

ANNUAL REPORT 2019



RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.p.A.

Subject to the direction and coordination of Rossini Luxembourg S.à r.l.

Legal headquarters: Via Matteo Civitali, 1 – Milano

Share capital: € 26,140,644.50

Tax code and Registro delle Imprese di Milano registration number 00748210150

The Company prepares the consolidated financial statements for the Recordati group

BOARD OF DIRECTORS

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LIVIA AMIDANI ALIBERTI

Auditors

PATRIZIA PALEOLOGO ORIUNDI

ANDREA BALELLI

Alternate auditors

MANAGEMENT REVIEW

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) and comply with the European Union's guidelines on the preparation of consolidated financial statements as well as the provisions issued in execution of art. 9 of the Italian Legislative Decree 38/2005. The same accounting standards were used in the preparation of the financial statements at 31 December 2018.

FINANCIAL HIGHLIGHTS

REVENUE

€ (thousands)	2019		2018		Change 2019/2018	
		%		%		%
TOTAL REVENUE	1,481,848	100.0	1,352,235	100.0	129,613	9.6
Italy	287,289	19.4	273,197	20.2	14,092	5.2
International	1,194,559	80.6	1,079,038	79.8	115,521	10.7

KEY CONSOLIDATED P&L DATA

€ (thousands)	2019	% of revenue	2018	% of revenue	Change 2019/2018	%
Revenue	1,481,848	100.0	1,352,235	100.0	129,613	9.6
EBITDA ⁽¹⁾	543,967	36.7	499,079	36.9	44,888	9.0
Operating income	465,266	31.4	442,219	32.7	23,047	5.2
Net income	368,866	24.9	312,422	23.1	56,444	18.1

⁽¹⁾ Net income before net interest, provision for taxes, depreciation, amortization and write down of both property, plant and equipment and intangible assets.

KEY CONSOLIDATED BALANCE SHEET DATA

€ (thousands)	31 December 2019	31 December 2018	Change 2019/2018	%
Net financial position ⁽²⁾	(902,681)	(588,380)	(314,301)	53.4
Shareholders' equity	1,198,811	963,586	235,225	24.4

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

PER SHARE DATA

€	2019	2018	Change 2019/2018	%
Net income ⁽³⁾	1.800	1.529	0.271	17.7
Shareholders' equity ⁽³⁾	5.825	4.724	1.101	23.3
Dividend	1.00 ⁽⁴⁾	0.92	0.08	8.7

SHARES OUTSTANDING:

- average during the year	204,959,193	204,379,165
- at December 31	205,816,585	203,971,585

⁽³⁾ Net income per share is based on average shares outstanding during the year net of average treasury stock. Shareholders' equity per share is based on total shares outstanding at year end. Shares outstanding are net of treasury stock. Treasury stock amounted to 3,308,571 shares at 31 December 2019 and 5,153,571 shares at 31 December 2018. Average treasury stock amounted to 4,165,963 shares in 2019 and 4,745,991 shares in 2018.

⁽⁴⁾ Proposed by the Board of Directors.

LETTER TO OUR SHAREHOLDERS

The financial results obtained in 2019 demonstrate the continued growth of the Group, with increased revenues and profits. All business segments, the main products as well the new business development initiatives, contributed to these results. Group consolidated revenue for 2019 is € 1,481.8 million, up 9.6% over the preceding year. International sales are € 1,194.6 million, up 10.7% and now represent 80.6% of total revenue. As regards our Specialty and Primary Care portfolio, which represents 83.1% of revenues growing by 8.3%, Zanidip[®], Urorec[®] and Livazo[®] performed well and our self-medication products showed significant growth. During the year Reagila[®], the innovative antipsychotic drug for the treatment of schizophrenia, was successfully launched in the majority of Western European countries. Furthermore, the performance of our business dedicated to treatments for rare diseases was noteworthy. This business now represents 16.9% of revenues and grows by 16.3% which includes the contribution from recently acquired and licensed in products (Juxtapid[®] in Japan, Ledaga[®] in Europe and Signifor[®]/Signifor[®] LAR worldwide).

Profits also showed solid growth. EBITDA, at 36.7% of sales, is € 544.0 million, an increase of 9.0% over 2018. Operating income, at 31.4% of sales, is € 465.3 million, a growth of 5.2% compared with the preceding year. Net income is € 368.9 million, an increase of 18.1%, with a margin on sales of 24.9%, significantly higher compared to that of the preceding year due to the growth of operating income and to the tax benefit provided by the so-called “Patent box” agreed with the Italian tax authorities in December 2019. The total benefit is of € 35.3 million, of which € 27.0 million refers to previous years and € 8.3 million is relative to 2019. Excluding the previous years’ benefit net income would be of € 341.9 million, up by 9.4% and 23.1% of revenue.

At 31 December 2019 the Group’s net financial position records a net debt of € 902.7 million compared to net debt of € 588.4 million at 31 December 2018. During the year dividends were paid for an amount of € 190.9 million. Furthermore, an important acquisition of product rights was made and licenses obtained for new products for a total investment of around € 425 million. Shareholders’ equity at 31 December 2019 is € 1,198.8 million.

In 2019 a number of initiatives were pursued in line with the group’s strategy of continued growth and development.

In February, Recordati signed a license agreement with Aegerion Pharmaceuticals Inc., a subsidiary of Novilion Therapeutics Inc., for the exclusive rights to commercialize Juxtapid[®], currently approved for the treatment of homozygous familial hypercholesterolemia (HoFH), in Japan. The agreement includes a right of first negotiation for product commercialization in Japan of any potential new indications that may be developed by Aegerion. Upon signing of the agreement an upfront payment of \$ 25 million was paid to Aegerion and a milestone of \$ 5 million was paid in June. The agreement includes commercial milestones and royalty payments. In 2018 sales of the product in Japan were of \$ 10.8 million. The addition of Juxtapid[®] to our portfolio of rare disease products in Japan is very important for the development of our recently established subsidiary in this country, given its potential for significant growth.

Recordati Rare Diseases, a worldwide leader in rare diseases and orphan drugs, recently announced that its strategy aimed at establishing a direct presence in the key markets across all continents has been successfully executed. Local Recordati Rare Diseases companies are now active in North America, Latin America, Europe, Middle East and Asia Pacific. Several companies formerly operating under the name of Orphan Europe were recently renamed Recordati Rare Diseases, which is today the global brand of Recordati’s organization dedicated to treatments for rare diseases and orphan drugs. Orphan Europe, founded in 1990, pioneered the development of orphan drugs in Europe and became part of Recordati in 2007.

On 12 July 2019 an agreement was signed with Novartis for the acquisition of worldwide rights to Signifor® and Signifor® LAR® for the treatment of Cushing's disease and acromegaly in adult patients for whom surgery is not an option or for whom surgery has failed. Worldwide sales of Signifor® in 2019 were \$ 75 million. The agreement also covers the acquisition of worldwide rights to Isturisa® (osilodrostat), an investigational innovative drug for the treatment of endogenous Cushing's syndrome, for which marketing authorization was granted by the European Commission in January 2020 and approval obtained in the USA in March 2020. The transaction was completed on 23 October 2019 and a consideration of \$ 390 million, funded by existing liquidity and new debt facilities, was paid to Novartis. Subsequently, additional milestone payments contingent upon the approval and market access of Isturisa® as well as royalties on sales of this new product, will be due. Cushing's syndrome includes Cushing's disease, a severe endocrine disease caused by a pituitary adenoma which results in over-production of cortisol by the adrenal glands and is associated with increased morbidity and mortality. Acromegaly is caused by an overexposure to growth hormone consequent to a pituitary adenoma. Signifor® contains the active substance pasireotide, a somatostatin analogue that helps to control the over-production of cortisol and improve the symptoms of Cushing's disease. The active ingredient in Isturisa®, osilodrostat, orally administered, inhibits the final step of cortisol synthesis in the adrenal cortex. This new drug for endogenous Cushing's syndrome is expected to represent an effective new treatment option for patients.

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 as well as 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 2019 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.

As from the month of February Italy and all the main countries in which the Group operates are impacted by the epidemiologic emergency due to the COVID-19 virus, declared a pandemic by the OMS in March. To face the emergency, in Italy, and subsequently also in other countries, restrictions to the circulation of people and provisions to support companies' economic activities have been introduced. The Group is implementing all possible measures and initiatives to guarantee the supply of medicines to its patients and the safety of its employees. We believe that the rigorous execution of these actions and 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 2019.

DIVIDENDS

Based on the results obtained, the Board of Directors of the parent company will propose to the shareholders a dividend of € 0.52 per share, in full balance of the interim 2019 dividend of € 0.48, to be paid to all shares outstanding at ex-dividend date, excluding those in treasury stock, as from 20 May 2020 (record date 19 May 2020), with ex-dividend on 18 May 2020 (against presentation of coupon no. 25). The full 2019 dividend is therefore of € 1.00 per share (€ 0.92 per share in 2018).

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 2019 the Group generated revenues of € 1,481.8 million and has a staff of 4,323 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.

The Group's most important products belonging to its specialty and primary care business 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.

Recordati has acquired a vast specific know-how in the uro-genital therapeutic area in which it is present with well-recognized drugs for the treatment of benign prostatic hyperplasia, such as silodosin, and urinary incontinence, such as flavoxate. Furthermore, in the metabolic area, pitavastatin, a latest generation statin for controlling hypercholesterolemia, is marketed in a number of countries. More recently, cariprazine, an innovative anti psychotic drug for the treatment of schizophrenia, has been launched in most of Western Europe.

Recordati develops, produces and sells drugs for the treatment of rare diseases through Recordati Rare Diseases, a group of companies which operates on a worldwide basis, dedicated mainly to metabolic deficiencies of a genetic nature. Recently, this business segment was reinforced with the addition of two new products to its product portfolio and with the acquisition of important drugs in the area of rare endocrinology diseases.

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 \$ 1,200 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.

The growth determined by the entry of new drugs will be limited by the loss of exclusivity of a number of important products and the cost containment of pharmaceutical expenditure worldwide. It is expected that, thanks to the continued success rates associated with research and development pipelines, there will be an increase in new product launches with an average of 54 new drugs every year over the next five years. Research is shifting towards specialty products, those for rare diseases and oncological treatments. Most of the impact due to loss of exclusivity took place in 2019. *Source: IQVIA – Predictions and Areas to Watch in the global pharma market ahead. 2019- 2023.*

Over the counter (OTC) products, which have reached a total value of \$ 138 billion (MAT June 2019, up by 3.6% - *source: Nicholas Hall's OTC Dashboard*), are expected to continue to grow, at a more moderate rate, in developed countries as well as in emerging markets. In developed economies, growth drivers are linked mainly to the increasing average age of the population and to the relative increased attention to prevention, while the reduction in the rate of change of Rx products to OTC (over the counter) status and the impact of e-commerce on retail sales have affected the evolution of market values. 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 2019, \$ 136 billion (+4% over 2018) were spent for treatments for rare diseases, a market estimated to grow on average by 12.3%, reaching \$ 242 billion by 2024 when it will represent 20% of the global prescription drug market, excluding generics (*source: Evaluate Pharma – Orphan Drug report 2019*).

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 2019 research and development activities were concentrated on programs in rare diseases. Regarding the rare diseases segment the pharmaceutical and clinical development of the projects REC 0559 (treatment of neuropathic keratitis) and REC 0545 (treatment of Maple Syrup Urine Disease) progressed. New formulation development continued as part of the life cycle management of carglumic acid, hemin and cysteamine. In the area of specialty and primary care, maintenance activities progressed for the support of marketed products as well as pre clinical studies involving new drugs.

PRODUCT DEVELOPMENT PIPELINE

NAME	ORIGINATOR	INDICATION	DEVELOPMENT STATUS
ISTURISA®	Novartis	Endogenous Cushing's syndrome/Cushing's disease	Approved in Europe Approved in the USA
CYSTADROPS®	Recordati	Corneal cysteine crystal deposits in patients with cystinosis	Filed in the USA Development of new formulations in EU and in USA
REAGILA®	Gedeon Richter	Schizophrenia	Pediatric post-approval development plan
methadone		Treatment of cancer-related pain in cases of resistance or intolerance to other opioids	Approved in France
CARBAGLU®	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
REC 0438	Recordati/UFPeptides	New indications	Preclinical development
REC 0559	Recordati/MimeTech	Neurotrophic keratitis	Formulation development Clinical development planning
REC 0545	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 2019 to enrich our pipeline and ensure the group's future growth. The product pipeline was strengthened with the acquisition from Novartis of the worldwide rights to Isturisa® (osilodrostat), recently approved in Europe and in the U.S.A.. 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 2019 are summarized in the following paragraphs.

Urology and andrology

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 2019 a second European multicenter study in patients with spinal lesions who presented signs of hyperactive bladder and episodes of urinary incontinence, despite on-going treatment with anticholinergic drugs, was completed. The results of the study showed that repeated intravesical administrations of the drug by the patients themselves at home, is feasible, well tolerated and is not associated with systemic exposure. However, despite the slight reduction in urinary incontinence episodes observed, the urodynamic test made to evaluate the maximum vesical capacity showed highly variable responses, with results not in line with the minimum expected benefit to be able to continue development in a pediatric population with hyperactive bladder due to *spina bifida*. It was therefore decided to interrupt the clinical development. The final report is being prepared. At the same time, toxicology studies in animal models were completed and formulation as well as preclinical studies are ongoing to evaluate the possible use of the treatment in other indications.

Urorec® (silodosin)

The results of an integrated statistical analysis of the randomized controlled pre-registration studies as well as the extensive phase IV studies in patients with severe urinary symptoms were published. As expected, because the drug is highly selective, silodosin's efficacy was confirmed in the more severe patients resulting in a marked improvement in quality of life.

A generic version of the drug, as an own generic of Urorec®, identical in all respects to the reference product except for the brand, was approved in all the EEA (European Economic Area) countries through a centralized procedure. Recordati Ireland Ltd is the holder of the marketing authorization of both the generic and reference products and the production sites of the raw material and of the finished product as well as the production process and control are the same for both.

