

# ANNUAL REPORT 2018

## FINANCIAL HIGHLIGHTS

### REVENUE

€ (thousands)	2018	%	2017	%	Change 2018/2017	%
<b>TOTAL REVENUE</b>	<b>1,352,235</b>	<b>100.0</b>	<b>1,288,123</b>	<b>100.0</b>	<b>64,112</b>	<b>5.0</b>
Italy	273,197	20.2	258,551	20.1	14,646	5.7
International	1,079,038	79.8	1,029,572	79.9	49,466	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

<sup>(1)</sup> 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)

<sup>(2)</sup> 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 <sup>(4)</sup>	0.85	0.07	8.2

#### SHARES OUTSTANDING:

- average during the year	204,379,165	207,030,319
- at December 31	203,971,585	208,261,894

<sup>(3)</sup> 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.

<sup>(4)</sup> Proposed by the Board of Directors.

## LETTER TO OUR SHAREHOLDERS

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 ginkgo biloba which are very well known on the French market. The company also promotes Alodont®, 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).

## RECORDATI, AN INTERNATIONAL GROUP

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.

## 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.

## RESEARCH AND DEVELOPMENT

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 carglumic 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>	Orphan Europe (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 EQUIMETH2 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

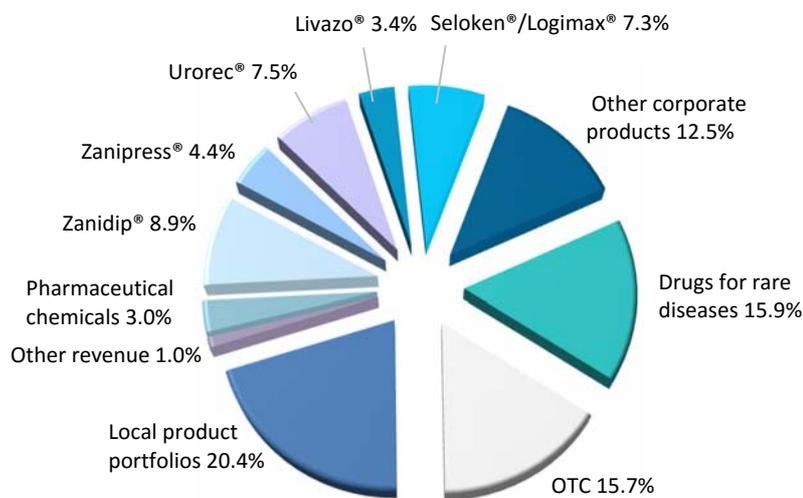
Maple syrup urine disease (MSUD), also called branched-chain ketoaciduria, is a rare metabolic disorder affecting branched-chain amino acids (leucine, isoleucine and valine) which results in a build up of these amino acids and their metabolites. This build-up manifests with severe symptoms affecting 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.

## 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<sup>®</sup>, Seloken<sup>®</sup> ZOK and Logimax<sup>®</sup> 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.

