In 2016 the control system of the entire machine was replaced with a new, more reliable system.

Both the gas turbine and the reduction gearbox are covered by Maintenance Service Agreements and are continuously monitored by the manufacturer. Furthermore, both the turbine and the reduction unit are subject to ordinary maintenance activities twice a year by Turbomach technicians.

This enables the Recordati site at Campoverde di Aprilia to guarantee the constant supply of electricity to its systems for safety reasons.

### Principle initiatives to reduce energy consumption implemented by the Recordati Group

In recent years, the Italian Parent Group has launched a reduced energy consumption policy through the implementation of initiatives aimed at company vehicles, the technological modernisation of IT equipment such as printers and photocopiers, and the use of LED lighting. This plan is enabling the Group to reduce energy usage and mitigate the environmental impact resulting from the use of company equipment, promoting a more efficient use of energy resources and reducing CO<sub>2</sub> equivalent gases. Continued focus on the environment has been confirmed as one of the primary themes for 2018. This year, the Group aims to optimise investments and acquisitions at a general level in order to ensure maximum respect for the environment and optimise the regions in which it operates without damaging the efficacy of its operational tools.

In 2018 the Group also carried out a monitoring and control activity to assess the emissions of its global fleet of company vehicles. This led the Parent Group to request a detailed six-monthly report from all branches in order to highlight the energy consumption and CO<sub>2</sub> emissions of vehicles used by the Group. This enabled the Group to optimise investments and evaluate corrective actions, where necessary. In 2018, a total of 1,782 company cars were in use by employees of the Recordati Group, while the average CO<sub>2</sub> emissions emitted by the vehicles was 107 g/km, according to the new Worldwide Harmonized Light-Duty Vehicles Test Procedures (WLTP).

For internal combustion vehicles, the application of the WLTP translate to higher official values for fuel consumption and emissions compared to the measurements made with the previous procedure; as a result, the data for 2018 is not easily comparable with the data for 2017. Nonetheless, the Group is continuing its objective to progressively and consistently reduce this statistic over the coming years<sup>18</sup>.

In this regard, the Group has a rigorous vehicle selection policy, encouraging the selection of technologically advanced hybrid solutions which have a reduced environmental impact.

In the last few years the Group has promoted various energy efficiency initiatives implemented at individual branches, including the gradual and systematic replacement of bulbs with new LED or energy-efficient bulbs at the sites in Milan (Italy), Utebo (Spain), Kalaat El Andalous (Tunisia) and Saint Victor (France). In the Saint Victor plant in France, a feasibility study was launched aimed at assessing the replacement of the neon bulbs through the use of leased equipment with motion-activated LED lights to increase the site's energy efficiency; this study is due to conclude in 2019.

Furthermore, in order to further reduce energy consumption, in 2019 the roof at the Saint Victor plant will be renovated and insulated. These works are also aimed at improving roof access for future maintenance.

In 2018 at the Czech plant in Pardubice, an electricity supply contract was signed benefiting from an overnight tariff with ecological and economic benefits.

In particular, the following initiatives have been implemented at the Milan plant:

- in 2016 a heating and air-conditioning system was installed with a geothermal heat pump that uses groundwater as a thermal carrier and can reduce the plant's natural gas usage;
- following the energy analysis conducted in 2015, the consumption of the most energy-intensive equipment (refrigerators, pressurised air compressors, air treatment units) was measured as part of a project to install energy-efficient smart devices. To measure the expected improvements, in 2018 an INTELIGENS system was installed to measure variations in voltage in the electricity supply network, stabilise current outputs and configure the voltage, ensuring the best possible energy saving and maximum performance of connected devices.

This system is an electronically operated static device that operates at high frequency without moving parts, ensuring maximum efficiency (>99%). The system eliminates system harmonics, peaks and micro-outages, reducing device failure rates by 50%. The system is managed by a remote system able to monitor electricity consumption and savings (estimated at around 10%) in real time. As well as reducing energy use, the system also provides significant environmental benefits by reducing CO<sub>2</sub> emissions;

- in 2018, the hot water production and distribution system was reconditioned and optimised, with the installation of a new system consisting of two boilers with a capacity of approximately 2,000 litres each, two electric recirculation pumps and a thermostat system. Furthermore, the distribution lines on various floors were modified and, at the same time, a new return line was installed in order to guarantee the availability of hot water at the time of use;
- in the case of faults or new installations, neon lights are being replaced with LED bulbs and motion sensors have been installed to automatically activate the lighting in certain areas of the galenic department when people are present;
- thanks to a contract signed in 2017 with a new electricity provider, 14% of all purchased electricity derives from renewable sources;
- during the works to renovate the third and fourth floors, the old heating and air-conditioning units were demolished and replaced with energy-efficient devices.

In recent years the Irish plant in Cork has been committed to optimising and streamlining its production chain through the use of a programming procedure and preventive maintenance. The Energy Manager at the plant has promoted initiatives to increase employee awareness regarding energy saving according to a training plan agreed with Parent Group and smaller projects approved at local level. In a tangible demonstration of this commitment, in 2012 the plant's efforts to reduce energy consumption were recognised by the SEAI (Sustainable Energy Authority of Ireland) with the *Energy Efficiency Award* for SMEs. Other energy efficiency initiatives that have taken place at the Cork plant include:

- the replacement of warehouse lighting with LED bulbs, saving energy and reducing fire risk through the replacement of incandescent bulbs which reached high temperatures during use;
- the replacement of all steam distribution pipes with insulated pipes, resulting in less heat dispersion.

### Greenhouse gases and other emissions

The Recordati Group's commitment to protecting the environment is also expressed through policies and initiatives aimed at reducing the emission of greenhouse gases and other air pollutants.

In all of the Group's production plants, old equipment containing fluorinated greenhouse gases is being progressively replaced with new machinery that does not use substances which are harmful to the ozone. Other initiatives to reduce emissions have taken place:

- at the Saint Victor plant in France, where emission points have been equipped with air filters to prevent the release of hazardous particles. Each filtering system is regularly maintained by the internal maintenance department;

<sup>18</sup> Average emissions of the vehicle fleet were calculated on the basis of estimated annual CO<sub>2</sub> emissions and annual mileage of company vehicles.

- at the Cork plant in Ireland, with the completion in 2017 of the project to replace obsolete refrigerators which used R-22 as the refrigerating gas with new units using R404a, a gaseous mix with a much lower impact on the ozone layer. Furthermore, all emission points at the plant in Ireland are monitored according to the requirements of the National Environment Agency. A study is currently being carried out to assess the possibility of installing an automatic air sampling and analysis system;
- at the Pardubice plant in the Czech Republic, where a new air conditioning unit was installed in cleanrooms which does not contain gases such as freon which are harmful to the ozone layer. The new system also offers greater efficiency and reduces energy consumption;
- at the Cerkezkoj plant in Turkey, where all emission points were constantly monitored in 2018, with the installation of new ventilation systems in production and laboratory areas and the insertion of six new emission sources (a total of 31 points of emission have been declared). Emissions were measured by an accredited laboratory; emission values related to the production process are well below permitted limits.

At the Campoverde di Aprilia plant in 2018, measures implemented to reduce emissions of harmful substances into the atmosphere specifically regarded the following actions:

- after a study was conducted in 2017 to assess the optimisation of atmospheric emission treatment and mitigation systems, a new control system to moderate emissions related to the works at the Ala Latina plant was installed, replacing the two existing water scrubbers (joint project with the company Amec Foster Wheeler). In 2019 the aim is to optimise the emission control system at Ala Roma;
- in 2018 the works to recondition the discharge areas of the centrifuges used to isolate wet active substances were completed. The project aimed to isolate the discharge zone from the surrounding area and to install UTA air treatment units able to monitor particulate contamination according to the parameters set forth by the ISO 14644 guidelines for class 8 environments, or class D environments according to EU GMP;
- in order to minimise polluting emissions and fuel use, the steam generators at the Plan were equipped with control systems to monitor fuel efficiency, based on an analysis of the oxygen content of the fumes.

In 2018, Scope 1 direct emissions relating to the use of energy for industrial production (natural gas, diesel and fuel oil) remained mainly in line with those of the previous year; furthermore, in 2017 the proportion of Scope 1 direct emissions caused by the Group's fleet of vehicles fell by approximately 20%. However, Scope 2 indirect emissions linked to the purchase of electricity from the National Grid increased by 8%.

#### GREENHOUSE GAS EMISSIONS (TONNES OF CO<sub>2</sub>) AT RECORDATI GROUP PRODUCTION PLANTS AND COMPANY VEHICLE FLEET<sup>19</sup>

	2018	2017	Variation %
Direct emissions (Scope 1)	35,232	34,458	2%
<i>Relating to energy consumption</i>	28,056	28,073	-0.1%
<i>Relating to the company vehicle fleet<sup>20</sup></i>	7,176	6,385	12%
Indirect emissions (Scope 2) - Location-based approach <sup>21</sup>	11,407	10,567	8%
Indirect emissions (Scope 2) - Market-based approach <sup>22</sup>	13,427	12,384	8%

With reference to other air pollutants, depending on the type of pollutant various thresholds have been defined; these are respected by the Group thanks to continuous monitoring and control activities of the emission points. In particular, the list of authorised emission points at the Milan plant is included by the Autorizzazione Unica Ambientale certification awarded in 2018.

The reduction in other atmospheric emissions from 2017 to 2018 (in particular NO<sub>x</sub>) predominantly relates to the production plant in Campoverde di Aprilia. In fact, in 2017 the increase in emissions recorded at the plant was attributable to the activation of the after-burner of the co-generation system during the final inspection phase to meet an increase in demand of steam for production purposes.

#### OTHER EMISSIONS (KG/YEAR) OF RECORDATI GROUP PRODUCTION PLANTS<sup>23</sup>

	2018	2017
Nitric oxide (NO <sub>x</sub> )	11,389	20,038
Sulphur oxide (SO <sub>x</sub> )	25	82
Persistent Organic Pollutants (POP)	0	0
Volatile Organic Pollutants (VOC)	4,178	13,304
Hazardous Air Pollutants (HAP)	1,923	2,948
Particulate Matter (PM)	4,103	3,546
Methane (CH <sub>4</sub> )	0	1
Others	415	1,923

19 Source of emission coefficient data for natural gas, diesel and fuel oil: Italian Ministry of the Environment and the Protection of Land and Sea, Table of National Standard Limits, 2018.

20 Scope 1 emissions relating to the use of fuel oil by company vehicles have been estimated based on the average mileage of each car and the average emission rating of fleet vehicles (107 g/km).

21 The reporting standards applied (GRI Sustainability Reporting Standards 2016) provide for two different approaches for the calculation of Scope 2 emissions: "location-based" and "market-based". The location-based approach uses national average emission factors relating to the specific configuration of national electricity production (source of emission factors: TERNA, Confronti Internazionali, 2016).

22 The market-based approach uses an emission factor defined on a contractual basis with the electricity supplier. Given the absence of specific contractual agreements between Group companies and the energy supplier (e.g. acquisition of Guarantees of origin), for this approach the national "residual mix" emission factors were applied (source of residual mixes: AIB European Residual Mixes 2016 (Version 1.2, 15th June 2017) and AIB European Residual Mixes 2017 (Version 1.13, 2018-07-11)).

23 Any significant changes in the other emissions into the atmosphere are due to the way the data are calculated, because the annual value of emissions are calculated by multiplying the result of a single emissions analysis (taken over one hour) by the annual operating hours.

### 5.3. MANAGEMENT OF WATER RESOURCES

In recognition of the value of natural resources, the Recordati Group is developing production processes aimed at reducing water usage. In particular:

- at the head office in Milan, since 2016 the new heating and air conditioning unit equipped with geothermal heat pumps has used groundwater as the principle thermal carrier. The groundwater is drawn from a shaft and channelled into the system for use in the heating or air conditioning systems before being returned in its original condition to the groundwater reserves via two return channels. The quantity of water used and recycled by the heat pump is 110,330 m<sup>3</sup>/year and corresponds to approximately 4% of the Group's annual water intake. Each year, the chemical and physical characteristics (pH, suspended solids, BOD5, COD, metals, aromatic solvents, chlorinated aromatic solvents, aliphatic solvents and surfactants) of the waste water, non-potable groundwater and potable water from the aqueduct are monitored at the Milan plant on a monthly basis;
- at the Campoverde di Aprilia plant, a project to extend the water treatment plant for the disposal of waste water was implemented in 2016 through the maintenance and use of disused tanks. This project enabled the development of a pre-treatment system for water used in various processes considered critical to the plant's operation, ensuring higher levels of compliance with the limits established by the Autorizzazione Integrata Ambientale (AIA). At the same plant, in 2017 and 2018 an important project was carried out to revamp and reline the sewage pipes (surface water drains and sewage pipes) and outflow pipes for clarified water treated at the plant;
- at the Cork plant in Ireland, particular focus was given to water use, particularly water used to ensure the correct operation of the scrubbers. In any case, water usage is constantly monitored to identify any anomalies and facilitate prompt intervention when required. At the same plant, in 2017 a study was carried out to assess the current performance of the biological process used to treat waste water, identifying any measures that could improve the treatment process in terms of stability and the effective removal of polluting substances. This study, which aimed to verify the plant's compliance with the more stringent regulations due to enter into force in the coming years, was completed in 2018. The study identified three solutions that could be implemented if necessary: the direction of untreated water to a public body (Irish Water), the direction of partially treated water to Irish Water, or the complete reconditioning of the waste water treatment process. It is also noted that new apparatus was installed at this plant in 2017 to enable the automatic analysis of the total organic carbon (TOC) and total nitrogen (TN) content of water discharged into the sewage system. This device provides detailed analysis in real time and facilitates the control and management of the waste water treatment plant, promptly revealing any anomalies and enabling preventive measures to be implemented before the water is discharged;

- at the Utebo factory in Spain, groundwater used to ensure the correct operation of the heat pumps in the heating and air conditioning system is returned to the groundwater system;
- at the Saint Victor plant in France, all industrial waste water is treated in a 20 m<sup>3</sup> tank before being disposed of as pharmaceutical waste. In order to reduce the amount of water disposed of as pharmaceutical waste, water used in the first cleaning process which contains high concentrations of pollutants is recovered and stored in vats for processing as pharmaceutical waste. Furthermore, a study is currently being conducted into the recovery of grey water for cooling and irrigation purposes.

In 2018, the overall water intake at the Group's production plants fell by 3% compared to 2017. In particular, total water intake in 2018 was 2.8 million cubic metres, of which 42% was surface water, 48% was groundwater and the remaining 17% was taken from aqueducts. It should also be noted that in 2018, 17% of total water intake at the Group's production plants was recycled and reused internally.

#### WATER INTAKE AT RECORDATI GROUP PRODUCTION PLANTS BY SOURCE

	Unit of measurement	2018	2017	Variation %
Surface water	m <sup>3</sup>	1,204,150	1,415,480	-15%
Groundwater	m <sup>3</sup>	1,364,326	1,280,560	7%
Aqueduct	m <sup>3</sup>	248,506	220,095	13%
<b>Total</b>	<b>m<sup>3</sup></b>	<b>2,816,982</b>	<b>2,916,135</b>	<b>-3%</b>

#### PERCENTAGE OF RECYCLED WATER AT RECORDATI GROUP PRODUCTION PLANTS

Unit of measurement m <sup>3</sup>	2018		2017	
	Total	% of total water intake	Total	% of total water intake
Quantity of water recycled and reused	471,287	17%	419,997	14%



## 5.4. WASTE MANAGEMENT

The Recordati Group's commitment to environmental protection is also evidenced by its activities to reduce the waste produced by its activities and ensure the correct disposal of chemical and pharmaceutical products, particularly at its production sites.

In particular, at the Milan plant waste management is regulated by a specific internal procedure which assigns each waste product a specific code: HW (Hazardous Waste) such as solvents, excess pharmaceuticals, filters, pharmaceutical waste and contaminated celite, and SNHW (Special Non-Hazardous Waste) such as clean glass, special waste similar to sold urban waste (SUW), paper, cardboard, wood and iron. In particular, the various types of waste produced at the plant are classified as hazardous or non-hazardous. In accordance with internal operating procedures, all waste is assigned an EWC code which defines the relative management procedure for that type of waste.

In accordance with Italian law (Legislative Decree no. 231/01), the Group's organisational model includes the appointment of various waste management officers within the company. Furthermore, waste disposal is contracted to specialist firms that hold the relative authorisations to act as carriers, intermediaries and recipients. As well as the paper forms used to identify transported waste, the SISTRI Waste Tracking System is also applied, enabling the prompt and accurate tracking of special waste throughout the supply chain.

Correct spillage management is regulated by a specific standard operating procedure, which states that the spilled product must be collected using absorbent sheets and pads suitable for use with all types of hazardous and non-hazardous materials. Once used, the absorbent sheets are managed and destroyed in the most appropriate way, considering the hazardous nature of the product.

Other important waste disposal initiatives implemented at plants by the Group include:

- the research programme at the Campoverde di Aprilia plant to investigate the possibility of internally managing certain types of waste that have previously been disposed of externally. For certain types of waste, this project has resulted in a significant reduction in costs, due not only to the internal management but also the reduction in number of transport journeys and containers used. The reduction in the number of journeys is in line with the policy of reducing external environmental impacts;

- at the Cork plant in Ireland, solid hazardous waste is segregated on site by production operators as soon as it is produced and is then sent off site for incineration by specialised contractors. Liquid hazardous waste is managed internally using closed systems: part of this waste is sent via a specialised contractor for disposal, while the majority is treated at the waste treatment plant of the Recordati Ireland branch. Biological sludge extracted by the waste treatment plant is sent for incineration by the specialist contractor. Furthermore, a specialist study is current being conducted at the plant in Cork to evaluate and provide a detailed emergency plan to manage leaks of thionyl chloride, the most reactive and hazardous chemical substance used in plant processes. To align with the guidelines issued by the Environmental Protection Agency (EPA), the study was made official in January 2019;
- at the Cerkezkoj plant in Turkey, all waste is classified according to three main categories: domestic waste (such as food waste), recyclable and non-hazardous waste (such as paper, cardboard, plastic, glass and aluminium packaging) and hazardous waste. A specific policy has been adopted at the plant to regulate waste collection, storage, recycling and transfer procedures. This policy includes a waste tracking system which monitors the transfer of special waste throughout the supply chain in real time. In 2018 a new area equipped with a controlled access system was designated for the temporary storage of waste awaiting final disposal; In 2018, the waste water treatment system was subjected to various maintenance works, with a consequent reduction in waste water pollution levels. Furthermore, these optimisation measures reduced the consumption of chemical substances used in treatment plants, with a consequent reduction in operating costs;
- at the Milan plant, in order to limit the number of collections made by the carrier, two waste compressor units have been installed, one for paper and cardboard and one for special waste similar to SUW.

A total of 5,892 tonnes of waste was produced in 2018, of which 54% was hazardous waste (substances defined as hazardous in the country of origin) and 46% was non-hazardous waste (all other forms of liquid and solid waste). In line with 2017, the majority of the hazardous waste produced by the production plants in 2018 (equal to 2,686 tonnes) was exported for disposal, while the remaining 516 tonnes were processed internally.

**TOTAL WASTE PRODUCED BY RECORDATI GROUP PLANTS, SUBDIVIDED BY TYPE AND DISPOSAL METHOD**

Disposal method	Unit of measurement	2018			2017		
		Hazardous waste	Non-hazardous waste	Total	Hazardous waste	Non-hazardous waste	Total
Reuse	tonnes	-	1	1	-	1	1
Recycling	tonnes	36	551	587	42	504	546
Compost	tonnes	-	24	24	-	14	14
Recovery	tonnes	1,606	957	2,563	1,627	897	2,524
Incineration	tonnes	403	18	421	276	29	305
Landfill	tonnes	34	72	106	50	162	212
Storage on site	tonnes	2	-	2	3	-	3
Other <sup>24</sup>	tonnes	1,121	1,067	2,188	1,384	977	2,361
<b>Total</b>	<b>tonnes</b>	<b>3,202</b>	<b>2,690</b>	<b>5,892</b>	<b>3,382</b>	<b>2,584</b>	<b>5,966</b>

**TOTAL HAZARDOUS WASTE PRODUCED BY RECORDATI GROUP PLANTS, SUBDIVIDED BY DESTINATION**

Hazardous waste	Unit of measurement	2018		2017	
		Total	% of Total	Total	% of Total
Exported	tonnes	2,686	84%	2,862	85%
Processed	tonnes	516	16%	520	15%
<b>Total</b>	<b>tonnes</b>	<b>3,202</b>	<b>100%</b>	<b>3,382</b>	<b>100%</b>

As regards the various disposal methods, particular emphasis was given to the recycling of packaging materials and the use of reliable suppliers of waste transportation and disposal services. In order to reduce the volume of waste produced, the Recordati Group is committed to reducing the amount of packaging entering the waste system and increasing consumer recycling activities through re-engineering its products.

The Group ensures that the materials used in its packaging can be recycled or incinerated without causing any negative environmental impacts or producing hazardous waste. For example, the paper and cardboard used for the boxes and the paper used for the package leaflets are completely recyclable and use ecologically sustainable materials such as wood pulp from responsibly managed forests. Moreover, where possible the Recordati Group is committed to reducing the weight of packaging material and the proportion of non-recyclable waste. When coordinating these initiatives, the Group works with national recycling organisations such as CONAI (Consorzio Nazionale Imballaggi).

<sup>24</sup> This category includes the disposal methods classified as D8, D9, D13, D14 and D15 used at the Campoverde di Aprilia plant and listed in Annex B of Italian Legislative Decree no. 152/06.

# GRI Index

The following table shows the material topics identified by Recordati relating to the GRI Reporting Standards and the topics covered by Legislative Decree no. 254/2016. For these topics, the column "Scope of material topics" lists all parties who may generate an impact for each topic, both internally and externally to the Group. The column "Type of impact" indicates Recordati's role in relation to the general impact for each material topic.

Material topics of the Recordati Group	Correlation with GRI Standards	Correlation with the topics covered by Legislative Decree no. 254/2016	Scope of material topics	Type of impact
Compliance and business ethics	GRI 419: Socio-economic compliance	Fight against active and passive corruption	Recordati Group	Caused by the Group
	GRI 206: Anti-competitive practices			
Anti-corruption	GRI 205: Anti-corruption	Fight against active and passive corruption	Recordati Group	Caused by the Group
Risk management	N/A	N/A	Recordati Group	Caused by the Group
Corporate Governance	N/A	N/A	Recordati Group	Caused by the Group
Financial performance	GRI 201: Financial performance	Social	Recordati Group; Investors and the financial community	Caused by the Group
Market presence	GRI 202: Market presence	Relating to staff	Recordati Group;	Caused by the Group
Commitment to local communities	GRI 203: Indirect financial impacts	Social	Recordati Group; Local community;	Caused by the Group
Access to medical products and health insurance	N/A	Social	Recordati Group; Clients and consumers; Patients and associations	Caused by the Group
Research and development	N/A	N/A	Recordati Group; Scientific organisations and Universities	Caused by the Group
Patient health and safety	GRI 416: Customer health and safety	Social	Recordati Group; Clients and consumers; Patients and associations	Caused by the Group
Anti-counterfeiting	GRI-417: Marketing and labelling	N/A	Recordati Group	Caused by the Group
Responsible marketing	GRI-417: Marketing and labelling	N/A	Recordati Group;	Caused by the Group
Product quality and safety	GRI 416: Customer health and safety	Social	Recordati Group	Caused by the Group
Procurement practices	GRI 414: Supplier Social Assessment	Social	Recordati Group; Suppliers and strategic partners	Caused by the Group and directly connected to its activities
	GRI 308: Supplier Environmental Assessment	Environmental		
HR management	GRI 401: Employment	Relating to staff	Recordati Group; Employees	Caused by the Group
Diversity and equal opportunities	GRI 405: Diversity and equal opportunities	Relating to staff	Recordati Group; Employees	Caused by the Group
Employee health and safety	GRI 403: Health and safety in the workplace	Relating to staff	Production plants; Suppliers and strategic partners	Caused by the Group and directly connected to its activities
Training and development	GRI 404: Training and education	Relating to staff	Recordati Group; Employees	Caused by the Group
Human rights	GRI 414: Supplier Social Assessment	Human rights	Recordati Group; Suppliers and strategic partners	Caused by the Group and directly connected to its activities
Efficient use of natural resources	GRI 302: Energy	Environmental	Production plants	Caused by the Group
	GRI 303: Water			
Environmental conservation	GRI 305: Emissions	Environmental	Production plants	Caused by the Group
	GRI 307: Environmental compliance			
Disposal of chemical products and pharmaceuticals	GRI 306: Effluents and waste	Environmental	Production plants	Caused by the Group

In accordance with the “Core” option of the “GRI Sustainability Reporting Standards”, performance indicators are presented in the table below. Each indicator includes a reference to the section of the Non-Financial Statement where the indicator can be found or other relevant reference sources in the public domain.

Indicator	References and other information	Omission
<b>GRI 102: GENERAL DISCLOSURES (2016)</b>		
<b>Organisation Profile</b>		
102-1	Name of Organisation	Page 110
102-2	Activities, brands, products, and services	Pages 112; Annual Report, “Business activities” section
102-3	Location of headquarters	Page 110
102-4	Location of operations	Pages 12-13; page 112
102-5	Ownership and legal form	Corporate Governance Report and Ownership Structure, “Profile of the issuer and general information” section
102-6	Markets served	Page 112
102-7	Scale of the organisation	Pages 128; Annual Report, “Summary of results” section; Corporate Governance Report and Ownership Structure, “Profile of the issuer and general information” section
102-8	Information on employees and other workers	Page 31; page 33
102-9	Supply chain	Pages 124-125
102-10	Significant changes to the organisation and its supply chain	Pages 110-111; Corporate Governance Report and Ownership Structure, “Introduction” and “Ownership structure”
102-11	Precautionary Principle or approach	Pages 114-115
102-12	External initiatives	Pages 116-118
102-13	Membership of associations	Page 118; pages 121-122
<b>Strategy</b>		
102-14	Statement from senior decision-maker	Annual Report, “Letter to Shareholders” section
102-15	Principle impacts, risks and opportunities	Page 115
<b>Ethics and integrity</b>		
102-16	Values, principles, standards, and norms of behaviour	Pages 112-114
<b>Governance</b>		
102-18	Governance structure	Corporate Governance Report and Ownership Structure, “Profile of the issuer and general information” section
<b>Stakeholder engagement</b>		
102-40	List of stakeholder groups	Page 117
102-41	Collective bargaining agreements	Page 132
102-42	Identifying and selecting stakeholders	Page 117
102-43	Approach to stakeholder engagement	Pages 116-117
102-44	Key topics and concerns that have been raised through stakeholder engagement	Page 119
<b>Reporting practices</b>		
102-45	Entities included in the Consolidated Financial Statements	Pages 110-111
102-46	Defining report content and topic boundaries	Pages 110-111; page 153
102-47	List of material topics	Page 119; page 153

Indicator		References and other information	Omission
102-48	Restatements of information	Pages 110-111	
102-49	Changes in reporting	Pages 110-111; page 119; page 153	
102-50	Reporting period	Page 110	
102-51	Date of most recent report	The previous Consolidated Non-Financial Statement was published by the Recordati Group on 15 March 2018.	
102-52	Reporting cycle	Page 111	
102-53	Contact point for questions regarding the report	Page 111	
102-54	Chosen "in accordance" option	Page 110	
102-55	GRI content index	Pages 154-160	
102-56	External assurance	Pages 161-163	

#### TOPIC-SPECIFIC STANDARDS

##### GRI 200: ECONOMIC SERIES (2016)

###### Material aspect: Financial performance

###### GRI-103: Management approach (2016)

103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Page 120
103-3	Evaluation of the management approach	Page 120

###### GRI-201: Financial performance (2016)

201-1	Direct economic value generated and distributed	Page 120
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###### Material aspect: Market presence

###### GRI-103: Management approach (2016)

103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Pages 128-129
103-3	Evaluation of the management approach	Pages 128-129

###### GRI-201: Financial performance (2016)

202-2	Proportion of senior management hired from the local community	Page 129
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###### Material aspect: Indirect financial impacts

###### GRI-103: Management approach (2016)

103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Page 121
103-3	Evaluation of the management approach	Page 121

###### GRI-203: Indirect financial impacts (2016)

203-1	Infrastructure investments and services supported	Page 121
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**Material aspect: Anti-corruption****GRI-103: Management approach (2016)**

103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Pages 112-114
103-3	Evaluation of the management approach	Pages 112-114

**GRI-205: Anti-corruption (2016)**

205-1	Operations assessed for risks related to corruption	Pages 112-114
205-3	Confirmed incidents of corruption and actions taken	Page 114

**Material aspect: Anti-competitive behaviour****GRI-103: Management approach (2016)**

103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Pages 112-114
103-3	Evaluation of the management approach	Pages 112-114

**Material aspect: Anti-competitive behaviour (2016)**

206-1	Legal actions for anti-competitive behaviour, anti-trust, and monopoly practices	No legal action for anti-competitive behaviour, anti-trust cases or monopoly practices was reported during the year.
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**GRI 300: ENVIRONMENTAL SERIES (2016)****Material aspect: Energy****GRI-103: Management approach (2016)**

103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Pages 142-148
103-3	Evaluation of the management approach	Pages 142-148

**GRI-302: Energy (2016)**

302-1	Energy consumption within the organisation	Pages 144-145 This indicator considers production plants only, except for the site in Milan, Italy, where site offices were also considered.
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**Material aspect: Water****GRI-103: Management approach (2016)**

103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Pages 142-143; page 150
103-3	Evaluation of the management approach	Page 150

**GRI-303: Water (2016)**

303-1	Water intake by source	Page 150 This indicator considers production plants only, except for the site in Milan, Italy, where site offices were also considered.
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## Material aspect: Emissions

GRI-103: Management approach (2016)		
103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Pages 142-143; pages 148-149
103-3	Evaluation of the management approach	Pages 148-149
GRI-305: Emissions (2016)		
305-1	Direct (Scope 1) GHG emissions	Page 149 This indicator considers company vehicle fleet and production plants only, except for the site in Milan, Italy, where site offices were also considered.
305-2	Indirect (Scope 2) GHG emissions	Page 149 This indicator considers production plants only, except for the site in Milan, Italy, where site offices were also considered.
305-7	Nitrogen oxides (NOX), sulphur oxides (SOX), and other significant air emissions	Page 149 This indicator considers production plants only, except for the site in Milan, Italy, where site offices were also considered.

## Material aspect: Effluents and waste

GRI-103: Management approach (2016)		
103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Pages 142-143; pages 151-152
103-3	Evaluation of the management approach	Pages 151-152
GRI-306: Effluents and waste (2016)		
306-2	Waste by type and disposal method	Pages 151-152 This indicator considers production plants only, except for the site in Milan, Italy, where site offices were also considered.

## Material aspect: Environmental compliance

GRI-103: Management approach (2016)		
103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Pages 142-143
103-3	Evaluation of the management approach	Pages 142-143
GRI-307: Environmental compliance (2016)		
307-1	Non-compliance with environmental laws and regulations	In 2018 a € 45,015.49 fine was issued to the Recordati S.p.A. following certain cases of non-compliance detected at the Campoverde di Aprilia plant regarding the sampling and treatment of atmospheric emissions.