Fortacin™ (lidocaine+prilocaine)

The regulatory dossier supporting the over-the-counter use of this topical spray formulation of lidocaine and prilocaine, specifically developed for the treatment of premature ejaculation, was completed. Furthermore, the variation to the marketing authorization for the change from prescription to over-the-counter status was filed with the European Medicines Agency.

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 2019 the registration dossier for the product was updated in support of possible new registrations and the safety information in the European specification of product characteristics and leaflet was updated and harmonized with the use of a work-sharing procedure.

Seloken® (metoprolol) and Logimax® (metoprolol + felodipine)

During 2019 the regulatory activities needed to transfer the production authorizations of the AstraZeneca (AZ) products based on metoprolol and metoprolol + felodipine to Recordati, were completed. Additional alternative packaging sites were added as per the agreement with AstraZeneca.

Psychiatry

Reagila® (cariprazine)

During 2019, as provided for in the agreement between Recordati and Gedeon Richter, the pediatric clinical development program in Europe involving cariprazine, a new antipsychotic drug approved in Europe for the treatment of schizophrenia, continued. The clinical trials conducted in adults demonstrated the efficacy of cariprazine, not only in the improvement of the positive symptoms but also of the negative symptoms associated with schizophrenia.

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 and the “Transparency Commission” approved the reimbursement of Zoryon® for the treatment of moderate and severe oncological pain in patients who do not respond adequately to other opioids.

Lomexin® (fenticonazole)

Fenticonazole is a topical antimycotic drug originated by Recordati. A number of different projects were conducted in support of the development of the product, given its increase in sales and the potential associated with its change of status from prescription to over-the-counter in various European countries as well as the scientific evidence supporting the fenticonazole molecule as a treatment for vaginal infections with different aetiology. Regarding the dermatology and vaginal cream formulations, the finished product specifications in all registrations were updated worldwide and an alternative production site was added (Vamfarma). The Danish authorities (RMS) validated the worksharing procedure for the European updating and harmonization of the safety information in the specification of product characteristics and information leaflet for the different forms of fenticonazole for the gynaecological indication. The evaluation of environmental risk was updated with the presentation of the results of the phase II A ERA study to the Danish authorities (RMS). Further in-depth studies will be completed by February 2022 (phase II B).

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).

Signifor®/Signifor® LAR (pasireotide) and Isturisa® (osilodrostat)

During 2019 the worldwide rights to Signifor® and Signifor® LAR for the treatment of Cushing’s disease and acromegaly in adult patients for whom surgery is not an option or for whom surgery has failed were acquired from Novartis. The agreement also covers the acquisition of worldwide rights to Isturisa® (osilodrostat), an investigational innovative drug for the treatment of endogenous Cushing’s syndrome, for which marketing authorization was granted by the European Commission in January 2020 and by FDA in the U.S.A. in March 2020. In October 2019 preparatory activities started for the transfer of sponsorship from Novartis to Recordati AG of a number of worldwide trials involving the abovementioned products including the following:

- an interventional study on a worldwide basis with Signifor® and Signifor® LAR (SOM230B2412)
- and observational study (PASS) with Signifor® (SOM230B2410)
- an interventional study on a worldwide basis with osilodrostat (CLCI699C2X01B)
- a pediatric study with osilodrostat (CLCI699C2203).

Therefore, a working group was created within the Recordati group to interact with Novartis and define a plan for the transfer of said studies, the management of studies independently sponsored by researchers and the requests for compassionate use. These ongoing activities will be completed in 2020.

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 has been filed in the U.S.A. for this indication.

Recordati is developing a new oral 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. Cystadrops® is currently available in the countries belonging to the European Union and has been filed for approval in the U.S.A..

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

REC 0559

In June 2017 Recordati and Recordati Rare Diseases (formerly 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



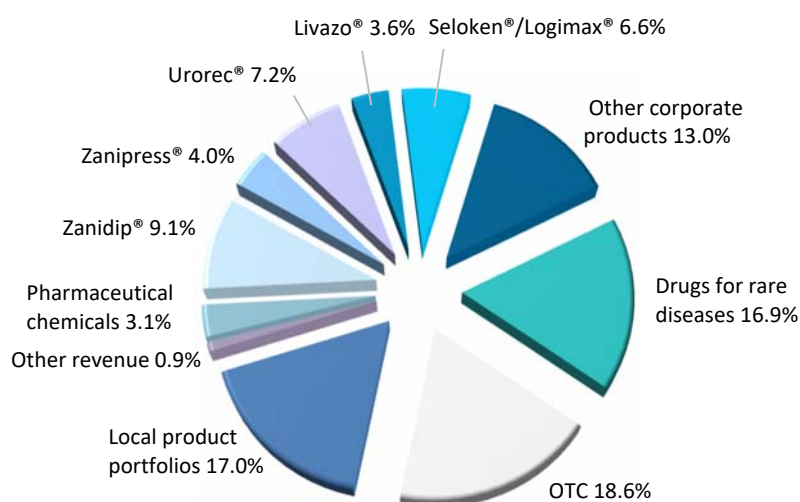
treated, patients may be subject to acute metabolic decompensation episodes that manifest with severe neurological symptoms which if not addressed can be life-threatening.

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. Formulation development has been completed and the regulatory approval process requirements are being planned.

REVIEW OF OPERATIONS

Net revenue in 2019 is € 1,481.1 million, up 9.6% over the same period of the preceding year, and includes sales for the full year 2019 generated by Natural Point S.r.l., consolidated as from 1 July 2018, of which € 9.7 million realized in the first half, sales generated by Tonipharm S.a.s., acquired at the end of 2018 and consolidated as from 1 January 2019, of € 22.7 million, the sales of Juxtapid®, a product acquired under license in February 2019 in Japan, of € 9.6 million and the margin on sales of Signifor® and Signifor® LAR, realized by Novartis starting 23 October 2019 and transferred to Recordati, for an amount of € 10.1 million, in addition to an estimated positive currency exchange rate effect of € 1.0 million. Excluding these items growth would be of 5.7%. International sales grow by 10.7% to € 1,194.6 million, which represent 80.6% of total sales. Pharmaceutical sales are € 1,435.7 million, up by 9.5% while pharmaceutical chemicals sales are € 46.1 million, up by 13.4%, and represent 3.1% of total revenues.

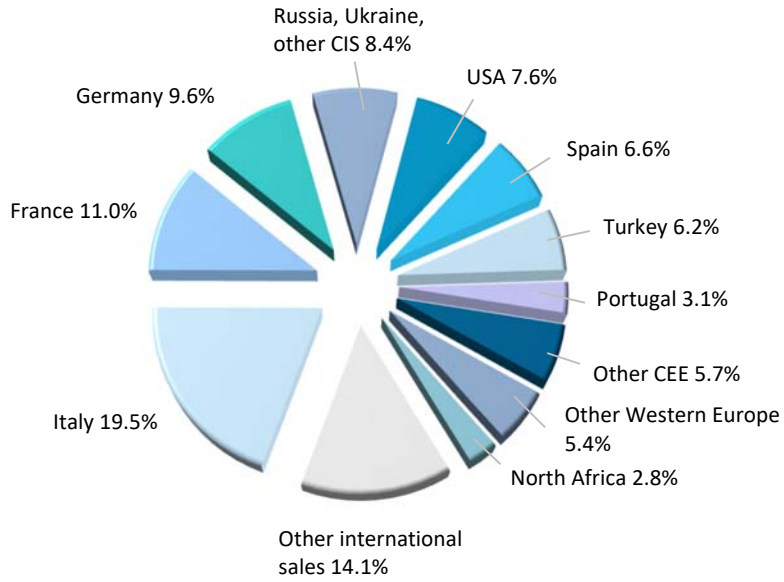
Sales by business



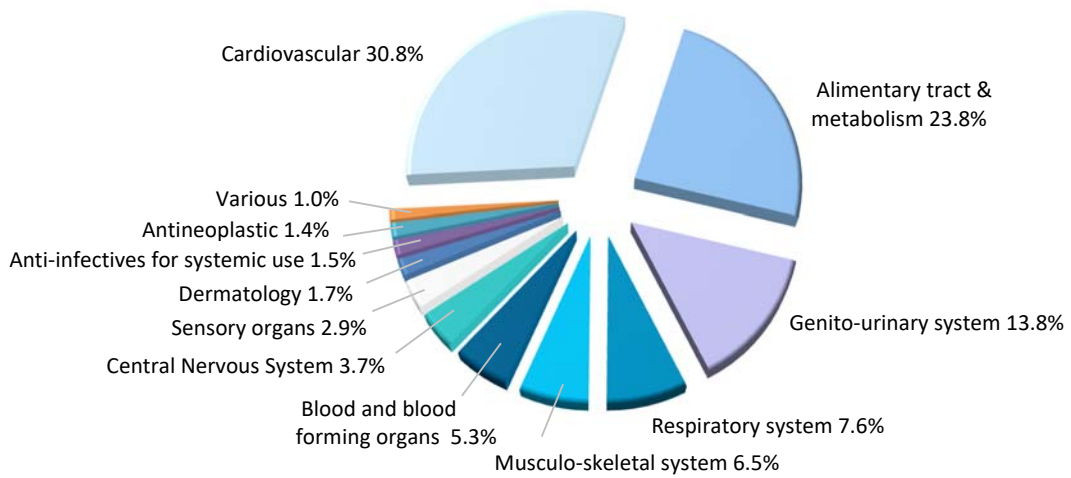
PHARMACEUTICALS

The group's pharmaceutical business, which represents 96.9% 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, the Middle East, Japan and Australia, through our own subsidiaries and, in the rest of the world, mainly through licensing agreements with pharmaceutical companies of high standing. Our direct presence in markets in which our Specialty and Primary Care portfolio is sold was progressively extended 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. Regarding the business segment dedicated to treatments for rare diseases new Recordati Rare Diseases subsidiaries have been established worldwide.

Pharmaceutical sales by geography in 2019 are shown below:



Pharmaceutical sales by therapeutic area in 2019 are shown below:



Corporate products

The performance of products sold directly in more than one market (corporate products) during 2019 is shown in the table below.

€ (thousands)	2019	2018	Change 2019/2018	%
Zanidip® (lercanidipine)	134,381	120,762	13,619	11.3
Zanipress® (lercanidipine+enalapril)	58,938	59,366	(428)	(0.7)
Urorec® (silodosin)	107,128	101,090	6,038	6.0
Livazo® (pitavastatin)	53,807	46,416	7,391	15.9
Seloken®/Seloken® ZOK/Logimax® (metoprololo/metoprololo+felodipina)	98,321	98,877	(556)	(0.6)
Other corporate products*	306,327	274,040	32,287	11.8
Drugs for rare diseases	249,850	214,832	35,018	16.3

* Include the OTC corporate products for an amount of € 113.9 million in 2019 and € 105.2 million in 2018 (+8.3%).

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)	2019	2018	Change 2019/2018	%
Direct sales	74,587	67,362	7,225	10.7
Sales to licensees	59,794	53,400	6,394	12.0
Total lercanidipine sales	134,381	120,762	13,619	11.3

The direct sales of lercanidipine based products are up by 10.7% mainly due to sales growth in Germany, Italy, Turkey and Poland as well as to the direct to market sales by our organizations now operational in the Nordic countries and in BeNeLux, areas where sales were previously realized by our licensees. Sales to licensees, which represent 44.5% of total lercanidipine sales, are up by 12.0% mainly thanks to the good sales performance in Australia and China.

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)	2019	2018	Change 2019/2018	%
Direct sales	53,021	47,991	5,030	10.5
Sales to licensees	5,917	11,375	(5,458)	(48.0)
Total lercanidipine+enalapril sales	58,938	59,366	(428)	(0.7)

Direct sales of Zanipress® in 2019 are up by 10.5% due to the growth of sales in Turkey and to the direct to market handling by our own organization in France of the sales that were previously realized by a licensee under a co-marketing agreement. Sales to licensees represent 10.0% of total Zanipress® sales and are down by 48.0% mainly due to lower sales to licensees in France.

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 40 countries. Silodosin based products are sold directly by our subsidiaries under the brand Urorec® and by licensees under the brand Silodyx™ and generated sales in 2019 of €107.1 million, up by 6.0%. Urorec® is doing particularly well in Turkey, Italy and Russia. The product is also growing significantly in Tunisia and Switzerland. In February 2020 the exclusivity covering the use of silodosin clinical data expired and consequently generic versions of the product may enter the market.

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 2019, including sales to co-marketers in Spain, Portugal and Greece, are € 53.8 million, up by 15.9%. The product is growing significantly in Turkey, Russia, Greece and Switzerland. In August 2020 the exclusivity covering the use of pitavastatin clinical data will expire and consequently generic versions of the product may enter the market.

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. The products are sold directly in around 20 countries and through distribution agreements in other European countries. Sales of these products in 2019 are € 98.3 million.

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

- Reagila® (cariprazine) is an innovative atypical antipsychotic for the treatment of schizophrenia. Cariprazine is an orally active and potent dopamine D₃/D₂ receptor partial agonist with preferential binding to D₃ receptors and partial agonist at serotonin 5-HT_{1A} 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. The product has been launched in Germany, Switzerland, Spain, Italy, BeNeLux, United Kingdom, the Nordic countries, Portugal and Ireland where overall sales generated are of € 7.6 million.
- Polydexa®, Isofra® and Otofa® are combination products for the treatment of ENT infections sold mainly in Russia. In 2019 sales of Polydexa® are € 31.6 million, those of Isofra® are € 20.6 million while Otofa® generated sales of € 4.6 million. Overall sales are up compared to the preceding year.
- 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 2019 are € 30.5 million, up by 22.7%.
- 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 2019 are € 29.1 million, up by 12.1%, 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 in around 15

countries but mainly in Spain and in Germany. In 2019 sales of CitraFleet® are € 28.6 million (+14.7%) and those of PhosphoSoda® are € 4.4 million (+5.0%). Fleet enema and Casenlax®, two other gastrointestinal products, generated sales of € 12.7 million (+8.3%) and € 12.9 million (+31.4%) respectively.