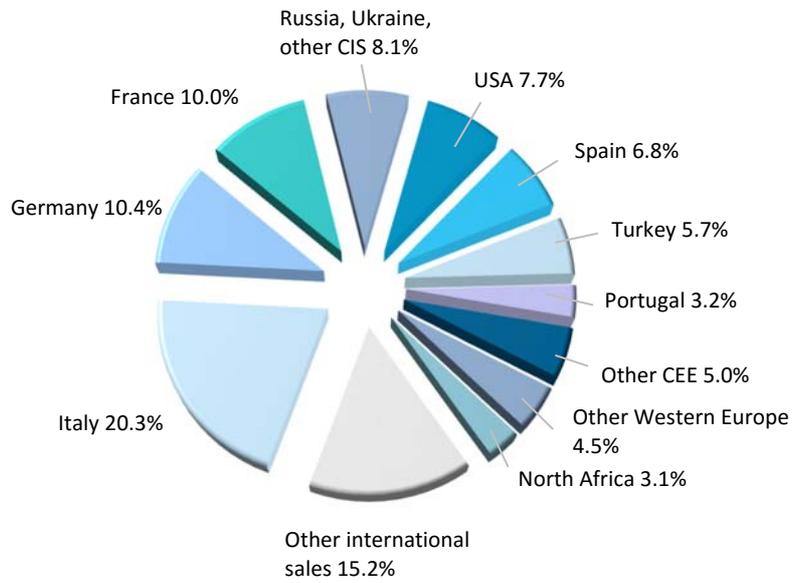
### Sales by business



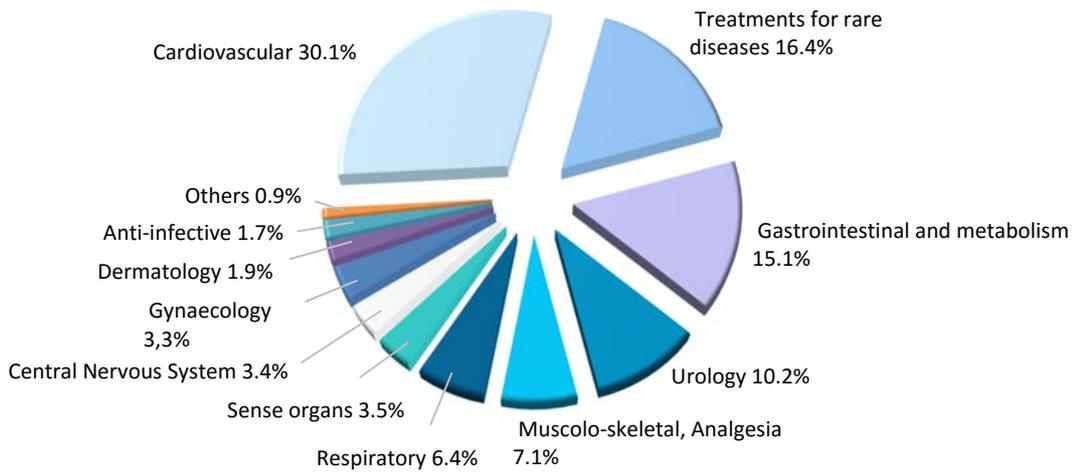
## PHARMACEUTICALS

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 € 105.2 million in 2018 and € 102.5 million in 2017 (+2.6%).

**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 D<sub>3</sub>/D<sub>2</sub> receptor partial agonist with preferential binding to D<sub>3</sub> receptors and partial agonist at serotonin 5-HT<sub>1A</sub> 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<sup>®</sup> and in France as Wystamm<sup>®</sup>. 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<sup>®</sup>/Virirec<sup>®</sup> (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<sup>®</sup> 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<sup>®</sup> and Muvagyn<sup>®</sup> 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<sup>®</sup> (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 Pedeia®/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., Italchimici 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 <sup>®</sup>	benign prostatic hyperplasia	28,622	24,890	3,732	15.0
Cardicor <sup>®</sup>	heart failure	27,195	25,005	2,190	8.8
Peptazol <sup>®</sup>	gastric ulcers	18,571	20,831	(2,260)	(10.8)
Zanedip <sup>®</sup> /Lercadip <sup>®</sup>	hypertension	18,194	18,224	(30)	(0.2)
Rextat <sup>®</sup> /Lovinacor <sup>®</sup>	hypercholesterolemia	14,345	13,719	626	4.6
Tora-Dol <sup>®</sup>	pain	12,594	12,259	335	2.7
Zanipril <sup>®</sup> /Lercaprel <sup>®</sup>	hypertension	12,085	14,927	(2,842)	(19.0)