## Material aspect: Supplier Environmental Assessment

GRI-103: Management approach (2016)		
103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Page 123; pages 124-126
103-3	Evaluation of the management approach	Pages 124-126
GRI-308: Supplier Environmental Assessment (2016)		
308-1	New suppliers that were screened using environmental criteria	Page 113; pages 125-126  As per the new procurement process, all suppliers for Italian Companies are selected based on compliance to environmental regulations. This process will be extended to all Group Companies by the end of 2021

**GRI 400: SOCIAL SERIES (2016)****Material aspect: Employment**

<b>GRI-103: Management approach (2016)</b>		
103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Pages 128-130; pages 132-134
103-3	Evaluation of the management approach	Pages 128-130; pages 132-134
<b>GRI-401: Employment (2016)</b>		
401-1	New employee hires and employee turnover	Page 130
401-2	Benefits provided to full-time employees that are not provided to temporary or part-time employees	Pages 132-133 The benefits described do not vary based on contract type or professional level.

**Material aspect: Health and safety in the workplace**

<b>GRI-103: Management approach (2016)</b>		
103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Pages 136-138
103-3	Evaluation of the management approach	Pages 136-138
<b>GRI-403: Occupational health and safety (2016)</b>		
403-2	Types of injury and rates of injury, occupational diseases, lost days, and absenteeism, and number of work-related fatalities	Pages 139-141 This indicator considers production plants only, with the exception of sites in Italy (Milan), Spain, Tunisia and France (Bouchara), for which office and commercial staff are also considered.

**Material aspect: Training and education**

<b>GRI-103: Management approach (2016)</b>		
103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Pages 134-135
103-3	Evaluation of the management approach	Pages 134-135
<b>GRI-404: Training and education (2016)</b>		
404-1	Average hours of training per year per employee	Page 134
404-2	Programs for upgrading employee skills and transition assistance programs	Pages 134-135

**Material aspect: Diversity and equal opportunities**

<b>GRI-103: Management approach (2016)</b>		
103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Pages 131-132; page 133
103-3	Evaluation of the management approach	Pages 131-132; page 133
<b>GRI-405: Diversity and equal opportunities 2016</b>		
405-1	Diversity of governance bodies and employees	Page 131; Corporate Governance Report and Ownership Structure, "Board of Directors" section
405-2	Ratio of basic salary and remuneration of women to men	Pages 133



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**Material aspect: Supplier Social Assessment**
**GRI-103: Management approach (2016)**

103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Page 113; page 123; pages 124-126
103-3	Evaluation of the management approach	Pages 124-126

**GRI-414: Supplier Social Assessment (2016)**

414-1	New suppliers that were screened using social criteria	Page 123; pages 124-125	As per the new procurement process, all suppliers for Italian Companies are selected based on compliance to environmental regulations. This process will be extended to all Group Companies by the end of 2021.
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**Material aspect: Customer health and safety**
**GRI-103: Management approach (2016)**

103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Page 123
103-3	Evaluation of the management approach	Page 123

**GRI-416: Customer health and safety (2016)**

416-1	Assessment of the health and safety impacts of product and service categories	Page 123
416-2	Incidents of non-compliance concerning the health and safety impacts of products and services	Page 123

**Material aspect: Marketing and labelling**
**GRI-103: Management approach (2016)**

103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Page 123; page 127
103-3	Evaluation of the management approach	Page 123; page 127

**GRI-417: Marketing and labelling 2016**

417-2	Incidents of non-compliance concerning product and service information and labelling	Page 123
417-3	Incidents of non-compliance concerning marketing communications	Page 123

**Material aspect: Socio-economic compliance**
**GRI-103: Management approach (2016)**

103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Page 123
103-3	Evaluation of the management approach	Page 123

**GRI-419: Socio-economic compliance (2016)**

419-1	Non-compliance with laws and regulations in the social and economic area	A fine of € 13,500 was issued to Recordati S.p.A. in 2018 following the reintegration of an employee dismissed in 2012. A fine for a negligible amount was issued in 2018 to the Turkish branch Recordati İlaç Sanayi ve Ticaret Anonim Şirketi following certain incidences of non-compliance regarding the application of occupational health and safety regulations.
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**Material aspect: Risk management****GRI-103: Management approach (2016)**

103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Pages 114-115
103-3	Evaluation of the management approach	Pages 114-115

**Material aspect: Corporate Governance****GRI-103: Management approach (2016)**

103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Pages 112-114
103-3	Evaluation of the management approach	Pages 112-114

**Material aspect: Access to medical products and health insurance****GRI-103: Management approach (2016)**

103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Page 122
103-3	Evaluation of the management approach	Page 122

**Material aspect: Research and development****GRI-103: Management approach (2016)**

103-1	Explanation of the material topic and its boundary	Page 110; page 119; page 153
103-2	The management approach and its components	Page 123; page 124
103-3	Evaluation of the management approach	Pages 123; page 124

Milan, 28 February 2019

Andrea Recordati  
Chief Executive Officer

# INDEPENDENT AUDITORS' REPORT ON THE CONSOLIDATED NON FINANCIAL STATEMENT



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(Translation from the Italian original which remains the definitive version)

## **Independent auditors' report on the consolidated non-financial statement pursuant to article 3.10 of Legislative decree no. 254 of 30 December 2016 and article 5 of the Consob Regulation adopted with Resolution no. 20267 of 18 January 2018**

*To the board of directors of  
Recordati Industria Chimica e Farmaceutica S.p.A.*

Pursuant to article 3 of Legislative decree no. 254 of 30 December 2016 (the "decree") and article 5 of the Consob (the Italian Commission for listed companies and the stock exchange) Regulation adopted with Resolution no. 20267 of 18 January 2018, we have been engaged to perform a limited assurance engagement on the 2018 consolidated non-financial statement of the Recordati Group (the "group") prepared in accordance with article 4 of the decree and approved by the board of directors on 28 February 2019 (the "NFS").

### **Responsibilities of the directors and board of statutory auditors ("Collegio Sindacale") of Recordati Industria Chimica e Farmaceutica S.p.A. (the "parent") for the NFS**

The directors are responsible for the preparation of a NFS in accordance with articles 3 and 4 of the decree and the "Global Reporting Initiative Sustainability Reporting Standards" issued in 2016 by GRI - Global Reporting Initiative (the "GRI Standards").

The directors are also responsible, within the terms established by the Italian law, for such internal control as they determine is necessary to enable the preparation of a NFS that is free from material misstatement, whether due to fraud or error.

Moreover, the directors are responsible for the identification of the content of the NFS, considering the aspects indicated in article 3.1 of the decree and the group's business and characteristics, to the extent necessary to enable an understanding of the group's business, performance, results and the impacts it generates.

The directors' responsibility also includes the design of an internal model for the management and organisation of the group's activities, as well as, with reference to the aspects identified and disclosed in the NFS, the group's policies for the identification and management of the risks generated or borne.

KPMG S.p.A. è una società per azioni di diritto italiano e fa parte del network KPMG di entità indipendenti affiliate a KPMG International Cooperative ("KPMG International"), entità di diritto svizzero.

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**Recordati Group**  
*Independent auditors' report*  
 31 December 2018

The *Collegio Sindacale* is responsible for overseeing, within the terms established by the Italian law, compliance with the decree's provisions.

#### ***Auditors' independence and quality control***

We are independent in compliance with the independence and all other ethical requirements of the Code of Ethics for Professional Accountants issued by the International Ethics Standards Board for Accountants, which is founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behaviour. Our company applies International Standard on Quality Control 1 (ISQC Italia 1) and, accordingly, maintains a system of quality control including documented policies and procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

#### ***Independent auditors' responsibilities***

Our responsibility is to express a conclusion, based on the procedures performed, about the compliance of the NFS with the requirements of the decree and the GRI Standards. We carried out our work in accordance with the criteria established by "International Standard on Assurance Engagements 4 (revised) - Assurance Engagements other than Audits or Reviews of Historical Financial Information" ("ISAE 3000 revised"), issued by the International Auditing and Assurance Standards Board applicable to limited assurance engagements. This standard requires that we plan and perform the engagement to obtain limited assurance about whether the NFS is free from material misstatement. A limited assurance engagement is less in scope than a reasonable assurance engagement carried out in accordance with ISAE 3000 revised, and consequently does not enable us to obtain assurance that we would become aware of all significant matters and events that might be identified in a reasonable assurance engagement.

The procedures we performed on the NFS are based on our professional judgement and include inquiries, primarily of the parent's personnel responsible for the preparation of the information presented in the NFS, documental analyses, recalculations and other evidence gathering procedures, as appropriate.

Specifically, we carried out the following procedures:

1. Analisi dei temi rilevanti in relazione alle attività e alle caratteristiche del Gruppo rendicontati nella DNF, al fine di valutare la ragionevolezza del processo di selezione seguito alla luce di quanto previsto dall'art. 3 del Decreto e tenendo presente lo standard di rendicontazione utilizzato.
2. Analysing and assessing the identification criteria for the reporting scope, in order to check their compliance with the decree.
3. Comparing the financial disclosures presented in the NFS with those included in the group's consolidated financial statements.
4. Gaining an understanding of the following:
  - the group's business management and organisational model, with reference to the management of the aspects set out in article 3 of the decree;
  - the entity's policies in connection with the aspects set out in article 3 of the decree, the achieved results and the related key performance indicators;



**Recordati Group**  
*Independent auditors' report*  
 31 December 2018

- the main risks generated or borne in connection with the aspects set out in article 3 of the decree.

Moreover, we checked the above against the disclosures presented in the NFS and carried out the procedures described in point 5.a).

5. Understanding the processes underlying the generation, recording and management of the significant qualitative and quantitative information disclosed in the NFS.

Specifically, we held interviews and discussions with the parent's management personnel. We also performed selected procedures on documentation to gather information on the processes and procedures used to gather, combine, process and transmit non-financial data and information to the office that prepares the NFS.

Furthermore, with respect to significant information, considering the group's business and characteristics:

- at parent and subsidiaries level,
  - a) we held interviews and obtained supporting documentation to check the qualitative information presented in the NFS and, specifically, the business model, the policies applied and main risks for consistency with available evidence,
  - b) we carried out analytical and limited procedures to check the correct aggregation of data in the quantitative information;
- we visited Recordati Industria Chimica e Farmaceutica S.p.A. and the Campoverde site, which we have selected on the basis of their business, contribution to the key performance indicators at consolidated level and location, to meet their management and obtain documentary evidence supporting the correct application of the procedures and methods used to calculate the indicators.

### **Conclusion**

Based on the procedures performed, nothing has come to our attention that causes us to believe that the 2018 consolidated non-financial statement of the Recordati Group has not been prepared, in all material respects, in accordance with the requirements of articles 3 and 4 of the decree and the GRI Standards.

Milan, 20 March 2019

KPMG S.p.A.

(signed on the original)

Claudio Mariani  
 Director of Audit

# CORPORATE GOVERNANCE REPORT AND OWNERSHIP STRUCTURE

## FINANCIAL YEAR 2018

pursuant to article 123 bis of the Consolidated Finance Act no 58 of 24 February 1998

Approved on 28 February 2019 by the Board of Directors

Website: [www.recordati.it](http://www.recordati.it)

## GLOSSARY

**CG Code:** the Corporate Governance Code for listed companies approved in July 2018 by the Corporate Governance Committee and promoted by Borsa Italiana S.p.A., the Italian Banking Association, Ania (national insurance association), Assogestioni (national association of asset management companies), Assonime (association of joint stock companies) and Confindustria (Confederation of Italian Industry).

**CC:** the Italian Civil Code.

**Board:** the Board of Directors of the Recordati S.p.A.

**Issuer:** Recordati S.p.A.

**Year:** the financial year to which this Report relates (2018).

**Consob Issuers' Regulations:** regulations governing issuers as established by Consob regulation no. 11971 of 1999 (as subsequently amended).

**Consob Markets Regulations:** regulations governing markets as established by Consob regulation no. 16191 of 2007 (as subsequently amended).

**Consob related-party regulations:** the regulations issued by the Consob with Resolution No. 17221 of 12th March 2010 (as subsequently amended) concerning transactions with related parties.

**Report:** the corporate governance report and the ownership structure that issuers are required to prepare pursuant to article 123 bis of the TUF.

**Company:** Recordati S.p.A.

**TUF:** Legislative Decree No. 58 dated 24th February 1998, (Testo Unico della Finanza) the TUF.

## INTRODUCTION

In 2018, an important change occurred in the majority shareholding of Recordati S.p.A. ("Recordati" or "Company").

On 29 June 2018, the members of the Recordati family, as shareholders of Fimei S.p.A. - majority shareholder of the Company - announced that they had reached an agreement for the transfer to a consortium of investment funds controlled by CVC Capital Partners VII of the entire capital of Fimei S.p.A. which, on that date, held 51.79% of the Company's capital.

On 6 December 2018, in the performance of the aforementioned agreement, the shareholders of Fimei S.p.A. completed the transfer of their entire shareholding in Fimei S.p.A. to Rossini Investimenti S.p.A. (a company designated for this purpose under the aforementioned agreement).

As a result of this transfer, CVC Capital Partners VII Limited became the controlling shareholder of the Company pursuant to article 2359, paragraph 1, number 2, of the Civil Code and article 93 of the TUF, as evidenced by the notification received pursuant to article 120 of Legislative Decree no. 58/1998.

Also on 6 December 2018, following the transfer of the aforementioned shares, the legal requirements were met for the promotion by Rossini Investimenti S.p.A. of a mandatory takeover bid, pursuant to and for the purposes of articles 102 and 106, paragraph 1-bis, of the TUF concerning a maximum of 97,735,180 ordinary shares of the Company, representing 46.735% of the share capital of Recordati S.p.A. and excluding the 5,172,571 of the Issuer's treasury shares, equal to 2.473%, and including a maximum of 2,091,500 ordinary shares of Recordati S.p.A. in the event that all stock options deriving from the existing Stock Option Plans are exercised (the "Mandatory Takeover Bid").

On 21 December 2018, the Mandatory Takeover Bid was authorised by Consob and on 2 January 2019 the subscription period began.

On 1 February 2019, the subscription period for the Mandatory Takeover Bid was completed: 59,816 ordinary shares of Recordati S.p.A. were subscribed, equal to 0.061% of the shares that were object of the Bid and, therefore, equal to approximately 0.029% of the Company's share capital. Therefore, on 8 February 2019, the date of payment of the transfer price owed to the holders of the subscribed shares and the contemporaneous transfer of these shares to the bidder, the shareholding held by Fimei (as the actual buyer designated in the Bid) in Recordati S.p.A. was equal to 51.820% of the share capital.

In consideration of the final results of the Mandatory Takeover Bid, the conditions for the exercise of the Commitment and the Right to Squeeze-out pursuant to article 108, paragraphs 1 and 2, and article 111 of the TUF were not met.

For more information on the Mandatory Takeover Bid, please refer to the notifications and documentation made available to the public pursuant to current legislation on the Company's website at:  
[http://www.recordati.it/en/investors/public\\_tender\\_offer/](http://www.recordati.it/en/investors/public_tender_offer/)

Following the events referred to above, on 5 February 2019, the Shareholders' Meeting appointed a new Board of Directors. For more information, please refer to section 4.2. ("Composition") of this Report.

### **Comment by Mr Andrea Recordati, Chief Executive Officer:**

*"In the course of 2018, an important transfer of the majority shareholding of Recordati occurred. An agreement was reached with a consortium of investment funds controlled by CVC Capital Partners, a recognised group of investors, for the indirect acquisition of 51.791% of the share capital of Recordati S.p.A. This change of ownership ensures continuity for the management and the employees and the development of the company in the future, following the strategic guidelines that have been the basis of our Group's success for many years. Furthermore, our new shareholders will contribute their expertise and their international network in the pharmaceutical market to the expansion of our activities, supporting an acceleration of our growth strategy."*

## **1. PROFILE OF THE ISSUER AND GENERAL INFORMATION**

Recordati S.p.A. (Reuters RECI.MI, Bloomberg REC IM) was founded in 1926 and is a joint stock company listed on the Mercato Telematico Azionario (electronic stock exchange) operated by Italian Borsa Spa (ISIN IT 0003828271).

The Company and the Group that it leads has approximately 4,100 employees. They perform research and development, production, marketing and sales of pharmaceuticals – both original and licensed, belonging to different therapeutic areas including a specialised activity in rare diseases – supplements and medical devices, as well as pharmaceutical chemical products. They perform their activities in the principal European countries, including Russia, Turkey, North Africa, the United States of America, Canada, Mexico, some countries in South America, Japan and Australia.

As at 31 December 2018, the Group was composed of 46 subsidiaries (of which 4 are Italian), in addition to the Parent Company, Recordati S.p.A.

The primary objective of Recordati's corporate governance system is the creation of value for shareholders, without, however, losing sight of the social importance of the activity performed and of all the stakeholders involved. Recordati's values are identified in the Code of Ethics, updated, most recently, by the Board of Directors on 5 May 2017 (which may be consulted on the Recordati website<sup>1</sup>).

The corporate governance structure of the Company is based on a conventional organisational model and therefore consists of the following corporate bodies: (i) the Shareholders' Meeting, (ii) the Board of Directors, (iii) the Board of Statutory Auditors. Accounting control is delegated, in compliance with the relative legislation in force, to a firm of auditors registered in the special roll maintained by the Consob. A "231" (administrative liability) Supervisory Committee has also been appointed which oversees the proper functioning of the "231 Model" and is responsible for updating it.

The Board of Directors has formed two committees from among its members with consultative and proposal-making functions: the Remuneration Committee and the Control, Risk and CSR Committee, both consisting exclusively of independent directors.

Recordati adheres to and complies with the Corporate Governance Code for listed companies as published in July 2018<sup>2</sup> with the additions and necessary amendments resulting from the characteristics of the Group as mentioned in this Report.

The information contained in this document, unless otherwise indicated, refers to the financial year ended 31 December 2018 and, in relation to specific issues, updated at the date of its approval by the Board of Directors (28 February 2018).

In some cases the Report makes reference to documents and information which may be consulted on the corporate website (<http://www.recordati.it>).

## **2. OWNERSHIP STRUCTURE**

### **(PURSUANT TO ART. 123-BIS, PARAGRAPH 1 OF THE TUF)**

#### **a) Structure of the share capital and rights attaching to shares (pursuant to Art. 123 bis, paragraph 1, letter a) of the Consolidated Finance Act)**

The subscribed and paid up share capital amounts to € 26,140,644.5 and is represented by 209,125,156 ordinary shares each with a par value of € 0.125 as reported in the table at the end of this section. The shares are listed on the Mercato Telematico Azionario (electronic stock exchange) operated by Borsa Italiana and issued under a dematerialisation regime.

The rights attaching to the shares are set out in the By-Laws. More specifically, each share entitles the holder to a proportional part of the profits allocated for distribution; Art. 28 of the By-Laws provides that the net profits on the balance sheet are to be distributed as follows: (a) 5% (five percent) to the legal reserve fund up to the amount established by the law; (b) the remainder, unless the Shareholders' Meeting, as proposed by the Board, resolves to allocate funds for extraordinary reserves or for other purposes, or to postpone part or all of the distribution to all shares to successive years, to be distributed to all shares. The Board of Directors may resolve to distribute interim dividends, within the limits and according to the procedures established by law. Dividends not collected within five years following the day on which they became payable shall revert to the Company and are recognised in the extraordinary reserve.

As reported in the table below, there are no other categories of shares, nor other financial instruments that assign the right to subscribe to new share issues, with the exception of the conditions indicated below in the context of stock option plans.

As concerns outstanding stock option plans and any share capital increases there may be at the service of those plans, reference is made to the information documents prepared in accordance with Art. 84-bis of the Consob Issuers' Regulations relating to each outstanding stock option plan, available on the Company website at the address: [http://www.recordati.it/en/corporate\\_governance/remuneration/stock\\_option\\_plans/](http://www.recordati.it/en/corporate_governance/remuneration/stock_option_plans/).

The Remuneration Report pursuant to 84-quater of the Issuers' Regulations may also be consulted, available on the Company website ([http://www.recordati.it/en/corporate\\_governance/remuneration/remuneration\\_reports/](http://www.recordati.it/en/corporate_governance/remuneration/remuneration_reports/)).

<sup>1</sup> [http://www.recordati.it/en/corporate\\_governance/compliance\\_programmes\\_/recordati-code-of-ethics-amended-on-4th-may-2017.pdf](http://www.recordati.it/en/corporate_governance/compliance_programmes_/recordati-code-of-ethics-amended-on-4th-may-2017.pdf)

<sup>2</sup> This may be consulted on the website of Borsa Italiana: <http://www.borsaitaliana.it>.

## STRUCTURE OF THE SHARE CAPITAL

	Number of shares	% of share capital	Listed/unlisted
Ordinary shares	209,125,156	100	Listed on the Mercato Telematico Azionario (electronic stock exchange) managed by Borsa Italiana
Shares with multiple voting rights	0	0	
Shares with limited voting rights	0	0	
Shares with no voting rights	0	0	

No other financial instruments exist which give the right to subscribe newly issued shares.

### b) Restrictions on transfer of securities (pursuant to Art. 123-bis, paragraph 1, letter b) of the TUF)

The By-Laws of the Company establish that the shares of the Company are freely transferable.

### c) Significant investments in the share capital (pursuant to Art. 123-bis, paragraph 1, letter c) of the TUF)

On the basis of notifications received, in accordance with article 120 of Legislative Decree No. 58/1998 and other information received, as at 27 February 2019, the following parties held shares, either directly or indirectly, amounting to more than 3% of the share capital ("significant holdings").

## SIGNIFICANT SHAREHOLDINGS

Declarer	Direct shareholder	Percentage (%) of ordinary share capital	Percentage (%) of voting share capital*
CVC CAPITAL PARTNERS	FIMEI S.p.A.	51.82%	51.82%
	Fidelity Management & Research (Japan) Limited FMR Co Inc FIAM LLC FMR Investment Management (UK) Limited Fidelity Institutional Asset Management Trust Company	4.34%	4.34%

\* As is known treasury stock consists of shares on which voting rights are only temporarily suspended in accordance with the law.

As at 27 February 2019, Recordati S.p.A. also held 5,055,071 treasury shares equal to 2.42% of the capital on which voting rights are suspended in accordance with the law.

Significant shareholdings may be consulted on the Consob website ([www.consob.it](http://www.consob.it)).

### d) Securities with special rights (pursuant to Art. 123-bis, paragraph 1, letter d) of the TUF)

No securities with special rights of control have been issued.

### e) Shareholding by employees: exercise of voting rights (pursuant to Art. 123-bis, paragraph 1, letter e) of the TUF)

No shareholding system exists for employees which involves the exercise of voting rights which is different from that provided for shareholders in general.

### f) Restrictions on voting rights (pursuant to Art. 123-bis, paragraph 1, letter f) of the TUF)

Each ordinary share gives the right to vote without any restrictions.

### g) Shareholders' Agreements (pursuant to Art. 123-bis, paragraph 1, letter g) of the TUF)

On 29 June 2018, the members of the Recordati family, as shareholders of Fimei S.p.A. - majority shareholder of the Company - announced that they had reached an agreement for the transfer to a consortium of investment funds controlled by CVC Capital Partners VII of the entire capital of Fimei S.p.A. which, on that date, held 51.79% of the Company's capital (the "Contract").

On July 4, 2018, this Contract was published pursuant to art. 122 of the TUF, as it contains inter alia certain agreements (the "Agreements") functional to the execution of the transaction governed by the Contract itself, which can be considered as agreements of a shareholder nature and have therefore been prudently subject to the related publication formalities.

On 6 December 2018, in the performance of the aforementioned Contract, the shareholders of Fimei S.p.A. transferred their entire shareholding in Fimei S.p.A. to Rossini Investimenti S.p.A. (a company designated for this purpose under the aforementioned agreement).

Following the completion of this transfer, all the Agreements of the Contract ceased to apply.

On 29 June 2018, Rossini Holdings S.à.r.l. ("Rossini Holdings"), executed two investment agreements with Andrea Recordati and an investment agreement with Fritz Squindo (collectively, the "Investment Agreements"). The aforementioned agreements govern the investment conditions of Andrea Recordati and Fritz Squindo respectively in Rossini Luxembourg S.à.r.l., a subsidiary of Rossini Holdings, subject to the acquisition by Rossini Luxembourg of the entire share capital of FIMEI S.p.A., a company that holds ordinary shares representing 51.791% of the subscribed share capital of Recordati. The Investment Agreements contain, inter alia, certain agreements (the "Agreements"), functional to the execution of the transaction governed by the Investment Agreements themselves, which are likely to take on a significant shareholder nature for the purpose of fulfilling the related publication formalities.

On 4 July 2018, these Agreements were disclosed pursuant to art. 122 of the TUF.

On 6 December 2018, two agreements were executed amending the aforementioned Investment Agreements, both of which were notified pursuant to art. 122 of the TUF on 11 December 2018.

On 6 December 2018, Rossini Holdings S.à.r.l. société à responsabilité limitée established under Luxembourg law, with registered office at 20 avenue Monterey, L-2163 Luxembourg, Grand Duchy of Luxembourg, R.C.S. Luxembourg: B 224480 ("CVC Luxco"), Rossini Luxembourg S.à.r.l. société à responsabilité limitée established under Luxembourg law, with registered office at 20 avenue Monterey, L-2163 Luxembourg, Grand Duchy of Luxembourg, R.C.S. Luxembourg: B 224498 ("Lux Equityco") and Rossini Co-Invest GP Limited ("General Partner"), in its capacity as general partner of Rossini Co-Invest L.P. (the "Partnership") both having their registered office at 1 Waverley Place, Union Street, St Helier, Jersey, and Channel Islands JE1 1SG, executed with PSP Investments Holding Europe Limited with its registered office in London, 10 Bressenden Place SW1E 5DH, United Kingdom, ("PSP") some significant shareholders' agreements pursuant to art. 122 of the TUF (the "PSP Shareholders' Agreement").

This PSP Shareholders' Agreement was published pursuant to art. 122 of the TUF on 11 December 2018.



On 6 December 2018, Rossini Holdings S.à r.l. société à responsabilité limitée established under Luxembourg law, with registered office at 20 avenue Monterey, L-2163 Luxembourg, Grand Duchy of Luxembourg, R.C.S. Luxembourg: B 224480 ("CVC Luxco"), Rossini Luxembourg S.à r.l. société à responsabilité limitée established under Luxembourg law, with registered office at 20 avenue Monterey, L-2163 Luxembourg, Grand Duchy of Luxembourg, R.C.S. Luxembourg: B 224498 ("Lux Equityco") and Rossini Co-Invest GP Limited ("General Partner") in its capacity as general partner of Rossini Co-Invest L.P. (the "Partnership") both having their registered office at 1 Waverley Place, Union Street, St Helier, Jersey, Channel Islands JE1 1SG, executed with Finance Street SSMA C.V., AlInvest LIVE Co C.V., ACIF VII C.V., ACIF (Euro) VII C.V., AG Co-Investment C.V., AJ Co C.V., AlInvest GA Co 2018 C.V. and APSS Co-Investment C.V. (collectively, "AlInvest") some significant shareholders' agreements pursuant to art. 122 of the TUF (the "AlInvest Shareholders' Agreement"). This AlInvest Shareholders' Agreement was published pursuant to art. 122 of the TUF on 11 December 2018.

On 19 February 2019, with reference to the investment agreements executed between Andrea Recordati, on one hand, and Rossini Luxembourg S.à r.l. and Rossini Holdings S.à r.l., on the other hand, on June 29<sup>th</sup> 2018 (as amended on December 6<sup>th</sup> 2018) (hereinafter referred to as the "AR Agreements"), which include some significant shareholders' agreements pursuant to art. 122 of the TUF, paragraph 1 and 5 and were already disclosed to public on 1st July and 11st December 2018, the following amendment was disclosed: on February 14th 2019, (i) Mr. Andrea Recordati subscribed for No. 6,350,000 ordinary shares and No. 1,150,000 preference shares (the ordinary and preference shares, the "Shares") of Rossini Luxembourg; (ii) Mr. Andrea Recordati transferred these Shares to his controlled company Indio s.s., with registered office in Milan, via Paolo Andreani 4, fiscal code 97832790154 ("Indio"); (iii) through the signing of certain adhesion agreements with Andrea Recordati, Rossini Luxembourg and Rossini Holdings S.à r.l. (the "Indio Adhesion Agreements"), Indio has adhered to the AR Agreements, taking upon itself the rights and obligations arising from the AR Investment Agreements held by Andrea Recordati, who in any case remained a party to those agreements; and (iv) the Shares are held by Cordusio Società Fiduciaria per Azioni, a company subject to the management and coordination of Unicredit S.p.A., with registered office in Milan, via Borromei n.5, registered at No. 863916 with the Companies Register of Milan ("Cordusio"), in its capacity as fiduciary company (*società fiduciaria*) appointed by Indio, which has given Cordusio irrevocable instructions, as they are also conferred in the interest of Rossini Luxembourg and Rossini Holdings, to comply with the provisions of the AR Agreements and the By-laws of Rossini Luxembourg.

Through the Indio Adhesion Agreements, Indio has undertaken the rights and obligations which Andrea Recordati was entitled to on the basis of the AR Agreements, Mr Andrea Recordati remaining although part to such agreements.

Furthermore, pursuant to the Indio Adhesion Agreements, Indio has undertaken towards Rossini Holdings and Rossini Luxembourg to transfer the ordinary and privileged shares of Rossini Luxembourg held by the latter to Mr Andrea Recordati or to a related party to him, in case Indio ceases to be qualified as related party to Mr Andrea Recordati.

No amendments occurred in relation to the same agreements executed on 29<sup>th</sup> June 2018 between Fritz Squindo, on one hand, and Rossini Luxembourg S.à r.l. and Rossini Holdings S.à r.l., on the other hand, as subsequently amended on December 6<sup>th</sup>, 2018 likewise the AR Agreements the "FS Agreements"), which were disclosed to the market on 4<sup>th</sup> July and 11<sup>st</sup> December 2018. On 14<sup>th</sup> February 2019, the Rossini Luxembourg shares subject to the FS Agreement have been subscribed by Cordusio on behalf of Mr Fritz Squindo, who granted Cordusio irrevocable instructions, as they were also granted in the interest of Rossini Luxembourg and Rossini Holdings, to comply with the provisions of the FS Agreement and the By-laws of Rossini Luxembourg.

For the sake of completeness, it should be noted that the extract of the aforementioned shareholders' agreements published pursuant to the law and the essential information on the relevant agreements mentioned above, as also possibly amended, in line with the applicable legislation, are available on the Company's website: [http://www.recordati.it/en/corporate\\_governance/shareholders\\_agreements](http://www.recordati.it/en/corporate_governance/shareholders_agreements).

#### **h) Change of control clauses (pursuant to Art. 123 bis, paragraph 1, letter h) of the TUF and Article of Association provisions concerning public tender offers to purchase (pursuant to Art. 104, paragraph 1-ter and 104-bis, paragraph 1)**

The Company and some of its subsidiaries are, in relation to their business operations, parties to some licensing agreements that include a clause, which is a normal provision in international agreements, authorising the Licensor to dissolve the contracts in the event of change of direct or indirect control of the Licensee.

In addition, bonds issued by the Company (in 2014 and 2017) - for totals of US\$75 million and €125 million - both privately placed with international institutional investors and most of the major loan agreements executed by the Company - for a total of €511 million - set out, as is normal in financial operations of this type, a clause, which authorises the creditors to obtain immediate repayment if the control of the Company changes.