- 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 2019 are € 27.3 million.
- 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 Lomexin® in 2019 are € 21.4 million, up by 28.5% compared to the preceding year thanks mainly to the growth of sales in Poland.
- 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 2019 are € 18.9 million, down by 2.1%, and are generated mainly in France, North Africa and Russia.
- 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 € 11.0 million (+2.2%) in 2019.
- 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 incontinence and the treatment of bladder and urethral spasms and is marketed under the brands Genurin® and Urispas®. Sales of this product in 2019 are € 8.8 million, up by 7.4%.
- 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 but mainly in Germany. Sales of Kentera® are € 7.6 million (+7.2%) in 2019.
- 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 2019 are € 6.2 million (-0.3%) and are generated mostly in Greece and in Germany.
- Lactigest® (lactase) is an enzyme based preparation indicated in cases of lactose intolerance due to primary and secondary lactase deficiency. Sales of this product in 2019 are € 5.1 million (+11.3%) and are generated in Italy and in Switzerland.
- Rupatadine is a systemic antihistamine indicated for the treatment of allergies and in particular allergic rhinitis. Under license from Uriach, it is marketed in Italy and Germany as Rupafin® and in France as Wystamm®. Sales of all brands of rupatadine in 2019 total € 3.8 million, down by 9.6% following the entry of generic versions of the product on the market.
- Abufene® and Muvagyn® are gynaecological products indicated for menopausal symptoms. Sales of these products in 2019 are € 5.6 million (+0.4%) and € 2.6 million (-4.6%) respectively.
- Vitaros®/Virirec® (alprostadil) is the first topically applied cream formulation of alprostadil for the treatment of erectile dysfunction. The topical administration and local mechanism of action minimizes any systemic

adverse reaction or interaction with other drugs, food or alcoholic beverages, and therefore Vitaros® can be considered an effective and safe alternative to existing orally administered products. It is sold under license from the US pharmaceutical company Apricus Biosciences. The product is available in Spain, Italy, Portugal, Romania, Greece, Ireland, the Czech Republic and Slovakia. Sales generated in 2019 are € 4.6 million (+57.0%).

- Fortacin® (lidocaine+prilocaine) is an easy-to-use fast acting topical spray formulation of lidocaine and prilocaine for the treatment of premature ejaculation. The product, launched during 2018, is on the market in Italy, Germany, Spain, Portugal, France, the United Kingdom and Greece. Sales of the product in 2019 are of € 1.2 million (+50.9%).

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 Recordati Rare Diseases, its group of subsidiaries entirely dedicated to the research, development and marketing of medicines for the treatment of 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 Rare Diseases operates directly in Europe, the Middle East, North Africa, U.S.A., Canada, Mexico, Colombia, Brazil, Japan and Australia. 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.

Sales of products for the treatment of rare diseases in 2019 are of € 249.9 million, up by 16.3%, and include the revenues generated by the recently acquired or licensed in products (Juxtapid® in Japan, Ledaga® in Europe and Signifor®/Signifor® LAR worldwide). Sales in the United States of America are up by 8.5% despite the competition from a generic version of Cosmegen®. Sales in the rest of the world grow by 23.2%.

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. Juxtapid® (lomitapide) for the treatment of homozygous familial hypercholesterolemia, Ledaga® (chlormethine hydrochloride) for the topical treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) and Pedeas®/Neoprofen® (i.v. ibuprofen) used in the treatment of a serious congenital cardiac malformation, the persistence of *patent ductus arteriosus* (PDA).

During 2019, Ledaga® (chlormethine hydrochloride) indicated for the topical treatment of mycosis fungoides, a type of cutaneous lymphoma (MF-CTCL, mycosis fungoides cutaneous T-cell lymphoma), obtained under license from the Swiss pharmaceutical company Helsinn in 2018, was launched. Sales of this product in 2019 are of € 2.6 million.

Furthermore, in February, Recordati obtained from Aegerion Pharmaceuticals Inc. the exclusive rights to commercialize Juxtapid® in Japan. Juxtapid® (lomitapide) is a microsomal triglyceride transfer protein inhibitor indicated for the treatment of homozygous familial hypercholesterolemia (HoFH). HoFH is a serious, rare genetic disease that impairs the function of the receptor responsible for removing LDL-C ("bad" cholesterol) from the body. A loss of LDL receptor function results in extreme elevation of blood cholesterol levels. HoFH patients often develop premature and progressive atherosclerosis, a narrowing or blocking of the arteries. Sales of Juxtapid® in 2019 are of € 8.3 million.

During 2019 the worldwide rights to Signifor® and Signifor® LAR for the treatment of Cushing's disease and acromegaly in adult patients for whom surgery is not an option or for whom surgery has failed were acquired from Novartis. Revenues generated by Signifor® and Signifor® LAR starting 23 October 2019 are € 10.1 million. The agreement also covers the acquisition of worldwide rights to Isturisa® (osilodrostat), an investigational innovative drug for the treatment of endogenous Cushing's syndrome, for which marketing authorization was granted by the European Commission in January 2020 and approval obtained in the U.S.A. in March 2020. Cushing's syndrome includes Cushing's disease, a severe endocrine disease caused by a pituitary adenoma which results in over-production of cortisol by the adrenal glands and is associated with increased morbidity and mortality. Acromegaly is caused by an overexposure to growth hormone that leads to the production of insulin-like growth factor-1. The most common cause of acromegaly is a pituitary adenoma. Signifor® contains the active substance pasireotide, a somatostatin analogue that blocks the production of ACTH, helping to control the over-production of cortisol and improve the symptoms of Cushing's disease. The active ingredient in Isturisa®, osilodrostat, is an orally administered steroidogenesis inhibitor of 11Beta-hydroxylase, an enzyme which catalyses the final step of cortisol synthesis in the adrenal cortex. This new drug for endogenous Cushing's syndrome is expected to represent an effective new treatment option for patients.

Pharmaceutical sales by geographical area

The pharmaceutical sales by geography of the Recordati subsidiaries (including those dedicated to treatments for rare diseases) are broken down as follows:

€ (thousands)	2019	2018	Change 2019/2018	%
Italy	280,068	265,705	14,363	5.4
France	157,270	131,772	25,498	19.4
Germany	138,602	136,764	1,838	1.3
Russia, other C.I.S. countries and Ukraine	120,160	105,611	14,549	13.8
U.S.A.	109,570	101,003	8,567	8.5
Spain	94,699	88,880	5,819	6.5
Turkey	88,610	74,968	13,642	18.2
Portugal	44,454	41,679	2,775	6.7
Other C.E.E. countries	82,108	65,328	16,780	25.7
Other Western European countries	77,577	59,021	18,556	31.4
North Africa	40,318	40,679	(361)	(0.9)
Other international sales	202,310	200,173	2,137	1.1
Total pharmaceutical sales	1,435,746	1,311,583	124,163	9.5

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)	2019	2018	Change 2019/2018	%
Russia (RUB)	6,852,418	6,166,623	685,795	11.1
Turkey (TRY)	538,730	402,459	136,271	33.9
United States of America (USD)	130,484	123,407	7,077	5.7

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., Recordati Rare Diseases Italy S.r.l., Italchimici S.p.A. and 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 around 5,000 sq. m., built vertically over a number of floors for a total 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 5.4% over the preceding year and include, for the full year 2019, revenues generated by Natural Point S.r.l., consolidated as from 1 July 2018. The performance of the main products in Italy is the following:

€ (thousands)	2019	2018	Change 2019/2018	%
Prescription pharmaceuticals ^(a)	194,301	190,450	3,851	2.0
Self-medication pharmaceuticals ^(b)	85,767	75,255	10,512	14.0
Pharmaceuticals, Italy	280,068	265,705	14,363	5.4

(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	2019	2018	Change 2019/2018	%
Cardicor [®]	heart failure	31,733	27,195	4,538	16.7
Urorec [®]	benign prostatic hyperplasia	29,848	28,622	1,226	4.3
Zanedip [®] /Lercadip [®]	hypertension	19,555	18,194	1,361	7.5
Peptazol [®]	gastric ulcers	17,364	18,571	(1,207)	(6.5)
Aircort [®]	bronchial asthma	13,537	13,790	(253)	(1.8)
Tora-Dol [®]	pain	13,252	12,594	658	5.2
Zanipril [®] /Lercaprel [®]	hypertension	12,822	12,085	737	6.1

Cardicor[®] (bisoprolol), Urorec[®] and the lercanidipine based products performed well, together with the treatments for rare diseases which are up by 5.3%. Sales of Peptazol[®] (pantoprazole) and the lercanidipine based products have been affected by the competition from generic versions of the products.

Sales of self-medication products are € 85.8 million, significantly up compared to the preceding year, and have benefited from the full year sales of Natural Point's self-medication products (consolidated as from July 2018), in particular of Magnesio Supremo[®], a magnesium based food supplement which has become the main product in our Italian consumer health portfolio with sales of € 16.5 million. Reuflor[®], a food supplement indicated for the rebalancing of intestinal bacterial flora, is the second largest product with sales of € 11.9 million. Alovex[™], indicated for the treatment of oral cavity aphthae, is our third best-selling self-medication product with sales of € 8.9 million, up by 11.8%, and remains market leader with a share of 34%. Proctolyn[®] (treatment of haemorrhoids) with sales of € 7.1 million also remains market leader with a share of more than 41%. Eumill[®] (eye drops and nasal spray) is leader in its class with a market share of 24% and generated sales of € 6.4 million, up by 4.6%. Dentosan[®], a line of oral care products, generated sales of € 4.2 million.

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, a market in which Tonipharm S.a.s., acquired at the end of 2018 and consolidated as from 1 January 2019, operates. Recordati Rare Diseases S.à r.l., a company dedicated exclusively to treatments for rare diseases, is headquartered 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 2019 revenue realized by our subsidiaries in France is € 157.3 million, up by 19.4% compared to the preceding year, and include the integration of the Tonipharm S.a.s. products, acquired end 2018. Below is the performance of the main products:

€ (thousands)	Indication	2019	2018	Change 2019/2018	%
Methadone	drug addiction	31,399	31,609	(210)	(0.7)
Urorec®	benign prostatic hyperplasia	17,703	17,320	383	2.2
Ginkor®	ginkgo biloba based food supplement	12,934	0	12,934	n.s.
Zanextra®/Lercapress®	hypertension	11,861	9,592	2,269	23.7
Seloken®/Seloken® ZOK/ Logimax®	Hypertension, cardiac disorders	9,997	9,716	281	2.9
Lercan®/Zanidip®/lercanidipine	hypertension	7,716	8,289	(573)	(6.9)
Transipeg®	laxative	7,117	4,708	2,409	51.2
Hexa line	antibacterial	7,945	7,432	513	6.9

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 2019 are € 31.4 million, substantially in line with those of the preceding year.

Sales include those of Lercapress® (lercanidipine+enalapril), now marketed by our subsidiary following the expiry of the license agreement with Pierre Fabre. Sales of lercanidipine based products decrease due to the competition from generic versions of the drug. Regarding the OTC portfolio, sales include Ginkor®, a ginkgo biloba based food supplement, and Alodont®, for oral hygiene, the main products belonging to Tonipharm S.a.s., acquired in December 2018 and consolidated as from 1 January 2019. Sales of the Hexa line of products grow by 3.3%. Sales of products for the treatment of rare diseases grow by 6.3%.

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 quality products 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 Recordati Rare Diseases Germany GmbH.

Sales generated by our subsidiaries in Germany are € 138.6 million, an increase of 1.3% compared to the preceding year. The following table shows sales of the main products.

€ (thousands)	Indication	2019	2018	Change 2019/2018	%
Ortoton®	muscle relaxant	32,652	37,277	(4,625)	(12.4)
Seloken®/Seloken® ZOK/ Logimax®	Hypertension, cardiac disorders	20,075	21,235	(1,160)	(5.5)
Corifeo®/lercanidipine	hypertension	12,152	9,639	2,513	26.1
Claversal®	ulcerative colitis	11,425	11,164	261	2.3
Zanipress®	hypertension	9,353	10,788	(1,435)	(13.3)
Mirfulan®	healing ointment	8,352	7,901	451	5.7
Recosyn®	musculo-skeletal	6,614	6,355	259	4.1

Overall, sales in Germany increase moderately compared to the preceding year. Worth mentioning is the performance of Reagila® (cariprazine), a new drug for the treatment of schizophrenia launched in 2018, and the continued success of the lercanidipine based products. The reduction in sales of Ortoton® (methocarbamol) is to be attributed to competition from generic versions of the product. The overall sales of self-medication products in Germany are € 26.7 million, up by 6.4% compared to the preceding year thanks mainly to the growth of Laxbene® (+42.7%), Mirfulan® and Recosyn®. Sales of the treatments for rare diseases in this country are up by 14.9%.

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 € 120.2 million, up by 13.8% compared to the preceding year and include an estimated positive currency exchange effect of € 3.5 million. Sales in Russia, in local currency, are RUB 6,852.4 million, up by 11.1% over the preceding year.

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

RUB (thousands)	Indication	2019	2018	Change 2019/2018	%
Polydexa®	ear infections	1,776,476	1,766,378	10,098	0.6
Tergynan®	gynaecological infections	1,428,009	1,258,320	169,689	13.5
Isofra®	nasal infections	1,257,005	1,081,030	175,975	16.3
Procto-Glyvenol®	hemorrhoids	646,310	529,471	116,839	22.1

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 and sales of Tergynan®, leader in its class, are growing compared to 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[®], Livazo[®] and Lomexin[®] record strong growth. In 2019 the growth of the treatments for rare diseases is significant (+17.5%).

Sales generated in Ukraine and in the C.I.S. (Commonwealth of Independent States), mainly Belarus, Kazakhstan and Georgia are growing significantly and have reached € 23.1 million (+19.4%).

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 2019 are € 109.6 million, up by 8.5% despite competition from a generic version of Cosmegen[®].

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, Recordati Rare Diseases 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 7,100 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 19 million packs a year.

Revenues in Spain are € 94.7 million, up by 6.5% compared to the preceding year. The following table shows sales of the main products.