Urorec<sup>®</sup>, Cardicor<sup>®</sup> (bisoprolol) and the statins Rextat<sup>®</sup> and Lovinacor<sup>®</sup> (lovastatin)<sup>®</sup> show sustained growth as well as the treatments for rare diseases which are up by 11.9%. Sales of Peptazol<sup>®</sup> (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<sup>®</sup>, a magnesium based food supplement. Alovex<sup>™</sup>, 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<sup>®</sup> (treatment of haemorrhoids) with sales of € 7.1 million also remains market leader with a share of more than 40%. TransAct<sup>®</sup> 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<sup>®</sup>, a line of oral care products, generated sales of € 4.6 million. Sales of Eumill<sup>®</sup> (eye drops) at € 6.1 million are up by 9.2%. Sales of Imidazol<sup>®</sup> (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 disintoxication 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 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 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
Tergyan®	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 Tergyan®, 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 İlaç, 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 İlaç 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
Mictonorm®	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 GmHH) 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<sup>®</sup>, Livazo<sup>®</sup>, Laccigest<sup>®</sup> (tilattase) and Tretinac<sup>®</sup> (tretinoin) as well as the metoprolol based products acquired from AstraZeneca in 2017. During the year Reagila<sup>®</sup>, 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<sup>®</sup>, Urorec<sup>®</sup> and Lopresor<sup>®</sup> 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<sup>®</sup> (lercanidipine) and Zaneril<sup>®</sup> (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<sup>®</sup> was also launched in the UK.

#### *Ireland*

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

#### *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	% of revenue	2017	% of revenue	Change 2018/2017	%
<b>Revenue</b>	<b>1,352,235</b>	<b>100.0</b>	<b>1,288,123</b>	<b>100.0</b>	<b>64,112</b>	<b>5.0</b>
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
<b>Employees at year-end</b>	<b>4,142</b>	<b>4,176</b>
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, 4,089 in 2018 and 4,061 in 2017.

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 <sup>(1)</sup>	(135,278)	(51,710)	(83,568)	161.6
Net liquid assets	45,853	233,790	(187,937)	(80.4)
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>

<sup>(1)</sup> 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	% of revenue	31.12.2017	% of 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 rigorous 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	<b>1,352,235</b>	<b>1,288,123</b>
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 ( <i>cash flow hedge</i> )	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

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

**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 ( <i>cash flow hedge</i> )		(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>	19	<b>963,393</b>	<b>1,027,090</b>
Minority interest		193	147
<b>Shareholders' equity</b>	20	<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 ( <i>cash flow hedge</i> )	30	9,746	9,559
Loans – due within one year	21	130,583	51,710
Bank overdrafts and short-term loans	31	16,905	16,577
<b>Total current liabilities</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
Net income for the year	312,422	288,799
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
<b>Balance at 31.12.2016</b>	<b>26,141</b>	<b>83,719</b>	<b>(76,761)</b>	<b>(7,420)</b>	<b>(78,309)</b>	<b>35,295</b>	<b>756,004</b>	<b>237,406</b>	<b>(72,245)</b>	<b>110</b>	<b>903,940</b>
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)
Short-term financial position at end of period *	181,131	285,500

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

<sup>(1)</sup> 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.

<sup>(2)</sup> 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 30<sup>th</sup> 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 intra-group 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.

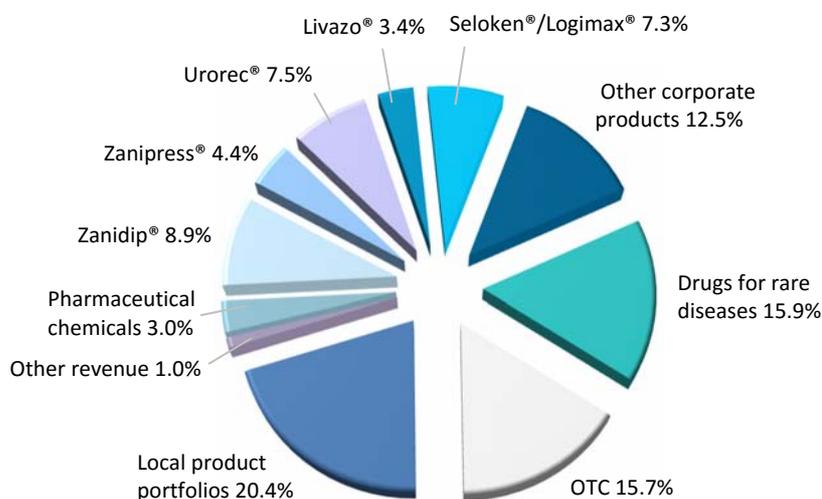
Diluted earnings per share is calculated by adjusting the number of shares for the effects of all dilutive potential ordinary shares.