The By-Laws of the company do not allow exceptions to the provisions concerning takeovers on the passivity rule pursuant to Art. 104, paragraphs 1 ter of the Consolidated Finance Act nor do they allow the application of neutralisation rules pursuant to Art. 104-bis, paragraphs 1 of the Consolidated Finance Act.

#### **i) Authorisation for increase of share capital and acquisition of treasury shares**

##### **(pursuant to Art. 123-bis, paragraph 1, letter m) of the TUF)**

The Board of Directors was authorised to increase share capital, pursuant to CC Art. 2443, by a Shareholders' Meeting of 11 April 2017.

The increase in the share capital may be performed in one or more tranches, free of charge or by payment, for a total maximum nominal amount of € 50,000,000 within a period of no more than five years from the date of the resolution, by issuing ordinary shares and/or warrants for the subscription to such shares, to assign or to offer as an option to shareholders, with the right pursuant to the joint provisions of CC Art. 2441, last paragraph and TUF Art. 134, second paragraph, to offer subscription to the shares to Recordati S.p.A. employees or to subsidiaries of the Company in relation to the stock option plans decided by the Shareholders' Meeting (and therefore with the possibility to exclude the option rights to one fourth of the new issue).

The Board of Directors may also decide that the issue should be performed with a share premium, setting the amount and also specifying that if the issue decided is not fully subscribed within the time limits set from time to time, the share capital shall be increased by an amount equal to the subscriptions received by the time limit set.

To-date, the Board has not yet acted on this mandate, not even partially.

That same Shareholders' Meeting authorised Directors, in accordance with Art. 2420-ter of the C.C. to decide the issue in one or more tranches, for a total maximum nominal amount of € 80,000,000, of bonds convertible to ordinary shares, or valid warrants to subscribe to such shares, to offer in option to shareholders within a period of no more than five years from the date of resolution, in observance of applicable law and regulations concerning the issuing of bonds, and at the same time, deciding an increase of share capital for the amount that corresponds to the nominal value of the shares to be attributed in conversion.

To date, the Board has not yet acted on this mandate not even partially.

The By-Laws do not authorise the Board to issue financial instruments of participation.

In ordinary session, by means of a resolution of 18 April 2018 a Shareholders' Meeting renewed the authorisation to purchase and assign treasury shares, pursuant to CC articles 2357 et seq., until approval of the financial statements at 31 December 2018, scheduled for 11 April 2019. In particular, the maximum number of shares that may be acquired, after accounting for the number of treasury shares already held in the Company's portfolio, is 15,000,000, which corresponds to a total potential payment of not more than € 300,000,000, at a minimum price not less than the nominal value of Recordati shares (€ 0,125) and a maximum price not greater than the average of official Borsa prices during the five sessions prior to the acquisition, plus 5%. Purchases must be made on regulated markets, in observance of Art. 144bis, paragraph one, letter b), of the Consob Issuers' Regulations and according to standard practices recommended by the Consob in accordance with article 180 of the TUF.

At Year end, the Company held 5,153,571 treasury shares in portfolio, which represented 2.4643% of the share capital.

As at the present date, the Board has not made use of this authorisation and has not initiated any plans to purchase its treasury shares.

In consideration of the expiry of the current authorisation which will occur when the Shareholders' Meeting is held to approve the financial statements as at 31 December 2018, the Board resolved to submit a proposal to the Shareholders' Meeting convened to approve the 2018 financial statements to renew the authorisation to purchase and assign treasury stock in order to maintain the necessary operational flexibility over an appropriate time horizon. The Directors Report on the relative item on the agenda, which will be made available within the legal time limits on the Company website and elsewhere, may be consulted for further information.

### **j) Management and co-ordination**

#### **(pursuant to Art. 2497 et seq of the CC)**

On 28 February 2019, the Company's Board of Directors, newly appointed by the Shareholders' Meeting of 5 February 2019, established the management and coordination activities carried out by Rossini Luxembourg S.à.r.l. in relation to Recordati S.p.A. pursuant to articles 2497 and following of the CC. On the same date, the Board of Directors verified that the Company meets the requirements set out in Article 16, paragraph 1, letter b), c) and d) of the Market Regulations approved by Consob with resolution 20249/2017. With reference to the disclosure requirements set forth in art. 2497-bis of the Italian Civil Code, as per art. 16, paragraph 1, letter a) of the same Regulation, the appropriate actions will be timely taken within the terms of the law.

Previously, although controlled by Fimei S.p.A., the Company did not consider itself to be subject to management and co-ordination by the same, pursuant to CC articles 2497 et seq.

This is because Fimei S.p.A. turned out to be a mere financial holding company with no operations of any kind; no procedures existed to furnish authorisations or instructions to the Company in its relations with the Parent Company and therefore the Company set its own strategic and operating policies in full autonomy.

The fully controlled Italian subsidiaries have acknowledged management and co-ordination by the Company and have fulfilled legal disclosure requirements in this respect.

### **k) Other information**

The information required by Art. 123 bis, paragraph one, letter i) of the TUF ("agreements between the Company and directors, members of the board of directors or the supervisory board, which provide for the payment of indemnities in the event of resignation, dismissal without just cause or if the contract of employment is interrupted following a public tender offer") is given in the Report on Remuneration published in accordance with Art. 123-ter of the TUF.

The information required by Art. 123 bis, paragraph one, letter l) of the TUF ("regulations for the appointment and replacement of directors and for amendments to the By-Laws, if different from those applicable by law in the absence of alternative provision") are given in the section of the report on the Board of Directors (section 4.1).

## **3. COMPLIANCE (PURSUANT TO ART. 123-BIS, PARAGRAPH 2, LETTER A) OF THE TUF)**

As illustrated in section 1, in accordance with the procedures contained in this report, the Company adheres to the CG Code, which may be consulted on the website of Borsa Italiana at the address <https://www.borsaitaliana.it/comitato-corporate-governance/codice/2018clean.pdf>. Reasons are given where it was decided not to follow those principles or operating criteria either in the corresponding section of this report or in the corresponding section of the Report on Remuneration.

Furthermore, as already reported, on 20 June 2016 Recordati was admitted to the FTSE MIB share index. In this respect, even if for the purposes of the application of the CG Code on which Recordati is required to give account in this report, the Company does not consider that it is included in the FTSE MIB share index (see note 1 at the foot of page 4), this report nevertheless also give details of that which is already in place – and of that which may need to be assessed – with reference to the specific recommendations formulated for companies belonging to that index.

The Company is not subject to foreign laws that influence the corporate governance structure of the Company itself.

The main characteristics of the risk and internal control management systems in relation to financial reporting, including consolidated reporting, requested by Art. 123-bis paragraph 2, letter b) of the TUF are illustrated in the report on internal control and risk management (Sect. 11a).

The procedures for the functioning of shareholders' meetings, its principal powers, the shareholder rights and the procedures for exercising them, required by Art. 123-bis, paragraph 2, letter C) of the TUF, are illustrated in the section of the Report on Shareholders' Meeting (Sect. 11a).

The information concerning the criteria and policies concerning diversity applied in relation to the composition and functioning of management and supervision bodies and their committees, required by Art. 123-bis paragraph 2, letter d) of the TUF, are illustrated in the section of the Report on the Board of Directors (Sect. 4) and, in more detail for the Committees, in the section of the Report on internal Board Committees (Sect. 6).

## 4. BOARD OF DIRECTORS

### 4.1 APPOINTMENT AND SUBSTITUTION OF DIRECTORS (PURSUANT TO ART. 123-BIS, PARAGRAPH 1, LETTER L) OF THE TUF)

The appointment and replacement of Directors is regulated by articles 15, 16 and 18 of the By-Laws, the text of which, for the sake of completeness, is reproduced in full below:

*Art. 15) The Board of Directors shall be appointed from slates of candidates presented by shareholders, in compliance with the existing legislation in force on gender balance, according to the procedures as indicated below, in which the candidates are identified by progressive numbers.*

*The slates, signed by the shareholders who present them, must be deposited at the registered office of the Company at least twenty-five days prior to the date of the first convention of the Shareholders' Meeting, available to anyone who requests to see them, and they will also be subject to other forms of publicity in accordance with laws and regulations in force at the time.*

*Every shareholder, shareholders who participate in a significant shareholders' agreement pursuant to TUF Art. 122, the parent company, subsidiaries and companies subject to joint control pursuant to TUF Art. 93, may not present or contribute to the presentation of more than one slate, not even by means of another person or trustee, nor may they vote for different slates, and each candidate may be listed in only one slate or will be disqualified. The subscriptions and votes expressed in violation of this prohibition will not be attributed to any slate.*

*Only shareholders individually or jointly possessing a total number of shares with voting rights representing at least 2.5% of capital stock with voting rights at ordinary meetings, or representing a lesser percentage as established by binding legislative or regulatory provisions which shall be specified in the notice of meeting, shall have the right to submit slates.*

*The following items must be filed for each slate within the respective deadlines set out above and as provided by applicable regulations: (i) statements by each candidate to the effect that each accepts candidacy and declares, assuming full responsibility, that there are no reasons preventing the candidate from being elected or rendering him unsuitable for the office, and that the candidate meets any specific requirements for the relevant office; (ii) a curriculum vitae detailing each candidate's personal and professional characteristics and indicating that the candidate may be considered independent.*

*The specific certification demonstrating title to the necessary number of shares for the presentation of the slate, issued by a legally authorised intermediary must also be deposited within the time limits set by the relative regulations at the time when the slates are deposited at the Company.*

*Slates containing a number of candidates equal to or greater than three must be composed of candidates belonging to both genders, so that a percentage equal to that required by the legislation in force at the time concerning gender balance for the composition of the Board of Directors belongs to the less represented gender.*

*Slates that are presented but are not in accordance with the provisions as above will be considered as not presented.*

*The Board of Directors will be elected as follows:*

*a) all of the Directors to be appointed, except one, will be selected from the slate that obtained the greatest number of votes, following the progressive order in which they are listed on the slate;*

*b) the remaining director shall be the candidate placed at the number one position on the minority slate, which shall not be connected in any way, even indirectly, with those who submitted or voted for the slate indicated in letter a) above, which obtains the second highest number of votes. For this purpose, slates that did not obtain a percentage of votes equal to at least half of that required for presentation of the slates as at the fourth paragraph of this article will not be considered.*

*For the purposes of the appointment of directors as indicated at point b) above, in the event of a tie between slates, the slate presented by shareholders possessing the larger shareholding, or subordinately the larger number of shareholders, shall prevail.*

*If the candidates elected by the method as above do not include an adequate number of independent Directors with the characteristics as established for statutory auditors at TUF Art. 148, third paragraph, equal to the minimum number established by the law in relation to the total number of Directors, the last non-independent candidate, according to the progressive numbering, of the slate that obtained the greatest number of votes as at letter a) of the paragraph above, will be substituted by the first independent candidate, according to the progressive numbering, of the non-elected candidates on the same slate, or if not possible, by the first independent candidate, according to the progressive numbering, of the non-elected candidates of the other slates, according to the number of votes obtained by each. This procedure of substitution will be followed until the board of directors is composed of a number of members who have the qualifications as at TUF Art. 148, third paragraph, equal at least to the minimum legal number. If this procedure does not produce the latter result, the substitution will be effected by resolution of the Shareholders' Meeting by relative majority, after presentation of candidates who possess the qualifications as cited above.*

*Furthermore, if with the candidates elected according to the above procedures the composition of the Board of Directors in compliance with the legislation in force at the time concerning gender balance is not ensured, the candidate of the gender most represented elected as last in order on the slate which obtained with the largest number of votes shall be replaced by the first candidate of the less represented gender not elected in order on the same slate. That replacement procedure shall be followed until the composition of the Board of Directors in compliance with the legislation in force at the time concerning gender balance is ensured. Finally, if this procedure does not produce the result just indicated, then the replacement shall be made by a resolution of the Shareholders' Meeting by relative majority, after presentation of candidates belonging to the less represented gender.*

*If only one slate is presented, all of the Directors will be selected from the same slate. If no slate is presented the Shareholders' Meeting will decide by legal majority, without following the procedure as above. All of the foregoing is subject to compliance with the legislation in force at the time concerning gender balance.*

*Any different or additional compulsory provisions of the law or regulations will form an exception to these provisions.*

*Article 16) - The fees to be paid to the Board of Directors shall be established by the Shareholders' Meeting for the entire period of their term, or for each financial year, and may take the form of profit-sharing.*

*Article 18) - Unless already provided for by the Shareholders' Meeting, the Board shall appoint a Chairman and may appoint a Vice-Chairman from among its members. The Board shall also appoint one or more Managing Directors from among its members. The Chairman shall have all the powers vested in him by law; in the case of his absence or inability to attend for any reason, the said powers shall be exercised by the Vice-Chairman, or in his absence, by the most senior Director.*

*Finally, the Board shall appoint a Secretary, who need not be a member of the Board.*

It is also underlined that, on the basis of the By-Laws in force, the right to submit slates is only held by shareholders who, individually or together with other shareholders submitting slates, hold voting shares representing at least 2.5% of the voting capital in an Ordinary Meeting, or representing a lower percentage established by mandatory laws or regulations. In this respect, in accordance with articles 144-quater and 144-septies of the Issuers'

Regulations adopted by Consob Resolution No. 19856 of 25 January 2017, as well as CONSOB resolution no. 13 of 24 January 2019, the percentage of the share capital required to present slates of candidates to the Board of Directors of the Company is currently 1%.

On the basis of Art. 147-ter, paragraph one of the TUF, the By-Laws also state that for the purposes of the distribution of votes among directors to be elected, no account is taken of slates that have not obtained a percentage of votes equal to at least half of that required for the presentation of slates.

In order to ensure the election of at least one minority director, the By-Laws state that all the directors to be elected except for one shall be drawn from the slate which obtained the greatest number of votes in the order in which they are slated on that slate. The remaining director is the candidate placed in the number one position on the minority slate, which shall not be connected in any way, even indirectly, with the shareholders who submitted or voted for the majority slate and which obtained the majority of votes from the shareholders. In the case of a tied vote between slates, the minority director shall be drawn from the slate presented by the shareholders in possession of the greater number of shares or, secondarily, with the greatest number of shareholders.

As concerns the mechanism adopted to ensure that a minimum number of independent directors are elected in compliance with Art. 147-ter, paragraph four of the TUF, the By-Laws state that if the number of independent directors is not reached, the non-independent candidate elected in last place on the majority slate shall be replaced by the first independent candidate in progressive order not elected on that slate, or, if there is none, by the first independent candidate in progressive order not elected on the other slates, according to the number of votes obtained by each.

Finally, if this procedure does not lead to the aforementioned result, the directors shall be replaced by a resolution passed by relative majority of the Shareholders' Meeting upon presentation of candidates satisfying the above requirements of independence.

If only one slate is presented, the By-Laws also state that all of the Directors to be elected shall be selected from that slate. If no slate is presented the Shareholders' Meeting shall decide by legal majority, without following the procedures just described.

The By-Laws do not lay down any additional requirements for the independence of Directors with respect to those contained in Art. 148, paragraph 3, of Legislative Decree No. 58/1998, because the Company adheres to the CG Code and the Board of Directors verifies possession of the requirements of independence in accordance with the CG Code and consequently when a Shareholders' Meeting appoints Directors, the Board of Directors invites candidates to the position of Director contained on slates to declare also these requirements, as adopted by the Company.

In particular, the table at the end of this section may be consulted for details of those Directors currently in office who meet the requirements for independence in accordance with the TUF and those that are independent in accordance with the CC.

With regard to the regulations on gender balance in corporate bodies (Law No. 120/2011, new articles 147-ter and 148 of the Consolidated Finance Act, new Art. 144-undecies of the Issuers Regulations), which apply to the renewal of corporate bodies subsequent to 18 August 2012, the Company made the necessary amendments to the By-Laws on 8 May 2012 in order to comply with the new regulations.

In particular, the Board of Directors shall be appointed in compliance with the existing legislation in force on gender balance (and in any case on the basis of slates of candidates presented by shareholders).

We report that when the Board of Directors is renewed, which must be resolved by the Shareholders' Meeting convened to approve the 2016 Annual Report, since this is the second period of office subject to the application of Law No. 120/2011, a proportion equal to at least one third of the directors must be reserved to the least represented gender, with the figure rounded up to the next whole number.

Furthermore, the By-Laws set out the procedures to follow to ensure that the composition of the Board of Directors complies with the existing legislation in force concerning gender balance: the candidate of the gender most represented elected as last in order on the slate which obtained with the largest number of votes shall be replaced by the first candidate of the less represented gender not elected in order on the same slate. That replacement procedure shall be followed until the composition of the Board of Directors in compliance with the legislation in force at the time concerning gender balance is ensured. Finally, if this procedure does not produce the result just indicated, then the replacement shall be made by a resolution of the Shareholders' Meeting by relative majority, after presentation of candidates belonging to the less represented gender.

The Company also acknowledged the recommendations concerning diversity, including as regards gender, in the composition of the corporate bodies introduced in the Corporate Governance Code in July 2018.

It should be noted that with the renewal of the Board of Directors resolved by the Shareholders' Meeting of 5 February 2019, the third mandate began within the meaning of Law 120/2011, which provides that for the third mandate of a board of directors, at least one third of Directors be of the less-represented gender, rounded up in the case of a decimal.

The Issuer reports that it is not governed by any further laws and regulations concerning the composition of the Board of Directors.

#### **4.2 COMPOSITION (PURSUANT TO ART. 123- BIS , PARAGRAPH 2, LETTER D) OF THE TUF)**

The By-Laws currently in force state that the Company is managed by a Board of Directors consisting of a number of members varying between six and sixteen.

#### **Composition from 1 January 2018 to 6 December 2018/5 February 2019**

The Shareholders' Meeting of 11 April 2017 had appointed a Board composed of nine directors, of which six are independent, for three years, expiring with the shareholders' meeting called to approve the financial statements for the year ended on 31 December 2019; among these directors, three were female, in accordance with the criteria indicated by the applicable provisions on gender balance (at least 1/3 of the members must be represented by the less-represented gender) and a minimum number of independent directors (at least one third of the Board in the issuers belonging to the FTSE-Mib index<sup>3</sup>). On the occasion of the aforementioned appointment, a single slate of candidates for the office of Director was presented by the majority Shareholder FIMEI S.p.A.<sup>4</sup> The Board of Directors was elected with a favourable vote of 75.3% of the share capital.

Subsequently, in the context of the completion of the corporate changes relating to the shareholding structure of Recordati S.p.A. occurring on

<sup>3</sup> The Corporate Governance Code recommends (application criterion 3.C.3) that at least one third the board of directors of issuers belonging to the FTSE-Mib be made up of independent directors. In the case that is not a whole number, the result is rounded down.

<sup>4</sup> The slate presented by FIMEI S.p.A., together with the additional related documentation filed pursuant to the law and the applicable regulations available on the [www.recordati.it](http://www.recordati.it) (section: Investors / Shareholders' Meetings / 2017). The slate submitted the candidature of the following: Mr Alberto Recordati, Mr Andrea Recordati, Mr Fritz Squindo, Ms Rosalba Casiraghi, Ms Michaela Castelli, Ms Elisa Corghi, Mr Marco Vitale, Mr Mario Garraffo, Mr Paolo Fresia.

6 December 2018, which has already been disclosed in section 2 dedicated to Ownership Structure, the Chairman of the Board of Directors, executive director, Alberto Recordati, the non-independent and non-executive director Marco Vitale and the independent director Paolo Fresia have resigned from all positions held respectively in Recordati S.p.A.

The Board of Directors, at its meeting of 6 December 2018, following the completion of the aforementioned corporate changes:

- acknowledged the resignation of the aforementioned directors and consequently resolved, pursuant to art. 2386 of the CC and art. 17 of the By-Laws, the appointment by co-optation of Mr Giampiero Mazza, of Ms Cathrin Petty and Mr Søren Vestergaard-Poulsen, who remained in office until the next shareholders' meeting;
- appointed Giampiero Mazza as Chairman of the Board of Directors;
- in order to allow for full replacement with voting rights of the management body slate of Recordati pursuant to article 15 of the By-Laws, also

acknowledged the resignation of 6 December 2018 from the other Directors in office on the same date (appointed by the Shareholders' Meeting of 11 April 2017 at the proposal of the majority shareholder FIMEI S.p.A.) – namely, Andrea Recordati (Vice Chairman & CEO), Fritz Squindo (non-independent and executive director) and Rosalba Casiraghi, Michaela Castelli, Elisa Corghi and Mario Garraffo (these last four all being independent and non-executive directors) with effect from the next Shareholders' Meeting, following the completion of the corporate changes relating to the indirect shareholding structure of Recordati S.p.A. that occurred on 6 December 2018;

- consequently, resolved to convene the Ordinary Shareholders' Meeting for the replacement of the management body on 5 February 2019.

The composition of the Board of Directors from 1 January 2018 to 6 December 2018 and the qualifications of each Director during this period are summarised below:

Alberto Recordati	Chairman	Executive	-	*Board of Directors 19.03.1986
Andrea Recordati	Vice Chairman and CEO	Executive	-	*Shareholders' meeting of 29.04.1998
Rosalba Casiraghi	Director	Non-executive	Independent	*Shareholders' meeting of 17.04.2014
Micaela Castelli	Director	Non-executive	Independent	*Shareholders' meeting of 17.04.2014
Elisa Corghi	Director	Non-executive	Independent	*Shareholders' meeting of 17.04.2017
Paolo Fresia	Director	Non-executive	Independent	*Shareholders' meeting of 17.04.2014
Mario Garraffo	Director	Non-executive	Independent	*Shareholders' meeting of 29.04.1999
Fritz Squindo	Director	Executive	-	*BoD meeting of 14.03.2013
Marco Vitale	Director	Non-executive	Independent	*Shareholders' meeting of 13.04.1997

\*Date of first appointment to the Board of Directors

The composition of the Board of Directors from 6 December 2018 to 5 February 2019 and the qualifications of each Director during this period are summarised below:

Giampiero Mazza	Chairman	Executive	-
Andrea Recordati	Vice Chairman and CEO	Executive	-
Rosalba Casiraghi	Director	Non-executive	Independent
Micaela Castelli	Director	Non-executive	Independent
Elisa Corghi	Director	Non-executive	Independent
Mario Garraffo	Director	Non-executive	Independent
Cathrin Petty	Director	Executive	-
Søren Vestergaard-Poulsen	Director	Executive	-
Fritz Squindo	Director	Executive	-

### Current composition

The Board of Directors in office at the date of this report was appointed by a Shareholders' Meeting held on 5 February 2019 for three years, with the term of office expiring at the time of the Shareholders' meeting held to approve the financial statements for the year ended 31 December 2021.

The Shareholders' Meeting held on 5 February 2019 had appointed a board composed of eleven directors, of which four were women and three were independent, in compliance with the criteria laid down by the applicable legal and corporate governance provisions on the matters of gender balance (at least one fifth of the members must be of the least represented gender) and the minimum number of independent directors (at least two for a Board composed of more than seven members)<sup>5</sup>:

- 10 directors (Flemming Ørnkov, Andrea Recordati, Fritz Squindo, Giampiero Mazza, Francisco Javier de Jaime Guijarro, Søren Vestergaard-Poulsen, Cathrin Petty, Joanna Le Couilliar, Michaela Castelli, Alfredo Altavilla) taken from the majority slate presented by the shareholder FIMEI S.p.A., holder, as at that date, of 51.79% of the share capital;
- 1 director (Silvia Elisabetta Candini) taken from the minority slate presented by SGR and institutional investors holding a total of 1.303% of the share capital.

The most voted slate was the one presented by FimeI S.p.A. which obtained 71.315% of the share capital with voting rights represented at the Shareholders' Meeting, while the second list was voted by 28.544% of the voting capital<sup>6</sup>. The voting capital represented 78.454% of the Issuer's share capital.

<sup>5</sup> The Corporate Governance Code recommends (Application Criterion 3.C.3) that for issuers included in the FTSE-MIB index, at least one third of the Board of Directors is comprised of independent directors. If that portion does not correspond to a whole number, the number is rounded down.

<sup>6</sup> The presented slates, together with the extra relevant documentation filed pursuant to applicable law and regulations are available at [www.recordati.it](http://www.recordati.it), (section: Investors/Shareholders' Meetings /2019).

Please note that the outgoing Board of Directors with the Shareholders' Meeting of 5 February 2019, taking into account the results of the Board self-assessment process at the beginning of the 2018 financial year and the recommendations of the Corporate Governance Code, also following the amendments introduced in July 2018, sent to the Shareholders guidelines in relation to the appointment of the new Board of Directors in the Directors' Report on the only item on the agenda of the Shareholders' Meeting, concerning the appointment of the new administrative body.

In particular, the outgoing Board of Directors "Having regard to the consolidated rules of corporate governance according to which the number of members of the board must be adequate to the size and complexity of the organizational structure of the Company and having regard to the positive operating dynamics of the administrative body registered in the last three years" expressed guidelines pursuant to which "at the time of formulating the proposals to the Shareholders' Meeting, the Shareholders should ensure that the number of directors to be elected for the 2019-2021 three-year period be between nine and twelve and so that the new composition, as already recommended by the same Code and in continuity with the past, adequately represent, in relation to the activity carried out by the Company, the different components (executive, non-executive, independent) and the professional and managerial skills and experience necessary for good business management, also taking into account the international dimension of Recordati"<sup>7</sup>.

The controlling shareholder accepted these guidelines.

The composition of the Board of Directors as at the date of this Report and the qualifications of each Director at that date are summarised below:

Flemming Ørnkov	Chairman	Non-Executive	-	*Board of Directors meeting of 05.02.2019
Alfredo Altavilla	Vice Chairman	Non-Executive	-	*Board of Directors meeting of 05.02.2019
Andrea Recordati	CEO	Executive	-	*Shareholders' meeting of 29.04.1998
Silvia Candini	Director	Non-executive	Independent	*Shareholders' meeting of 05.02.2019
Michaela Castelli	Director	Non-executive	Independent	*Shareholders' meeting of 17.04.2014
Joanna Le Couilliard	Director	Non-executive	Independent	*Shareholders' meeting of 05.02.2019
Francisco Javier de Jaime Guijarro	Director	Executive		*Shareholders' meeting of 05.02.2019
Giampiero Mazza	Director	Executive	-	*Board of Directors meeting of 06.12.2018
Cathrin Petty	Director	Executive		*Board of Directors meeting of 06.12.2018
Soren Vestergaard-Poulsen	Director	Executive		*Board of Directors meeting of 06.12.2018
Fritz Squindo	Director	Executive		*Board of Directors meeting of 14.03.2013

<sup>7</sup>Date of first appointment to the Board of Directors

The personal and professional characteristics of each Director - which range from economic, financial and managerial subjects also, for some of them, with significant international experience in the business sectors in which the Company and the Group operate, to legal and corporate governance matters - are documented in Attachment 1 to this Report along with the offices held by Directors in other listed companies.

In this regard, as it was in the interest of the Company to strengthen the Board's experience, also internationally, in the business sectors in which the Company and the Group operate, the Shareholders' Meeting of 5 February 2019 approved the proposal of the majority shareholder FIMEI S.p.A. to authorise the exemption of members of the Board of Directors from the competition prohibition provided for by art. 2390 of the CC with reference to the positions held by them in other companies and disclosed on that date.

On 5 February 2019 the Board of Directors confirmed that Silvia Candini, Michaela Castelli and Joanna Le Couilliard met the independence requirements.

<sup>7</sup> The Directors' report on the only point on the agenda of the Shareholders' Meeting of 5 February 2019 can be consulted at [www.recordati.it](http://www.recordati.it), (section: Investors/Shareholders' Meetings/2019)

Note at pages 173:

<sup>8</sup> Appointed by co-optation by the Board of Directors on 6.12.2018.

<sup>9</sup> Member since 8.5.2018.

<sup>10</sup> Appointed Chairman on 8.5.2018.

<sup>11</sup> Appointed LID on 9.07.2018.

<sup>12</sup> It should be noted that one of the designated meetings of the Board took place over two days. The presence of Alberto Recordati has been counted taking into account his participation only in the second part thereof.

<sup>13</sup> LID until 8.05.2018.

<sup>14</sup> Member until 8.5.2018.

**TABLES COMPOSITION AND STRUCTURE OF THE BOARD AND COMMITTEES**

Board of Directors in office as at 31.12.2018												Control, Risk and CSR Committee		Remuneration Committee	
Position	Members	Year of birth	In office since	In office until	Slate (M/m)*	Exec.	Non-Exec.	Indep. as per CG Code	Indep. as per TUF	% ***	Number of other positions in listed companies ****	**** % ***	**** % ***		
Chairman	GIAMPIERO MAZZA	1969	6.12.2018	Shareholders' Meeting of 5.02.2019	Na <sup>b</sup>	X				4/4	0				
Vice Chairman and CEO ◊	ANDREA RECORDATI	1971	11.4.2017	Shareholders' Meeting of 5.02.2019	M	X				17/17	0				
Director	ROSALBA CASIRAGHI	1950	11.4.2017	Shareholders' Meeting of 5.02.2019	M		X	X	X	17/17	1	M	3/3 <sup>9</sup>	M	5/5
Director	MICHAELA CASTELLI	1970	11.4.2017	Shareholders' Meeting of 5.02.2019	M		X	X	X	17/17	4	P <sup>10</sup>	5/5	M	5/5
Director	ELISA CORGHI	1972	11.4.2017	Shareholders' Meeting of 5.02.2019	M		X	X	X	17/17	2	M	5/5		
Director ○ <sup>11</sup>	MARIO GARRAFFO	1937	11.4.2017	Shareholders' Meeting of 5.02.2019	M		X	X(**)	X	17/17	1			P	5/5
Director	CATHRIN PETTY	1973	6.12.2018	Shareholders' Meeting of 5.02.2019	Na <sup>b</sup>	X				4/4	0				
Director •	FRITZ SQUINDO	1956	11.4.2017	Shareholders' Meeting of 5.02.2019	M	X				17/17	0				
Director	SØREN VESTERGAARD-POULSEN	1969	6.12.2018	Shareholders' Meeting of 5.02.2019	Na <sup>b</sup>	X				3/4	1				

**DIRECTORS WHO CEASED TO HOLD OFFICE DURING THE REFERENCE YEAR (2018)**

Chairman	ALBERTO RECORDATI	1953	11.4.2017	6.12.2018	M	X				12 <sup>12</sup> /13	0				
Director	PAOLO FRESIA	1988	11.4.2017	6.12.2018	M		X	X	X	10/13	0				
Director ○ <sup>13</sup>	MARCO VITALE	1937	11.4.2017	6.12.2018	M		X	X(**)	X(**)	8/13	1	P	2/2 <sup>14</sup>		

• This symbol indicates that the director is responsible for the internal control and risk management system.

◊ This symbol indicates the principal manager of the issuer (chief executive officer or CEO).

○ This symbol indicates the lead independent director (LID).

(\*) M/m are given in this column where "M" indicates a member elected from the majority slate and "m" from a minority slate.

(\*\*) The Board has qualified Mario Garraffo as independent, even though he has been director of the Company for more than nine years during the past twelve, considering that by his specific expertise and professional commitment to constant control and stimulation of the Board, he has demonstrated that he has maintained his characteristics of independence and freedom of judgement in evaluating the operations carried out by management. Please be informed that on 8th May 2018 the Board has resolved that Marco Vitale did not satisfied any more the independent requirements. For more information please refer to Section 4.6.

(\*\*\*) This column contains the percentage attendance of directors at the relative board and committee meetings (number of presences/number of meetings held during the actual period office of the person concerned).