€ (thousands)	Indication	2019	2018	Change 2019/2018	%
CitraFleet [®]	bowel cleansing	15,567	14,317	1,250	8.7
Livazo [®]	hypercholesterolemia	15,250	14,184	1,066	7.5
Urorec [®]	benign prostatic hyperplasia	10,038	9,724	314	3.2
Enema Casen	bowel cleansing	7,740	7,746	(6)	(0.1)
Bi-OralSuero	rehydrating solution	6,506	5,784	722	12.5
Casenlax [®]	laxative	5,501	4,601	900	19.6
Cidine [®]	gastroprokinetic	5,429	5,377	52	1.0
Virirec [®]	erectile dysfunction	3,548	2,638	910	34.5
Zanipress [®]	hypertension	3,491	3,112	379	12.2

Sales of the main product in the portfolio, CitraFleet[®], a preparation for colonoscopy grow by 8.7%. Livazo[®], Urorec[®], Bi-OralSuero[®], Casenlax[®] and Zanipress[®] are performing well and the treatments for rare diseases record a 28.0% growth. Sales of Cidine[®] (cinitapride) are slightly growing despite the presence of generic

competition in the market. Sales of Virirec®, the product for erectile dysfunction, are growing significantly (+34.5%).

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 11,300 sq. m. and has a total production capacity of 80 million packs annually. It currently produces 66 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 € 88.6 million, up by 18.2%, and were impacted by the devaluation of the Turkish Lira which generated a negative currency exchange effect estimated at € 9.6 million. In local currency, sales in Turkey increase by 33.9%, benefitting from an increase in the price of our products in this country of around 20% on average.

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

TRY (thousands)	Indication	2019	2018	Change 2019/2018	%
Mictonorm®	urinary incontinence	96,447	67,272	29,175	43.4
Lercadip®	hypertension	83,217	68,553	14,664	21.4
Cabral®	muscle relaxant	80,669	55,411	25,258	45.6
Urorec®	benign prostatic hyperplasia	71,870	51,281	20,589	40.1
Zanipress®	hypertension	48,891	33,710	15,181	45.0
Kreval®	cough	45,075	33,351	11,724	35.2
Livazo®	hypercholesterolemia	43,096	28,163	14,933	53.0
Ciprasid®	anti-infective	35,768	31,446	4,322	13.7
Procto-Glyvenol®	hemorrhoids	33,608	26,607	7,001	26.3

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

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 € 44.5 million, up by 6.7%. The performance of the main products is listed below.

€ (thousands)	Indication	2019	2018	Change 2019/2018	%
Livazo®	hypercholesterolemia	7,932	7,446	486	6.5
TransAct® LAT	anti-inflammatory	4,929	4,438	491	11.1
Urorec®	benign prostatic hyperplasia	3,269	3,057	212	6.9
Microlax®	laxative	3,191	3,117	74	2.4
Zanipress®	hypertension	2,950	2,915	35	1.2
Egostar®	vitamin D3	2,529	2,522	7	0.3

Sales of Zanipress® are substantially stable despite competition from generic versions of the product. Worth mentioning is the good performance of Livazo® and Urorec®. Regarding the portfolio of self-medication products, up by 9.8%, TransAct® LAT and Procto-Glyvenol® (+30.7%) are performing well. Furthermore, sales of the treatments for rare diseases are up by 1.8%.

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.

Poland

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 2019 are € 31.6 million, up by 19.4% thanks mainly to the inclusion of Citrafleet® in the product portfolio and the significant growth of the self-medication products. Worth mentioning is the good performance of Lercan® (lercanidipine), up by 50.0% and of Lercaprel® (lercanidipine+enalapril), up by 76.0%. Sales of the self-medication portfolio are up by 50.2% thanks to the significant growth of Procto-Glyvenol®, the Polish subsidiary's main OTC product, and of Gynoxin® (fenticonazole) that generated sales of € 8.7 million (+29.9%) and € 4.4 million (+362.1%) respectively.

Czech Republic and Slovakia

Herbacos Recordati S.r.o., the group's subsidiary present in the Czech Republic and in Slovakia, successfully markets pharmaceutical products belonging to a number of therapeutic areas, including cardiovascular, urology, 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 € 25.7 million, up by 8.1% compared the preceding year, mainly thanks to the significant growth of Mictonorm®, a propiverine based product for the treatment of urinary incontinence launched in 2018, of the metoprolol based cardiovascular products and of Urorec®. The self-medication product portfolio grows by 7.4% mainly due to the good performance of the brands Valetol® (paracetamol) and Acylpyrin® (acetylsalicylic acid).

Romania and Bulgaria

Recordati Romania S.R.L. promotes both prescription and self-mediation products successfully. Sales in Romania are € 12.5 million, up by 4.2%, mainly thanks to the good performance of the product for hemorrhoids Procto-Glyvenol® and of Tergynan®.

During 2019 our new subsidiary Recordati Bulgaria Ltd was established and generated sales of € 3.1 million in the year, almost entirely composed of the metoprolol based cardiovascular products.

Baltic states

As from 2019 the Group is present with direct sales to the market in the Baltic states, generating sales of € 4.1 million entirely composed of the metoprolol based cardiovascular products.

Products for the treatment of rare diseases marketed by Recordati Rare Diseases

Sales in the Central and Eastern European markets of the specialty products indicated for the treatment of rare and orphan diseases amount to € 4.0 million, up by 31.4%.

OTHER WESTERN EUROPEAN COUNTRIES

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

Switzerland

Sales generated by Recordati AG in Switzerland are € 20.5 million and refer mainly to the metoprolol based cardiovascular products and to Zanidip[®], Livazo[®], Lactigest[®] (tilattase) and Tretinac[®] (tretinoin). In 2018 Reagila[®], the new drug for the treatment of schizophrenia was launched in this country.

Greece

Sales in Greece are € 17.9 million, up by 3.5% thanks to the good performance of Livazo[®], Zanidip[®] and Urorec[®].

United Kingdom

Sales in the United Kingdom are € 8.0 million and relate mainly to products for the treatment of rare diseases which account for 80.9% of our revenues in this country. During 2018 Reagila[®] was also launched in the UK.

Ireland

Sales in Ireland are € 1.6 million, mainly generated by Urorec[®], Zanipress[®] (sold in Ireland with the brand Lercaril[®]), Kentera[®] and Zanidip[®].

Nordic countries and BeNeLux

During 2018, the organizational structure of our subsidiaries Recordati AB in Sweden and Recordati BVBA in Belgium was reinforced to allow the promotion and sales of our specialty products, in addition to our products for the treatment of rare diseases, in the Nordic countries and in BeNeLux. Sales in the Nordic countries in 2019 re of € 11.0 million and refer almost entirely to the metoprolol based cardiovascular products and to Zanidip[®], the latter previously sold by a licensee. Sales in BeNeLux are € 3.7 million and refer almost entirely to the metoprolol based cardiovascular products.

Products for the treatment of rare diseases marketed by Recordati Rare Diseases

Sales of products for the treatment of rare diseases in these Western European countries (UK excluded) are of € 14.9 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 9,100 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 19 million packs a year.

Overall, sales in North Africa are € 40.3 million, substantially in line with those of the preceding year. Sales in Tunisia in 2019 are of € 26.7 million, up by 12.3%. In local currency sales in Tunisia grow by 18.4%. The main products in this very diversified portfolio are Zanidip[®], Zanipress[®] (sold with the brand Zanextra[®]), Vitamin D3 and Urorec[®].

OTHER INTERNATIONAL SALES

Other international sales amount to € 202.3 million, up by 1.1%, 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 Recordati Rare Diseases's sales in all other countries not described above.

Sales to international licensees, including other revenues, are of € 127.7 million, down by 12.4%, mainly due to the shift to direct in-market sales by the Group's subsidiaries of the metoprolol based products, Seloken[®], Seloken[®] ZOK and Logimax[®], and of Zanipress[®], as well as other corporate products, in countries where they were previously distributed through agreements with third parties.

Sales outside France by our French subsidiary Laboratoires Bouchara Recordati, excluding North Africa, are € 18.2 million, up by 6.1%, while sales outside Spain by our Spanish subsidiary Casen Recordati are € 4.6 million, up by 6.1%.

Revenue generated by our treatments for rare diseases in other countries not described above, mainly in Canada, some countries in Latin America, the Middle East, Asia and Australia, mostly generated by our subsidiaries including the ones recently established in Japan and in Australia, are of € 51.8 million, up by 60.2%. Revenue includes sales of Juxtapid[®], a product obtained under license in 2019, in Japan and the launch of Panhematin[®] and Cystadrops[®] in Canada.

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, 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 € 46.1 million, up by 13.4%. In particular, the products manidipine, acyclovir, tribenoside, dimenhydrinate and diphenhydramine performed well.

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

€ (thousands)	2019	%	2018	%	Change 2019/2018	%
Italy	3,122	6.8	2,950	7.3	172	5.8
Europe (Italy excluded)	14,642	31.8	13,663	33.6	979	7.2
United States of America	7,755	16.8	8,219	20.2	(464)	(5.6)
America (U.S. excluded)	4,376	9.5	3,881	9.5	495	12.8
Australasia	15,014	32.6	11,062	27.2	3,952	35.7
Africa	1,193	2.6	877	2.2	316	36.0
Total	46,102	100.0	40,652	100.0	5,450	13.4

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 months of April and May 2019 the Campoverde di Aprilia plant underwent an inspection by ARPA (the regional agency for the protection of the environment) for the Lazio region. During the four days of the inspection the authorities carried out a site inspection, an audit of all the documents related to the system for environmental management and a sampling of waste water. No non conformities were found by the authorities and the analytical results of waste water were within the required limits.

During 2019 the Campoverde di Aprilia plant underwent an environmental audit by a consultancy firm, and, on the other hand conducted five environmental audits at the sites of intermediaries and waste processing plants. Furthermore, the verification for the renewal of the environmental certification ISO 14001:2015 conducted in the month of June 2019 by the accredited company DNV GL assumes particular importance. During the two visits by the Lead Auditor of DNV GL together with a Lead Assistant, the entire environmental management system at the Campoverde di Aprilia plant was inspected.

FINANCIAL REVIEW

INCOME STATEMENT

The following table shows the profit and loss accounts, including their expression as a percent of sales and change versus 2018:

€ (thousands)	2019	% of revenue	2018	% of revenue	Change 2019/2018	%
Revenue	1,481,848	100.0	1,352,235	100.0	129,613	9.6
Cost of sales	(436,901)	(29.5)	(395,569)	(29.3)	(41,332)	10.4
Gross profit	1,044,947	70.5	956,666	70.7	88,281	9.2
Selling expenses	(372,803)	(25.2)	(333,497)	(24.7)	(39,306)	11.8
Research and development expenses	(129,681)	(8.8)	(109,693)	(8.1)	(19,988)	18.2
General and administrative expenses	(72,783)	(4.9)	(67,722)	(5.0)	(5,061)	7.5
Other income (expense), net	(4,414)	(0.3)	(3,535)	(0.3)	(879)	24.9
Operating income	465,266	31.4	442,219	32.7	23,047	5.2
Financial income (expense), net	(21,122)	(1.4)	(24,284)	(1.8)	3,162	(13.0)
Pre-tax income	444,144	30.0	417,935	30.9	26,209	6.3
Provision for income taxes	(75,278)	(5.1)	(105,513)	(7.8)	30,235	(28.7)
Net income	368,866	24.9	312,422	23.1	56,444	18.1
Attributable to:						
Equity holders of the parent	368,825	24.9	312,376	23.1	56,449	18.1
Non-controlling interests	41	0.0	46	0.0	(5)	(10.9)

In 2019 international revenues went from € 1,079.0 million to € 1,194.6 million, an increase of 10.7%, and represent 80.6% of total revenue. Their breakdown by geographic area is shown in the table below:

€ (thousands)	2019		2018	
		%		%
Europe (Italy excluded)	904,185	75.7	828,728	76.8
United States of America	118,251	9.9	110,781	10.3
America (United States excluded)	34,375	2.9	25,970	2.4
Australasia	85,465	7.2	62,295	5.8
Africa	52,283	4.4	51,264	4.8
Total	1,194,559	100.0	1,079,038	100.0

Gross profit is € 1,044.9 million with a margin of 70.5% on sales, a slight decrease compared that of the preceding year due mainly to price and currency effects.

Selling expenses increase by 11.8% with a slight increase as a percent of revenue compared to the preceding year due to marketing expenses for the launch of Reagila®, the new commercial organizations in the Nordic

countries, BeNeLux and the Baltics and the initial reinforcement of the organization dedicated to the rare diseases segment following the acquisition of the products for rare endocrinology diseases Signifor[®], Signifor[®] LAR and Isturisa[®] from Novartis.

Research and development expenses are € 129.7 million, up by 18.2% compared to those recorded in 2018 due to the advancement of new development programs and the amortization of the amounts allocated to intangible assets following the acquisition of Natural Point S.r.l. and of Tonipharm S.a.s., of the up-front payments for the recently acquired licenses to the rare disease products Ledaga[®] and Juxtapid[®] and of the rights to the products Signifor[®] and Signifor[®] LAR acquired from Novartis.

General and administrative expenses are up by 7.5% but are slightly reduced as percent of sales.

Overall, labor cost in 2019 is € 289.1 million, an increase of 5.5% over 2018, with the cost per employee up by 4.1%.

Personnel and other human resources data at 31 December 2019 and 2018 are shown in the following table:

	2019	2018
Employees at year-end	4,323	4,142
Average age	43	43
Average service (years)	8.4	8.3
Labor productivity:		
Labor cost on net sales	19.5%	20.3%
Sales per employee (€ thousands) ^(a)	357.9	330.7
Value added per employee (€ thousands) ^(a)	201.1	189.1

Labor cost includes wages, related charges and additional costs.

(a) Data per employee for both years are computed on the average number of personnel, 4,141 in 2019 and 4,089 in 2018.

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 and of the specialist organizations for the management of the new endocrinology area. 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 € 4.4 million, up by € 0.9 million compared to the preceding year. They include an accrual of € 4.2 million for the early termination of a license agreement.