### 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 Italchimici 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 prilocaine 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.

€ (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>

Short term time deposits have maturities of three months or less.

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 (€)	Options outstanding at 1.1.2018	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 Ilaç 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 Ilaç 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>

€ (thousands)	31.12.2018	31.12.2017
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 Ilaç 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' tlibor 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 ( <i>cash flow hedge</i> )	6,414	6,414
<b>Financial liabilities</b>		
Borrowings		
- 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 ( <i>cash flow hedge</i> )	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 the 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.

€ (migliaia)	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.

€ (migliaia)	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>First nine months 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
<i>of which Italy</i>	<i>273,197</i>	<i>258,551</i>	<i>14,646</i>
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)	31.12.2018	31.12.2017	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>

<sup>(1)</sup> 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
RECORDATI S.P.A. <i>Development, production, marketing and sales of pharmaceuticals and pharmaceutical chemicals</i>	Italy	26,140,644.50	EUR	Line-by-line
INNOVA PHARMA S.P.A. <i>Marketing and sales of pharmaceuticals</i>	Italy	1,920,000.00	EUR	Line-by-line
CASEN RECORDATI S.L. <i>Development, production, marketing and sales of pharmaceuticals</i>	Spain	238,966,000.00	EUR	Line-by-line
BOUCHARA RECORDATI S.A.S. <i>Development, production, marketing and sales of pharmaceuticals</i>	France	4,600,000.00	EUR	Line-by-line
RECORDATI RARE DISEASES COMERCIO DE MEDICAMENTOS LTDA <i>Holds pharmaceutical marketing rights in Brazil</i>	Brazil	166.00	BRL	Line-by-line
RECORDATI RARE DISEASES INC. <i>Development, production, marketing and sales of pharmaceuticals</i>	U.S.A.	11,979,138.00	USD	Line-by-line
RECORDATI IRELAND LTD <i>Development, production, marketing and sales of pharmaceuticals</i>	Ireland	200,000.00	EUR	Line-by-line
LABORATOIRES BOUCHARA RECORDATI S.A.S. <i>Development, production, marketing and sales of pharmaceuticals</i>	France	14,000,000.00	EUR	Line-by-line
RECORDATI PHARMA GmbH <i>Marketing and sales of pharmaceuticals</i>	Germany	600,000.00	EUR	Line-by-line
RECORDATI PHARMACEUTICALS LTD <i>Marketing and sales of pharmaceuticals</i>	United Kingdom	15,000,000.00	GBP	Line-by-line
RECORDATI HELLAS PHARMACEUTICALS S.A. <i>Marketing and sales of pharmaceuticals</i>	Greece	10,050,000.00	EUR	Line-by-line
JABA RECORDATI S.A. <i>Marketing and sales of pharmaceuticals</i>	Portugal	2,000,000.00	EUR	Line-by-line
JABAFARMA PRODUTOS FARMACÊUTICOS S.A. <i>Marketing of pharmaceuticals</i>	Portugal	50,000.00	EUR	Line-by-line
BONAFARMA PRODUTOS FARMACÊUTICOS S.A. <i>Marketing of pharmaceuticals</i>	Portugal	50,000.00	EUR	Line-by-line
RECORDATI ORPHAN DRUGS S.A.S. <i>Holding company</i>	France	57,000,000.00	EUR	Line-by-line
ORPHAN EUROPE SWITZERLAND GmbH <i>Marketing and sales of pharmaceuticals</i>	Switzerland	20,000.00	CHF	Line-by-line
ORPHAN EUROPE MIDDLE EAST FZ LLC <i>Marketing and sales of pharmaceuticals</i>	United Arab Emirates	100,000.00	AED	Line-by-line
RECORDATI AB <i>Marketing and sales of pharmaceuticals</i>	Sweden	100,000.00	SEK	Line-by-line
ORPHAN EUROPE S.à R.L. <i>Development, production, marketing and sales of pharmaceuticals</i>	France	320,000.00	EUR	Line-by-line
ORPHAN EUROPE UNITED KINGDOM LTD <i>Marketing and sales of pharmaceuticals</i>	United Kingdom	50,000.00	GBP	Line-by-line
ORPHAN EUROPE GERMANY GmbH <i>Marketing and sales of pharmaceuticals</i>	Germany	25,600.00	EUR	Line-by-line
ORPHAN EUROPE SPAIN S.L. <i>Marketing and sales of pharmaceuticals</i>	Spain	1,775,065.49	EUR	Line-by-line
ORPHAN EUROPE ITALY S.R.L. <i>Marketing and sales of pharmaceuticals</i>	Italy	40,000.00	EUR	Line-by-line
RECORDATI BVBA <i>Marketing and sales of pharmaceuticals</i>	Belgium	18,600.00	EUR	Line-by-line