(\*\*\*\*) This column gives the number of appointments as a director or statutory auditor held by the person concerned in other companies listed on regulated markets, including foreign markets. For a complete list of other appointments including those in financial, banking or insurance companies or in large companies, please see the list contained in Attachment 1 of this document.

(\*\*\*\*\*) This column indicates the position of the director within the committee: "C" Chair and "M" member.

Information concerning the date of the first appointment of directors to the board is given on page 170/172.

**INDICATE THE QUORUM REQUIRED FOR THE PRESENTATION OF SLATES WHEN DIRECTORS WERE LAST APPOINTED: 1%**

Number of meetings held during 2018	Board meetings	Control, Risk and CSR Committee:	Remuneration Committee:
	17	5	5

**FOR COMPLETENESS, THE TABLE BELOW ILLUSTRATES THE CURRENT COMPOSITION OF THE BOARD OF DIRECTORS:**

Position	Members	Board of directors in office from 5 February 2019								Control, Risk and CSR Committee	Remuneration Committee	
		Year of birth	In office since	In office until	Approval	Slate (M/m)*	Exec.	Non-Exec.	Indep. as per CG Code	Indep. as per TUF	**	**
Chairman	FLEMMING ØRNSKOV	1958	5.2.2019	Approval of 2021 Annual Report	M		X					
Vice Chairman	ALFREDO ALTAVILLA	1963	5.2.2019	Approval of 2021 Annual Report	M		X					
CEO ◊	ANDREA RECORDATI	1971	5.2.2019	Approval of 2021 Annual Report	M	X						
Director	SILVIA ELISABETTA CANDINI	1970	5.2.2019	Approval of 2021 Annual Report	m		X	X	X	M		M
Director	MICHAELA CASTELLI	1970	5.2.2019	Approval of 2021 Annual Report	M		X	X	X	P		M
Director	FRANCISCO JAVIER DE JAIME GUIJARRO	1964	5.2.2019	Approval of 2021 Annual Report	M	X						
Director	JOANNA SUSAN LE COUILLIARD	1963	5.2.2019	Approval of 2021 Annual Report	M		X	X	X	M		P
Director	GIAMPIERO MAZZA	1969	5.2.2019	Approval of 2021 Annual Report	M	X						
Director	CATHRIN PETTY	1973	5.2.2019	Approval of 2021 Annual Report	M	X						
Director•	FRITZ SQUINDO	1956	5.2.2019	Approval of 2021 Annual Report	M	X						
Director	SØREN VESTERGAARD-POULSEN	1969	5.2.2019	Approval of 2021 Annual Report	M	X						

• This symbol indicates that the director is responsible for the internal control and risk management system.

◊ This symbol indicates the principal manager of the issuer (chief executive officer or CEO).

(\*) M/m are given in this column where "M" indicates a member elected from the majority slate and "m" from a minority slate.

(\*\*) This column indicates the position of the director within the committee: "C" Chair and "M" member. (\*\*\*)



#### 4.2.1. Succession Planning

In compliance with Principle 5.C.2 of the CG Code, the Board of Directors considered the situation when complying with amendments to that Code made in December 2011 and decided that it was not necessary to adopt an official succession plan for executive directors, and over time, no situations have emerged that showed an opportunity to obtain one.

Taking into account the changes in the ownership structure at the end of 2018 and the appointment of the new Board of Directors on 5 February 2019, the Company will be responsible for submitting it again to the newly appointed Board during 2019.

#### 4.2.2 Diversity criteria and policies (pursuant to article 123-bis, paragraph 2(d)-bis TUF and Principle 2.P.4 of the Corporate Governance Code)

Legislative Decree no. 254/2016 on non-financial information, implementing Directive 2014/95/EU, (which entered into force on 25 January 2017) introduces the obligation for listed companies to disclose, in the report on corporate governance relating to financial years beginning from 1 January 2017, detailed information on diversity policies "applied in relation to the administrative, management and supervisory bodies with regard to aspects such as, for instance, age, gender or educational and professional backgrounds, as well as a description of the objectives, methods of implementation and results of these policies. In the event that no policy is applied, the Company is required to clearly and articulate reasons for this choice.

As part of the self-assessment process of the Board of Directors that took place at the beginning of 2018, the Company carried out a specific study in this regard, inviting the Directors to provide comments in relation to the diversity issues of the members of the Board for the purpose of determinations about the adoption of specific policies aimed at promoting diversity.

The results of this study were examined by the Board of Directors as part of the general analysis of what emerged overall from the answers to the questionnaires received, held at the Board meeting of 8 February 2018; in this regard, it should be noted that no specific reports have emerged aimed at guiding the Board in relation to its policies in matters of member diversity with regard to aspects such as age, gender composition and training and professional development.

The Board, following an in-depth discussion, therefore deemed it unnecessary to prepare a formal policy to promote diversity in these aspects, taking into account that the Board, even in the absence of such a formal policy and, in particular, through the annual process self-assessment, can already effectively monitor and identify its optimal qualitative and quantitative composition over time; the Board considered - as part of a process of empowerment that involves, on the one hand, the board itself and on the other, the shareholders, which, if specific needs arise for the proper functioning of the Board - including critical issues related to aspects related to the diversity of its members - resorting, as already done in 2017 and again in 2018 preliminary to the shareholders' meeting of 5 February 2019, the formulation of any recommendations to members before the appointment of the new board and the board of statutory auditors or request the integration of the Board with the appointment of a new director(s) even during the term of office, if these needs cannot be postponed to the renewal of the mandate.

This assessment, as described above, also applies with regard to what is recommended more generally by the Corporate Governance Code, following the amendments introduced in July 2018 with reference to principle 2.P.4, regarding the application by the Issuer of diversity criteria, including as regards gender, in the composition of the board of directors and the Board of Statutory Auditors, with due regard to the priority objective of ensuring adequate competence and professionalism of its members.

In this regard, as already mentioned in the section concerning the composition of the Board of Directors, it is recalled that the outgoing Board with the Shareholders' Meeting of 5 February 2019, taking into account the outcomes of the Board self-assessment process at the beginning of the 2018 financial year as recommended by the Corporate Governance Code, also following the changes introduced in July 2018, sent to the Shareholders guidelines in relation to the appointment of the new Board of Directors in the Directors' Report on the only item on the agenda of the Shareholders' Meeting of 5 February 2019, concerning the appointment of the new administrative body.

In particular, the outgoing Board "having regard to the consolidated rules of corporate governance according to which the number of members of the board must be adequate to the size and complexity of the organisational structure of the Company and having regard to the positive operating dynamics of the management body registered in the last three years" expressed guidelines pursuant to which *"at the time of formulating the proposals to the Shareholders' Meeting, the Shareholders must ensure that the number of directors to be elected for the 2019-2021 three-year period be between nine and twelve and so that the new composition, as already recommended by the same Code and in continuity with the past, adequately represent, in relation to the activity carried out by the Company, the different components (executive, non-executive, independent) and the professional and managerial skills and experience necessary for good business management, also taking into account the international dimension of Recordati."*

It is confirmed that the controlling shareholder has accepted these guidelines and, in particular, that four out of the eleven members of the Board are of the less-represented gender (and therefore at least one third of the Board) and that, more generally, the new composition highlights that the objective of ensuring adequate competence and professionalism of the members of the Board, including those of an international nature, has been pursued. Therefore, the issue is correctly supervised.

Moreover, with reference to measures to promote equal gender treatment and gender opportunities within the entire corporate organisation, the Issuer and in general the Recordati Group is committed, as referred to in its applicable Code of Ethics, to offer equal job opportunities without discrimination on the basis of ethnicity, gender, age, sexual orientation, physical or psychological disability, nationality, religious belief, political and trade union membership and to ensure fair and merit-based treatment to its employees. For more details on the policies applied to this topic, refer to the respective section ("Diversity and equal opportunities") of the Non-Financial Statement.

#### 4.2.3. Maximum number of offices held in other companies

The Board of Directors has over time preferred not to set any general criterion for the maximum number of positions as director or statutory auditor in other companies that are considered compatible with performing duties as a director of the Company. It has done this until now because it feels that it is best to allow individual directors to assess this compatibility themselves.

The Board self-assessment process has, on several occasions and also at the beginning of 2018, confirmed the positive assessment made of the functioning of the Board and its committees also with particular reference to this aspect.

Taking into account the appointment of the new Board of Directors on 5 February 2019, in the course of 2019 the Company will take care of submitting to the newly appointed Board the updated guidelines relating to said criteria.

#### 4.2.4. Induction Programme

Following the appointment of the Board of Directors and the Board of Statutory Auditors on 11 April 2017, the Chairman and Chief Executive Officer

did not consider it necessary to organize a specific induction session because, with the exception of Ms Corghi and Mr Santi, the other directors and auditors were already part of the outgoing administrative and control bodies.

In May 2018, the Chairman and the Chief Executive Officer organised, as a specific induction session, a visit to the Milan production site for Independent Directors and Statutory Auditors.

Following the appointment of the new Board of Directors on 5 February 2019, the Chairman and the Chief Executive Officer are organising a special induction program for the new Directors.

Generally speaking, during the course of meetings of the Board of Directors, the Chief Executive officer gives information required to present the performance of the Company and the Group, constantly providing, amongst other things, information and the most important updates to the regulatory framework for the sector and their impact on the Company. Also, with regard to principles for the proper management of risks, during the course of meetings of the Board of Directors, the Chief Executive Officer ensures that appropriate details are given in this respect, if considered appropriate, in addition to the annual analysis of the Recordati Risk Catalogue.

#### **4.3 ROLE OF THE BOARD OF DIRECTORS (PURSUANT TO ART. 123-BIS, PARAGRAPH 2, LETTER D) OF THE TUF)**

During the course of the year, the Board of Directors met 17 times, with meetings lasting on average around an hour and thirty minutes. The percentage attendance of each Director at Board meetings and in the relative committees is shown in the table contained at the end of section 4.2.

With regard to the current year, 11 meetings are scheduled and the Board has already met 3 times; the calendar of meetings in which the results of the year and period are examined is communicated to the public annually within one month of the end of the previous year and published on the Company's website (<http://www.recordati.it/en/investors/calendar/>).

The promptness and completeness with which information is provided before board meetings is ensured by the Chairman with the distribution of documents relating to the items on the agenda to members a few days immediately preceding the date set for the meetings. On some occasions it has not been possible to provide information concerning some items on the agenda until the time of the board meeting itself for reasons of confidentiality and urgency. On these occasions, the arguments were in any case investigated by internal committees, within the scope of their remits, and the Chairman took care to provide adequate and detailed information during the Board meetings themselves. When making amendments to the CG Code in December 2011, the Board of Directors generally considered notice of three days to be appropriate and that time limit has normally been complied with in the meetings that followed (during the year documents relating to periodic accounts were in fact delivered approximately 4.2 days) before meetings on average). The Board self-assessment process held at the beginning of 2018 essentially confirmed the appropriateness of this notice.

The Chairman of the Board of Directors newly appointed on 5 February 2019 expressly submitted to the attention of the new Board of Directors, appointed on the same date, the adequacy of this term that has been confirmed, except for the presence of particular situations of urgency or confidentiality.

During the course of the year and in the meetings already held in 2019 various persons attended board meetings in order to provide additional information on the items on the agenda. These included the Chief of Administration, the Chief of Group Operational Control and Reporting, the Chief of Corporate Development, the Chief of the Legal Service and Corporate Affairs (who also acted as the Secretary to the Board), the Chief of the Group Internal Audit Function (who also

acted as Data Protection Officer and internal member of the Supervisory Body) as well as the General Manager of Pharmaceuticals - Italy.

The Board of Directors has the duty to set strategic policies for the Company and the Group it leads and it is responsible for overseeing its management. In accordance with article 22 of the By-Laws, the Board is the corporate body endowed with the broadest powers to handle ordinary and extraordinary management of the Company and it has the right to conclude all acts that it deems appropriate in order to conduct business and to achieve the corporate purposes, excluding only those reserved by the law exclusively for the Shareholders' Meeting. On the basis of the terms indicated below, the Board has assigned part of its management responsibilities to the Chief Executive Officer.

In accordance with CC. Art. 2365, paragraph 2, the Board of Directors is also authorised to decide on the following matters:

- mergers in the cases established by CC articles 2505 and 2505 bis;
- establishment or suppression of secondary offices;
- specification of the Directors who are entitled to represent the Company;
- reduction of share capital in the event of withdrawal of a shareholder;
- alignment of the By-Laws to provisions of the law and regulations;
- transfer of the registered office from one municipality to another in national territory.

The Board is also entitled to appoint and dismiss, following an obligatory opinion from the Board of Statutory Auditors, the Financial Reporting Officer, pursuant to TUF Art. 154-bis.

The Board is also responsible, in compliance with the CG Code, for the following:

- examination and approval of strategic, industrial and financial plans of the Company and the Recordati Group and monitoring implementation of these;
- definition of the nature and level of risk that is compatible with the Company's strategic objectives, including in its assessments, all risks that might be significant with a view to sustainability of the Company's activities in the medium to long-term;
- the definition of the corporate governance system of the Company itself and of the structure of the Group itself, setting guidelines for the governance of subsidiaries;
- evaluation of whether the organisational, administrative and financial structures of the Company and its strategic subsidiaries, as defined herein and as configured by the responsible organs, are adequate, with particular reference to the internal control and risk management system;
- attribution and cancellation of mandates to CEOs and the Executive Committee, defining the extent, means and intervals (at least quarterly), with which the delegates must refer to the Board about the activities carried out in exercising their mandates;
- the establishment, after examination of the proposals from the Remuneration Committee, and having been heard the opinion of the Board of Statutory Auditors, of the remuneration of executive directors and other Directors with special mandates, as well as the performance objectives link to variable remuneration of the latter and the division, for the individual members, of the total allotment for compensation of the Board, if the Shareholders' Meeting has not already decided the matter;
- evaluation of business trends, in accordance, amongst other things, with the law and the By-Laws, especially in the light of information provided by the delegated bodies and periodic comparison of results with budget provisions;
- examination and approval prior to strategic economic or financial operations of the Company and its subsidiaries, with particular attention to situations in which one or more Directors have an interest, whether personal or on behalf of third parties, and in general, to operations with related parties in accordance with the Regulations for Related-Party Transactions approved by the Board of Directors itself on 24<sup>th</sup> November 2010 (and last revised in 2017); establish guidelines to identify significant operations;

- conduct, once a year, an evaluation of the size, composition and functioning of the Board of Directors and its committees and possibly indicate the type of management and professional figures whose presence on the Board would be useful, before the appointment of a new Board;
  - communication, in the Corporate Governance Report, of the means of application of the CG Code;
  - subject to the opinion of the Audit, Risk and Sustainability Committee, the definition of the guidelines for the internal control and risk management system, so that the principal risks to which the issuer and its subsidiaries are exposed are correctly identified and adequately measured, managed and monitored. It also determines the degree to which risks are compatible with management of the Company that is consistent with its strategic objectives;
  - the selection of one or more Directors who are given responsibility for the creation and maintenance of an effective internal control and risk management system (Director/s responsible for the internal control system);
  - the selection of a Risk, Control and CSR Committee, which by conducting the appropriate fact-finding activity, has the task of supporting the Board of Directors in its assessments of the internal control and risk management system and also those relating to the approval of periodic financial reports;
  - subject to the opinion of the Risk, Control and CSR Committee, the assessment, at least annually, of the adequacy of the internal control and risk management system with respect to the nature of the company and its risk appetite and also of its effectiveness;
  - subject to the opinion of the Risk, Control and CSR Committee, the approval, at least annually, of the working plan drawn up by the Chief of the Internal Audit Function, after, amongst other things, consultation with the Board of Statutory Auditors and the Director with Responsibility for the internal control and risk management system;
  - subject to the opinion of the Risk, Control and CSR Committee, a description of the main characteristics of the internal control and risk management system in the Corporate Governance Report and a report on its assessment of its adequacy;
  - after consultation with the Board of Statutory Auditors, and assessment of the results furnished by the external statutory auditor in its letter of recommendations (if provided) and in its report on basic issues arising from its external statutory audit;
  - on the basis of a proposal submitted by the Director with Responsibility for the internal control and risk management system, subject to the approval of the Risk, Control and CSR Committee and after consultation with the Board of Statutory Auditors, the appointment and removal of the Chief of the Internal Audit Function ensuring that he or she has adequate resources and sets their remuneration consistent with company policies;
  - the appointment and removal of members of the Company's Supervisory Committee formed and functioning in accordance with Legislative Decree No. 231/2001;
  - the adoption of an Organisation and Control Model drawn up in accordance with Legislative Decree No. 231/2001 and the approval of amendments to it for compliance with changes in legislation and regulations as they come into force from time to time.
- examined the impairment analyses concerning the 2017 financial statements, the economic assessment assumptions and the forecast assumptions used for these purposes;
  - approved the most relevant company provisions;
  - at the beginning of 2018, provided a positive assessment as regards to the adequacy of the organisational, administrative and general accounting structure of the Company and of the subsidiaries of strategic importance prepared by the Chief Executive Officer, with the support of the Director in charge of the internal control and risk management system, with particular reference to the internal control system, to the management of risks on the basis of the information provided on the occasion of the Board's meeting, through specific reports and/or other documentation (e.g. organisation charts) presented by the Group Auditing Manager, the Control, Risk and CSR Committee, by the Supervisory Body pursuant to Legislative Decree 231/01, by the Director in charge of the internal control and risk management system and by the Managing Director;
  - set the performance targets related to the variable component of the remuneration of the Chairman (Mr Alberto Recordati) and the Deputy Chairman, Chief Executive Officer and General Manager (Mr Andrea Recordati);
  - with the favourable opinion of the Control, Risk and CSR Committee, adapted the guidelines for the internal control and risk management system of the Company and of the Recordati Group in order to incorporate the competences in terms of sustainability;
  - after hearing the Board of Statutory Auditors and the Director in charge of the internal control and risk management system, approved the work plan prepared by the head of the internal audit function for 2018;
  - confirmed as subsidiaries that have strategic importance, referring to mainly size criteria (turnover) or in consideration of the peculiarity of the market where the subsidiary operates (in particular, the orphan drug market): Laboratoires Bouchara Recordati S.a.s, Recordati Ireland Ltd., Jaba-Recordati S.A., Recordati Pharma GmbH, Innova Pharma S.p.A., Orphan Europe SARL, Recordati Ilac Recordati Rare Diseases Inc., Rusfic Llc and Casen Recordati SL;
  - examined and approved in advance the operations of the Company and its subsidiaries, when such transactions have had a significant strategic, economic, equity or financial importance for the Company or its subsidiaries (in particular: acquisitions of medicinal specialties and companies and contracts financing);
  - approved the proposal for a new 2018-2022 Stock Option Plan to be submitted to the Shareholders' Meeting of 18 April 2018 and resolved on 3 August 2018 a new allocation of stock options based on said new plan approved by the Shareholders' Meeting;
  - examined the organisational implementation of Regulation (EU) 2016/679 on the processing of personal data at the Company and Group level, sharing the designation of the Internal Audit Director as Data Protection Officer of Recordati;
  - examined and approved the updating of the corporate procedures in the field of market abuse that had been last amended in 2016 following the entry into force of Regulation (EU) no. 596/2014 containing the regulation of market abuse, for the purpose of adapting them to the legislation and regulations issued subsequently both at the national and at the Community level; this also as an update of the Model of management, organisation and control of the Company pursuant to Legislative Decree 231/2001;
  - designated Mr Mario Garraffo as Lead Independent Director;
  - also taking into account the results of the self-assessment process carried out at the beginning of 2018, the Board (which, as a reminder, carries out the functions assigned by the Code to the Appointments Committee) formalised through its own Report on guidelines to Shareholders on the composition of the Board of directors to be appointed by the Shareholders' Meeting called on 5 February 2019;
  - at the end of 2018, examined and approved the 2019 Group budget and set the targets for this year;
  - approved on 21 December 2018 the Notice pursuant to art. 103, paragraph 3, of the TUF and art. 39 of the Issuers Regulation relating to the mandatory

The Company has decided to take advantage, with effect from 20 December 2012, of the right not to comply with obligations to publish the reports required when significant operations are performed consisting of mergers, demergers, share capital increases through contributions in kind, acquisitions and disposals, in accordance with Art. 70, paragraph 8 and with Art. 71, paragraph 1-bis of the Issuers' Regulations.

It should be noted that, in implementation of the above, during 2018, the Board, in particular:

- assessed the general trend of management and monitored the implementation of the 2017-2019 Three-Year Business Plan, by comparing, amongst other things, actual with budgeted results taken from the approved 2018 budget, carried out as generally established practice when quarterly accounting reports are approved;

takeover bid promoted by Rossini Investimenti S.p.A. pursuant to and for the purposes of articles 102 and 106, paragraph 1-bis of the TUF, concerning a maximum of 97,735,180 ordinary shares of the Company, representing 46.735% of the share capital of Recordati S.p.A.

In 2019, as at the date of this Report, the Board, in particular:

- evaluated and approved the agreement to mutually terminate the long-term employment relationship between the Company and Mr Alberto Recordati.
- following the renewal of the Board of Directors by the Shareholders' Meeting of 5 February 2019, conferred the positions of Chairman (Flemming Ornskov) and Vice Chairman (Alfredo Altavilla) and confirmed the appointment of Chief Executive Officer (Mr Andrea Recordati), also renewing the assignment of previous operating powers. Furthermore, on the same date, it renewed the establishment of the Remuneration Committee and of the Control, Risk and CSR Committee. The Board also confirmed the previous assessment by the outgoing Board not to proceed with the establishment of a nomination committee;
- on 11 February 2019, the Board resolved, after consulting the Remuneration Committee and after consulting with the Board of Statutory Auditors, the remuneration of the Chairman and the Chief Executive Officer, including the fixing of the termination indemnity and the fee for participation in the internal board Committees; it has also evaluated and approved, after consulting the Remuneration Committee, the mutual resolution agreement of the long-term employment relationship between the Company and Mr Andrea Recordati, thus remaining, from that date, only an administrative relationship;
- on 28 February 2019 established the exercise by Rossini Luxembourg S.à.r.l of the management and co-ordination activity of the Company pursuant to articles 2497 and following of the Italian Civil Code.

During the 2018 financial year - in consideration of the extraordinary events that affected the life of the Company in relation to the transfer of the controlling interest by the Recordati family to the investment funds consortium controlled by CVC Capital Partners, the resignation on 6 December 2018 of the majority of the members of the Board of Directors taking effect from the subsequent renewal of the Board of Directors on 5 February 2019 - the examination of the 'Risk Catalogue' for the 2018 financial year, updated with respect to that examined for the 2017 financial year and the consequent assessment of the compatibility of the level and nature of the risks as identified by the Group Risk Catalogue presented to the Board (with the strategic objectives of the Group referred to in the 2017-2019 Three Year Plan) had been postponed to the meeting of the Board of Directors held on the date of this Report, also with a view to promoting mid- to long-term sustainability of the Company's activity, it being understood that the potential exposure to company risks is constantly monitored also through the measures adopted by management to prevent, monitor and control these risks.

In this regard, please note that the Group has developed - also with the support of the consulting firm Deloitte S.p.A. - its own model of mapping, management and control of the risks of the Company and the Group, which is kept constantly updated, in order to better identify the risks associated with the achievement of the strategic objectives of the Three Year Plan in force, also with a view to promoting mid- to long-term sustainability and, in general, in order to identify and manage the main internal and external risks of the Group in the most efficient way; this Model is inspired by the international principles of Enterprise Risk Management (ERM).

In principle, the updating of risk mapping is reviewed annually by the Board of Directors, on the occasion of the meeting where it approves the budget for the subsequent financial year.

On 28 February 2019, the Board examined the "Risk Catalogue" for the 2018 financial year, updated compared to the 2017 financial year and assessed that the level and nature of the risks as identified by the Group Risk Catalogue,

presented to the Board, also including in its assessment the risks that may be relevant with a view to mid- to long-term sustainability of the Company's activity, are compatible with the Group's strategic objectives as per the 2017-2019 Three Year Plan, it being understood that the process of updating and revising the mapping brought to the Board's examination will proceed in coherence with the definition of the new industrial plan that will be examined by the Board in the coming months.

#### 4.3.1. Self-assessment by the Board and its Committees

At the beginning of 2018, the Board of Directors conducted, in relation to the 2017 financial year, an assessment of the functioning of the Board itself and its committees as well as their size and composition, also taking into account elements such as the professional characteristics, experience (including managerial experience) and gender of its members as well as their seniority, with the support of the Company's Legal and Corporate Affairs Department. For more information, please refer to the Report on Corporate Governance and Ownership Structure relating to this financial year.

Unlike previous years, the Board of Directors has agreed not to carry out a self-assessment of the size, composition and functioning of the Board itself and its Committees between the end of 2018 and the beginning of 2019.

This is due to the substantial changes that occurred in 2018 in the Recordati control structure and which also affected the composition of the Board of Directors and its governance structure, finalised with the Shareholders' Meeting held on 5 February 2019, which appointed the new board of directors.

In fact, as a result of these changes, the Board of Directors appointed by the Shareholders' Meeting of 11 April 2017 resigned (for three directors, the resignation had already taken effect on 6 December 2018, and for the others, the resignation took effect from the Shareholders' Meeting called for 5 February 2019) and moreover, the three new co-opted directors could not have expressed their assessments with respect to a period that was too short. However, on 18 December 2018, the Board of Directors, availing itself of the results of the self-assessment process carried out at the beginning of 2018 (which had included a specific in-depth analysis concerning aspects of diversity of its members such as age, gender composition and the training and professional path) had decided to express itself, through a specific Report of the Directors, on the guidelines to be provided to the shareholders, and above all to the controlling shareholder, about the appropriate composition of the new Board, to be appointed at the Shareholders' Meeting of 5 February 2019.

As already detailed in the section entitled "Composition of the Board of Directors", the controlling shareholder has accepted these guidelines and as the Chief Executive Officer Mr Andrea Recordati commented at the end of the Shareholders' Meeting that appointed the new Board of Directors: *"I am very satisfied with the appointment of such a qualified Board, which has wide experience and leadership skills and combines new faces with the continuity of some executive and non-executive members already present. I am pleased to work with Flemming and the new Board members in the interest of all our shareholders to continue developing the Group on the strategic lines that have ensured our growth both in the area of rare diseases and in the area of primary and specialty care."*

## 4.4 EXECUTIVE OFFICERS AND BODIES

### Chairman, Vice Chairman and Chief Executive Officer

In accordance with article 23 of the By-Laws, representation of the Company shall be attributed to the Chairman of the Board of Directors or, in the event of his absence or inability to attend for any reason, to the Vice-Chairman, with

sole signing authority for implementation of all resolutions of the Board unless otherwise resolved. The Chairman or, in the event of his absence or impediment for any reason, the Vice-Chairman, shall represent the Company before the law, with the power to take legal action and institute judicial and administrative proceedings at all levels of jurisdiction, including with respect to revocation and cessation proceedings, and appointing lawyers and attorneys for lawsuits.

In accordance with article 24 of the By-Laws, the Board of Directors may delegate all or part of its powers and functions not only to the Chairman, but also to the Vice-Chairman and one or more executive directors and it may grant special mandates to individual Directors or managers of the Company, including the power of attorney, determining their functions and powers under the law. In accordance with article 25 of the By-Laws, the Board may also delegate all or part of its powers to an Executive Committee.

During 2018, the role of Chairman was held, until 6 December 2018, by Mr Alberto Recordati and, subsequently, by Mr Giampiero Mazza, appointed in office by the Board of Directors who had co-opted him at the meeting held on the same date.

Alberto Recordati, during his term as Chairman, contributed to the elaboration of the corporate strategies to be submitted to the Board of Directors within the Presidency Committee, chaired by him and of which the other executive directors were also members. Andrea Recordati and Fritz Squindo had the task of examining the main management facts of Recordati and its subsidiaries. This Committee has been dissolved as a result of the resignation of Alberto Recordati.

Alberto Recordati was qualified as executive director and also as Chairman and Chief Executive Officer of Fime S.p.A., a company that holds the majority shareholding in Recordati S.p.A.

Following the appointment of the new Board of Directors on 5 February 2019, the role of Chairman was assigned to Flemming Ørnskov; neither Mr Mazza, nor Mr Ørnskov have been assigned operational powers in their terms of office. The Chairman has institutional duties of direction and control to (i) convene Board meetings and ensure that the members of the Board and the Board of Statutory Auditors are provided, with advance notice of three days before the Board Meeting, except for exceptional cases of urgency and particular confidentiality, with the documentation and information necessary to enable them to express an informed opinion about the matters submitted to their examination and approval,<sup>15</sup> (ii) co-ordinate the activities of the Board and conduct the proceedings of Board meetings; (iii) continuously provide information about the frequent variations of the law and the regulations that govern the sector and their impact on the Company, in order to develop the awareness of all Directors in relation to the situation and dynamics of the Company.

Throughout 2018, the role of Vice Chairman and Chief Executive Officer was held by Andrea Recordati.

From 16 August 2016 - following confirmation and immediately after the appointment of the new board of directors resolved on 5 February 2019 - Andrea Recordati, as Managing Director, has been delegated, to the extent permitted by law, all the widest powers for the administration and ordinary and extraordinary management of the Company and the performance of the management and coordination activities carried out by the Company in comparison with Group companies, determining the adequacy of the organisational, administrative and accounting structure of the Company for the execution of strategic, industrial and financial plans approved by the Board of Directors, with the sole exclusion of the operations listed below (exhaustive

and mandatory in nature), which, because they are to be carried out directly by the Company and/or indirectly through subsidiaries, are operations reserved to the responsibility of the Board of Directors (except for intragroup operations, and that is performed with or between other companies of the Recordati Group):

- a) *the assumption of financial debt for an amount greater than €25 million for each transaction and the grant of secured or personal guarantees for amounts greater than €10 million for each transaction;*
- b) *the sale and purchase of real estate properties for amounts of greater than €10 million, in which industrial activities of the Company or its subsidiaries are carried out at the time of the sale;*
- c) *the purchase or provision of ownership, or the purchase or the grant of licences for intellectual property rights and more specifically by way of example, but not limited to these, intellectual property rights regarding specialty medicines, dietary supplements and medical devices for amounts not greater than €10 million each;*
- d) *acquisition, disposal or any other provision in relation to holdings in other companies and similarly the acquisition and disposal of companies or company operations, for an amount greater than €10 million each;*
- e) *the stipulation of agreements, including settlement agreements, concerning matters not included in those above for an amount greater than €10 million for each agreement.*

The Chief Executive Officer of Recordati does not hold interlocking directorships pursuant to Implementation Criterion 2.C.5 of the CG Code.

On 5 February 2019, Mr Alfredo Altavilla was appointed as Vice Chairman of the Board of Directors responsible for the functions provided for by the By-Laws in the case of the absence or impediment of the Chairman of the Board of Directors.

### **Executive Committee**

No Executive Committee has been formed as an internal committee of the Board of Directors.

### **Reporting to the Board**

The Chief Executive Office reported to the Board in individual Board meetings on the activities performed in exercising the powers conferred on him by the Board: in each meeting, and independently of the time elapsed since the previous meeting, the CEO provides a report on activities carried out and the main transactions performed by the Company and its subsidiaries, even if these are transactions which do not require prior approval by the Board of Directors.