EBITDA (earnings before interest, taxes, depreciation, amortization and write-downs), at 36.7% of sales, is € 544.0 million, an increase of 9.0% over 2018. Total depreciation and amortization charges, classified in the lines above, are € 78.2 million. Amortization charges are € 53.1 million, an increase of € 10.1 million over the preceding year due to the amounts allocated to intangible assets following the acquisition of Natural Point S.r.l. and of Tonipharm S.a.s., to the up-front payments for the recently acquired licenses to the rare disease products Ledaga[®] and Juxtapid[®] and to the rights for the products Signifor[®] and Signifor[®] LAR acquired from Novartis. Depreciation charges are € 25.1 million, up by € 11.2 million mainly due to the application of the new accounting principle IFRS 16 which at the same time led to lower leasing charges thus determining a positive effect of € 0.4

million on operating income and € 11.0 million on EBITDA.

The reconciliation of the net income and the EBITDA inclusive of write-down of intangible assets is reported below:

€ (thousands)	2018	2017
Net income	368,866	312,422
Provision for income taxes	75,278	105,513
Financial (income) expenses, net	21,122	24,284
Depreciation and amortization	78,248	56,860
Write-down of intangible asset	453	0
EBITDA inclusive of write-down of intangible assets⁽¹⁾	543,967	499,079

⁽¹⁾ Net income before provision for income taxes, financial (income) expenses, net, depreciation and amortisation and write-down of both property, plant and equipment and intangible assets

Net financial charges in 2019 are € 21.1 million, a decrease of € 3.2 million compared to the preceding year mainly due to lower foreign exchange losses and interest on tax assessments for a total of € 6.8 million, partially offset by € 3.6 million due to an increase in interest charges on new loans, higher charges on short-term positions and interest expense related to leasing contracts.

The effective tax rate during the year is 17.0%, significantly lower than that of the preceding year due to the tax benefit provided by the so-called “patent box”. In December an agreement was reached with the Italian tax authorities which allows the Parent Company to benefit from a discount on taxable income of 30% for the year 2015, 40% for 2016 and 50% for the 2017-2019 three year period with reference to patents, know-how and brands related to selected products provided for in the agreement. The “patent box” optional regime covers the period 2015-2019. The tax benefit for the period 2015-2018 is of € 27.0 million while that relative to 2019 is of € 8.3 million. The Company will renew the option for the next five year period but the tax benefit will be lower due to the exclusion of brands from the “patent box” regime.

Net income at 24.9% of sales is € 368.9 million, an increase of 18.1% over the preceding year mainly thanks to the abovementioned tax benefit.

FINANCIAL POSITION

The net financial position at 31 December 2019 records net debt of € 902.7 million compared to net debt of € 588.4 million at 31 December 2018.

€ (thousands)	31.12.2019	31.12.2018	Change 2019/2018	%
Cash and short-term financial investments	187,923	198,036	(10,113)	(5.1)
Bank overdrafts and short-term loans	(13,392)	(16,905)	3,513	(20.8)
Loans – due within one year ⁽¹⁾	(140,963)	(135,062)	(5,901)	4.4
Leasing liabilities – due within one year	(8,854)	(216)	(8,638)	n.s.
Net liquid assets	24,714	45,853	(21,139)	(46.1)
Loans – due after one year ⁽¹⁾	(908,542)	(632,823)	(275,719)	43.6
Leasing liabilities – due after one year	(18,853)	(1,410)	(17,443)	n.s.
Net financial position	(902,681)	(588,380)	(314,301)	53.4

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

During the period dividends were paid for a total of € 190.9 million, an amount of € 26.4 million were paid as per the license agreement with Aegerion Pharmaceuticals Inc. covering the exclusive rights to Juxtapid® (lomitapide) in Japan, a € 47.5 million milestone was paid to Helsinn as per the license agreement for Ledaga® (chlormethine) and € 350.1 million were paid to Novartis for the acquisition of the rights to Signifor®, Signifor® LAR and Isturisa®. Furthermore, the application of IFRS 16 generated an increase in leasing liabilities of € 26.3 million.

An amount of € 33.3 million was invested in property, plant and equipment, of which € 11.2 million related to leased assets, and involve mainly the Parent Company (€ 15.0 million), the Spanish subsidiary Casen Recordati (€ 5.3 million) and the Turkish subsidiary Recordati Ilaç (€ 2.1 million).

During the year the privately placed notes issued by Recordati Rare Diseases on 13 June 2013 for a total of \$ 70 million were fully repaid. The euro equivalent amount paid was of € 61.3 million.

In June Recordati S.p.A. undersigned a loan agreement for an amount of € 400.0 million to support the Group's growth strategy. The loan, initially undersigned by Mediobanca, Natixis and Unicredit was subsequently syndicated involving a pool of Italian and international banks. The terms of the loan provide for a variable interest rate at the 6 months' Euribor (with a zero floor) plus a 135 basis points spread and a duration of 5 years with principal repayment on a semi-annual basis starting 30 June 2020 through June 2024. Funding, net of up-front commissions, took place on 30 July 2019.

In August, the Parent undersigned a loan agreement with ING Bank for an amount of € 22.5 million. Terms include variable interest rate at the 6 months' Euribor plus a 135 basis points spread, semi-annual interest payments and principal repayment on a semi-annual basis starting December 2021 through December 2024.

Net working capital for operations at 31 December 2019 is € 198.7 million and is thus comprised:

€ (thousands)	31.12.2019	% of revenue	31.12.2018	% of revenue	Change 2019/2018	%
Trade receivables, net	296,961	20.0	245,742	18.2	51,219	20.8
Inventories	226,885	15.3	206,084	15.2	20,801	10.1
Other current assets	87,632	5.9	43,655	3.2	43,977	100.7
Current assets	611,478	41.3	495,481	36.6	115,997	23.4
Trade payables	175,481	11.8	165,020	12.2	10,461	6.3
Tax payable	21,094	1.4	42,149	3.1	(21,055)	(50.0)
Other current liabilities	216,182	14.6	126,339	9.3	89,843	71.1
Current liabilities	412,757	27.9	333,508	24.7	79,249	23.8
Net working capital for operations	198,721	13.4	161,973	12.0	36,748	22.7
Days of sales outstanding	63		61			
Inventories as % of cost of sales	51.9%		50.7%			

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

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	
	31.12.2019	31.12.2018	2019	2018
Recordati S.p.A.	435,426	336,058	241,092	217,330
Consolidation adjustments:				
- Margin in inventories	(59,066)	(58,411)	(655)	(23,361)
- Related deferred tax	16,618	16,296	322	6,577
- Other adjustments	(13,726)	(10,802)	(4,014)	(2,463)
Retained earnings of consolidated subsidiaries at beginning of the year, net of amounts already booked by Recordati S.p.A.	708,217	591,143	-	-
Net income for the year of consolidated subsidiaries, net of amounts already booked by Recordati S.p.A.	257,974	243,255	257,974	243,255
Dividends received from consolidated subsidiaries	-	-	(128,138)	(135,162)
Write-down of holdings in controlled companies	-	-	2,244	6,200
Translation adjustments	(146,866)	(154,146)	-	-
Consolidated financial statements	1.198,577	963,393	368,825	312,376

RELATED PARTY TRANSACTIONS

The Group's direct controlling company is FIMEI S.p.A., which since 2018 is owned by a consortium of investors controlled by CVC Capital Partners.

At 31 December 2019 the Parent Company had 3.308.571 own shares in treasury stock equivalent to 1.58% of its share capital, with a nominal value of € 0.125 each.

Tax receivables include an amount of € 40.6 million, computed by Recordati S.p.A. based on estimated taxable income, receivable from the controlling company FIMEI S.p.A. consequent to the participation in a tax consolidation grouping under tax laws in Italy. The amount includes the effect of the so-called "patent box" agreed with the Italian tax authorities in December 2019, for the part related to corporate tax.

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.

In compliance with the requirements of art. 4, comma 7, of the Italian Regulations on operations with related parties adopted by Consob on March 12 2010 as well as art. 2391-bis, comma 1, of the Civil Code, the Parent Company communicates that it has adopted the "Procedure governing the operations with related parties", available on the Company's internet website www.recordati.com (under "Corporate Governance"). For further information regarding corporate governance please refer to the Corporate Governance Report approved by the Board of Directors together with the Annual Report. Information regarding comma 1 and 2 of art. 123 bis of the Italian legislative decree 58/1998 can be found in the Corporate Governance Report available, in its entirety on the Parent Company's website www.recordati.com (under the Corporate Governance section).

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 2019 the provisions of art. 15 (ex 36) of the Financial Markets Regulation apply to the subsidiaries Recordati İlaç, Recordati Rare Diseases Inc., Rusfic LLC and Recordati AG and that the conditions indicated in the abovementioned art. 15 (ex 36) are fulfilled.

SIGNIFICANT OPERATIONS, PUBLICATION REQUIREMENTS DEROGATION

The Parent 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.

ATYPICAL AND/OR UNUSUAL OPERATIONS

In compliance with Consob's communication dated 28 July 2006 it is hereby stated that during 2019 no atypical or unusual operations, as defined by the communication itself, were put in place.

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, even on more than one occasion during the year, 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 anticorruption rules and specifically rules regulating medial information and relationship with the medical community). In particular, these risks of a non-financial nature 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 have been classified as follows:

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

For each risk, the strategies and management policies for efficacious and concrete protection and the consequent mitigation of the risk, are described

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. Furthermore, the export of medicinal products by the Group to countries subject to sanction programmes are marginal and are in any case allowed and in line with said programmes. To this purpose, in order to mitigate the risk of commercial and economic sanctions, the Group years ago adopted a specific model for the management and control of exports.

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, length of time involved and the intrinsic nature of 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 significant 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. The risks connected with these activities are of a diverse nature and could result in the interruption of production, the damage to plant, delays in the production cycle or risks linked to the denial of regulatory authorizations. As protection against these risks, first of all, 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. Opalia Pharma'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. 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.

A risk related to cyber attacks was added to the risk catalogue, in view of this growing phenomenon which could affect the company's information systems. In the face of this new risk the Group had, however, already introduced specific safeguards both of a technological safety nature as well as of an organizational nature and, in line with the impact and probability evaluation criteria, defined the consequent level of residual risk.

Instead, 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 is affected by 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

Each and every activity performed by the Group throughout the entire life cycle of a product, from research and development, to production, to scientific information provided, presupposes a compliance risk. To safeguard non compliance risks, the Company has in place an internal control system, composed of a series of procedures and structured and organic organizations in order to control the monitoring of risks of non compliance with laws, rules and regulations, guarantee correct and transparent information to the market, as well as prevent and limit the consequences of unexpected results, bearing in mind the achievement of the company's objectives.

The structural aspects of internal control and risk management are comprised by: the Code of Ethics, that defines the principles and values at the base of the Company's ethics, as well as the behavioural rules in respect of said principles; by the system for the delegation of powers based on general and special powers of attorney and internal delegations, corresponding to the responsibilities assigned by the Company's operational procedures; by the information systems supporting administration and production activities as well as the accounting and financial processes.

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 Note 38 to the financial statements.

BUSINESS OUTLOOK

On 14 February 2020 the company announced the following financial targets for 2020: sales ranging from € 1,550 million to € 1,580 million, an EBITDA of between € 580 and € 590 million, EBIT of between € 490 and € 500 million and net income of between € 360 and € 370 million.

Group consolidated sales during the first two months of 2020 are in line with our expectations. In the face of the epidemiologic emergency due to the COVID-19 virus, the Group is implementing all possible measures and initiatives to guarantee the supply of medicines to its patients and the safety of its employees. Given the complex and constantly evolving situation it is not possible to predict possible future impacts at this time. Considering the Company's business segment, recent performance and the high level of diversification of the Group it is not deemed necessary to change the asset or liabilities amounts recognised in the financial accounts.

Milan, 18 March 2020

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 2019

RECORDATI S.p.A. AND SUBSIDIARIES

CONSOLIDATED INCOME STATEMENT FOR THE YEAR ENDED 31 DECEMBER 2019

INCOME STATEMENT

€ (thousands) ⁽¹⁾	Note	2019	2018*
Revenue	3	1,481,848	1,352,235
Cost of sales	4	(436,901)	(395,569)
Gross profit		1,044,947	956,666
Selling expenses	4	(372,803)	(333,497)
Research and Development expenses	4	(129,681)	(109,693)
General and Administrative expenses	4	(72,783)	(67,722)
Other income (expense), net	4	(4,414)	(3,535)
Operating income		465,266	442,219
Financial income (expense), net	5	(21,122)	(24,284)
Pretax income		444,144	417,935
Provision for income taxes**	6	(75,278)	(105,513)
Net income		368,866	312,422
Attributable to:			
Equity holders of the parent		368,825	312,376
Non-controlling interests		41	46
Earnings per share			
Basic		€ 1.800	€ 1.529
Diluted		€ 1.764	€ 1.494

⁽¹⁾Except for share and per-share amounts.

Earnings per share (EPS) are based on average shares outstanding during each year, 204,959,193 in 2019 and 204,379,165 in 2018, net of average treasury stock which amounted to 4,165,963 shares in 2019 and 4,745,991 shares in 2018.

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

* The Group has initially applied IFRS 16 at 1 January 2019, using the modified retrospective approach. Under this approach, comparative information is not restated and the possible cumulative effect of initially applying IFRS 16, not significant for the Group, is recognised in retained earnings at the date of initial application. (See Note 2)

**Provision for income taxes in 2019 includes a non-recurring tax benefit provided by the so-called "patent box": € 27.0 million relative to previous years and € 8.3 million related to 2019 (see Note 6).

The accompanying notes are an integral part of these consolidated financial statements.