Consolidated Companies	Head Office	Share Capital	Currency	Consolidation Method
FIC MEDICAL S.à R.L. <i>Marketing of pharmaceuticals</i>	France	173,700.00	EUR	Line-by-line
HERBACOS RECORDATI s.r.o. <i>Development, production, marketing and sales of pharmaceuticals</i>	Czech Republic	25,600,000.00	CZK	Line-by-line
RECORDATI SK s.r.o. <i>Marketing and sales of pharmaceuticals</i>	Slovakia	33,193.92	EUR	Line-by-line
RUSFIC LLC <i>Marketing and sales of pharmaceuticals</i>	Russian Federation	3,560,000.00	RUB	Line-by-line
RECOFARMA İLAÇ Ve Hammaddeleri Sanayi Ve Ticaret L.Ş. <i>Marketing of pharmaceuticals</i>	Turkey	10,000.00	TRY	Line-by-line
RECORDATI ROMÂNIA S.R.L. <i>Marketing and sales of pharmaceuticals</i>	Romania	5,000,000.00	RON	Line-by-line
RECORDATI İLAÇ Sanayi Ve Ticaret A.Ş. <i>Development, production, marketing and sales of pharmaceuticals</i>	Turkey	180,000,000.00	TRY	Line-by-line
RECORDATI POLSKA Sp. z o.o. <i>Marketing and sales of pharmaceuticals</i>	Poland	4,500,000.00	PLN	Line-by-line
ACCENT LLC <i>Holds pharmaceutical marketing rights</i>	Russian Federation	20,000.00	RUB	Line-by-line
RECORDATI UKRAINE LLC <i>Marketing of pharmaceuticals</i>	Ukraine	1,031,896.30	UAH	Line-by-line
CASEN RECORDATI PORTUGAL Unipessoal Lda <i>Marketing and sales of pharmaceuticals</i>	Portugal	100,000.00	EUR	Line-by-line
OPALIA PHARMA S.A. <i>Development, production, marketing and sales of pharmaceuticals</i>	Tunisia	9,656,000.00	TND	Line-by-line
OPALIA RECORDATI S.à R.L. <i>Marketing of pharmaceuticals</i>	Tunisia	20,000.00	TND	Line-by-line
RECORDATI RARE DISEASES S.A. DE C.V. <i>Marketing of pharmaceuticals</i>	Mexico	16,250,000.00	MXN	Line-by-line
RECORDATI RARE DISEASES COLOMBIA S.A.S <i>Marketing of pharmaceuticals</i>	Colombia	150,000,000.00	COP	Line-by-line
ITALCHIMICI S.p.A. <i>Marketing of pharmaceuticals</i>	Italy	7,646,000.00	EUR	Line-by-line
RECORDATI AG <i>Marketing of pharmaceuticals</i>	Switzerland	3,000,000.00	CHF	Line-by-line
PRO FARMA GmbH <i>Marketing of pharmaceuticals</i>	Austria	35,000.00	EUR	Line-by-line
RECORDATI RARE DISEASES CANADA Inc. <sup>(1)</sup> <i>Marketing of pharmaceuticals</i>	Canada	350,000.00	CAD	Line-by-line
RECORDATI RARE DISEASES JAPAN K.K. <sup>(2)</sup> <i>Marketing of pharmaceuticals</i>	Japan	10,000,000.00	JPY	Line-by-line
NATURAL POINT S.r.l. <sup>(3)</sup> <i>Marketing of pharmaceuticals</i>	Italy	10,400.00	EUR	Line-by-line
RECORDATI RARE DISEASES AUSTRALIA Pty Ltd <sup>(2)</sup> <i>Marketing of pharmaceuticals</i>	Australia	200,000.00	AUD	Line-by-line
TONIPHARM S.A.S. <sup>(3)</sup> <i>Marketing of pharmaceuticals</i>	France	257,700.00	EUR	Line-by-line