## **4.5 OTHER EXECUTIVE DIRECTORS**

With regard to the Board of Directors in office from 1 January 2018 to 6 December 2018, in addition to Alberto Recordati, Chairman, and Andrea Recordati, Chief Executive Officer, Fritz Squindo, Director, is also an Executive Director.

The Administration, Finance and Control, Human Resources, Information Technology and Investor Relations & Corporate Communications functions report to Mr. Squindo, who serves as General Manager for the coordination of management and Chief Financial Officer (in addition to being responsible for drafting the accounting documents and serving as Director in charge of the internal control and risk management system, as also confirmed by the Board of Directors newly appointed on 5 February 2019). Mr. Squindo also holds the position of director in other companies of the Group.

<sup>15</sup> It should be noted that the Chairman of the Board of Directors newly appointed on 5 February 2019 has expressly submitted to the attention of the new Board of Directors, appointed on the same date, the adequacy of this term that has been confirmed, except for the presence of particular situations of urgency or confidentiality.

With regard to the Board of Directors in office from 6 December 2018 to 5 February 2019, in addition to Andrea Recordati, Chief Executive Officer, and Fritz Squindo, Director, in light of the functions performed by each, Giampiero Mazza, Chairman, on the one hand, and Cathrin Petty and Søren Vestergaard-Poulsen, the Directors who were co-opted by the Board of Directors on 6 December 2018, on the other hand, are also executive Directors, because they hold management positions in the indirect parent company or in other companies in the control chain.

With reference to the new Board of Directors appointed by the Shareholders' Meeting of 5 February 2019, Andrea Recordati, Chief Executive Officer, and Fritz Squindo, General Manager for the Coordination of Management and CFO, are executive directors, in light of the functions performed by each, as are Javier De Jaime Guijarro, Giampiero Mazza, Cathrin Petty and Søren Vestergaard-Poulsen, because they hold management positions in the indirect parent company or in other companies in the chain of control.

#### 4.6 INDEPENDENT DIRECTORS

With reference to the Board of Directors in office from 1 January 2018 until 6 December 2018, the Board of Directors of the Company was characterised by a number of independent Directors which constituted the absolute majority of its members (six until 8 May and five following that date), which is a more rigorous approach than that required by the TUF and the CG Code itself, even for issuers included in the FTSE-Mib index.

The procedure followed by the Board for verifying independence involves satisfaction of the requirement being declared by directors when they submit their candidatures and also when they accept their appointments. The Board ascertains that satisfaction in the first meeting subsequent to the appointment and discloses the results to the market.

Subsequently, and without prejudice to independent directors' commitments to promptly communicate to the Board the development of situations which determine failure to satisfy the requirement, the Board requires the directors concerned to annually confirm satisfaction of the requirements, as required by law and by the CG Code. The Board of Directors and the Board of Statutory Auditors then proceed to verify the contents and to verify the correct application of requirements and of the procedure to ascertain them respectively.

In the implementation of the provisions of the Code, the Board of Directors - on 8 February 2018 - confirmed, on the basis of the statements provided by the individuals concerned or of the information however available to the Company, that six Directors, Rosalba Casiraghi, Elisa Corghi, Michaela Castelli, Paolo Fresia, Mario Garraffo and Marco Vitale, fulfilled the requirements of independence pursuant to Art. 148, paragraph 3 of the TUF and the requirements of independence set forth in the CG Code, except for that which has been already reported in the notes to the table on page 23 and for that which is specified below.

On that occasion the Board confirmed its previous assessment concerning the relationship between the Company and Prof. Vitale, attributable to a professional engagement worth € 50,000.00 annually, considering the relationship cited as not significant for the purposes of independence in consideration of the small quantitative nature of the engagement. Furthermore, the Board of Directors decided not to include the requirement relating to a Director holding office for more than nine of the last twelve years among those pursuant to the CG Code on the basis of which the assessment of the independence of Directors is performed. This is because, with precise reference to Prof. Vitale, Dr. Garraffo and Avv. Pedersoli, the Board considered that because of their specific expertise and professionalism and for their constant work in supervising and stimulating the Board they have demonstrated that they have maintained their characteristics of independence and freedom of judgement in assessing the work of

management intact. Furthermore, the Board of Directors noted that the continuation of a Director in office for more than nine years should not in itself be considered a negative requirement for qualification as independent if the other requirements of the CG Code are satisfied. This is because great experience of the specific affairs of the issuer, the stature and professionalism of the persons considered, the absence of interests and significant relations with the Company constitute a value to be considered positively and such as to consider their capacity to judge freely and without bias to be untarnished. The Board therefore considered that the requirements of independence were met by the said directors in accordance with the CG Code, confirming its opinion that consideration must be given to substance and not form in an assessment of independence requirements, with account taken also of a widespread orientation among listed companies.

The Board of Statutory Auditors verified that the criteria and procedures of evaluation adopted by the Board to evaluate the independence of its members were implemented correctly.

However, on 7 May 2018, as a result of discussions between the Company and CONSOB regarding the existing relationship of collaboration between the Company and Mr Vitale and the assessments made by CONSOB in relation to his independence, other than those carried out by the Company, Mr Vitale sent a statement by which, although dissenting from the position of CONSOB, thus claiming his proven independence, he resigned from his position as Chairman and member of the Control, Risk and CSR Committee to protect the Company from the risk of further problematic discussions.

On 8 May 2018, once the Board of Directors acknowledged CONSOB's position regarding the non-independence of Mr Vitale, and of the statement of the latter, although confirming that it shared the view that Mr Vitale was essentially independent - as always made in the context of the periodic annual assessment in the perspective of the prevalence of the substance on the formal requirements - it resolved to align itself with the assessment carried out by Consob which concluded that Mr Vitale had failed to meet the independence requirements.

Following this assessment, the number of independent directors in the Board fell to five members, in any case in excess of the number recommended by the Corporate Governance Code for issuers belonging to the FTSE-Mib index (at least one third of the board of directors).

Subsequently, in the context of the completion of the corporate changes relating to the shareholding structure of Recordati S.p.A. that took place on 6 December 2018, which has already been disclosed in section 2 concerning Ownership Structure, the independent director Paolo Fresia resigned as a Director and the number of independent directors fell further to four (Michaela Castelli, Elisa Corghi, Rosalba Casiraghi and Mario Garraffo), but still amounted to more than one third of the board of directors.

With reference to the new Board of Directors appointed by the Shareholders' Meeting of 5 February 2019, three directors (Michaela Castelli, Silvia Candini and Joanna Le Couilliard) stated, when presenting the slates, that they meet the independence requirements established by art. 148, paragraph 3, of the TUF and by the Code of Corporate Governance, and the Board, on the same date, not having identified that the Company, on the basis of the information available, found itself in opposite situations, confirmed that said requirements for the same directors were met.

The independent Directors, on the occasion and before the beginning of the meetings of the Board of Directors, have from time to time verified the absence of specific problems that would be relevant in the context of their role as independent Directors.

During the 2018 financial year, the independent directors met on one occasion in March and then subsequently on several occasions for the purpose

of issuing the opinion pursuant to art. 39-bis of the Consob Issuers' Regulation in the context of the mandatory takeover bid, which has already been pointed out in the Introduction (released on 19 December 2018) without the other directors, also on the initiative of the Lead Independent Director.

#### 4.7 LEAD INDEPENDENT DIRECTOR

Currently, a lead independent director has not been appointed, and there have been no requests for such an appointment from the independent directors.

Previously, during the 2018 financial year and until 5 May 2018, the Board had designated as lead independent director the independent Director Mr Vitale, to which the independent Directors refer, for a better contribution to the activity and functioning of the Board, given the significant number of independent directors.

Following what has already been indicated in the previous paragraph regarding the Board's assessment of the independence of Mr Vitale, the Board had not deemed necessary to proceed with a new appointment.

On 9 July 2018, the independent Directors reported to the Board the need to appoint a lead independent director who could coordinate the activities of the independent directors for the purpose of issuing the opinion pursuant to art. 39-bis of the Consob Issuers' Regulation in the context of the mandatory takeover bid, already pointed out in the introduction (released on 19 December 2018). The Board, in accepting said request, appointed Mario Garraffo lead independent director, giving him the right to call, on his own initiative or at the request of other independent and/or non-executive Directors, specific meetings of independent or non-executive Directors only, to discuss issues of interest with respect to the obligations with reference to the aforementioned mandatory takeover bid and more generally with respect to the functioning of the Board or the company management.

As mentioned above, the Lead Independent Director has convened several meetings of only independent directors: in addition to a meeting in March and then subsequently on several occasions for the purpose of issuing the opinion pursuant to art. 39-bis of the Consob Issuers' Regulation in the context of the mandatory takeover bid, already pointed out in the Introduction (released on 19 December 2018).

## 5. CONFIDENTIALITY OF CORPORATE INFORMATION

The Company has adopted a procedure that regulates the internal management and external communication of information relating to the Company, with particular reference to Important and Inside Information, in order to prevent its improper circulation and disclosure both inside and outside the Company, in compliance with current EU and national regulations regarding market abuse: "Procedure for the internal management of Relevant Information and Inside Information and disclosure to the public of Inside Information" (in brief, the "Procedure for Relevant Information and Inside Information").

The Procedure is a fundamental component of the internal control and risk management system of the Company and the Group, as well as an integral part of the overall system of prevention of offenses pursuant to Legislative Decree no. 231/2001.

Over time, the Company has adopted a specific procedure for the management of corporate information and the version currently in force was last revised in the course of 2018, as an update of the company procedures in the field of

market abuse, which had been previously and significantly amended in 2016 following the entry into force of Regulation (EU) no. 596/2014 containing the regulation of market abuse, for the purpose of adapting them to the rules and regulations subsequently issued both at the national and at the Community level and, in particular, to the Guidelines issued by Consob on that subject in October 2017.

The rules of conduct established by the Procedure for Relevant Information and Inside Information are designed at implementing the necessary organisational controls for the following: proper management of information flows, guaranteeing the maximum confidentiality information that is Inside Information or otherwise likely to become so (Relevant Information), balancing the interest in the confidentiality of information in the course of its progressive formation and the obligation of the related disclosure in a non-selective form, protecting investors and the integrity of the market, since they are aimed at preventing the carrying out of transactions detrimental to their interests through the exploitation of information asymmetries, or the alteration of market variables, through the dissemination of untrue or misleading information; to reduce the risk of crimes or administrative offenses relating to market abuse; protecting the Company against any liability that may arise for the unlawful acts committed by parties that can be referable to the same; defining the processes for identifying and managing the Relevant Information; defining the processes for identifying and managing the Inside Information; defining the processes of communication to the public and to Consob of Inside Information.

The members of the administrative, management and control bodies of the Company and the employees and collaborators of the Company and of its Subsidiaries who have access for any reason to Important or Inside Information are required to comply with this procedure.

The Procedure for Relevant Information and Inside Information identifies the Chief Executive Officer as the person responsible for the public disclosure process of inside information concerning the Company also in relation to the decision to begin the procedure of any delay in communication to the market. The Chief Executive Officer has therefore been identified as holding the Inside Information Management Function (so-called "IIMF") pursuant to the 2017 Consob guidelines or as a function responsible for the management of inside information. For the carrying out of his activities, the Chief Executive Officer, as holder of the IIMF, avails himself of the technical consultancy support of an "info room" (always in line with the 2017 Consob guidelines) of which the General Manager for the coordination of management and CFO, the Director of Legal and Corporate Affairs and the Director of Investor Relations & Corporate Communication, are permanent members as well as, when needed, additional members of management concerned from time to time with specific information.

During 2018, the Board also approved the update of the "Procedure for keeping and managing the list of persons who have access to relevant information and the list of persons having access to inside information" which is aimed at regulating the methods of maintaining and regularly updating the List of persons who have access to inside information (hereinafter referred to as "Insider List") which is necessary for the Issuer to maintain pursuant to the legislation in force, and the List of persons having access to relevant information (hereinafter "Relevant Information List" or, in brief, "RIL") in implementation of the Procedure for Relevant Information and Inside Information, in compliance with the applicable Community and national legislation and regulations on the prevention and repression of market abuses, also taking into account the guidelines issued by ESMA and CONSOB. In particular, for the purposes of applying the Procedure for Relevant Information and Inside Information, the Company takes into account the interpretative and applicative indications contained in the Consob Guidelines.

In particular, the Company has, on a voluntary basis, proceeded to establish a list of persons who have access, in the performance of their duties, to Relevant Information, in compliance with the provisions of the Consob Guidelines. This list is aimed at ensuring the traceability of persons who have access to Relevant Information with a view to a more effective monitoring of corporate information also for the purpose of fulfilling the obligations of communication to the market of Inside Information and the prevention and repression of market abuses.

The Insider List, on the other hand, contains registered persons who have access, in the performance of their duties, to Inside Information and, in compliance with Community legislation, the Procedure provides that the Insider List also has a section of registrants in which to register subjects who are permanently aware of all the inside information and a section where registration is required for each event.

Also in the course of 2018 and always as an update of the company procedures on market abuse, the Board of Directors approved the update of its "Internal Dealing Procedure" which already envisaged, starting from 2016, the forecast of so-called *black-out periods* namely specific periods of the year - in the period from the thirtieth day before the Board of Directors called to approve an interim or year-end financial report that the Company is required to make public according to the rules of the registered office of trading in which the shares are admitted to trade or national law and until the disclosure to the public of the related information - in which there is an obligation to abstain from carrying out transactions on financial instruments issued by the Company and listed on regulated markets. During the audit, the Board confirmed that it did not apply the black-out periods to the publication process of the quarterly reports.

On the basis of the organisational structure of the Issuer, no new persons significant for the application of the regulations were identified in 2018.

## 6. INTERNAL COMMITTEES OF THE BOARD

The Board of Directors has formed a Remuneration Committee and an Control, Risk and CSR Committee among its members, both with consultative and proposal-making functions composed exclusively of independent directors.

## 7. APPOINTMENTS COMMITTEE

For some time, and most recently following the appointment of the new Board of Directors on 5 February 2019, the Board did not consider it necessary to form an Appointments Committee,<sup>16</sup> but expressly reserved the duties assigned to the latter by the CG Code to itself sitting in plenary session. This is mainly because until now no difficulty has been encountered in making appointment proposals, partly due to the presence of a shareholder who holds legal control of the Company, also following the transfer by the Recordati family to a consortium of funds controlled by CVC (and therefore in consideration of the narrow shareholder base) and also because it is therefore considered preferable to reserve the functions that the CG Code attributes to an Appointments Committee, and which the Board already performed, to the Board sitting in plenary session.

In this respect, at the end of 2018, the outgoing Board of Directors with the Shareholders' Meeting of 5 February 2019, taking into account the results of the Board self-assessment process completed at the beginning of the 2018 financial year and the recommendations of the Corporate Governance Code, also

following the amendments introduced in July 2018, sent to the Shareholders some guidelines in relation to the appointment of the new Board of Directors in the Directors' Report on the only item on the agenda of the Shareholders' Meeting, concerning the appointment of the new administrative body:

*In particular, the outgoing Board of Directors "having regard to the consolidated rules of corporate governance according to which the number of members of the board must be adequate to the size and complexity of the organisational structure of the Company and having regard to the positive operating dynamics of the management body registered in the last three years" expressed guidelines pursuant to which "at the time of formulating the proposals to the Shareholders' Meeting, the Shareholders should ensure that the number of directors to be elected for the 2019-2021 three-year period be between nine and twelve and so that the new composition, as already recommended by the same Code and in continuity with the past, adequately represent, in relation to the activity carried out by the Company, the different components (executive, non-executive, independent) and the professional and managerial skills and experience necessary for good business management, also taking into account the international dimension of Recordati".<sup>17</sup>*

The controlling shareholder has accepted these guidelines.

## 8. REMUNERATION COMMITTEE

Please consult the relevant part of the Report on Remuneration published in accordance with Art. 123-ter of the TUF for information on this section.

## 9. DIRECTORS' REMUNERATION

Please consult the relevant part of the Report on Remuneration published in accordance with Art. 123-ter of the TUF for information on this section.

## 10. CONTROL, RISK AND CSR (CORPORATE SOCIAL RESPONSIBILITY) COMMITTEE

As at the date of this report, the Control, Risk and CSR Committee is composed of the following non-executive and independent Directors: Michaela Castelli, Chairman, Silvia Candini and Joanna Le Couilliard.

Previously, from 1 January 2018 to 7 May 2018, the Control, Risk and CSR Committee was made up of the following non-executive and independent Directors (see, in this regard, section 4.6 concerning independent directors): Marco Vitale, Chairman, Michaela Castelli and Elisa Corghi.

Following the assessment concerning the non-fulfilment of the independence criteria by Mr Vitale on 8 May 2018 and the resignation by the Chairman and member of the Control, Risk and CSR Committee from the latter, the Board appointed a new Chairman to the Committee, Michaela Castelli, and new member of the same, Rosalba Casiraghi. This composition remained unchanged until the Shareholders' Meeting held on 5 February 2019 which appointed the new Board of Directors.

The Board which met on the same date resolved to set up the Control, Risk and CSR Committee, confirming previously assigned functions and competencies (including sustainability supervision) and appointing, as mentioned above, the following non-executive and independent Directors as above, Michaela Castelli, Chairman, Silvia Candini and Joanna Le Couilliard.

<sup>16</sup> Even if from the December 2011 edition onwards, the Corporate Governance Code recommends the creation of such a committee (Principle 5.P.1).

<sup>17</sup> The Directors' report on the only item on the agenda of the shareholders' meeting of 5 February 2019 can be consulted at [www.recordati.it](http://www.recordati.it) (section: Investors/Shareholders' Meetings/2019).



The Committee met five times during the year (sessions lasted around 1 hour). The Committee met three times during the current year. The percentage attendance of Committee members at meetings is shown in the table contained at the end of section 4.2 of this Report.

The Board determined that all members have adequate experience in accounting and finance or risk management matters.

The entire Board of Statutory Auditors has been constantly invited to participate in the Committee's work.

Invited by the Chairman of the Committee and with regard to individual items on the agenda, various non-members have participated in some meetings, in particular the General Manager for the Co-ordination of Operations (who is also the Director with responsibility for the internal control and risk management system), the Chief of Group Audit, the Chief of Group Human Resources, the Supervisory Committee pursuant to Legislative Decree 231/01, representatives of the Audit Firm and consultants who provided support to the Company on specific projects examined by the Committee.

The Legal and Corporate Affairs Department attended to take minutes of meetings.

### **Duties assigned to the Control, Risk and CSR Committee**

The Control, Risk and CSR Committee performs consultation functions and provides proposals to the Board of Directors. Through appropriate investigation and evaluation in its designated areas, it supports the Board with regard to the internal control and risk management system and on sustainability issues (intended as the processes, initiatives and activities carried out to oversee the Company's commitment to sustainable development along the value chain), as well as with regard to the approval of periodic financial reports. More specifically, it expresses opinions on the following:

- a) *the guidelines for the internal control and risk management system, so that the principal risks to which the Company and its subsidiaries are exposed are correctly identified and adequately measured, managed and monitored, and on the determination of criteria to assess whether such risks are compatible with management of the Company that is consistent with its strategic objectives and with a view to sustainability in the medium to long-term;*
- b) *on the selection of one or more Directors who are given responsibility for the creation and maintenance of an effective internal control and risk management system;*
- c) *an assessment, at least annually, of the adequacy of the internal control and risk management system with respect to the nature of the company and its risk appetite and also its effectiveness;*
- d) *the approval, at least annually, of the work plan drawn up by the Chief of the Group Audit Function;*
- e) *the description of the main characteristics of the internal control and risk management system and on the assessment of its adequacy in the Corporate Governance Report;*
- f) *the assessment of the results furnished by the external statutory auditor in its letter of suggestions (if provided) and in its report on basic issues arising from its external statutory audit;*
- g) *the appointment and removal of the Chief of the Group Audit Function (formerly the Internal Control Officer in accordance with Art. 150 of Legislative Decree No. 58/1998), on the assignment of adequate resources to the latter to fulfil his/her duties and on the remuneration set for him/her consistent with Company policy.*

Furthermore, in its work to support the Board of Directors, the Control, Risk and CSR Committee:

- shall assess, together with the Financial Reporting Officer appointed to prepare the corporate accounting documents and after consultation with the external statutory auditors and the Board of Statutory Auditors, the correct use of accounting policies and their consistency in the preparation of the consolidated financial statements, prior to approval of the consolidated financial statements by the Board of Directors;
- shall express opinions on specific aspects concerning the identification of the main corporate risks;
- shall examine periodic reports for the assessment of the internal control and risk management system and those of particular importance prepared by the Group Audit Function;
- shall monitor the independence, adequacy and effectiveness of the Group Audit Function;
- shall require the Group Audit Function to investigate specific operational areas, reporting promptly to the Chairman of the Board of Statutory Auditors;
- shall report to the Board, at least semi-annually, when annual and interim financial reports are approved, on its activities and also on the adequacy of the internal control and risk management system;
- shall make proposals to the Board of Directors regarding changes to be made to the Organisational Model established pursuant to Legislative Decree 231/01 adopted by the Company;
- shall make proposals to the Board of Directors regarding the appointment of members of the Supervisory Committee created pursuant to Legislative Decree No. 231/01 and regarding the allocation of an annual budget to that body;
- shall express an opinion on the appointment of the Financial Reporting Officer appointed to prepare the corporate accounting documents;
- shall express an opinion on the Regulations for Related-Party Transactions which the Company must adopt in compliance with Consob Regulation No. 17221 of 12<sup>th</sup> March 2010 and also on any subsequent amendments to those regulations;
- shall express an opinion, either binding or non-binding, on Related-Party Transactions of Major Importance and on Related-Party Transactions of minor importance in compliance with the aforementioned regulations governing related-party transactions adopted by the Company, unless they consist of Related-Party Transactions which concern remuneration;
- shall assist the Board of Directors on the implementation of recommendations contained in the Corporate Governance Code for listed companies in relation to the internal control and risk management system;
- monitors sustainability issues connected to business activities and to the dynamics of interactions with all stakeholders;
- examines sustainability plan guidelines and how to implement sustainability policies;
- examines the overall layout of the sustainability report and how the report's contents are presented, as well as the completeness and transparency of information provided in it;
- expresses, upon request by the Board, an opinion on sustainability issues.

At the meetings mentioned above, the Committee mainly carried out the following activities:

- it examined the periodic reports by the Supervisory Committee as per Legislative Decree 231/2001 and by the Group Audit Officer along with the results of audits conducted by the Audit Department;
- it examined the proposed Audit Plan for 2018;
- it acknowledged the Supervisory Committee's action plan for 2018;
- after consultation with the firm of auditors and the Board of Statutory Auditors and together with the financial reporting officer, it examined

the results of the audit of the accounts regarding the financial statements and the proper use of accounting policies and their consistency in the preparation of the consolidated financial statements;

- it formulated a proposal for submission to the Board concerning the expenditure budget of the Supervisory Committee for the operating expenses of the committee itself concerning the application of the Organisation, management and control model pursuant to Legislative Decree 231/01;
- it examined the adequacy of the guidelines for the internal control and risk management system;
- it examined the section of the Corporate Governance Report for the 2017 financial year concerning the internal control and risk management system;
- it examined the organisational structure of the Group Audit function;
- it examined the actions implemented by the Company with the aim of providing non-financial information, as required under Legislative Decree No. 254/2016 concerning the 2018 financial year as well as the relevant documentation, including the analysis of materiality giving a favourable opinion;
- it examined, in preparation for the examination and approval of the board, the updating of the company procedures in the field of market abuse in order to adapt them to the legislation and regulations issued after the previous 2016 revision both at the national and at Community level and, in particular, to the Guidelines issued by Consob on the subject in October 2017. In fact, as already specified, these procedures are a fundamental component of the internal control and risk management system of the Company and of the Group, as well as an integral part of the overall system of prevention of offenses pursuant to Legislative Decree no. 231/2001;
- in its capacity as the Committee for Related-Party Transactions, it examined a proposal to opt for consolidated tax treatment as per Article 117 of Presidential Decree No. 917/1986 (i.e., for the consolidation for fiscal purposes of Recordati S.p.A. and Fimei S.p.A. from 2019 to 2021);
- it also expressed its opinion to the Board on the following:
  - the adequacy of the guidelines for the internal control and risk management system;
  - the adequacy of the internal control system, at the time of approval of the 2017 Annual Report and the 2018 half yearly interim financial report;
  - the programme of work prepared by Chief of Group Audit for 2019;
- it reported to the Board twice on its activities, at the time of approval of the 2017 Annual Report and the 2018 half yearly interim financial report; the Chairman of the Committee in any case informed the Board of Directors at the first subsequent meeting of the decisions taken regarding the matters for which it is competent;
- in its capacity as the Committee for Related-Party Transactions, it carried out the three-year periodic review of the Related Party Transactions Procedure, not recognising the need to propose substantial changes to the Board;

During the 2018 financial year - in consideration of the events that interested the life of the Company in relation to the transfer of the controlling interest by the Recordati family to the investment funds consortium controlled by CVC Capital Partners, the resignation on 6 December 2018 of the majority of the members of the Board of Directors taking effect from the subsequent renewal of the Board of Directors on 5 February 2019 - the examination of the 'Risk Catalogue' for the 2018 financial year (updating with respect to that examined for the 2017 financial year) and the consequent assessment of the compatibility of the level and nature of the risks as identified by the Group Risk Catalogue presented to the Board with the strategic objectives of the Group referred to in the 2017-2019 Three Year Plan, also with a view to promoting mid- to long-term sustainability of the Company's activity, have been postponed to 2019. Said examination and assessment took place with positive opinion in the meeting of 25th February 2019.

Meetings of the Committee were properly minuted.

The Committee had access to the information and Company functions that were necessary for the performance of its duties; it did not consider it necessary to make use of outside consultants.

The Board of Directors approved a specific budget for the Control, Risk and CSR Committee for 2018 in order to provide it with adequate financial resources for the performance of its duties.

## 11. INTERNAL CONTROL AND RISK MANAGEMENT SYSTEM

The Internal Control and Risk Management System, which is based on the Enterprise Risk Management (ERM) approach, consists of a structured process of risk management in line with international best practice and in accordance with the primary requirements of applicable laws and regulations. The goal of the Internal Control and Risk Management System is to guide activities in line with company objectives while promoting informed decisions and ensuring the efficiency and efficacy of internal processes and the reliability of financial information. The principles underlying the Company's risk management processes are based on the Borsa Italiana Corporate Governance Code.

A catalogue of company risks within the Internal Control and Risk Management System makes it possible to measure and control the exposure of all companies of the Group to the various risk factors, as well as to manage overall exposure and implement controls and procedures that are able to reveal anomalous situations. The main risk factors to which the Group is exposed may be related to the external context, strategic and operational risks (including in relation to research and development, environment risks, health and safety risks, and pharmacovigilance risks), financial risks, and legal and compliance risks.<sup>18</sup>

The Group periodically reassesses the Catalogue of Risks throughout the year, including by way of a bottom-up approach to the critical assessment of risks, in conjunction with significant company events, such as the definition of the budget, the revision of organisation charts, and other events that could have an impact on the Company's risks.

As already mentioned under section 4.3, during the 2018 financial year - in consideration of the events that interested the life of the Company in relation to the transfer of the controlling interest by the Recordati family to the investment funds consortium controlled by CVC Capital Partners, the resignation on 6 December 2018 of the majority of the members of the Board of Directors taking effect from the subsequent renewal of the Board of Directors on 5 February 2019 - the examination of the 'Risk Catalogue' for the 2018 financial year, updating with respect to that examined for the 2017 financial year and the consequent assessment of the compatibility of the level and nature of the risks as identified by the Group Risk Catalogue presented to the Board (with the strategic objectives of the Group referred to in the 2017-2019 Three Year Plan) had been postponed to the Board of Director's meeting which took place at the date of this Report, it being understood that the potential exposure to company risks is constantly monitored also through the measures adopted by management to prevent, monitor and control these risks.

In this regard, please note that the Group has developed - also with the support of the consulting firm Deloitte S.p.A. - its own model of mapping, management and control of the risks of the Company and the Group, which is kept constantly updated, in order to better identify the risks associated with

<sup>18</sup> For more information, see the section "Main Risks and Uncertainties" of the 2017 Consolidated Financial Statements of the Recordati Group.s' Meetings/2019).

the achievement of the strategic objectives of the Three Year Plan in force, also with a view to promoting mid- to long-term sustainability and, in general, in order to identify and manage the main internal and external risks of the Group in the most efficient way.

In principle, the updating of risk mapping is reviewed annually by the Board of Directors, at the meeting at which it approves the budget for the subsequent financial year.

On 28 February 2019, the Board examined the "Risk Catalogue" for the 2018 financial year, updating with respect to the 2017 financial year and assessed that the level and nature of the risks as identified by the Group Risk Catalogue, presented to the Board, also including in its assessment the risks that may be relevant with a view to mid- to long-term sustainability of the Company's activity, are compatible with the Group's strategic objectives as per the 2017-2019 Three Year Plan, it being understood that the process of updating and revising the mapping brought to the Board's examination will proceed in coherence with the definition of the new industrial plan that will be examined by the Board in the coming months.

Furthermore, in a meeting held on 15 March 2018, with the opinion in favour of the Control, Risk and CSR Committee, the Board considered that the 2018 guidelines for the internal control and risk management system of the Company and the Recordati Group, approved the previous year (except for some changes made for compliance concerning sustainability competencies regarding the Control, Risk and CSR Committee) were still adequate, so that the principal risks to which the Company and its subsidiaries are exposed are correctly identified and adequately measured, managed and monitored.

The internal control and risk management System consists of a structured and organic set of procedures and organisational units designed to prevent or limit the consequences of unexpected results, to enable corporate objectives to be achieved and to ensure both compliance with the law and regulations and proper and transparent reporting internally and to markets. The System also makes it possible to identify, measure, manage, and monitor the main risks in order to improve the efficiency and efficacy of company processes, to protect the value of company assets, to ensure the reliability and integrity of accounting and operational information, and to ensure that operations comply with all applicable laws and regulations.

The internal control and risk management System permeates the whole Company, involving a variety of staff with specific roles and responsibilities. The Company has had special whistle blowing channels of reporting in place for some time as part of its organisational models pursuant to Legislative Decree No. 231/2001 (administrative liability) and the Group's anti-bribery system.<sup>19</sup> In the course of 2018, these whistle blowing channels were strengthened with the introduction of additional communication tools: a new procedure was implemented in the French branches of the group and new reporting channels were introduced in compliance with new local legislation (Loi Sapin 2) and in the Italian branches, already in compliance with Law 179/2017, containing "Provisions to protect people reporting crimes or irregularities they became aware of within their public or private employment" (so-called "Whistleblowing Law") some improvements are under way on reporting systems.

The Board positively assessed the adequacy, effectiveness and actual functioning of the internal control and risk management system on the basis of information provided in meetings in the form of reports presented by the Internal Control, Risk and CSR Committee and by the Supervisory Committee pursuant to Legislative Decree 231/01.

The heads of each department are responsible for designing and managing the internal control system and for monitoring its effective functioning on the basis of the guidelines approved by the Board of Directors.

The structural components of the internal control and risk management System consist of: the Code of Ethics, which defines the principles and underlying values of the Company's ethical code and the rules of conduct that are based on those principles; the system of powers and delegations with general and specific authorisations and the internal delegation of powers, according to the responsibilities assigned; corporate operating procedures; IT systems to support both management and production activities and also accounting and financial processes. With regard to compliance, the Issuer has had an organisational model in place pursuant to Legislative Decree No. 231/2001 since April 2003 which is continuously updated and also a control model pursuant to Law No. 262/2005 for financial reporting (further information is given below on the "Risk management and internal control systems in relation to financial reporting").