RECORDATI S.p.A. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEET AT 31 DECEMBER 2019

ASSETS

€ (thousands)	Note	31 December 2019	31 December 2018*
Non-current assets			
Property, plant and equipment	7	133,342	103,582
Intangible assets	8	1,161,760	672,106 **
Goodwill	9	577,973	577,786 **
Other investments	10	38,566	20,773
Other non-current assets	11	16,426	5,860
Deferred tax assets	12	71,513	81,227 **
Total non-current assets		1,999,580	1,461,334
Current assets			
Inventories	13	226,885	206,084
Trade receivables	14	296,961	245,742
Other receivables	15	79,949	38,462
Other current assets	16	7,683	5,193
Fair value of hedging derivatives (<i>cash flow hedge</i>)	17	9,949	6,414
Short-term financial investments, cash and cash equivalents	18	187,923	198,036
Total current assets		809,350	699,931
Total assets		2,808,930	2,161,265

*The Group has initially applied IFRS 16 at 1 January 2019, using the modified retrospective approach. Under this approach, comparative information is not restated and the possible cumulative effect of initially applying IFRS 16, not significant for the Group, is recognised in retained earnings at the date of initial application. (See Note 2)

** Restated amounts following the change in the allocation of the price paid for the acquisition of Tonipharm S.a.s. (see Notes 9 and 34)

The accompanying notes are an integral part of these consolidated financial statements.

RECORDATI S.p.A. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEET AT 31 DECEMBER 2019

EQUITY AND LIABILITIES

€ (thousands)	Note	31 December 2019	31 December 2018*
Shareholders' equity			
Share capital		26,141	26,141
Additional paid-in capital		83,719	83,719
Treasury stock		(93,480)	(145,608)
Hedging reserve (<i>cash flow hedge</i>)		(5,357)	(8,399)
Translation reserve		(146,866)	(154,146)
Other reserves		64,651	43,081
Retained earnings		999,708	897,990
Net income for the year		368,825	312,376
Interim dividend		(98,764)	(91,761)
Group shareholders' equity	19	1,198,577	963,393
Non-controlling interest	20	234	193
Shareholders' equity		1,198,811	963,586
Non-current liabilities			
Loans – due after one year	21	937,344	640,647
Staff leaving indemnities and other benefits	22	20,557	19,547
Deferred tax liabilities	23	43,172	43,486 **
Other non-current liabilities	24	22,292	3,257
Total non-current liabilities		1,023,365	706,937
Current liabilities			
Trade payables	25	175,481	165,020
Other payables	26	185,706	85,534
Tax liabilities	27	21,094	42,149
Other current liabilities	28	12,543	19,359
Provisions	29	17,933	21,446
Fair value of hedging derivatives (<i>cash flow hedge</i>)	30	10,788	9,746
Loans – due within one year	21	149,817	130,583
Bank overdrafts and short-term loans	31	13,392	16,905
Total current liabilities		586,754	490,742
Total equity and liabilities		2,808,930	2,161,265

* The Group has initially applied IFRS 16 at 1 January 2019, using the modified retrospective approach. Under this approach, comparative information is not restated and the possible cumulative effect of initially applying IFRS 16, not significant for the Group, is recognised in retained earnings at the date of initial application. (See Note 2)

** Restated amounts following the change in the allocation of the price paid for the acquisition of Tonipharm S.a.s. (see notes 9 and 34)

The accompanying notes are an integral part of these consolidated financial statements.

RECORDATI S.p.A. AND SUBSIDIARIES
STATEMENT OF COMPREHENSIVE INCOME FOR THE YEAR ENDED 31 DECEMBER 2019

€ (thousands) ⁽¹⁾	2019	2018*
Net income for the year	368,866	312,422
Gains/(losses) on cash flow hedges, net of tax	3,042	(2,532)
Gains/(losses) on translation of foreign financial statements	7,280	(30,142)
Gains/(losses) on equity-accounted investees, net of tax	17,455	(1,659)
Other gains/(losses), net of tax	(459)	944
Income and expense for the year recognized directly in equity	27,318	(33,389)
Comprehensive income for the year	396,184	279,033
Attributable to:		
Equity holders of the parent	396,143	278,987
Non-controlling interests	41	46
Per share data		
Basic	€ 1.933	€ 1.365
Diluted	€ 1.894	€ 1.334

⁽¹⁾Except for share and per-share amounts.

Earnings per share (EPS) are based on average shares outstanding during each year, 204,959,193 in 2019 and 204,379,165 in 2018, net of average treasury stock which amounted to 4,165,963 shares in 2019 and 4,745,991 shares in 2018.

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

*The Group has initially applied IFRS 16 at 1 January 2019, using the modified retrospective approach. Under this approach, comparative information is not restated and the possible cumulative effect of initially applying IFRS 16, not significant for the Group, is recognised in retained earnings at the date of initial application. (See Note 2)

The accompanying notes are an integral part of these consolidated financial statements.

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

€ (thousands)	Equity attributable to the owners										Total
	Share capital	Add. paid-in capital	Treasury stock	Hedging reserve	Translation reserve	Other reserves	Retained earnings	Net income for the year	Interim dividend	Non-controlling interests	
Balance at 31.12.2017	26,141	83,719	(17,029)	(5,867)	(124,004)	40,684	822,154	288,762	(87,470)	147	1,027,237
Change following first time application of IFRS 15							(18,759)				(18,759)
Balance at 1.1.2018	26,141	83,719	(17,029)	(5,867)	(124,004)	40,684	803,395	288,762	(87,470)	147	1,008,478
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
Balance at 31.12.2018*	26,141	83,719	(145,608)	(8,399)	(154,146)	43,081	897,990	312,376	(91,761)	193	963,586
Allocation of 2018 net income:											
- Dividends							29,486	(217,330)	91,761		(96,083)
- Retained earnings							95,046	(95,046)			0
Change in the reserve for share based payments						4,574	2,475				7,049
Sale of own shares			52,128					(25,941)			26,187
Interim dividend									(98,764)		(98,764)
Other changes							652				652
Comprehensive income for the year				3,042	7,280	16,996		368,825		41	396,184
Balance at 31.12.2019	26,141	83,719	(93,480)	(5,357)	(146,866)	64,651	999,708	368,825	(98,764)	234	1,198,811

*The Group has initially applied IFRS 16 at 1 January 2019, using the modified retrospective approach. Under this approach, comparative information is not restated and the possible cumulative effect of initially applying IFRS 16, not significant for the Group, is recognised in retained earnings at the date of initial application. (See Note 2)

The accompanying notes are an integral part of these consolidated financial statements.

RECORDATI S.p.A. AND SUBSIDIARIES

CONSOLIDATED CASH FLOW STATEMENT FOR THE YEAR ENDED 31 DECEMBER 2019

€ (thousands)	2019	2018*
Cash flow from operating activities		
Net Income	368,866	312,422
Depreciation of property, plant and equipment	25,170	13,901
Amortization of intangible assets	53,078	42,959
Write-down of assets	453	0
Equity-settled share-based payment transactions	7,049	5,020
Total	454,616	374,302
(Increase)/decrease in deferred tax assets	10,048	(6,637)
Increase/(decrease) in staff leaving indemnities	1,010	(1,660)
Increase/(decrease) in other non-current liabilities	(1,950)	1,337
	463,724	367,342
Changes in working capital		
Trade receivables	(51,219)	5,502
Inventories	(20,801)	(20,932)
Other receivables and other current assets	(43,977)	1,629
Trade payables	10,461	17,458
Tax liabilities	(21,055)	15,290
Other payables and other current liabilities	407	(1,575)
Provisions	(3,513)	(26,876)
Changes in working capital	(129,697)	(9,504)
Net cash and cash equivalents from/(used in) operating activities	334,027	357,838
Cash flow from investing activities		
Net (investments)/disposals in property, plant and equipment	(31,267)	(19,362)
Net (investments)/disposals in intangible assets	(427,178)	(65,192)
Net (investments)/disposals in subsidiaries	-	(74,626) ⁽¹⁾
Net (investments)/disposals in subsidiaries	-	(72,807) ⁽²⁾
Net (increase)/decrease in other non-current receivables	(10,566)	209
Net cash and cash equivalents from/(used in) investing activities	(469,011)	(231,778)
Cash flow from financing activities		
Loans	429,965	153,876
Re-payment of loans	(130,058)	(50,564)
Payment of leasing liabilities	(10,345)	
Purchase of Treasury stock	0	(169,769)
Sale of Treasury stock	26,187	20,217
Other changes in equity	194	439
Dividends paid	(190,916)	(178,887)
Net cash and cash equivalents from/(used in) financing activities	125,027	(224,688)
Changes in net cash and cash equivalents	(9,957)	(98,628)
Net cash and cash equivalents at beginning of year **	181,131	285,500
Change in translation reserve	3,357	(5,741)
Net cash and cash equivalents at end of period **	174,531	181,131

* The Group has initially applied IFRS 16 at 1 January 2019, using the modified retrospective approach. Under this approach, comparative information is not restated and the possible cumulative effect of initially applying IFRS 16, not significant for the Group, is recognised in retained earnings at the date of initial application. (See Note 2)

⁽¹⁾ Acquisition of **Natural Point S.r.l.**: Working capital (1,628), Net cash and cash equivalents** (8,971), Property, plant and equipment and Intangible Assets (63,764), Goodwill (27,892), Staff leaving indemnity 114, Loans 1,351, Deferred tax liabilities 17,193.

⁽²⁾ Acquisition of **Tonipharm S.a.s.**: Working capital (3,653), Net cash and cash equivalents** 171, Property, plant and equipment and Intangible Assets (50,006)***, Goodwill (28,416)***, Deferred tax assets (760)***, Deferred tax liabilities 10,153***, Non-current receivables (125).

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

*** Amounts restated following the change in the allocation of the price paid for the acquisition of Tonipharm S.a.s. (see Notes 9 and 34)

The accompanying notes are an integral part of these consolidated financial statements.

RECORDATI S.p.A. AND SUBSIDIARIES
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEAR ENDED 31 DECEMBER 2019

1. GENERAL INFORMATION

The consolidated financial statements of the Recordati group for the year ended 31 December 2019 have been prepared by Recordati Industria Chimica e Farmaceutica S.p.A. (“Recordati S.p.A. or the “Parent”), Via Matteo Civitali 1, Milan, Italy.

The consolidated financial statements are presented in accordance with the International Financial Reporting Standards (IFRS) as adopted by the European Union’s guidelines on the preparation of consolidated financial statements and with the Italian regulations implementing article 9 of Legislative decree no. 38/05. 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 distinction between current and non-current was adopted for the presentation of assets and liabilities in the balance sheet. In preparing the cash flow statement, the indirect method was used.

These consolidated financial statements were approved by the Board of Directors on 18 March 2020, that also authorized their publication, and are available at the company’s headquarters.

The consolidated financial statements at 31 December 2019 comprise Recordati S.p.A and its controlled subsidiaries. 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 Note 41.

During the year the consolidation perimeter changed consequent to the establishment of the company Recordati Bulgaria Ltd and the liquidation of Orphan Europe Switzerland GmbH. Furthermore, in order to improve the recognition of the Group’s business in the segment dedicated to rare diseases, its operational dedicated subsidiaries have changed their names from Orphan Europe to Recordati Rare Diseases: in France Recordati Rare Diseases S.à r.l., and in the other countries Recordati Rare Diseases Italy S.r.l., Recordati Rare Diseases Germany GmbH, Recordati Rare Diseases Spain S.L., Recordati Rare Diseases UK Limited, Recordati Rare Diseases Middle East FZ LLC.

The recognition in the accounts of the purchase price allocation following the acquisition in June 2018 of Natural Point S.r.l. and in December 2018 of Tonipharm S.a.s. is now definite. In note n. 9 details about both acquisitions are exposed.

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

2. SUMMARY OF ACCOUNTING POLICIES

The financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union’s guidelines on the preparation of consolidated financial statements. The same accounting policies applied in the preparation of the consolidated financial statements at 31 December 2018, except for what reported in paragraph “Application of new accounting principles” below.

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 Financial Reporting Standards. The criteria applied is consistent with that of the consolidated financial statements at 31 December 2018.

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 2019 the Group applied the new accounting principle IFRS 16 "Leases" which substitutes the accounting principle IAS 17 and its relative interpretations and eliminates the classification of leases as operating or financial in the financial statements of the lessees. Under IFRS 16, a contract is, or contains, a lease if the contract conveys a right to control the use of an identified asset for a period of time in exchange for consideration. At inception, 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.

At inception or on reassessment of a contract that contains a lease component, the consideration in the contract is allocated to each lease and non-lease component on the basis of their relative stand-alone prices. The Group has applied judgement to determine the lease term for some lease contracts that include renewal options. The assessment of reasonable certainty of exercising such options impacts the lease term, which significantly affects the amount of lease liabilities and right-of-use assets recognized. As allowed by the accounting principle, the Group has elected not to recognize right-of-use assets and lease liabilities for some leases of low-value assets, IT equipment included. The Group recognizes the lease payments associated with these leases as an expense on a straight-line basis over the lease term.

The Group presents right-of-use assets in "Property, plant and equipment", the same line item in which it presents underlying assets of the same nature that it owns, and lease liabilities in "Loans" in the consolidated balance sheet. The right-of-use asset is initially measured at cost, and subsequently at cost less any accumulated depreciation and impairment losses.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Group's incremental borrowing rate. Generally, the Group uses its incremental borrowing rate as the discount rate. The lease liability is subsequently increased by the interest cost on the lease liability and decreased by lease payments made.

The Group applied the new principle at the date of first time application using the modified retrospective approach which provides for the possible cumulative effect of the adoption of IFRS 16 to be recognized as an adjustment to retained earnings at 1 January 2019 without restating the comparative information. On transition to IFRS 16, the Group, as allowed by the principle, elected to apply the IFRS 16 only to contracts that were previously identified as leases under IAS 17 and IFRIC 4.

At transition, for leases classified as operating leases under IAS 17, the lease liabilities were measured at the present value of the remaining lease payments, discounted at the Group's incremental borrowing rate as at 1 January 2019. The Group identified specific incremental borrowing rates based on the country, currency

and duration of the related lease contracts. The rates identified were in a range between 0.20% and 22.65%. Right-of-use assets are measured at an amount equal to the lease liability, adjusted by the amount of any prepaid or accrued lease payments.

The Group used the following practical expedients when applying IFRS 16 to leases previously classified as operating leases under IAS 17:

- applied the exemption not to recognize right-of-use assets and liabilities for leases with less than 12 months of lease term.
- excluded initial direct costs from the measurement of the right-of-use asset at the date of initial application.
- used hindsight when determining the lease term if the contract contains options to extend or terminate the lease.