<sup>(1)</sup> Established in 2017

<sup>(2)</sup> Established in 2018

<sup>(3)</sup> Acquired in 2018

Consolidated companies	PERCENTAGE OF OWNERSHIP											Total
	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.à R.L.	Herbacos Recordati s.r.o.	Recordati Ilaç A.Ş.	Opalia Pharma S.A.	Recordati AG		
INNOVA PHARMA S.P.A.	100.00											100.00
CASEN RECORDATI S.L.	100.00											100.00
BOUCHARA RECORDATI S.A.S.	100.00											100.00
RECORDATI RARE DISEASES COMERCIO DE MEDICAMENTOS LTDA	99.398					0.602						100.00
RECORDATI RARE DISEASES INC.	100.00											100.00
RECORDATI IRELAND LTD	100.00											100.00
LABORATOIRES BOUCHARA RECORDATI S.A.S.			100.00									100.00
RECORDATI PHARMA GmbH	55.00			45.00								100.00
RECORDATI PHARMACEUTICALS LTD	100.00											100.00
RECORDATI HELLAS PHARMACEUTICALS S.A.	100.00											100.00
JABA RECORDATI S.A.				100.00								100.00
JABAFARMA PRODUTOS FARMACÊUTICOS S.A.				100.00								100.00
BONAFARMA PRODUTOS FARMACÊUTICOS S.A.				100.00								100.00
RECORDATI ORPHAN DRUGS S.A.S.	90.00	10.00										100.00
ORPHAN EUROPE SWITZERLAND GmbH					100.00							100.00
ORPHAN EUROPE MIDDLE EAST FZ LLC					100.00							100.00
RECORDATI AB					100.00							100.00
ORPHAN EUROPE S.à R.L.					100.00							100.00
ORPHAN EUROPE UNITED KINGDOM LTD						100.00						100.00
ORPHAN EUROPE GERMANY GmbH						100.00						100.00
ORPHAN EUROPE SPAIN S.L.						100.00						100.00
ORPHAN EUROPE ITALY S.R.L.							99.00					99.00
RECORDATI BVBA					99.46	0.54						100.00
FIC MEDICAL S.à R.L.			100.00									100.00
HERBACOS RECORDATI s.r.o.	100.00											100.00

Consolidated companies	PERCENTAGE OF OWNERSHIP										Total
	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.à R.L.	Herbacos Recordati s.r.o.	Recordati İlaç A.Ş.	Opalia Pharma S.A.	Recordati AG	
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

<sup>(1)</sup> Established in 2017

<sup>(2)</sup> Established in 2018

<sup>(3)</sup> 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

## 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