The control mechanisms described above are monitored by management, by the functions and bodies of management and control (i.e. the Board of Directors; the Control, Risk and CSR Committee; the Board of Statutory Auditors; the executive director responsible for overseeing the internal control system; and the Supervisory Body) and involve all personnel of the Recordati Group. The Group's Auditing function also conducts the independent audits called for under the annual audit plan. The results of these audits are reported to the Chairman and Chief Executive Officer, the executive director responsible for the internal control and risk management system, and to company management, as well as periodically to the Board of Statutory Auditors, the Control, Risk and CSR Committee, and the Board of Directors.

#### 11.a) Principal characteristics of the risk and internal control management system in relation to the financial reporting process.

The internal control and risk management system, as just defined, covers financial reporting which forms an integral part of it, the preparation of which is governed by organisational procedures and instructions which ensure compliance with the general principles of control laid down by the Issuer (e.g. a proper separation of functions, a proper system of authorisations and powers, checks and balances, accountability, etc.). It is based on the main established reference models (e.g. CoSO Report) being subject at the same time to verification and periodic update by means of a review of the risks to which the Company is exposed.

A description is given below, in accordance with the regulations in force, of the characteristics of the system adopted, with particular reference to (a) the stages of the risk and internal control management system in relation to the financial reporting process and (b) the roles and functions involved and the procedures for co-ordination between the parties involved.

##### (a) The stages of the risk and internal control management system in relation to the financial reporting process

The Issuer has implemented a model for the administrative and accounting control of the system (hereinafter also the "262 Control Model") for some time now in order to ensure the effectiveness of that system. It has also assigned responsibility for verifying proper application of that model and for monitoring the functioning and adequacy of the Internal Control System in relation to the model to the Manager appointed to prepare corporate accounting documents. The 262 Control Model consists of a set of corporate rules and procedures designed to enable objectives of reliability, accuracy,

<sup>19</sup> Corporate Governance Code, comment on Art. 7: "The Committee considers that at least in companies belonging to the FSTE - Mib index, an adequate internal control and risk management system must possess an internal system for employees to report any irregularities or violations of the applicable legislation and regulations and internal procedures ("whistle blowing"), in line with existing best practices nationally and internationally, which guarantee the existence of a dedicated and reserved channel for reporting these as well as the anonymity of the reporter".

completeness and promptness in financial reporting to be achieved by identification and management of the main risks attached to the preparation and disclosure of financial information.

The 262 Control Model consists of

- administrative and accounting risk assessment;
- administrative and accounting manuals and procedures, which are closely related to one another and are subject to continuous update and periodic assessment.

More specifically, administrative and accounting risk assessment is a continuous process of identifying and assessing risks attached to accounting and financial information and it is performed by the Manager appointed to prepare corporate accounting documents with the support of the Group Internal Audit Function. This process is performed annually by means of:

- the identification, by means of quantitative (size) and qualitative (importance) criteria, of items in the financial statements and in financial information which may be highly sensitive and significant or involve risks of error or omission, with reference to the financial statements of the Parent or to the consolidated financial statements of the Group;
- the identification of the relative processes and accounting information input for each significant item of the financial statements and of financial information and of the relative controls to manage the risks identified.

If control activities are not found to be adequately documented or regulated in relation to risk areas identified following periodic risk assessment, the function responsible for the process shall provide adequate support documentation, with the support of the Financial Reporting Officer and, if necessary, the Internal Audit Function, to enable the existing controls in the area subjected to analysis to be assessed.

When risks were identified as a result of annual risk assessment activities, the Company and the Group put procedures, protocols and documents in place to control administrative and accounting activities. The body of the administrative and accounting manuals and procedures is comprised of the following principal documents:

- the Group Accounting and Reporting Manual, designed to ensure the application of uniform criteria in the Group with regard to the recognition, classification and measurement in the accounts of operating and financial events;
- a system of internal certification by the management and administrative chiefs (CEO and Financial Controller) of the subsidiaries of the Recordati Group with regard to the accuracy, reliability and completeness of accounting information and its compliance with Group accounting policies and local regulations. This system, set out in the Group Accounting and Reporting Manual, is designed, amongst other things, to support the signing of certifications and attestations required by law of the Financial Reporting Officer and of the Chief Executive Officer;
- administrative and accounting procedures and protocols for closing accounts at the end of accounting periods and preparing annual financial statements and reporting packages which define control responsibilities, activities and rules to follow for the administration and accounts of the Parent Company and its subsidiaries;
- procedures for preparation of the consolidated financial statements which regulate the operations and controls to be performed for the preparation of the consolidated financial statements, describing, amongst other things, the activities to be performed in the consolidation IT system adopted by the Group and used in its subsidiaries and which define the responsibilities of the various functions for the proper functioning of that system;
- calendar of end of period activities: a document which is updated and distributed monthly, which gives deadlines for the process of closing accounts and preparing financial statements, reporting packages and the consolidated financial statements;

- operational procedures which define the activities, responsibilities and management operations in terms of authorisation, implementation, control, official approval and recognition in the accounts for those accounting and reporting areas considered significant, in co-ordination with annual accounting and administrative risk assessment. Those responsible for the functions and for the subsidiaries involved in the process of preparing and managing accounting and financial information are responsible for the proper functioning and update of the administrative and accounting internal control system in relation to all the processes and accounting reporting under their control and they must constantly monitor those administrative and accounting procedures in order to ensure that they are properly applied and appropriate to the existing processes;
- tables of administrative and accounting controls, which describe the control activities implemented in each administrative and accounting process in relation to the risk identified and the related control objectives and which summarise the results of control testing activities performed by the Internal Audit Function. The controls described by those tables represent the application of control principles described in administrative and accounting control procedures. These tables are therefore used as a tool for the identification of the key controls in place, specific to each significant process, and for the identification of tests to be performed to assess the adequacy of the administrative and accounting internal audit system. These tables are constantly updated by the Internal Audit Function.

The Financial Reporting Officer appointed to prepare corporate accounting documents assesses and testifies to the adequacy of the 262 Control Model, which is the administrative and accounting internal control system just described and to the proper functioning of the procedures in place at least twice annually, when the interim half year and annual financial statements (consolidated financial statements of the Group and separate financial statements of the Parent Company) are approved. He is supported by the testing activity performed by the Group Internal Audit Function designed to assess the adequacy of the design and proper implementation and operational effectiveness of the controls in place.

Independent testing is performed continuously throughout the year on the basis of the annual audit plan drawn up by the Chief of Group Audit. The results of testing activities, assessments of possible areas for improvement and the relative corrective action are officially published in an annual report addressed to the Chief of Group Audit, the Financial Reporting Officer and the CEO.

The Financial Reporting Officer appointed to prepare corporate accounting documents is also responsible for monitoring the administrative and accounting internal control system on the basis of information received from the chiefs of corporate functions and reports on the activities performed by the Internal Audit Function, in order to ensure that the body of procedures is updated and that the controls identified by means of the administrative and accounting procedures are actually implemented.

#### (b) Roles and functions involved in the system for the management of risks and internal control in relation to the financial reporting process

The roles involved with specific reference to financial reporting processes are: the Board of Directors, CEO, the Chief of Group Audit, the Control, Risk and CSR Committee and the Financial Reporting Officer (as well as the Director with responsibility for the internal control and risk management system).

The Financial Reporting Officer in conjunction with the CEO is responsible for putting adequate administrative and accounting procedures in place for the preparation of the separate Parent Company and consolidated financial statements.

The Board of Statutory Auditors is also called upon to perform the functions assigned by the current regulations to the Committee for internal control and accounting audit ("CICAA"), established by Legislative Decree 39/2010

(so-called "consolidated law on statutory audits"), implementing Directive 2006/43/EC on statutory audits of annual accounts and consolidated accounts, and therefore oversees the financial information process, on the effectiveness of the internal control, internal audit and risk management systems, the revision of the annual accounts and consolidated accounts, and the independence of the auditing company. Further information is given in Section 14 on the Board of Statutory Auditors.

### 11.1 DIRECTOR WITH RESPONSIBILITY FOR THE INTERNAL CONTROL AND RISK MANAGEMENT SYSTEM

On 5 February 2019 (and previously on 11 April 2017), the Board of Directors confirmed the appointment of Dr Fritz Squindo as Executive Director with responsibility for the internal control system the General Manager for the co-ordination of operations and CFO.

The Director Responsible for supervising the functionality of the internal control and risk management system:

- has identified, with the help of the Chief of Group Audit, the principal business risks, taking account of the characteristics of the activities undertaken by the Company and by its subsidiaries. In detail, he has completed the update of the Recordati Catalogue of Risks for 2018 (again with the assistance of the outside company Deloitte S.p.A.) of which he informed the Control, Risk and CSR Committee and the Board in the course of 2019 (and therefore not in parallel with the presentation of the budget for 2018 as per previous practice) in consideration of the events that interested the life of the Company and mentioned throughout this Report;
- has implemented the guidelines defined by the Board and, with the assistance of the Chief of Group Audit and other competent functions within the Company, has designed, constructed and managed the internal control and risk management system, while constantly checking its adequacy and effectiveness;
- has brought the system, again with the help of the Chief of Group Audit and other competent functions within the Company, into line with changes in operating conditions and in the legislative and regulatory framework.

The Executive Director responsible for monitoring the functionality of the internal control system:

- may request the Group Audit Function to investigate specific operational areas and compliance with internal rules and procedures in carrying out company operations, reporting promptly to the Board of Directors, to the Chairman of the Control, Risk and CSR Committee and to the Chairman of the Board of Statutory Auditors;
- shall report promptly to the Control, Risk and CSR Sustainability Committee (or to the Board of Directors) with regard to problems and difficulties found in carrying out their activities or of which they have nevertheless learnt, so that the Committee (or the Board) make undertake appropriate initiatives.
- shall submit a proposal to the Board of Directors for the appointment and removal of the Chief of the Group Audit Function and also on the remuneration for him, consistent with Company policy.

### 11.2 CHIEF OF THE GROUP AUDIT FUNCTION

It is the responsibility of the Board of Directors to appoint and remove the chief of that function on the basis of a proposal submitted by the Director Responsible for the internal control and risk management system, and also to ensure that he has adequate resources to carry out the relative functions and to set the remuneration consistent with Company policies.

The Group Audit Department, headed by Dr. Giovanni Minora, is not responsible for any operational area whatsoever and reports hierarchically from 20 December

2012 to the Board of Directors; the ordinary management of employment relationships has been assigned to the Chairman, also following the renewal of the Board of Directors on 5 February 2019. Additionally, the Board confirmed the Chief of the Group Audit Function as the Internal Control Officer pursuant to Art. 150 of Legislative Decree No. 58/1998.

When he was appointed, the Board, having consulted with the Risk, Control and CSR Committee, assessed the appropriateness of the remuneration paid to the Chief of Group Audit as an employee of the Company with respect to the Company's policies.

The duties of the Chief of Group Audit are as follows:

- to oversee, both on a continuous basis and in relation to specific needs and in observance of international standards, the functioning and the adequacy of the internal control and risk management system, by carrying out an audit plan approved by the Board of Directors, based on a structured process to analyse and set priorities in relation to the main risks;
- to prepare periodic reports containing adequate information on his activities, on the procedures employed to manage risks and on compliance with the plans drawn up to mitigate them. These periodic reports contain an assessment of the appropriateness of the internal control and risk management system;
- to promptly prepare reports on events of particular importance;
- to submit periodic reports to the Board of Statutory Auditors, the Control, Risk and CSR Committee, the Board of Directors, the Director with responsibility for the internal control and risk management system and the CEO;
- as part of the audit plan, to oversee the reliability of IT systems, including those responsible for bookkeeping.

For the purposes of the above the Chief of Auditing has direct access to all information useful for performing his/her duties;

Furthermore, the Chief of Group Audit:

- explains the proposed annual work programme to the Control, Risk and CSR Committee in order to implement any recommendations that the Committee may intend to make;
- assists the Executive Director responsible for overseeing the functionality of the internal control and risk management system with the design, management and monitoring of the internal control and risk management system and with the identification of the various risk factors;
- schedules and carries out, consistent with the annual work plan, direct and specific audit activities at Recordati S.p.A. and at all the subsidiaries, with particular regard to companies of strategic importance, in order to detect any failings there may be in the internal control and risk management system, in the various risk areas.
- checks that the rules and procedures for auditing and risk management processes are observed and that all individuals involved act in accordance with the predetermined objectives;
- carries out checks on his own initiative or at the request of the Board of Directors, the Control, Risk and CSR Committee, the Executive Director responsible for monitoring the functionality of the internal control and risk management system or the Board of Statutory Auditors.

In detail, during the course of the Year and in meetings of the Board of Directors already held in 2019, the Chief of Group Audit:

- explained the annual work programme and the organisational structure of his function to the Audit, Risk and Sustainability and Risk Committee;
- had direct access to all the necessary information to carry out his role;
- carried out direct and specific auditing tasks, in a manner consistent with the annual work plan;
- reported to the Executive Director responsible for monitoring the functionality of the internal control system on the results of the auditing activities undertaken during the Year;

- reported on his actions and on the results of the activities undertaken to the Control, Risk and CSR Committee and to the Board of Statutory Auditors of the Company.

The Chief of Group Audit had an operating budget which was used to carry out the audits and checks performed during the Year.

The Board of Directors was informed by the Control, Risk and CSR Committee of the organisational structure of the Group Audit Function and it agreed with the assessment of its adequacy in carrying out the responsibilities assigned to it and drawing up the audit plan approved for 2018.

### 11.3 ORGANISATIONAL MODEL PURSUANT TO LEGISLATIVE DECREE 231/2001.

The Italian companies of the Recordati Group (Recordati S.p.A., Innova Pharma S.p.A., Orphan Europe Italia S.r.l. and Italcimici S.p.A.) have adopted their own model of organisation, management and control as envisaged under Italian Legislative Decree 231/2001 concerning the administrative liability of organisations. More specifically, Recordati, the Group Parent, adopted its model in 2003, with the latest update in 2017, and the subsidiaries Innova Pharma Orphan Europe Italy updated their Model in July 2018. In addition, in 2018, the company Italcimici S.p.A., acquired by Recordati in June 2016, also adopted its own Organisational model. In 2018, a plan was drawn up for the implementation and adoption of an Organisational Model pursuant to Legislative Decree 231/2001 also for the company Natural Point S.r.l., acquired by Recordati in June 2018. Natural Point is expected to adopt its Organisational Model pursuant to the aforementioned decree by the first half of 2019.

In accordance with Confindustria guidelines, the organisational models of the Italian companies of the Recordati Group are dynamic, effective mechanisms as a result of constant monitoring and updating by the Supervisory Bodies. The organisational models call for specific, confidential channels for the reporting of violations or other anomalies by employees and periodic personnel training on the content of Decree 231/2001 and of the organisational model. The Supervisory Bodies, which have been appointed within the Group's Italian companies, are boards comprising of the Chief of the Internal Audit unit and outside experts. Each Supervisory Body has its own internal regulations and operate in accordance with a specific programme. The Supervisory Bodies also periodically report to the boards of directors and of statutory auditors (where applicable).

For the subsidiaries located abroad, policies with a function similar to those of the organisational model pursuant to Legislative Decree 231/01 adopted by the Company have been implemented or are being implemented, where considered necessary based on local laws and regulations.

In particular, on 14 March 2018 Spanish subsidiary Casen Recordati adopted a Management and Control Organisational Model in compliance with Ley Organica 2015/1 of 30 March 2015 which introduced in the Spanish criminal code some relevant changes concerning the criminal liability of legal persons. This law, in relation to the conditions for the exemption from administrative liability for legal persons, borrowed the legislative structure envisaged in Italy by Legislative Decree 231/01. The model adopted by the Spanish subsidiary therefore has a similar approach to the 231 Models adopted by the Italian companies of the Group. Also, in the Spanish subsidiary, a collective Supervisory Body has been appointed and is operative, as required by best practices. In 2018, the Supervisory Body of the Spanish subsidiary adopted its own operating regulations, prepared a plan of activities and verifications and provided training sessions on the themes of the Model (including, in particular, those concerning anti-corruption) to all staff of the subsidiary.

In 2012, the Board of Directors, assisted by the then Risk, Control and CSR Committee, had also assessed whether to assign the functions of the Supervisory Committee (pursuant to Legislative Decree No. 231/2001 in accordance with Law No. 183/2011 – the 2012 "Stability" Law), and decided in favour of Recordati continuing to maintain a Supervisory Committee as a highly specialised unit, dedicated entirely to the supervision of ethical, preventative, organisational and management procedures adopted to prevent incurring liability within the meaning of Legislative Decree No. 231/2001 and therefore with specific expertise on compliance with a particular area of law which applies to the Company. These functions were not therefore assigned to the Board of Statutory Auditors.

The Organisation, Management and Control Models adopted by the Group's Italian companies, pursuant to Legislative Decree 231/2001, are constantly monitored by the Supervisory Bodies in charge. The Models are subject to constant updating both for the introduction or updating of the regulations of interest and for organisational changes or internal processes. The updates concern the General part of the Model, with adjustments to risk mapping, the disciplinary system and other general elements and the Special part of the Model, made up of behavioural protocols.

The Models consist of a general part and a specific part, arranged into different sections. The general part includes, inter alia, the Code of Ethics, the Disciplinary System and the By-Laws of the Supervisory Board. The specific part includes, inter alia, a "map" of the areas where the risk of crime is more marked and a significant number of "protocols" through which measures are put in place to prevent offences being committed in the areas identified in the map.

A presentation of the Model adopted by the Company is available on the Company's website at [http://www.recordati.it/en/corporate\\_governance/compliance\\_programmes/](http://www.recordati.it/en/corporate_governance/compliance_programmes/)

### 11.4 CODE OF ETHICS

Approved by Recordati S.p.A. in 2002 and constantly updated and supplemented, the Code of Ethics is a clear embodiment of the Company's values, including: protection of the individual; fairness and equality; ethical conduct and compliance with the law; loyalty; the confidentiality of information; respect of the interests of all stakeholders; professionalism; and the protection of health and the environment.

The Code of Ethics is normally adopted by all the companies of the Recordati Group.

By way of the Code of Ethics, the Group undertakes to ensure equal employment opportunities without discrimination, to lead the way in the protection of the environment and of individual health, to promote and protect the health of our employees, and to provide technical and career training for them.

In conducting operations, the Group ensures that there is a constant balance between the pursuit of profit and the observance of the law and of ethics, while taking account of corporate social responsibility and the need to prevent the risk of violations of the law.

The Code of Ethics establishes the rights, duties and responsibilities of all those who work for Recordati in whatever capacity and represents a point of reference in regulating the various activities of all companies of the Group. The conduct specified in the Code of Ethics concerns a range of areas within the organisation. The rules of conduct established in the Code of Conduct include:

the need to avoid conflicts of interest; the prohibition of corruption, unlawful favouritism, and collusion; responsibilities in the use and protection of company information; and relations with government, political organisations, trade unions, and the media.

The Code of Ethics, which has been or is being adopted by all companies of the Group, is an integral part of the model of management, organisation and control pursuant to Legislative Decree 231/2001 for Italian companies and is one of the cornerstones of the model itself.

Observance of the Code of Ethics is not only required of directors, management, employees, and all who work within the Group, but is also an integral part of the obligations of trading partners and other third parties, such as vendors, consultants, agents, partners, and whoever has relations with the companies of the Recordati Group.

Distribution and dissemination of the Code of Ethics is handled directly by the Parent Company for the Italian companies of the Group.

All employees are provided with a copy of the Code of Ethics, and it is also available on the Company's website. In 2018, a new distribution of the Code was made to 1325 employees of companies of the Group.

The current version of the Recordati Group's Code of Ethics will be subject to a general review in the course of 2019. Subject to all the principles already present in the Code, the document will be reviewed with a view to greater legibility and usability and will be updated with further behavioural guidelines.

### **The Recordati Group's Anti-Bribery Model**

Because of our international reach, the Recordati Group is present in a diverse range of social, cultural, economic and political contexts and is responsible for acting in accordance with applicable laws based on an awareness that any act of corruption would compromise the integrity of the business would jeopardise the organisation and would expose the company to legal and financial risks and risks to the company image.

The Group is firmly committed to conducting business transparently, honestly and ethically in every nation in which we operate, and we reject all forms of corruption, aware of the potential risks deriving from numerous relations with government that are typical of the industry in which the Group operates.

To that end, since 2009, the Group has been conducting an assessment of the status of internal mechanisms in accordance with the main international and supranational anti-bribery laws and regulations in the countries in which we have branches.

The Group's anti-bribery programme involves the employees of both the Parent Company and of the various branches and is made up of four stages:

1. assessment of local and supranational legislation;
2. assessment of the local systems, procedures and models to protect against corruption;
3. analysis of inherent risks and of existing mechanisms for identifying residual risks;
4. definition and release of the Group's Anti-Bribery Model.

Based on the documentation and information gathered, 13 areas of the organisation potentially exposed to a risk of corruption were identified, and the principles of conduct to avoid corruption have been defined for these areas. Based on this analysis, an Anti-Bribery Manual for the Group has been implemented.

The 13 areas most exposed to the potential for corruption risk are the following: Research and Development; Production; relations with doctors and healthcare organisations; regulatory activities; transactions with government; consulting; medicine samples; courses and conferences; promotional material; donations; financial transactions; Human Resources; and relations with politicians and political organisations.

The Manual was distributed to Recordati's subsidiaries in Spain, France, Russia, Turkey, Portugal and Germany and is being distributed in the remaining Group subsidiaries.

The current version of the Antibribery Manual is under revision and, in the course of 2019, an updated version of the Manual is expected to be distributed in all Group companies.

The Group's German subsidiary adopted its own Compliance Manual in 2018 aimed at guiding behaviours and regulating activities in relation to the medical profession in accordance with the introduction of articles 299 a/b of the German Criminal Code (corruption of operators in the health sector).

In 2018, the French subsidiaries of the group adopted procedures and systems to comply with national whistle blowing legislation. In the course of 2019, the same subsidiaries will start, with the support of the Group Audit Department, an anti-corruption assessment in reference to the French legislation called "Loi Sapin 2". Although the French subsidiaries are both below the thresholds for the obligations established by the aforementioned law, the Recordati Group intends to check the existing anti-corruption control measures existing in light of the aforementioned legislation.

In order to improve the communication, coordination and auditing of activities between the Parent Company and the Group's various subsidiaries, specific information flows regarding anti-corruption and counter-terrorism were defined in 2018, which will allow them to be managed through dedicated channels managed by the Group Audit Department for the knowledge and management of situations of potential risk. The aforementioned system of information flows will be fully implemented during 2019.

With regard to communication and training on the issues of corruption and the principles defined in the Recordati Group's Code of Ethics, all members of the Recordati S.p.A. Board of Directors were informed of the policies and procedures adopted in 2017. In 2018, anti-bribery training was also provided to a total of 933 employees, of which 292 in Italy and 641 in the Group's branches outside Italy.

### **Other models of control and adoption of national codes of ethics**

The systemic approach of the model of organisation, management and control defined under Legislative Decree 231/2001 may also be found in other models in other areas of the company, such as within the scope of health and safety in the workplace, environmental management, and data protection.

Regarding data management and privacy, the Recordati Group has conformed to the new General Data Protection Regulation (No. 2016/679, hereinafter "GDPR"). The project allowed all the companies of the Group to adopt the measures envisaged by European regulation. More specifically, compliance with the GDPR led to the definition and implementation of a privacy management model with new rules and business processes, both at the group level and at the local level, in Recordati's European subsidiaries. On the organisational front, the most significant change was the appointment of a Data Protection Officer (in the person of the Group Auditing Director) and of a Key Privacy Person in each subsidiary concerned. With regard to the processes

and operating rules, a set of Group policies was adopted, from which local procedures already adopted by the various branches derive. Activities that will lead to the adoption of an IT tool that will be used to allow a better and more effective operating activity in application of company procedures are underway and will continue in 2019.

The Recordati Group also adheres to the codes of self-regulation issued by industry associations that oversee activities related to detailing activities. A large portion of the Group's branches has adopted the codes of ethics defined by their local pharmaceutical associations. These codes of conduct are based on the European Federation of Pharmaceutical Industries and Associations (EFPIA) code, which establishes the ethical standards for European pharmaceutical firms for the management of detailing activities and relations with the medical community.

Within the scope of involvement with the industry associations and adoption of their codes of ethics, the branches are taking specific action aimed at maximising transparency in their management of relations with the medical and scientific community. This includes Project Transparency (and publication of the "Transfers of Value" for healthcare organisations and operators) and the certification of detailing procedures. This disclosure is provided by many of the Group's companies, in compliance with legal rules (such as those that apply in France, Portugal and the USA) and with ethical standards (in addition to Italy, Spain, Germany and others).

### 11.5 AUDIT FIRM

KPMG S.p.A. is the firm of external auditors appointed to audit the Company. The appointment was formally made by a Shareholders' Meeting on 13 April 2011 for the years 2011-2019, as proposed by the Board of Statutory Auditors.

### 11.6 THE FINANCIAL REPORTING OFFICER

From 3 May 2007 the role of Manager in charge of preparing the accounting and corporate documents is entrusted to Fritz Squindo, General Manager for the coordination of management by the Board of Directors. The Board of Directors appointed on 5 February lastly expressly confirmed this appointment.

Already during the first appointment, it was confirmed that he satisfied the requirements of respectability and professionalism laid down in the applicable legislation and in the Company's By-Laws, which stipulate, in Art. 25, that the Financial Reporting Officer must not only satisfy the requirements of respectability laid down by law for those performing administrative and managerial duties but also the requirements of professionalism characterised by specific competence in administrative and accounting matters. This competence, to be verified by the Board of Directors, must be acquired through working experience in a position of adequate responsibility over a suitable period of time.

The manager appointed to prepare the corporate accounting documents is given duties and powers to perform that assignment which include the provisions of the operational guidelines for that manager approved by the Board of Directors on 3 May 2007.

### 11.7 CO-ORDINATION BETWEEN THOSE INVOLVED IN THE INTERNAL CONTROL AND RISK MANAGEMENT SYSTEM

The Company has specified the roles and responsibilities of those involved in the internal control and risk management system in detail, in the guidelines for the internal control and risk management system of Recordati S.p.A. and of the Recordati Group and also the procedures for co-ordination between the parties involved

In this respect, the Company encourages meetings between the different roles involved in order to exchange information and to co-ordinate. As already reported, the entire Board of Statutory Auditors in particular is constantly invited to participate in the proceedings of the Control, Risk and CSR Committee and also the Director Responsible for the internal control and risk management system, the Chief of Group Audit, the Supervisory Committee pursuant to Legislative Decree No. 231/01, and senior representatives of the external audit firm have participated in various meetings on invitation of the Chairman of the Committee and on individual items on the agenda.

The Board of Statutory Auditors of the Company and the Supervisory Committee pursuant to Legislative Decree No. 231/01 have organised and held joint meetings during the year for the same purposes of co-ordination on matters of common interest.

Finally, the Board of Statutory Auditors meets periodically with the Financial Reporting Officer, the external auditors and the various corporate functions involved in the processes and procedures that must be subject to specific audit by the Board of Statutory Auditors, including those relating to the internal control and risk management system.

### 11.8 REGULATIONS FOR CONTROLLED FOREIGN COMPANIES LOCATED IN NON-EU COUNTRIES

In relation to the provisions of Art. 15 and Art. 18 of the Markets Regulations concerning the conditions for the listing of the parent companies of companies formed and regulated under the laws of countries that do not belong to the EU and which are of significant importance for the purposes of consolidated financial statements, since 31 December 2018 the regulatory provisions of Art. 16 of the Markets Regulations have applied to the Turkish subsidiary Recordati İlaç Sanayi Ve Ticaret Anonim İrketi, to the American subsidiary Recordati Rare Diseases Inc and to the Russian subsidiary Rusfic Llc.

With reference to those companies, the Company:

- publicly discloses its financial statements used for preparing consolidated financial statements;
- ensures that they regularly deliver information to the external auditor of the Parent Company needed to audit the annual and interim accounts of the Parent Company itself.

Finally, the Company possesses continuous knowledge of the composition of the corporate bodies of the controlled companies with information on the company officers and on the corporate by-laws of the companies.



## 12. DIRECTORS' INTERESTS AND RELATED-PARTY TRANSACTIONS

Subject to the opinion in favour of the Risk, Control and CSR Committee identified as the Committee Responsible pursuant to Art. 4 paragraph 3 of Consob Regulation No. 17221 of 12 March 2010, in a meeting held on 24 November 2010, the Board adopted "Regulations for related-party transactions" in accordance with Art. 2391-bis of the Italian Civil Code and with the Regulations just mentioned to replace the "Procedure for significant transactions with related parties or when a Director has an interest in the transaction" adopted in 2008.

The Regulations for Related-Party Transactions (the full text is available on the Company website at [http://www.recordati.it/en/corporate\\_governance/related\\_parties/regulations\\_for\\_related-party-transactions](http://www.recordati.it/en/corporate_governance/related_parties/regulations_for_related-party-transactions)) in force since 1 January 2011, defines the guidelines and the criteria for the identification of related-party transactions and gives details of the roles, responsibilities and operating procedures designed to ensure adequate reporting transparency and the relative proper conduct in form and substance for those transactions. The Company has also issued internal rules in order to ensure that the Regulations are fully implemented.

At the beginning of 2017, the Board therefore carried out a periodic review of the Related Party Transactions Regulations, three years having passed since it was last updated and, having taken note of the opinion given by the Risk, Control and CSR Committee, it considered that those regulations were still adequate, not requiring substantial modifications, but only modifications of a formal character.

The following was performed on the basis of these Regulations:

- the Risk, Control and CSR Committee (now the Control, Risk and CSR Committee) was identified as the Committee Responsible for issuing a reasoned opinion on both transactions of Major Importance and transactions of Minor Importance, except for related-party transactions concerning remuneration, for which the Committee Responsible would be the Remuneration Committee. As already reported both committees are composed exclusively of independent Directors;
- a related-party transaction is defined as any transfer of resources, services or obligations
- (i.e. any contractual commitment) between Recordati – either directly or through its subsidiaries – and one or more Recordati Related Parties, independently of whether any consideration has been agreed upon;
- a Recordati related-party is defined as:
  - (a) the parent of Recordati and its shareholders;
  - (b) any other party which, either directly or indirectly, including through subsidiaries, trust companies or intermediaries and/or jointly with other parties (also defined as related parties):
    - (i) exercises Control over Recordati, is controlled by it or is subject to Common Control;
    - (ii) holds an interest in the share capital of Recordati such that it is able to exert Significant Influence over it;
  - (c) an associate company of Recordati;
  - (d) a joint venture in which Recordati S.p.A. is a venturer;
  - (e) an executive with strategic responsibilities of Recordati or its parent;
  - (f) a close member of the family of one of the parties referred to in letters (a), (b) or (e);
  - (g) entity in which one of the parties referred to in letters (e) or (f) exercises Control, Joint Control or Significant Influence or holds, either directly or indirectly, a significant proportion, and in any case not less than 20%, of the voting rights;

(h) a collective or individual, Italian or foreign, supplementary pension fund, formed for the benefit of Recordati employees, or any other entity related to it, to the extent by which that fund has been formed or promoted by Recordati, or in the circumstance that Recordati may influence its decision-making processes.