The Group leases a number of items classified as financial leases under IAS 17. For these financial leases, the carrying amount of the right-of-use asset and the lease liability at 1 January 2019 were determined at the carrying amount of the lease asset and lease liability under IAS 17 immediately before that date.

The transition on January 1, 2019 gave rise to non significant changes to assets and liabilities. Right-of-use assets and financial liabilities were recognized by the Group for an amount of € 25.0 million, in addition to € 1.6 million related to leased assets at 31 December 2018, recognized as per IAS 17.

During 2019 further right-of-use assets and the corresponding lease liabilities were recognized for an amount of € 11.2 million, while payments were booked for € 10.3 million. Furthermore, amortization charges were booked for an amount of € 10.9 million as well as interest charges of € 1.2 million in substitution for leasing costs.

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. Non-controlling interests in the equity of consolidated subsidiaries are shown separately under equity, while non-controlling 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 held to be representative of the estimated useful life of the assets:

- Industrial 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 – The Group applied IFRS 16 using the modified retrospective approach.

Accounting model for lessee

At commencement or on modification of a contract that contains a lease component, the Group allocates the consideration in the contract to each lease component on the basis of its related stand-alone price.

The Group recognises a right of use asset and a lease liability at the lease commencement date. The right of use asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred and an estimate of costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located, less any lease incentive received.

The right of use asset is subsequently depreciated using the straight-line method from the commencement date to the end of the lease term, unless the lease transfers ownership of the underlying asset to the Group by the end of the lease term or the cost of the right of use asset reflects that the Group will exercise a purchase option. In that case the right of use asset will be depreciated over the useful life of the underlying

asset, which is determined on the same basis of those of property, plant and equipment. In addition, the right of use asset is periodically reduced by impairment losses, if any, and adjusted for certain remeasurements of the lease liability.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interests rate implicit in the lease or, if that rate cannot be readily determined, the Group's incremental borrowing rate. Generally, the Group uses its incremental borrowing rate as the discount rate.

The Group determines its incremental borrowing rate by obtaining interest rates from various external financing sources and makes certain adjustments to reflect the terms of the lease and type of the assets leased.

Lease payments included in the measurement of the lease liability comprise the following:

- fixed payments (including in-substance fixed payments);
- variable lease payments that depend on an index or a rate, initially measured using the index or rate as at the commencement date;
- amounts expected to be payable under a residual value guarantee; and
- the exercise price under a purchase option that the Group is reasonably certain to exercise, lease payments in an optional renewal period if the Group is reasonably certain to exercise an extension option, and penalties for early termination of a lease unless the Group is reasonably certain not to terminate early.

The lease liability is measured at amortised cost using the effective interest method. It is remeasured when there is a change in future lease payments arising from a change in an index or rate, if there is a change in the Group's estimate of the amount expected to be payable under a residual value guarantee, if the Group changes its assessment of whether it will exercise a purchase, extension or termination option or if there is a revised in-substance fixed lease payment.

When the lease liability is remeasured in this way, a corresponding adjustment is made to the carrying amount of the right of use asset, or is recorded in profit or loss if the carrying amount of the right of use asset has been reduced to zero.

The Group presents right of use assets that do not meet the definition of investments property in "property, plant and equipment" and lease liabilities in "loans" in the balance sheet.

Short-term leases and leases of low value assets

The Group has elected not to recognise right of use assets and lease liabilities for leases of low value assets and short-term leases, including IT equipment. The Group recognises the lease payments associated with these leases as an expense on a straight-line basis over the lease term.

Policy applicable before 1 January 2019

For contracts entered into before 1 January 2019, the Group determined whether the arrangement was or contained a lease based on the assessment of whether:

- fulfilment of the arrangement was dependent on the use of a specific asset or assets; and
- the arrangement had conveyed a right to use asset. An arrangement conveyed the right to use the asset if one of the following was met:
 - the purchaser had the ability or right to operate the asset while obtaining or controlling more than an insignificant amount to the output;
 - the purchaser had the ability or right to control physical access to the asset while obtaining or controlling more than an insignificant amount to the output; or
 - facts and circumstances indicated that it was remote that other parties would take more than an insignificant amount to the output, and the price per unit was neither fixed per unit of output nor equal to the current market price per unit of output.

In the comparative period, as a lessee the Group classified leases that transferred substantially all of the risks and rewards of ownership as finance leases. When this was the case, the leased assets were measured initially at an amount equal to the lower of their fair value and the present value of the minimum lease payments. Minimum lease payments were the payments over the lease term that the lessee was required

to make, excluding any contingent rent. Subsequent to initial recognition, the assets were accounted for in accordance with the accounting policy applicable to the asset.

Assets held under other leases were classified as operating leases and were non recognised in the Group's balance sheet. Payments made under operating leases were recognised in profit or loss on a straight-line basis over the term of the lease. Lease incentives received were recognised as an integral part of the total lease expense, over the term of the 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, using the following rates which are held to be representative of the estimated useful life of the 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, or more frequently if necessary, 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.

Financial instruments

Recognition and measurement

Trade receivables and debt securities issued are initially recognized when they are originated. All other financial assets and financial liabilities are initially recognized when the Group becomes a party to the contractual provisions of the instrument. A financial asset (unless it is a trade receivable without a significant financing component) or financial liability is initially measured at fair value plus, for an item not at FVTPL, transaction costs that are directly attributable to its acquisition or issue. A trade receivable without a significant financing component is initially measured at the transaction price.

Classification and subsequent measurement

Financial assets

On initial recognition, a financial asset is classified as measured at: amortised cost; Fair value through other comprehensive income (“FVOCI”) – debt investment; Fair value through other comprehensive income (“FVOCI”) – equity investment; or Fair value through profit or loss (“FVTPL”).

Financial assets are not reclassified subsequent to their initial recognition unless the Group changes its business model for managing financial assets, in which case all affected financial assets are reclassified on the first day of the first reporting period following the change in the business model.

A financial asset is measured at amortised cost if it meets both of the following conditions and is not designated as at FVTPL:

- it is held within a business model whose objective is to hold assets to collect contractual cash flows; and
- its contractual terms give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

A debt investment is measured at FVOCI if it meets both of the following conditions and is not designated as at FVTPL:

- it is held within a business model whose objective is achieved by both collecting contractual cash flows and selling financial assets; and
- its contractual terms give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

On initial recognition of an equity investment that is not held for trading, the Group may irrevocably elect to present subsequent changes in the investment’s fair value in OCI. This election is made on an investment-by-investment basis.

All financial assets not classified as measured at amortised cost or FVOCI as described above are measured at FVTPL. This includes all derivative financial assets. On initial recognition, the Group may irrevocably designate a financial asset that otherwise meets the requirements to be measured at amortised cost or at FVOCI as at FVTPL if doing so eliminates or significantly reduces an accounting mismatch that would otherwise arise.

Financial assets: Subsequent measurement and gains and losses

- *Financial assets at FVTPL*
These assets are subsequently measured at fair value. Net gains and losses, including any interest or dividend income, are recognised in profit or loss.
- *Financial assets at amortised cost*

These assets are subsequently measured at amortised cost using the effective interest method. The amortised cost is reduced by impairment losses. Interest income, foreign exchange gains and losses and impairment are recognised in profit or loss. Any gain or loss on derecognition is recognised in profit or loss.

- *Debt investments at FVOCI*

These assets are subsequently measured at fair value. Interest income calculated using the effective interest method, foreign exchange gains and losses and impairment are recognised in profit or loss. Other net gains and losses are recognised in OCI. On derecognition, gains and losses accumulated in OCI are reclassified to profit or loss.

- *Equity investments at FVOCI*

These assets are subsequently measured at fair value. Dividends are recognised as income in profit or loss unless the dividend clearly represents a recovery of part of the cost of the investment. Other net gains and losses are recognised in OCI and are never reclassified to profit or loss.

Financial liabilities: classification, subsequent measurement and gains and losses

Financial liabilities are classified as measured at amortised cost or FVTPL. A financial liability is classified as at FVTPL if it is classified as held-for-trading, it is a derivative or it is designated as such on initial recognition. Financial liabilities at FVTPL are measured at fair value and net gains and losses, including any interest expense, are recognised in profit or loss. Other financial liabilities are subsequently measured at amortised cost using the effective interest method. Interest expense and foreign exchange gains and losses are recognised in profit or loss. Any gain or loss on derecognition is also recognised in profit or loss.

Derecognition

Financial assets

The Group derecognises a financial asset when the contractual rights to the cash flows from the financial asset expire, or it transfers the rights to receive the contractual cash flows in a transaction in which substantially all of the risks and rewards of ownership of the financial asset are transferred or in which the Group neither transfers nor retains substantially all of the risks and rewards of ownership and it does not retain control of the financial asset.

The Group enters into transactions whereby it transfers assets recognised in its statement of financial position, but retains either all or substantially all of the risks and rewards of the transferred assets. In these cases, the transferred assets are not derecognised.

Financial liabilities

The Group derecognises a financial liability when its contractual obligations are discharged or cancelled, or expire. The Group also derecognises a financial liability when its terms are modified and the cash flows of the modified liability are substantially different, in which case a new financial liability based on the modified terms is recognised at fair value.

On derecognition of a financial liability, the difference between the carrying amount extinguished and the consideration paid (including any non-cash assets transferred or liabilities assumed) is recognised in profit or loss.

Offsetting

Financial assets and financial liabilities are offset and the net amount presented in the statement of financial position when, and only when, the Group currently has a legally enforceable right to set off the amounts and it intends either to settle them on a net basis or to realise the asset and settle the liability simultaneously.

Derivative financial instruments and hedge accounting

The Group holds derivative financial instruments to hedge its foreign currency and interest rate risk exposures.

Derivatives are initially measured at fair value. Subsequent to initial recognition, derivatives are measured at fair value, and changes therein are generally recognised in profit or loss.

The Group designates certain derivatives as hedging instruments to hedge the variability in cash flows associated with highly probable forecast transactions arising from changes in foreign exchange rates and interest rates and certain derivatives and non-derivative financial liabilities as hedges of foreign exchange risk on a net investment in a foreign operation.

At inception of designated hedging relationships, the Group documents the risk management objective and strategy for undertaking the hedge. The Group also documents the economic relationship between the hedged item and the hedging instrument, including whether the changes in cash flows of the hedged item and hedging instrument are expected to offset each other.

Cash flow hedges

When a derivative is designated as a cash flow hedging instrument, the effective portion of changes in the fair value of the derivative is recognised in OCI and accumulated in the hedging reserve. The effective portion of changes in the fair value of the derivative that is recognised in OCI is limited to the cumulative change in fair value of the hedged item, determined on a present value basis, from inception of the hedge. Any ineffective portion of changes in the fair value of the derivative is recognised immediately in profit or loss.

If the hedge no longer meets the criteria for hedge accounting or the hedging instrument is sold, expires, is terminated or is exercised, then hedge accounting is discontinued prospectively. When hedge accounting for cash flow hedges is discontinued, the amount that has been accumulated in the hedging reserve remains in equity until, for a hedge of a transaction resulting in the recognition of a non-financial item, it is included in the non-financial item's cost on its initial recognition or, for other cash flow hedges, it is reclassified to profit or loss in the same period or periods as the hedged expected future cash flows affect profit or loss.

If the hedged future cash flows are no longer expected to occur, then the amounts that have been accumulated in the hedging reserve and the cost of hedging reserve are immediately reclassified to profit or loss.

Net investment hedges

When a derivative instrument or a non-derivative financial liability is designated as the hedging instrument in a hedge of a net investment in a foreign operation, the effective portion of, for a derivative, changes in the fair value of the hedging instrument or, for a non-derivative, foreign exchange gains and losses is recognised in OCI and presented in the translation reserve within equity. Any ineffective portion of the changes in the fair value of the derivative or foreign exchange gains and losses on the non-derivative is recognised immediately in profit or loss. The amount recognised in OCI is reclassified to profit or loss as a reclassification adjustment on disposal of the foreign operation.

Inventories - Inventories are stated at the lower of cost and net realizable value, 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.

Cash and cash equivalents - Cash in banks on demand and highly liquid investments at fair 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.

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.

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 – Revenue is measured based on the consideration specified in a contract with a customer. The Group recognizes revenue when it transfers control over a good or service to a customer. Revenues are stated net of discounts, rebates and returns. Information about the nature and the timing of the satisfaction of performance obligations in contracts with customers and the related revenue recognition policies are as follows. Revenues mainly comprise product sales and revenue from licensing-out agreements. Product sales

represent net invoice value less estimated rebates, returns and chargebacks and are recognized when the control of the goods has been transferred to a third party. This is usually when title passes to the customer, either on shipment or on receipt of goods by the customer, depending on local trading terms. Revenue from licensing-out agreements includes income from collaborative arrangements on the Group's products where the Group has licensed certain rights associated with those products, but retains a significant ongoing economic interest, through for example the ongoing supply of finished goods. Income may take the form of up-front payments, milestones, profit sharing and royalties. Where control of a right to use intangible asset passes at the outset of an arrangement, revenue is recognized at a point in time. Where the substance of an arrangement is that of a right to access intangible asset, revenue is recognized over time, normally on a straight-line basis over the life of the contract. Where the Group provides ongoing services (i.e. supply), revenue in respect of this element is recognized over the duration of those services. Sales performance milestones are accounted for when the licensee achieves the sales target, so these are recognized at a point in time. Royalties received from the licensee are accounted for when the licensor is entitled to the payment, so these are to be recognized at a point in time.

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 - Research and development costs are expensed in the income statement in the year in which they are incurred in accordance with IAS 38, except the cases for which the same IAS 38 prescribes the capitalization. IAS 38 prescribes that development costs must be capitalized when, in relation to the products of the activity, technical and commercial feasibility is achieved with high probability of success and future economic benefits are probable. 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. Interests are recognized in the profit and loss using the effective interest method.