- Key Management Personnel are those persons defined as such in accordance with the legislation and regulations in force from time to time. At present these are such persons who have power over and responsibility, either directly or indirectly, for the planning, management and control of the activities of the Company, including the Directors (executive and non-executive) of the company itself, full members of the Board of Statutory Auditors, the General Managers, the manager appointed to prepare corporate accounting documents (the "Financial Reporting Officer") and all those additional persons identified from time to time as such by the Board of Directors, and proposed by the Chief Executive of the Company.
- Transactions of Major Importance are defined as those related-party transactions for which at least one of the relevance indicators contained in the aforementioned Attachment No. 3 of the Consob Regulations and which are applicable according to the characteristics of each related-party transaction (i.e. value of the transaction in relation to shareholders' equity or, if greater, to capitalisation; total assets of the entity involved in the transaction compared to the total assets of the Company; total liabilities of the entity acquired compared to the total assets of the Company) exceeds 5%;
- Transactions of Minor Importance are defined as those related-party transactions which are not transactions of Major Importance and not transactions of negligible amounts i.e. transactions for an individual amount of less than €150,000.

The Regulations do not apply to:

- Transactions of Negligible Amounts unless more than one Transaction of Negligible Amounts is performed as part of a single plan, the total value of which exceeding the sum of €150,000;
- intercompany transactions provided that no Significant Interests of other related parties of the Company exist in the subsidiaries of Recordati or in associate companies of Recordati which counterparties to the transaction are. It is considered that the existence of "Significant Interests" of other related parties could be determined by:
  - the existence of a significant amount receivable by the Chief Executive Officer of the Parent from a subsidiary;
  - one or more directors or other executives with strategic responsibilities shared between companies who benefit from share-based incentive schemes (or in any case variable remuneration) dependent on the results of subsidiaries or associate companies with which the transaction is performed;
  - an interest held in a subsidiary or associate company (even indirectly) by the party that controls the parent.
- shareholders' resolutions pursuant to Art. 2389, paragraph one of the Italian Civil Code, concerning the remuneration due to members of the Board of Directors and resolutions concerning the remuneration of Directors appointed to special positions which forms part of the total amount determined in advance by shareholders in accordance with Art. 2389, paragraph three of the Italian Civil Code;
- shareholders' resolutions pursuant to Art. 2402 of the Italian Civil Code, concerning the remuneration due to members of the Board of Statutory Auditors;
- remuneration schemes based on financial instruments approved by shareholders in accordance with Art. 114-bis of the Consolidated Finance Law and the relative transactions to implement them;
- decisions (other than those referred to under the preceding letter c) concerning the remuneration of Directors, Directors appointed to special positions and other executives with strategic responsibilities, when (i) the

Company has adopted a remuneration policy (the formulation of which involved a committee formed exclusively of non-executive directors, the majority of which are independent) (ii) the Company has submitted a report which illustrates the remuneration policy to a Shareholders' Meeting for approval or a consultative vote, and (iii) the remuneration actually assigned is consistent with that policy;

- decisions, to be taken when a professional arrangement is established with Recordati, concerning the remuneration of executives with strategic responsibilities, other than Directors and members of the Board of Statutory Auditors;
- transactions which fall within the ordinary performance of operating activities and the related financial activities concluded under conditions equivalent to market conditions or standards (i.e. conditions similar to those normally practiced with non-related parties for transactions of an analogous nature, magnitude and risk or based on regulated tariffs or on compulsory prices or those practiced for parties with which the Company is obliged by law to negotiate at a determined consideration). The "ordinary performance" is identified by considering the contents, recurrence, function or purpose and timing of the transaction and also the nature of the counterparty, even if it is a related-party. Operating Activities are defined as the main revenue generating activities and all other normal activities of the Company that are not classifiable as investment or financial activities pursuant to International Financial Reporting standard seven adopted by EC Regulation No. 1126 of 2008, as subsequently amended from time to time. Should the exemption contained in this point apply, the Company is nevertheless required, without prejudice to Art. 114, paragraph 1 of the Consolidated Finance Law, to comply with the provisions of Art. 13, paragraph 3, letter c), points i) and ii) of the Consob Regulation No. 17221 of 12<sup>th</sup> March 2010;
- demerger transactions in the strict sense of the proportional type, share issues with option rights reserved to shareholders and to any holders of financial instruments (therefore issuances which are performed without excluding their option rights) and transactions for the purchase/sale of treasury stock if performed, other conditions remaining the same, to the benefit of both related parties and all others holding rights;
- transactions to be performed on the basis of instructions for the purpose of stability issued by the supervisory authority, without prejudice to disclosure obligations under Consob Regulations.

The Company Annual Report may be consulted with regard to transactions with related parties carried out in 2018.

### 13. APPOINTMENT OF STATUTORY AUDITORS

The appointment of Statutory Auditors is governed by art. 26 of the By-Laws, which is given below:

*"Art. 26) The Shareholders' Meeting shall appoint the Board of Statutory Auditors, comprising three statutory auditors and two alternate auditors, who may be re-elected, and shall determine their remuneration. Their powers, duties and term of office shall be as established by law. Auditors shall satisfy the requirements laid down in current laws and regulations. As regards requirements of professionalism, the matters and sectors of activity strictly connected with that of the company are the research, production and sale of chemical and pharmaceutical products. The minority shareholders shall elect one Statutory Auditor and one Alternate Auditor.*

*Unless otherwise provided for in laws or regulations, the Board of Statutory Auditors shall be appointed according to the procedures set out in the following paragraphs on the basis of slates submitted by Shareholders in which candidates are listed by means of a progressive number and in compliance with the existing legislation in force concerning gender balance.*

*The slate must specify whether each candidate is nominated for the position of Statutory Auditor or for the position of Alternate Auditor.*

*Only Shareholders individually or jointly possessing a total number of shares with voting rights representing at least 2.5% of capital stock or representing a lesser percentage as established or provided by binding legal or regulatory provisions which shall be specified in the notice of meeting, shall have the right to present slates.*

*Each shareholder, including shareholders who have signed a shareholders' agreement identified in article 122 of Italian Legislative Decree No. 58/1998, controlling entities, subsidiaries, and jointly controlled entities, is prohibited from individually or jointly submitting more than one slate or voting for different slates, even through a third party or trust company. Each candidate may only run on one slate on penalty of disqualification. Endorsements of slates and votes cast in violation of this prohibition shall not be attributed to any slate.*

*The slates submitted shall be deposited at the Company's head offices at least twenty-five days before the date scheduled for the first convocation of the Shareholders' Meeting without prejudice to further disclosure required by regulatory or other provisions in force at the time. Without prejudice to any further procedural duty required by the legislation and also by the regulations currently in force, the following must be deposited together with each slate, within the time limit already mentioned:*

- a) information on the identity of the shareholders who have submitted the slates, indicating the total percentage of capital stock held;*
- b) a declaration by shareholders other than those who hold, singly or jointly, a controlling interest or relative majority, attesting to the absence of any forms of association with such shareholders, as provided for by the regulations in force;*
- c) a thorough report of the personal characteristics of candidates and a declaration from the said candidates attesting that they possess the requirements established by law, together with their acceptance of the candidature.*

*Slates containing a total number of candidates equal to or greater than three must be composed of candidates belonging to both genders, so that a percentage of candidates to the position of Statutory Auditor and candidates to the position of Alternate Auditor are equal to that required by the legislation in force at the time concerning gender balance for the composition of the Board of Statutory Auditors belongs to the less represented gender in a given slate. Slates not satisfying the requirements specified above shall be considered as not having been submitted.*

*Statutory Auditors shall be elected as follows:*

- 1. from the slate which obtained the highest number of votes at the Shareholders' Meeting, two Statutory Auditors and one Alternate Auditor shall be elected, based on the progressive order with which they are listed in the sections of the slate;*
- 2. from the second slate which obtained the highest number of votes at the Shareholders' Meeting and which, in accordance with regulations in force, has no connection, not even indirectly, with those who submitted and voted for the slate which obtained the highest number of votes, one Statutory Auditor, who shall chair the Board of Statutory Auditors, and one Alternate Auditor shall be elected, based on the progressive order with which they are listed in the slate.*

*In the event of a tie between slates for the appointment of the Auditors indicated in point 2 of the foregoing paragraph, the slate submitted by shareholders owning the largest shareholding or, alternatively, the slate submitted by the largest number of shareholders shall prevail.*

*If by following the above procedures, the composition of the full members of the Board of Statutory Auditors in compliance with the legislation in force at the time concerning gender balance is not ensured, the necessary replacements shall be made from the candidates to the position of full Statutory Auditor on the slate that obtained the majority of votes on the basis of the order of the names on the slate.*

*Should a single slate or no slate be submitted, all candidates for that position named on the aforesaid slate or those voted by a Shareholders' Meeting (as long as they receive a relative majority of the votes cast in the Shareholders' Meeting) shall be elected as Statutory and Alternate Auditors and provided the existing legislation in force on gender balance is complied with.*

*Should they no longer satisfy the requirements laid down by law and in the by-laws, the auditor shall leave office.*

*Should it become necessary to replace a Statutory Auditor, the Alternate Auditor belonging to the same slate as the outgoing auditor shall take the latter's place or, failing this, should the minority auditor leave office, he shall be replaced by the next candidate on the slate from which the outgoing auditor was elected, or, alternatively, by the first candidate on the minority slate that obtained the second highest number of votes.*

*It is understood that the Board of Statutory Auditors shall continue to be chaired by the minority auditor and the composition of the Board of Statutory Auditors must comply with the existing legislation in force on gender balance.*

*The procedure outlined below shall be followed when the Shareholders' Meeting is required to appoint Statutory and/or Alternate Auditors to complete the board: if it is necessary to replace auditors elected on the basis of the majority slate, the replacements shall be appointed by relative majority vote without slate voting; if, however, it is necessary to replace auditors elected on the basis of the minority slate, the Shareholders' Meeting shall replace them by a relative majority vote by choosing them from the candidates on the slate from which the outgoing auditor was elected or on the slate that obtained the second highest number of votes.*

*Should the application of the above procedures not result in the replacement of the auditors designated by minority shareholders for whatever reason, the shareholders' meeting shall hold a relative majority vote, following the presentation of candidatures by shareholders that, individually or together with others, possess shareholdings with voting rights that represent at least the percentage indicated above in relation to the procedure for the presentation of slates. However, votes registered by shareholders who hold the relative majority of voting rights that may be exercised in the meeting as identified in disclosures made in accordance with applicable regulations, whether directly, indirectly, or jointly with other shareholders who have signed a shareholders' agreement as indicated in article 122 of Italian Legislative Decree No. 58/1998, shall not be considered in establishing the outcome of said vote.*

*The replacement procedures set forth in the above paragraphs must in any event ensure compliance with the legislation in force at the time concerning gender balance.*

*Members of the Board of Statutory Auditors may participate in meetings remotely by means of audio-visual connection, video conferencing or telephone link-up systems.*

*In the above case:*

- *the following must always be established:*
  - a) *the identity of all members attending, at each point of connection, shall be confirmed;*
  - b) *each member attending shall be permitted to express a personal opinion verbally, to view, receive or send any documentation and to participate simultaneously in the discussion of the points at issue and pass resolutions;*
- *meetings of the Board of Statutory Auditors shall be considered to be held at the place where both the Chairman and Secretary are located. The statutory audit of the Company's accounts shall be performed by the Audit Firm on the basis of applicable regulations".*

It is underlined that the right to submit slates is only held by shareholders who, individually or together with other shareholders submitting slates, hold voting shares representing at least 2.5% of the voting capital in the Ordinary Meeting, or representing any lower percentage established by mandatory laws or regulations. In accordance with articles 144- quater and 144- septies of CONSOB resolution no. 13 of 24 January, the percentage of the share capital required to present slates of candidates to the Board of Statutory Auditors of the Company is currently 1%.

The minority slates shall elect one Statutory Auditor and one Alternate Auditor. As regards the appointment mechanism adopted for choosing the candidates on the various slates submitted, note that, again according to the above transcribed Art. 26 of the By-Laws, two Statutory auditors and one Alternate auditor are elected from the slate which obtained the highest number of votes in the Shareholders' Meeting, based on the progressive order with which they are listed in the sections of the slate; from the second slate which obtained the highest number of votes after the first slate and which has no connection, not even indirectly, with the shareholders who submitted or voted for the slate which obtained the highest number of votes, one Statutory Auditor, who will chair the Board of Statutory Auditors, and one Alternate Auditor are elected, based on the progressive order with which they are listed in the slate.

With regard to the legislation on gender balance in corporate bodies (articles 147-ter and 148 of the TUF, Art. 144-undecies of the Issuers Regulations, as amended by Law No. 120/2011), which apply to the renewal of corporate bodies subsequent to 18 August 2012, the Company made the necessary amendments to the By-Laws on 8 May 2012 in order to comply with the new regulations. Reference may be made in this respect to the text of article 26 reported above in full.

In particular, the Board of Statutory Auditors shall be appointed in compliance with the existing legislation in force on gender balance (and in any case on the basis of slates of candidates presented by shareholders).

Furthermore, it is noted that the Company acknowledged recommendations concerning diversity, including gender diversity, in the composition of the corporate bodies, including the Board of Statutory Auditors, introduced in the Corporate Governance Code in July 2018.

Finally, we report that article 19, paragraph 3 of Legislative Decree No. 39/2010, as amended by Legislative Decree No. 135/2016, requires that members of the committee for internal control and the accounting audit – which for "public interest entities" is the Board of Statutory Auditors – are competent as a whole and also in the sector in which the company operates.

## 14. STATUTORY AUDITORS

### (COMPOSITION AND FUNCTIONING OF THE BOARD OF STATUTORY AUDITORS PURSUANT TO ART. 123 BIS, PARAGRAPH 2, LETTERS D AND D-BIS, OF THE CONSOLIDATED FINANCE LAW)

The composition of the Board of Statutory Auditors in office on the closing date of the Year is shown below. The Board was appointed by the Ordinary Shareholders' Meeting of 11<sup>th</sup> April 2017 and its term of office will expire at the Shareholders' Meeting called to approve the financial statements for the year ended 31 December 2019.

At the Ordinary Shareholders' Meeting of 11 April 2017, two slates for the position of statutory auditor were presented: one by the shareholder FIMEI S.p.A., holder of 108,308,905 ordinary shares equal to 51.791% of the Recordati S.p.A. share capital, and another, following the shareholding required in order to present a minority slate being cut in half, presented by other institutional investors, who collectively held 1,587,431 shares equal to 0.7591% of share capital.

In detail:

The first slate, presented by FIMEI S.p.A., named the following individuals to be members of the Board of Statutory Auditors:

#### Statutory Auditors

Dr. Marco Nava

Dr. Marco Rigotti

Dr. Livia Amidani Aliberti

#### Alternate Auditors

Dr. Patrizia Paleologo Oriundi

Dr. Marco Viganò

The second slate presented by the institutional investors named the following individuals to be members of the Board of Statutory Auditors:

#### Statutory Auditors

Dr. Antonio Santi

#### Alternate Auditors

Dr. Andrea Balelli

As a result, and in accordance with the mechanism established to ensure female representation on the board, the following individuals were elected:

Dr. Antonio Santi Statutory Auditor and Chairman

Dr. Marco Nava Statutory Auditor

Dr. Livia Amidani Aliberti Statutory Auditor

Dr. Patrizia Paleologo Oriundi Alternate Auditor

Dr. Andrea Balelli Alternate Auditor

The voting share capital represented 78.595% of the share capital with voting rights of the Issuer. A total of 117,279,915 shares were in favour of slate no. 1 (56.081% of the share capital with voting rights). A total of 46,973,778 shares were in favour of slate no. 2 (22.462% of the share capital with voting rights).

The composition of the Board of Statutory Auditors complies with the criteria indicated in the applicable provisions on balance between genders and therefore at least one third of the actual and alternate members are members of the less represented gender.

Curricula vitae providing information on the personal and professional characteristics of each candidate were attached to the slates presented by FIMEI and by institutional investors, accompanied by a list of the management and supervisory positions occupied in other companies and which are significant in accordance with the law and also by declarations made by each candidate that they accept their candidature and that there are no grounds for ineligibility or incompatibility and that they satisfy the requirements prescribed by law and in the By-Laws for the office of Statutory Auditor. The above documentation may be consulted on the website [www.recordati.it](http://www.recordati.it) (in the section Investor Relations, Shareholders' Meetings, financial year 2017). The personal and professional characteristics of each auditor are in any case contained in Attachment 1 of this Report.

#### QUORUM TABLE OF THE COMPOSITION AND STRUCTURE OF THE BOARD OF STATUTORY AUDITORS AS AT 31 DECEMBER 2018 AND CURRENTLY IN OFFICE<sup>1</sup>

Chairman	ANTONIO SANTI	2017	1977	11.4.2017	Approval of 2019 financial statements	m	X	X	8/8	1
Statutory Auditor	LIVIA AMIDANI ALIBERTI	2014	1961	11.4.2017	Approval of 2019 financial statements	M	X	X	8/8	2
Statutory Auditor	MARCO NAVA	2008	1960	11.4.2017	Approval of 2019 financial statements	M	X	X	8/8	0
Alternate Auditor	PATRIZIA PALEOLOGO ORIUNDI	2014	1957	11.4.2017	Approval of 2019 financial statements	M	X	X	N/A	2
Alternate Auditor	ANDREA BALELLI	2017	1975	11.4.2017	Approval of 2019 financial statements	m	X	X	N/A	1

\* M/m are given in this column where "M" indicates a member elected from the majority slate and "m" from a minority slate.

\*\* This column contains the percentage attendance of Auditors at the relative board meetings of Statutory Auditors (number of presences/number of meetings held during the actual period office of the person concerned).

\*\*\* This column gives the number of positions as a Director or Statutory Auditor held by the person in accordance with article 148-bis of the TUF and the relative provisions for implementation contained in the Consob Issuers' Regulations. The full list of appointments is published by the Consob on its website in accordance with Art. 144 quinquiesdecies of Consob's Issuers' Regulations. Furthermore, all positions held by Statutory Auditors are given in full in the section of this Corporate Governance Report containing the curricula vitae of the Statutory Auditors.

#### QUORUM REQUIRED FOR THE PRESENTATION OF SLATES WHEN DIRECTORS WERE LAST APPOINTED: 1%

Number of meetings held during 2018

8

Statutory auditors' fees are set by a Shareholders' Meeting when they are appointed.

The fees for the Board of Statutory Auditors in office were set by a Shareholders' Meeting held on 11 April 2017, at the same amounts as previously set, with an annual fee of €50,000 for the Chairman of the Board of Statutory Auditors and of €35,000 for each Statutory Auditor, gross of withholding tax.

Details of the fees earned in 2018 are nevertheless given in detail in the Remuneration Report.

During the Year the Board of Statutory Auditors met 8 times, with meetings lasting approximately 2 hours and 15 minutes on average.

As regards the current year, 7 meetings are scheduled and the Board of Statutory Auditors has already met three times in 2019. The percentage attendance of Auditors in these meetings in 2018 is shown in the table above.

In application of Art. 144-novies of the Issuers' Regulations and the Corporate Governance Code, the satisfaction of the requirements mentioned above by members of the Board of Statutory Auditors is assessed by the latter, which submits the results to the board of directors which discloses them, after the appointment, by means of a press release, and subsequently on an annual basis in the corporate governance report.

The Board of Statutory Auditors conducted an internal verification process concerning its independence after its appointment. It was found from the outcome of that verification that all the Statutory Auditors in office possessed the requirements for independence according to Art. 148 of the TUF and also with regard to independence requirements contained in the CG Code. This assessment was repeated, with a positive outcome, on February 7, 2019.

The Board of Statutory Auditors noted, in particular, that the requirement of independence of the statutory auditor Dr. Marco Nava continued to be met, despite holding the position for more than nine years, having taken account of the parameters of substance and not of form.

The Board of Statutory Auditors has checked the independence of the audit firm KPMG S.p.A., checking both compliance with legislative provisions and the nature and extent of services other than financial auditing provided to a number of subsidiaries by the same audit firm and by the entities belonging to the latter's network. For information concerning services other than those of auditing the accounts provided by the audit firm to the Company and its subsidiaries, reference may be made to the relative attachment "Disclosure of auditors' fees for accounting audits and other services" to the consolidated financial statements at 31 December 2018 and the draft separate financial statements of Recordati S.p.A. at 31 December 2018.

The Board of Statutory Auditors, in the performance of its activities, liaised with the Chief of Group Audit and with the Risk Committee through the constant presence in Committee meetings, in which the Chief of Group Audit also usually participates. It also worked with the Supervisory Committee appointed in accordance with Legislative Decree No. 231/2001. The Board reported to the Director with Responsibility for the internal control and risk management system. Finally, it participated in the work of the Remuneration Committee.

As part of its oversight of procedures for the concrete implementation of corporate governance rules, the Board of Statutory Auditors verified that the criteria and procedures of evaluation adopted by the Board to evaluate the independence of its members were implemented correctly.

The Board of Statutory Auditors is also called upon to carry out the duties assigned by the legislation in force to the Committee for internal control and accounting audit (CICAA), set up by Legislative Decree No. 39/2010 (the "Consolidated Statutory Audit Act"), which implements Directive No. 2006/43/EC concerning the statutory audit of annual accounts which entered into force on 7 April 2010, as subsequently amended.

More specifically, the CICAA is required to monitor the efficacy of systems for the internal control of a company's quality and risk management and, if applicable, internal audit, as far as the financial reporting of the entity subject to audit is concerned, without violating its independence.

Furthermore, from the specific viewpoint of the statutory audit, on the basis of the current article 19 of Legislative Decree No. 39/2010, the duties of the CICAA are as follows:

- to monitor the statutory audit of the annual separate company and consolidated financial reports;
- to report to the management body and the results of the statutory audit and to submit to it the additional report required by article 11 of Regulation No. 537/2014, accompanied by any remarks that there may be;
- to verify and monitor the independence of the statutory auditors or the firm of statutory auditors, especially with regard to the adequacy of non-auditing services provided;
- these activities also include responsibility for the procedure for the selection of the auditing firm as well as the indication of the firm to be appointed in the recommendation (in accordance with the provisions of article 16 of Regulation No. 537/2014).

The Board of Statutory Auditors systematically meets with the head of the main company functions, who provide any additional information requested by the Board.

In May 2018, the Chairman and the Chief Executive Officer organised, as a specific induction session, a visit to the Milan production site for Independent Directors and Statutory Auditors.

During the year, given the experience of the members of the Board of Statutory Auditors in the specific industry segments in which the Company is involved and the information provided to them during the individual meetings of the Board and in the meetings mentioned above, the Chairman did not deem it necessary to organise further specific induction sessions.

It should also be noted that the Board of Statutory Auditors, by participating in the meetings of the Board of Directors, receives periodic updates on operations and on developments within the regulatory and legislative framework.

Information on the criteria and policies on diversity applied in relation to the composition of the auditing bodies in relation to aspects such as age, gender composition and the training and professional path required by art. 123-bis, paragraph 2, letter d-bis, of the TUF, are illustrated in the section of the Report concerning the Board of Directors (Section 4.2.2.).

## 15. RELATIONS WITH SHAREHOLDERS

The Company has created a specific section on its website called "Investors", which is easily identifiable and accessible, and which contains important information about the Company for its shareholders so that they can exercise their rights in an informed manner. The Company has also created a special section of its website dedicated to corporate governance containing full documentation, including this report and an archive of past reports.

With regard to the publishing and storage of regulatory information pursuant to article 113 of the TUF we report that the company:

- from 28 May 2012 and until 14 January 2018 used the SDIR - NIS network managed by Blt Market Services, a company belonging to the London Stock Exchange Group, located at 6 Piazza degli Affari, Milano, for the transmission of regulatory information;
- from 15 January 2018, for the transmission of regulatory information, the Company makes use of the dissemination system "1Info SDIR" at [www.1info.it](http://www.1info.it), which is managed by Computershare S.p.A. based in Milan (Via L. Mascheroni 19) and has been authorised by CONSOB with Resolution no. 18994 of 30 July 2014;
- from 19 May 2014 uses the centralised storage system for regulatory information named "1Info" to store regulatory information. This can be consulted at the website [www.1info.it](http://www.1info.it) and it is operated by Computershare S.p.A. with registered offices in Milan and is authorised by the Consob with Resolution No. 18852 of 9 April 2014.

As part of the Company's organisational structure, Marianne Tatschke, the Investor Relations & Corporate Communications Manager, is the person responsible for managing relations with shareholders.

In addition, the tasks of the Group Legal Service and Corporate Affairs Office also include the task of looking after relations with shareholders in general.

The Investor Relations Department of the Company is also responsible for relations with financial analysts who cover the Company and with institutional investors. This department organises periodic conference calls regarding periodic financial information, and the documentation presented for these calls is also made available to the public on the Company's website and by way of the centralised storage system for regulatory information named "1Info" (see [www.1info.it](http://www.1info.it)).

## 16. SHAREHOLDERS' MEETINGS

In accordance with Art. 9 of the By-Laws in force, Shareholders' Meetings are convened in the manner and within the legal time limits on the Company website and, where necessary due to mandatory provisions or decided by the directors, in the Official Gazette and in at least one of the following national newspapers: "Il Corriere della Sera", "La Repubblica", "La Stampa", "Il Giornale", "Milano Finanza", as well as according to other procedures provided for by the legislation and regulations currently in force.

Article 3 of Legislative Decree No. 91 of 18.6.2012 (the "Corrective Decree") has established that Shareholders' Meetings are convened by a notice published on the Company website by the thirtieth day prior to the date of the Shareholders' Meeting and also using other procedures and within the time limit set by the Consob with regulations issued in accordance with article 113-ter, paragraph 3 of Consolidated Finance Act, inclusive of the publication of extracts in daily newspapers. These provisions apply to Shareholders' Meetings for which the notice to convene is published after 1 January 2013.

Following amendments made by the Shareholders' Meeting of 13 April 2011 to the By-Laws, Art. 9 states that "notice to convene may also contain the date of meetings convened subsequent to the first. The Board of Directors may decide, if it considers it appropriate, to convene Ordinary and Extraordinary Shareholders' Meetings to be held following one single Notice of Meeting. In the case of a single call the legal majorities for that purpose apply."

Furthermore, that same Art. 9 of the By-Laws also states that: "Ordinary Shareholders' Meetings are called to approve the financial statements within one hundred and twenty days of the end of the company's financial year. Where permitted by the law, a Shareholders' Meeting may be convened within one hundred eighty days from the end of the financial year. Directors shall indicate the reasons for the delay in the report required by Article 2428 of the Italian Civil Code. Other than on the initiative of the Board of Directors, a Shareholders' Meeting may be called pursuant to the law by the Board of Statutory Auditors or by only two of its members, or upon the request of shareholders representing at least 5% of the capital stock."

In accordance with Art. 12 of the By-Laws in force, resolutions of ordinary and extraordinary meetings, on the first and successive calls, as well as for single calls, are valid if made in the presence of the required number of persons and the majorities required by law. Therefore, an ordinary Shareholders' Meeting is validly constituted in first call with the attendance of shareholders accounting for at least half of the share capital with voting rights at the meeting itself and resolutions are passed by an absolute majority of those participating, including abstentions.

An ordinary shareholders' meeting is validly constituted in second call no matter what proportion of the share capital is represented and resolutions are passed by an absolute majority of those participating, including abstentions.

An extraordinary shareholders' meeting is validly constituted in first call with the attendance of shareholders accounting for at least half of the share

capital and resolutions are passed with the vote in favour of shareholders representing at least two thirds of the share capital.

An extraordinary shareholders' meeting is validly constituted in second call with the attendance of shareholders accounting for at least a third of the share capital and resolutions are passed with the vote in favour of shareholders accounting for at least two thirds of the share capital present at the meeting.

In the case of a single call: an Ordinary Shareholders' Meeting passes resolutions with an absolute majority, whatever the percentage of the capital stock represented and an Extraordinary Shareholders' Meeting is validly constituted when at least one fifth of the capital stock is represented and it passes resolutions with the vote in favour of at least two thirds of the share capital represented in the Shareholders' Meeting.

In relation to the right to participate in Shareholders' Meetings and voting rights, on the basis of Art. 83-sexies of the TUF, legitimate authorisation to participate in Shareholders' Meetings and to exercise voting rights is certified by a communication to the issuer, performed by the intermediary, in compliance with its accounting entries, certifying the party entitled to vote on the basis of information relating to the end of the accounting day of the seventh trading day prior to the date set for the Shareholders' Meeting in first call or a single call. Nevertheless, the legitimate right to participate and vote remains, should the communications be received by the Company later than the aforementioned time limit, provided they are received before the commencement of the proceedings of each single session of the shareholders' meetings.

In accordance with Art. 10 of the By-Laws, those holding the right to vote may be represented by a written proxy, where no incompatibilities and limitations exist pursuant to the legislation and regulations in force. The Company may be notified of the proxy for participation in the Shareholders' Meeting by sending the document to the email address indicated in the Notice of Meeting.

Furthermore, Art. 135-undecies of the TUF, inserted by Legislative Decree No. 27/2010 introduced a "Designated representative of a listed company" "unless the By-Laws stipulate otherwise, listed companies designate a representative for each Shareholders' Meeting to which shareholders may grant an authorisation, by the end of the second day of market trading prior to the date set for the Shareholders' Meeting in first or second call, with voting instructions on all or some of the motions on the agenda. The proxy is valid solely for proposals in relation to which voting instructions have been given." At present Recordati's Corporate By-Laws contain no provisions in this respect, and this new provision is therefore considered applicable to future Shareholders' Meetings of the Company, until different provisions are introduced to the Company By-Laws.

The Board believes that there are no conditions that require the adoption of particular initiatives regarding attendance of Meetings and the exercise of voting rights by shareholders such as, for example, postal voting.

In accordance with Art. 127-ter of the TUF, shareholders may submit questions on the items on the agenda even before the Shareholders' Meeting. Answers are given to questions received prior to the Shareholders' Meeting, subject to verification of the relevance and the legitimacy of the asker, at the latest during the meeting itself and the Company has the right to give a single answer to questions having the same content.

In this respect article 127-ter of the Consolidated Finance Act, expressly allows the Company to set a time limit within which questions formulated prior to a Shareholders' Meeting must be received if they are to be considered. The time limit is at the discretion of the Company, but may not be greater than three days prior to the date of the Shareholders' Meeting (in first or single call) or five days prior to the Shareholders' Meeting with, however, the obligation of the Company to furnish a reply at least two days prior to the Shareholders' Meeting, which may be by publication on the Company website. Cases where a reply is not obligatory are then specified: when the information required is already available in the format "answer and reply" in the relevant section of the website and also when the reply has already been published on the website.

When implementing amendments made to the CG Code made in December 2011, the Board felt it would be advisable to draw up regulations for proceedings in Shareholders' Meetings, even though no particular difficulties had been encountered in past meetings. The objective is to further ensure that the proceedings in Shareholders' Meetings are well-organised and practical and to ensure that each shareholder is able to speak on the items on the agenda.

The Shareholders' Meeting held on 17 April 2013 approved the text of the Shareholders' Regulations proposed by the Board of Directors, which is available on the Company website at [www.recordati.it](http://www.recordati.it), in the corporate governance section.

In 2018, the Shareholders met once, on 18 April 2018 on first call with 78.556% of the share capital with voting rights in attendance. At this Shareholders' Meeting, the Shareholders approved the financial statements for the year ended 31st December 2017 and authorised a new 2018-2022 Stock Option Plan and the purchase and use of treasury shares. The Shareholders' Meeting also cast a non-binding vote on the first section of the Remuneration Report.

During this Shareholders' Meeting (at which, in addition to the Chairman, the following members of the Board of Directors were in attendance: Rosalba Casiraghi; Michaela Castelli; Elisa Corghi; Mario Garraffo, chairman of the Remuneration Committee; Andrea Recordati, Vice Chairman and Chief Executive Officer - Fritz Squindo; the full statutory auditors Antonio Santi, Chairman of the Board of Statutory Auditors and Marco Nava, both serving as full statutory auditors; and Livia Amidani Aliberti, statutory auditor), the Chairman of the Board of Directors reported on the activity conducted and planned and answered a number of the Shareholders' questions. The volume containing a copy of the proposed separate financial statements and consolidated financial statements, with the accompanying reports and the Directors' Reports on the proposals concerning items placed on the agenda was handed out at the entrance and also sent to shareholders who had taken part in recent meetings and who had requested one in order to ensure adequate disclosure of the necessary information so that they could take the decisions for which they are responsible with full knowledge of the facts. The above documentation, together with the results of the votes, has been made available and it may be consulted on the Company website [www.recordati.it](http://www.recordati.it) in the section: Investors, Shareholders' Meetings, 2018.

The Remuneration Committee considered that there was no need to report to the Shareholders' Meeting on how it had carried out its duties, because that information was already contained in the Remuneration Report made available to shareholders before the meeting.

In 2019, as of the date of this report, the Shareholders' Meeting has already met on 5 February 2019 for the appointment of the new Board of Directors.

During the year, there were no significant changes in the market capitalisation of the Company's shares or in the composition of its corporate structure (in terms of variation of the percentage of control by the majority shareholder, even if the latter has changed according to the previous information contained in the Report) sufficient to require consideration of a proposal to the Shareholders' Meeting for changes to the Corporate By-Laws concerning the percentages established for the exercise of the actions and prerogatives provided for the protection of minorities.

## 17. ADDITIONAL CORPORATE GOVERNANCE PRACTICES (PURSUANT TO ART. 123-BIS, PARAGRAPH 2, LETTER A) OF THE TUF)

The Issuer does not apply any additional corporate governance practices, other than those described in the preceding sections of this Report.

## 18. CHANGES OCCURRING SINCE THE END OF THE YEAR

Starting from the end of the Year on 5 February 2019, the new Board of Directors of the Company was appointed. Extensive and detailed information has already been provided in this Report within the sections concerning the Board of Directors. There were no further changes in the Company's corporate governance structure.

## 19. OBSERVATIONS ON THE LETTER OF THE CHAIRMAN OF THE CORPORATE GOVERNANCE COMMITTEE OF 21 DECEMBER 2018

The recommendations in the letter of the chairman of the Corporate Governance Committee dated 21 December 2018 were brought to the attention, first, of the Chairman of the Board of Directors, the Chief Executive Officer, and the chairman of the Board of Statutory Auditors (to whom the letter was addressed) on 11 January 2019.

On the same date, the letter was also distributed to all other (Italian-speaking) directors and auditors.

Subsequently, after the appointment of the new Board of Directors on 5 February 2018, the letter was distributed to the new Board of Directors, newly appointed (including non-Italian speaking directors, through an English courtesy translation) on 11 February 2019.

As already highlighted in section 4.3.1, unlike previous years, the Board of Directors has agreed not to carry out a self-assessment of the size, composition and functioning of the Board itself and its Committees between the end of 2018 and the beginning of 2019. This is due to the substantial changes that occurred in 2018 in the Recordati control structure and which also affected the composition of the Board of Directors and its governance structure, completed at the Shareholders' Meeting held on 5 February 2019, which appointed the new board of directors. It was therefore not possible to make use of the self-assessment process to discuss the above-mentioned recommendations, since this also concerned an outgoing Board.

However, with reference to the recommendation on pre-meeting information, the Chairman appointed on 5 February 2019 took care, at the same board meeting, to expressly submit to the new Board the assessment on the adequacy of the timing of the pre-meeting information that previously had been set 3 days in advance of the board meeting (except for the presence of particular situations of urgency or confidentiality). The new Board concurred. In the process of self-assessment scheduled in 2019, care will be taken to verify that this timing has proven to be adequate during the financial year.

As for the other recommendations - assessments of the independence criteria, board reviews and certain profiles on the clarity and completeness of the remuneration policies such as the strengthening of the link of variable remuneration to parameters linked to long-term objectives and the limitation to single exceptional cases, after an adequate explanation, the possibility of disbursing sums not tied to predetermined parameters (i.e. "ad hoc" bonuses) - the necessity or opportunity of specific interventions for any improvement has not been currently assessed, as the newly appointed Board of Directors has not been able to express its own evaluations due to a limited time span.

Milan, 28 February 2019

for the Board of Directors  
Chief Executive Officer  
Andrea Recordati

## ATTACHMENT 1

### PROFESSIONAL OVERVIEW OF THE DIRECTORS AND STATUTORY AUDITORS

#### DIRECTORS

##### **Flemming Ørnskov**

From 2013 to 8 January 2019, Dr. Flemming Ornskov was Chief Executive Officer at Shire, the global leader in serving patients with rare diseases through the development of best-in-class therapies across a core of rare disease areas including immunology, hematology, genetic diseases, neuroscience, internal medicine and ophthalmics.

Flemming Ornskov has extensive international, strategic and operational experience in the pharmaceutical and biotech sectors, as well as medical expertise as a physician with training in pediatrics.

Prior to joining Shire, he held the positions of Non-Executive Chairman of Evotec and Non-Executive Director of PCI Biotech Holding. From 2010 to 2013, he was Chief Marketing Officer and Global Head, General and Specialty Medicine at Bayer.

Previous leadership roles included Global President, Pharmaceuticals and Over-the Counter (OTC) at Bausch & Lomb; Chairman, President and Chief Executive Officer of LifeCycle Pharma; and President and Chief Executive Officer of Ikaria.

Earlier in his pharmaceutical career, he held roles of increasing responsibility at Merck and Novartis, following a distinguished period working in hospitals and academic medicine.

Flemming Ornskov received his MD from the University of Copenhagen, MBA from INSEAD, and Master of Public Health from Harvard University.

He serves as Co-Chair of The Global Commission to End the Diagnostic Odyssey for Children with a Rare Disease, a multi-disciplinary group of experts led by Shire, Microsoft, and EURORDIS-Rare Diseases Europe, which seeks to address the diagnostic challenges for patients living with a rare disease, particularly for children.

He served previously as a Member of the Dolder Group, an organization of leading biotech and pharmaceutical CEOs dedicated to addressing industry-wide challenges, such as counterfeit medications, anti-microbial resistance, and pandemic preparedness.

Flemming Ornskov currently serves as Non-Executive Director for the Waters Corporation (listed company) and the Swiss-American Chamber of Commerce and works with Takeda Pharmaceuticals Co. under a fixed-term employment agreement that will last until 31 March 2019.

##### **Alfredo Altavilla**

Alfredo Altavilla was Chief Operating Officer Europe, Africa and Middle East (EMEA) of FCA from November 2012 till August 2018. He has also been a member of the Group Executive Council (GEC) and Head of Business Development since September 1, 2011.

He began his career as an assistant at Università Cattolica, Milan.

In 1990, he joined Fiat Auto, where he initially focused on international ventures in the area of strategic planning and product development.

In 1995, he was appointed Head of Fiat Auto China where he set up the first JV in Nanjing and in 1999 head of Asian Operations.

He has been involved in Business Development since 2001, becoming responsible for coordination of the alliance with General Motors and, in 2004, being assigned responsibility for management of all Group all alliances.

In September 2004, Mr. Altavilla was appointed Chairman of FGP (Fiat/GM Powertrain JV) and Senior Vice President of Business Development of Fiat Auto.

In July 2005, he became CEO of Turk Otomobil Fabrikasil A.S. (TOFAS) - a 50-50 joint venture between Fiat Auto and Koç Holding listed on the Istanbul stock exchange - while retaining his role as head of Business Development.

In November 2006, he was named Chief Executive Officer of FPT - Fiat Powertrain Technologies.

In July 2009, he became a member of the Board of Directors of Chrysler Group LLC (Member of the Audit Committee) and in October 2009 was named Executive Vice President of Business Development for Fiat Group.

From November 2010 to November 2012 he was President and Chief Executive Officer of Iveco. He was also a member of the Fiat Industrial Executive Council (FIEC) from January 2011 to November 2012.

He holds a degree in Economics from Università Cattolica, Milan.

He is a Member of the Board of Actuant Corp. (listed on the NYSE, Member of Audit Committee and Compensation Committee), Tim S.p.A. (listed in Milan and Chairman of the Nomination and Compensation Committee) and Conceria Pasubio S.p.A..

##### **Andrea Recordati**

Andrea Recordati gained a Bachelor of Arts in medieval and modern history from the University of London Royal Holloway and Bedford New College. Between September 1995 and March 1998, he participated in the SmithKline Beecham Management Access Program, in the United Kingdom, starting off as Assistant Product Manager in Consumer Healthcare and then, for one year, occupying the role of medical representative in Essex before becoming Project Manager responsible for the development and implementation of an innovative SmithKline Beecham marketing initiative.

He joined Recordati in 1998 as Project Leader for a project aimed at improving Sales Force productivity and better use of marketing investments. In April 1998, he joined the Board of Directors of the Company. In 1999, he was given responsibility for Pharmaceutical Business Development.



In March 2002, the Lercanidipine Business Unit was set up and he was appointed head of that unit. Since November 2002, he has been responsible for setting up the subsidiary Recordati Ireland and its industrial plant and, subsequently, for setting up the UK subsidiary. In September 2006, he was appointed Sole Director of the German subsidiary Recordati Pharma GmbH. In August 2007, the Northern and Central Europe Subsidiaries Division was set up and he was appointed head of that division. That division was enlarged in 2010 to include all western European companies. In February 2011 he was appointed General Manager of the International Pharmaceuticals Division. In July 2013 he was appointed Chief Operating Officer, being responsible for all the commercial and production activities of the Group and sitting on several boards of directors within the Group. From 16 August 2016 to 5 February 2019, he was appointed as Vice Chairman and CEO of Recordati S.p.A.. Currently, he is CEO of Recordati S.p.A..

### **Silvia Elisabetta Candini**

Liceo Classico degree, undergraduate degree in Economics (summa cum laude) at Università Commerciale Luigi Bocconi and Exchange Programme at The Wharton School (MBA) of University of Pennsylvania.

After graduation in 1994, she joins Lehman Brothers London in the Corporate Finance team and, subsequently, in the Origination team, where she works on marketing and structuring of IPOs and convertible bonds. In 1996, she moves to the Debt Origination team at JP Morgan London to cover Italian banks and local authorities as issuers.

From 1998 to 2008 she continues to work at JP Morgan in the fixed income sales & trading department, assuming responsibility for the distribution to Italian institutional clients of "plain vanilla" and structured fixed income products, such as senior and subordinated securities issued by financial institutions (including first subordinated bond issue of Generali), senior and subordinated corporate notes, high yield and emerging markets bonds, securitizations (ABS, MBS and CDOs), Credit Default Swaps, Credit linked Notes. Other relevant structured trades include equity linked notes to traditional funds (Henderson), Hedge Funds (GLG) and Indexes (Itraxx, Eurostock50).

Since 2009, co-founder and managing partner of Studio C&C, providing Family Office and financial advisory services to High Net Worth private clients. Current roles:

- Independent Director, Member of the Control, Risk and CSR Committee and Member of the Remuneration Committee with Recordati S.p.A.
- Independent Director, Member of the Appointments and Corporate Governance Committee and Member of the Remuneration Committee with Unipol Gruppo S.p.A.

### **Michaela Castelli**

She worked in leading Italian law firms dealing with corporate law and financial markets. She consolidated her professional experience in Borsa Italiana S.p.A., where she assisted listed companies with respect to extraordinary transactions, price sensitive information, compliance and corporate governance. She held the position of secretary of the scientific committee that was responsible for updating the listed companies' Code of Conduct and she was responsible for listing legal department in charge of the admission to listing of shares and other financial instruments, with delegations on sensitive procedures.

She participated in consultation procedures on regulations and on the preparation of company operating procedures for the market management's company, CONSOB supervised entity.

Expert in the organization, corporate compliance, internal controls, and legislation 231.

Consultant and member of Boards of Directors of listed companies, auditor in boards of statutory auditors and member of numerous supervisory bodies. Author of professional publications and lecturer in several continuous education courses on corporate law and financial markets; participation in numerous conferences as a speaker.

She currently holds the following positions:

Board of Directors

- Chairman of the Board of Directors of Sea S.p.A.
- Chairman of the Board of Directors, member of the Risk and Control Committee, member of the Executive Committee and of the Ethical and Sustainability Committee of Acea S.p.A..
- Member of the Board of Directors, Chairman of the Internal Control Committee of Sea Aeroporti di Milano S.p.A..
- Member of the Board of Directors, Chairman of the Internal Control Committee, Chairman of the Related Parties Transaction Committee and Member of the Remuneration Committee of Istituto Centrale delle Banche Popolari Italiane S.p.A. (Nexi Group).
- Member of the Board of Directors and of the Compensation Committee and Chairman of the Control, Risk and CSR Committee of Recordati S.p.A..
- Member of the Board of Directors, Member of the Remuneration Committee and Internal Control Committee of La Doria S.p.A..
- Member of the Board of Directors, Member of the Remuneration Committee and Related Parties Committee of Stefanel S.p.A..
- Member of the Board of Directors of My Best S.p.A..

Board of Statutory Auditors

- Member of the Board of Statutory Auditors of Nuova Sidap S.r.l. (Autogrill S.p.A. Group)
- Member of the Board of Statutory Auditors of Eurtel S.r.l. (Eur S.p.A. Group)
- Member of the Board of Statutory Auditors of Autogrill Italia S.p.A.
- Member of the Board of Statutory Auditors of Autogrill Europe S.p.A.

Supervisory Board

- Chairman of the Supervisory Board of Teva s.r.l. (Teva Pharmaceutical Industries Ltd Group, listed in the NYSE).
- Chairman of the Supervisory Board of La Doria S.p.A.

### Joanna Le Couilliard

Joanna Susan Le Couilliard has 25 years' healthcare management experience gained in Europe, the United States and Asia.

Much of her career has been in pharmaceuticals at GlaxoSmithKline where, amongst other roles, she headed the U.S. vaccines business and Asia Pacific Pharmaceuticals business and led a program to modernise the commercial model. She was previously Chief Operating Officer at the BMI group of private hospitals in the U.K. She was Non-Executive Director at Frimley Park NHS Foundation Trust in the UK and at the Duke NUS Medical School in Singapore. She is a graduate of Cambridge University and a Chartered Accountant.

She is currently a Non-Executive Director at Circassia Pharmaceuticals plc, Cello Health plc and Alliance Pharma plc, all listed on the London Stock Exchange.

### Francisco Javier de Jaime Guijarro

Francisco Javier de Jaime Guijarro graduated in law from Universidad Pontificia de Comillas (Madrid) in 1987 and in 1990 obtained a master in business administration at the University of Houston (USA).

He started his career in 3i Group in 1990 as investment controller at the London office (1990-1991) and after as regional director at the Madrid office (1992-1997).

In September 1997 he joined CVC Capital Partners as co-general director to lead the Spanish market, one of the most important market for CVC. In 2003 he was appointed as managing partner of CVC Capital Partners and since 2008 he took the responsibility to also lead the Italian market.

He is currently a member of the board of directors in the following companies: Baranoa Directorship S.L., Tendam Retail S.A., Tendam Brands S.A., Tendam Fashion S.L.U., Deoleo S.A., Servet Shareholdings S.L., Vitalia Plus SA, Vivaly Inversiones Globales S.L., Rioja Bidco Shareholdings S.L., Naturgy Energy Group, S.A., Promotora de Informaciones S.A., Clara Vision S.A., MEP Retail España S.L.U., Lecta S.A., Sub Lecta S.A., Torraspapel S.A., CVC Capital Partners (Luxembourg) S.à r.l., CVC Advisers (Luxembourg) S.à r.l., CVC Investment Advisory Services S.L., CVC Advisers (España) S.L.. In addition, he's director of the foundation Fundacion Humana Spes.

### Giampiero Mazza

Giampiero Mazza graduated *summa cum laude* from Rice University (Houston, Texas, USA) in 1991 with a degree in Economics and in 1996 completed a Master in Business Administration at the Harvard Business School (Boston, Massachusetts, USA).

He started his career as a business strategy advisor in Bain & Company (Dallas, Texas, USA). He joined James D. Wolfensohn Inc (New York, NY, USA), a firm specialized in M&A transactions.

From 2005 to 2010 he was a partner of BC Partners (London, UK), a private equity firm.

In 2010 he joined CVC Capital Partners, a private equity firm, where he is a Partner responsible for the Italian business.

Giampiero Mazza also holds the following positions: (i) director in CVC Advisers (Italia) S.r.l., Doc Generici S.r.l., Conceria Pasubio S.p.A., Sisal Group S.p.A., Sisal S.p.A., Recordati S.p.A. (ii) chairman with delegated powers in Rossini Investimenti S.p.A., and (iii) chairman in FIMEI S.p.A..

### Cathrin Petty

Cathrin Petty holds a Master of Arts in Natural Sciences from New Hall, Cambridge University and a post-graduate Diploma in Management Studies from the Judge Institute, Cambridge.

She started her career at Schroders and Schroder Ventures. She has been partner at APAX Partners, and prior to moving to CVC Capital Partners, she was Head of Healthcare EMEA with JP Morgan Chase & Co.

Cathrin Petty also held numerous non-executive positions, including at the NHS (Strategic Health Authority for Greater London), Circassia Pharmaceuticals Ltd, Icon Plc., Qualitest Inc. and Zeneus Pharma Ltd.

Currently, she serves as Partner and Head of European Healthcare at CVC Capital Partners, where she joined in July 2016.

She is currently i) member of the board of directors in the following companies: Theramex HQ UK Limited, IWH UK Investco Limited, IWH UK Finco Limited, IWH UK Holdco Limited, IWH UK Midco Limited, Sphinx Reserve Co., Rossini Holdings S.à r.l., Rossini Investments S.à r.l., Rossini Luxembourg S.à r.l., Rossini S.à r.l., FIMEI S.p.A. and Recordati S.p.A., and ii) director with delegated powers in Rossini Investimenti S.p.A..

### Fritz Squindo

Fritz Squindo graduated "cum laude" in Economics at the Bocconi University in Milan, Italy. He started his career in 1981 in Telettra S.p.A., a telecommunications company within the Fiat Group, where he was employed in the finance department. In 1986 he joined Sanofi S.p.A., the Italian subsidiary of the French pharmaceutical group Sanofi, where he was first Head of Finance and, as from 1990, Head of Management Accounting. In 1992 he joined Recordati S.p.A. as Head of the Management Accounting department. In 1995 he was appointed Chief Financial Officer and in 2008 also became Managing Director. Since 2013 Mr. Squindo is a member of the Board of Directors of Recordati S.p.A. and is also part of the managing bodies of several Recordati Group companies.

### Søren Vestergaard-Poulsen

Søren Vestergaard-Poulsen holds a Masters Degree in Economics and Business Administration from Copenhagen Business School.

He serves as Managing Partner at CVC Capital Partners, where he joined in 1998. Søren also oversees private equity activities in the Nordic region of Europe. He sits on the board of the CVC Capital Partners advisory business and is a member of the Europe/North America Private Equity Board and the Growth Fund Investment Committee.

Prior to joining CVC, he worked for McKinsey & Co.

He is currently a board member of the following companies: AR Packaging Group AB; Sarcina Holdings S.à r.l.; Sarcina Holdings Jersey Limited; Ahlsell AB (publ); Mholdings S.à r.l.; Kirk Beauty Investments S.A.; Keravel S.à r.l.; NEWS Capital (Luxembourg) S.à r.l., CVC Advisers (Luxembourg) S.à r.l. and Recordati S.p.A. He is also member of the supervisory board of Douglas GmbH.

## MEMBERS OF THE BOARD OF STATUTORY AUDITORS

### STATUTORY AUDITORS

#### Antonio Santi

Graduated in Business Administration - University of Rome "La Sapienza", with a PhD in Business Administration at University of Rome "Roma 3".

Registered with the Register of Italian Corporate and Tax Affairs Experts (*Albo dei Dottori Commercialisti*) and with the Register of Certified Auditors (*Registro dei Revisori Contabili*).

He carries out advisory activities with regards to the appraisal of companies and branches -of both the public and private sector-, economic and financial feasibility studies and restructuring plans. During his professional experience he has developed consistent expertise in accounting control and supervision activities carried out by company control subjects.

He is member of the Board of Directors of Enav S.p.A. - listed company, where he carries out the role of president of the CRPC Committee.

He is member of the Board of Statutory Auditors and accounting auditor of companies operating in different sectors; amongst the others he is CONI's Accounting Auditor, Chairman of the Board of Statutory Auditors of Acea Produzione S.p.A. and member of the Board of Statutory Auditors of Rothschild & Co Wealth Management Italy SIM.

#### Livia Amidani Aliberti

Livia Amidani Aliberti graduated in Economics and Commerce at LUISS (Rome, Italy) and holds a Post Graduate Diploma from FT-Pearson (UK). She has recently completed the INSEAD International Corporate Directors programme. She holds FCA - Financial Conduct Authority - status (CF 10, 11); she is a *Dottore Commercialista* (Chartered Accountant) and a member of the Scientific Committee of NedCommunity. She serves as Compliance Officer in FCA regulated entities. With more than ten years of consulting and research in corporate governance, her specialties include AIM Listings, Corporate Governance Assessment and Redesign, Strategic Evaluation of Boards; she is also engaged in gender diversity research, area where she authored several publications on gender diversity and directors.

Livia Amidani Aliberti occupies the following positions as corporate director:

- Unicredit Bank Austria A.G., part of the Unicredit Group: independent director, chair of the strategy and nomination committee and the remuneration committee.
- Credito Valtellinese, bank listed on the MTA: independent director, member of the Related Party Transactions Committee.
- Neodecortech S.p.A. (AIM Italy): independent director, chair of the Control, Risk, Remuneration, Nomination and OPC Committee.
- Amnesty International Charitable Trust UK (Company Limited by Guarantee): non- executive director, member of the Finance Risk, Control and CSR Committee.
- Quantyx UK Ltd: compliance officer and AML officer.

#### Marco Nava

Marco Nava graduated in Economics and Commerce and in Jurisprudence at the Università Cattolica del Sacro Cuore of Milan. He started his career as an accountant in 1988. He has been registered as an auditor since the first publication of the register (1995). He performs his principal activity as an accountant with his own offices in a partnership of accountants and lawyers. He is a statutory auditor and external auditor for companies operating in various sectors.

Marco Nava holds positions in the following companies:

1. Director of Nava Viganò Revisori Associati Srl.
2. Sole director of Tazat Srl.
3. Chairman of the Board of Statutory Auditors of Cavenaghi SpA.
4. Chairman of the Board of Statutory Auditors of Dott. G. Cavenaghi SpA.
5. Chairman of the Board of Statutory Auditors of Euclidea SIM SpA.
6. Chairman of the Board of Statutory Auditors of Fratelli Re SpA.
7. Chairman of the Board of Statutory Auditors of Italchimici srl.
8. Chairman of the Board of Statutory Auditors of LCS SpA.
9. Chairman of the Board of Statutory Auditors of Max Moda SpA.
10. Chairman of the Board of Statutory Auditors of RBR Valvole SpA.
11. Chairman of the Board of Statutory Auditors of Synlab Italia srl.
12. Chairman of the Board of Statutory Auditors of ICCS Spa.
13. Chairman of the Board of Statutory Auditors of Data Medica Padova Spa.
14. Chairman of the Board of Statutory Auditors of Natural Point Srl.
15. Chairman of the Board of Statutory Auditors of Innova Pharma Spa.
16. External Auditor Associazione Italiana Medicina Nucleare (AIMN).
17. External Auditor Musixmatch SpA.
18. External Auditor Tensive srl.
19. Statutory Auditor Beaumanoir Italy srl.
20. Statutory Auditor Campo SpA.
21. Statutory Auditor J Colors SpA.
22. Statutory Auditor Junionfin SpA.
23. Statutory Auditor National Instruments Italy srl.
24. Statutory Auditor S.I.S.A. Società Italiana Spalmature ed Affini SpA.
25. Statutory Auditor Yazaki Europe Limited Italia srl.
26. Statutory Auditor Synlab Holding Italy Srl.
27. Statutory Auditors of Recordati SpA.
28. Statutory Auditors of Giuseppe & Fratelli Bonaiti Srl.
29. Statutory Auditors of Motork Italia Srl.
30. Sole Member of Compliance Committee Giuliani SpA.
31. Sole Member of Compliance Committee CM Engineering srl.

## ALTERNATE AUDITORS

### **Patrizia Paleologo Oriundi**

Born in Milan on January 24<sup>th</sup> 1957, she is a 1980 Business Administration graduate of Università Commerciale L. Bocconi.

She is a member of the Milan Association of Certified Public Accountants since 1983 and a financial auditor since 1995.

She has built up her career working for renowned law firm specialized in tax regulation, becoming an expert in consulting for multinational and for non-commercial companies, tax litigations, in addition to legal and administrative control of companies, foundations and associations. She also deals with real estate, insurance and energy companies.

She has 30-years of experience as legal controller and member of the Supervising Body established by Legislative Decree no. 231/01.

Foreign Languages: English, Spanish and French.

She occupies the following management and supervisory positions in other companies:

- Chairman of Auditors' of the Associazione "Valore D – Donne al vertice per l'Azienda di Domani";
- Chairman of the Board of Statutory Auditors of Chiara Assicurazioni spa;
- Chairman of the Board of Statutory Auditors of Close up spa;
- Chairman of Auditors' of Consorzio Universitario per l'Ingegneria nelle Assicurazioni;
- Statutory Auditor of Esprinet spa;
- Statutory Auditor of Ge.si.ass scarl;
- External Auditor of Fondazione Antonio e Giannina Grillo Onlus;
- Vice Chairman of the Board of Directors of Fondazione Bisozzi- Rimbaud;
- Chairman of the Board of Statutory Auditors of Helvetia Vita spa;
- Statutory Auditor of ICIM spa;
- Chairman of the Board of Statutory Auditors of Helvetia Italia spa;
- Shareholder Director of Quisi snc di Patrizia Paleologo & C;
- Statutory Auditor of Virgin Active spa;
- Statutory Auditor of Banca Farmafactoring spa.
- Chairman of Auditors' of the Associazione AODV231

### **Andrea Balelli**

Graduated cum laude in Economics at La Sapienza University of Rome in 2000. Business Advisor, Certified Public Accountant and Auditor.

He started his professional experience at PricewaterHouseCoopers. He subsequently worked at the Government Printing Office and Mint and Capitalia Service Jv in Rome.

He then moved to Milan working for Archon Group (Goldman Sachs Group) as Vice President of the Corporate Accounting Team.

He is now top management advisor for both public and private companies on strategic, organizational and financial aspects such as M&A advisory (including mergers, acquisitions, spin-offs, liquidations, fairness opinions); corporate valuations; strategic plans; business and debt restructuring; performance measurement and control systems; organizational models pursuant to legislative decree 231 of 2001.

He is member of the Board of Directors and the Board of Statutory Auditors for companies operating in various sectors.

He occupies management and supervisory positions in the following companies:

- Sole Director of Fedaia Spv Srl;
- Sole Director of Gardenia Spv Srl;
- Sole Director of Italian Credit Recycle Srl;
- Sole Director of Restart Spv Srl;
- Sole Director of Rienza Spv Srl;
- Sole Director of Re Vesta Srl;
- Statutory Auditor Airport Cleaning Srl;
- Statutory Auditor of Leonardo Energia Scarl;
- Statutory Auditor of Infoblu SpA;
- Statutory Auditor of Pillarstone Italy SpA;
- Statutory Auditor of Pillarstone Italy Holding SpA;
- Statutory Auditor of PS Reti SpA;
- Chairman of the Board of Statutory Auditors of Salvatore Ferragamo SpA;
- Chairman of Supervisory Body ex D.Lgs 231/2001 of Salvatore Ferragamo SpA;
- Statutory Auditor of Sirti SpA.



This publication is a summary of the Annual Reports 2018 which contain the financial statements of Recordati S.p.A. and the consolidated financial statements together with management reports in their integral form, the Disclosure of Non-financial Information and the Corporate Governance Report. These documents are available in their integral version at the company's headquarters and on the company's website [www.recordati.com](http://www.recordati.com) and can also be viewed on the authorized storage system 1Info ([www.1Info.it](http://www.1Info.it)).

The information on the Recordati group's pharmaceutical specialties and other products contained in this document is intended solely to inform the reader of the general nature of the Company's activities and therefore, as such, it is not intended to be an indication or recommendation of medical or scientific nature, nor as any kind of promotional message.

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## BOARD OF DIRECTORS

(Elected by the Shareholders' Meeting of February 5, 2019)

**Flemming Ørnskov**  
Chairman

**Alfredo Altavilla**  
Vice Chairman

**Andrea Recordati**  
Chief Executive Officer

**Silvia Elisabetta Candini**  
Independent

**Michaela Castelli**  
Independent

**Joanna Le Couilliard**  
Independent

**Francisco Javier de Jaime Guijarro**

**Giampiero Mazza**

**Cathrin Petty**

**Fritz Squindo**  
Chief Financial Officer  
Managing Director

**Søren Vestergaard-Poulsen**

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## AUDIT, RISK AND SUSTAINABILITY COMMITTEE

**Michaela Castelli**  
Chairman

**Silvia Elisabetta Candini**  
**Joanna Le Couilliard**

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## REMUNERATION COMMITTEE

**Joanna Le Couilliard**  
Chairman

**Silvia Elisabetta Candini**  
**Michaela Castelli**

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## STATUTORY AUDITORS

**Antonio Santi**  
Chairman

**Livia Amidani Aliberti**  
**Marco Nava**  
Auditors

**Andrea Balelli**  
**Patrizia Paleologo Oriundi**  
Alternate auditors

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## EXTERNAL AUDITORS

**KPMG S.p.A.**

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## MANAGEMENT

**Andrea Recordati**  
Chief Executive Officer

**Enrico Baroncia**  
Pharmaceuticals, Italy

**Luca Bolliger**  
Licensing

**Corrado Castellucci**  
Orphan Drugs

**Gabriele Finzi**  
Corporate Development

**Daria Ghidoni**  
Legal Affairs

**Giuseppe Gualazzini**  
Human Resources

**Miguel Isla**  
International Primary and Specialty Care and Western Europe Subsidiaries

**Luisa Mainoli**  
Finance

**Giovanni Minora**  
Auditing

**Cédric Ripert**  
International Licensees Sales

**Paolo Romagnoli**  
Pharmaceutical Chemicals

**Raffaele Sabia**  
Pharmaceutical Research and Development

**Fritz Squindo**  
Chief Financial Officer  
Managing Director

**Marianne Tatschke**  
Investor Relations  
& Corporate Communications

**Roberto Teruzzi**  
Industrial Operations

**Witold Urban**  
Central and Eastern Europe Subsidiaries

**Ismail Yormaz**  
South Eastern Europe and North Africa Subsidiaries

# RECORDATI

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