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 income 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

The Group's revenue is derived from contracts with customers and is not subject to seasonal fluctuations. Revenue for the years 2019 and 2018 is € 1,481.8 million and € 1,352.2 million respectively and can be broken down as follows:

€ (thousands)	2019	2018*	Change 2019/2018
Net sales	1,451,797	1,334,124	117,673
Royalties	7,059	6,248	811
Up-front payments	6,970	6,491	479
Various revenues	16,022	5,372	10,650
Total revenue	1,481,848	1,352,235	129,613

* The Group has initially applied IFRS 16 at 1 January 2019, using the modified retrospective approach. Under this approach, comparative information is not restated and the possible cumulative effect of initially applying IFRS 16, not significant for the Group, is recognised in retained earnings at the date of initial application. (See Note 2)

The revenue from up-front payments is relative to the licensing and distribution of products in the portfolio. In 2019 they refer mainly to marketing agreements involving lercanidipine (€ 1.9 million), the combination of lercanidipine with enalapril (€ 1.6 million), pitavastatin (€ 1.1 million), Cystadrops® (cysteamine hydrochloride) (€ 0.7 million), silodosin (€ 0.7 million) and oxybutynin (€ 0.5 million).

The amount of € 11.9 million (€ 18.6 million at 31 December 2018) classified under other current liabilities (see Note 28), refers to advance payments received from customers, as per the product license and distribution agreements, which will be recognized as revenues when the products are delivered to the customers.

The increase in the amount related to various revenues is mainly due to the € 10.1 million margin on sales of Signifor® and Signifor® LAR transferred from Novartis AG starting 23 October 2019, closing date of the acquisition by Recordati of the rights to these products, as well as to the margin on sales of Juxtapid® (€ 1.3 million) and of Ledaga® (€ 0.8 million) transferred from Aegerion Pharmaceuticals Inc. and Helsinn respectively, over the period prior to the start of direct commercialization to the market by the Group.

In the following tables, revenue is disaggregated by primary geographical market, by product or product class and by geographic area by country. The tables also include a reconciliation of the disaggregated revenue with the Group's reportable segments.

Primary geographical markets

€ (thousands)	Specialty and Primary Care 2019	Specialty and Primary Care 2018	Rare Diseases 2019	Rare Diseases 2018	Total 2019	Total 2018
Europe	1,013,808	908,436	87,504	77,906	1,101,312	986,342
USA	7,755	8,219	109,570	101,003	117,325	109,222
Rest of the world	210,435	220,748	52,776	35,923	263,211	256,671
Total revenue	1,231,998	1,137,403	249,850	214,832	1,481,848	1,352,235

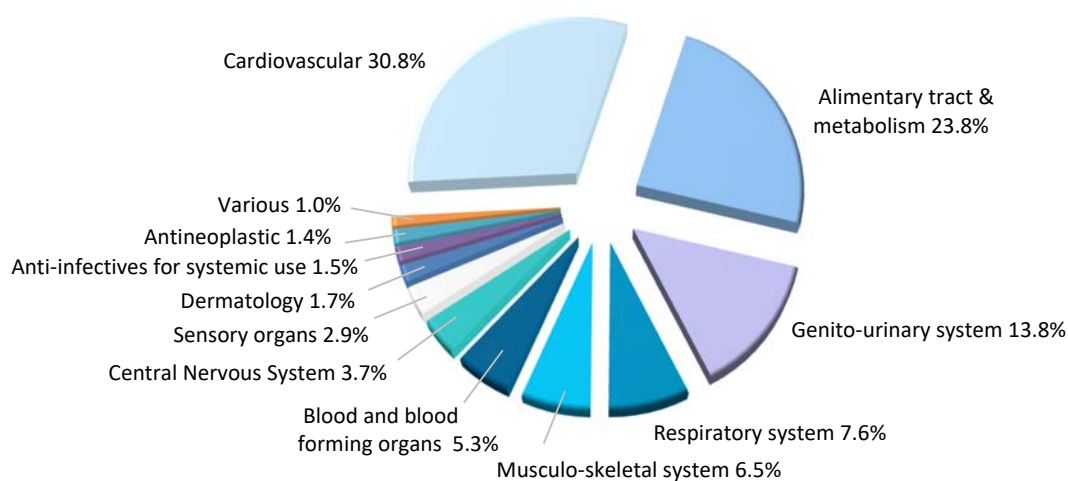
Product or product class

€ (thousands)	Specialty and Primary Care 2019	Specialty and Primary Care 2018	Rare Diseases 2019	Rare Diseases 2018	Total 2019	Total 2018
Zanidip®	134,381	120,762			134,381	120,762
Zanipress®	58,938	59,366			58,938	59,366
Urorec®	107,128	101,090			107,128	101,090
Livazo®	53,807	46,416			53,807	46,416
Seloken®/Logimax®	98,321	98,877			98,321	98,877
Other corporate products	192,455	168,875			192,455	168,875
Drugs for rare diseases			249,850	214,832	249,850	214,832
OTC	275,789	211,785			275,789	211,785
Local product portfolios	251,170	276,310			251,170	276,310
Other revenue	13,907	13,270			13,907	13,270
Pharmaceutical chemicals	46,102	40,652			46,102	40,652
Total revenue	1,231,998	1,137,403	249,850	214,832	1,481,848	1,352,235

Geographic area by country

€ (thousands)	Specialty and Primary Care 2019	Specialty and Primary Care 2018	Rare Diseases 2019	Rare Diseases 2018	Total 2019	Total 2018
Pharmaceuticals						
Italy	268,374	254,597	11,694	11,108	280,068	265,705
France	138,961	114,540	18,309	17,232	157,270	131,772
Russia, Ukraine, other CIS	116,670	102,640	3,490	2,971	120,160	105,611
Germany	124,333	124,342	14,269	12,422	138,602	136,764
Spain	85,563	81,743	9,136	7,137	94,699	88,880
Turkey	84,736	70,513	3,874	4,455	88,610	74,968
Portugal	43,123	40,371	1,331	1,308	44,454	41,679
Other CEE	78,083	62,265	4,025	3,063	82,108	65,328
Other Western Europe	56,201	40,811	21,376	18,210	77,577	59,021
North Africa	39,305	37,076	1,013	3,603	40,318	40,679
Other international sales	150,547	167,853	51,763	32,320	202,310	200,173
U.S.A	-	-	109,570	101,003	109,570	101,003
Total pharmaceutical revenue	1,185,896	1,096,751	249,850	214,832	1,435,746	1,311,583
Pharmaceutical chemicals						
Italy	3,122	2,950	-	-	3,122	2,950
Other European countries	14,642	13,663	-	-	14,642	13,663
U.S.A.	7,755	8,219	-	-	7,755	8,219
America (exc. U.S.A.)	4,376	3,881	-	-	4,376	3,881
Australasia	15,014	11,062	-	-	15,014	11,062
Africa	1,193	877	-	-	1,193	877
Total chemical pharmaceuticals revenue	46,102	40,652	0	0	46,102	40,652
Total revenue	1,231,998	1,137,403	249,850	214,832	1,481,848	1,352,235

Pharmaceutical sales by therapeutic area in 2019 are shown below:



4. OPERATING EXPENSES

Total operating expenses for the years 2019 and 2018 amount to € 1,016.6 million and € 910.0 million respectively and are analyzed by function as follows:

€ (thousands)	2019	2018*	Change 2019/2018
Cost of sales	436,901	395,569	41,332
Selling expenses	372,803	333,497	39,306
Research and development expenses	129,681	109,693	19,988
General and administrative expenses	72,783	67,722	5,061
Other (income) expense, net	4,414	3,535	879
Total operating expenses	1,016,582	910,016	106,566

* The Group has initially applied IFRS 16 at 1 January 2019, using the modified retrospective approach. Under this approach, comparative information is not restated and the possible cumulative effect of initially applying IFRS 16, not significant for the Group, is recognised in retained earnings at the date of initial application. (See Note 2)

Cost of sales is of € 436.9 million and is 29.5%, slightly higher than that of the preceding year mainly due to price and currency effects.

Selling expenses increase by 11.8%, with an increase as a percent of revenue compared to the preceding year due to marketing expenses for the launch of Reagila[®], the new commercial organizations in the Nordic countries, BeNeLux and the Baltics and the initial reinforcement of the organization dedicated to the rare diseases segment following the acquisition of the products for rare endocrinology diseases Signifor[®], Signifor[®] LAR and Isturisa[®] from Novartis.

Research and development expenses are € 129.7 million, up by 18.2% compared to those recorded in 2018 due to the advancement of new development programs and the amortization of the amounts allocated to intangible assets following the acquisition of Natural Point S.r.l. and of Tonipharm S.a.s., of the up-front payments for the recently acquired licenses to the rare disease products Ledaga[®] and Juxtapid[®] and of the rights to the products Signifor[®] and Signifor[®] LAR acquired from Novartis. The amortization of intangible assets related to licenses, brands and patents of acquired products for a total of € 52.6 million are charged

to research and development.

General and administrative expenses are up by 7.5% but are slightly reduced as percent of sales.

The following table summarizes the more significant components of “Other (income) expense, net”.

€ (thousands)	2019	2018	Change 2019/2018
Ancillary costs related to acquisitions	1,423	2,694	(1,271)
Write-downs of intangible assets	453	0	453
Accrual for early termination of a license agreement	4,150	0	4,150
Others	(1,612)	841	(2,453)
Other (income) expense, net	4,414	3,535	879

Ancillary costs related to acquisitions are mainly associated with the transfer from Novartis AG of the rights to Signifor®, Signifor® LAR and Isturisa®. In 2018 they were related to costs incurred by the Group for the acquisition of the companies Natural Point S.r.l. and Tonipharm S.a.s..

In compliance with Consob’s communication dated 28 July 2006 it is hereby stated that during 2019 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)	2019	2018*	Change 2019/2018
Material consumption	341,990	307,778	34,212
Payroll costs	252,632	234,494	18,138
Other employees costs	36,442	39,615	(3,173)
Variable sales expenses	80,686	66,935	13,751
Depreciation and amortization	78,248	56,860	21,388
Utilities and consumables	33,498	29,776	3,722
Other expenses	193,086	174,558	18,528
Total operating expenses	1,016,582	910,016	106,566

* The Group has initially applied IFRS 16 at 1 January 2019, using the modified retrospective approach. Under this approach, comparative information is not restated and the possible cumulative effect of initially applying IFRS 16, not significant for the Group, is recognised in retained earnings at the date of initial application. (See Note 2)

Material consumption as a percentage of sales is 23.1%, up by 0.3% compared to that in 2018.

Payroll costs include charges of € 7.0 million related to stock option plans, up by € 2.0 million over the preceding year. The average number of employees in 2019 is of 4,141, an increase as compared to the 4,089 in 2018.

During the year a number of Group employees were designated as beneficiaries of an incentive plan, with a vesting period of 5 years, under which they acquired shares of Rossini Luxembourg S.à r.l., indirect shareholder of Recordati S.p.A., at nominal value, and they will benefit from a return at termination of the vesting period. As prescribed by IFRS 2 a charge of € 0.9 million was booked to profit and loss.

Depreciation and amortization charges are € 78.2 million. Amortization charges are € 53.1 million, an increase of € 10.1 million over the preceding year due to the amounts allocated to intangible assets following the acquisition of Natural Point S.r.l. and of Tonipharm S.a.s., to the up-front payments for the recently acquired licenses to the rare disease products Ledaga® and Juxtapid® and to the rights to the products Signifor® and Signifor® LAR acquired from Novartis. Depreciation charges are € 25.1 million, up by € 11.2 million mainly due to the application of the new accounting principle IFRS 16 (see Note 2).

5. FINANCIAL INCOME AND EXPENSE

Financial income and expense record a net expense of € 21.1 million in 2019, down by 3.2 million compared to the preceding year due to lower currency exchange losses and interest on tax assessments for a total of € 6.8 million, partially offset by € 3.6 million due to an increase in interest charges on new loans, higher charges on short-term positions and interest expense related to leasing contracts.

The main items are summarized as follows:

€ (thousands)	2019	2018*	Change 2019/2018
Exchange (gains) losses	742	1,731	(989)
Interest expense on loans	13,555	12,628	927
Net interest (income) expense on s/t financial position	5,117	3,571	1,546
Charges related to leasing contracts (see Note 2)	1,202	47	1,155
Interest expense related to tax audits	222	6,034	(5,812)
Interest cost in respect of defined benefit plans	284	273	11
Total financial (income) expense, net	21,122	24,284	(3,162)

* The Group has initially applied IFRS 16 at 1 January 2019, using the modified retrospective approach. Under this approach, comparative information is not restated and the possible cumulative effect of initially applying IFRS 16, not significant for the Group, is recognised in retained earnings at the date of initial application. (See Note 2)

The increase in net interest on the short-term financial position is to be attributed mainly to the valuation of two loans between the Parent company and the US subsidiary Recordati Rare Diseases Inc. (stipulated in November 2016 for an overall amount of \$ 70 million and which correspond to the two tranches of the notes privately placed by the US subsidiary in 2013) and the relative cross-currency swaps. Following the early reimbursement of the notes in the first half of 2019, the derivative financial instruments no longer qualify as hedging instruments and the loss due to their change in fair value is recognized to the profit and loss, net of the effect of the conversion of the loans to the current Euro/Dollar exchange rate, for an amount of € 1.0 million.

The interest expense related to tax audits is attributable to the assessments with acceptance which took place in 2019 related to the years 2016 to 2017 (see Note 38). In 2018 they were related to the settlement for the years 2009 to 2015.

6. PROVISION FOR INCOME TAXES

The provision for income taxes amounts to € 75.3 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 effective tax rate during the year is 17.0%, significantly lower than that of the preceding year due to the

tax benefit provided by the so-called “patent box”. In December an agreement was reached with the Italian tax authorities which allows the Parent Company to benefit from a discount on taxable income of 30% for the year 2015, 40% for 2016 and 50% for the 2017-2019 three year period with reference to patents, know-how and brands related to selected products provided for in the agreement. The “patent box” optional regime covers the period 2015-2019. The tax benefit for the period 2015-2018 is of € 27.0 million while that relative to 2019 is of € 8.3 million. The Company will renew the option for the next five year period but the tax benefit will be lower due to the exclusion of brands from the “patent box” regime.

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:

	2019	2018
	%	%
Standard income tax rate on pre-tax income of the parent company	24.0	24.0
Dividends from foreign subsidiaries	0.4	0.4
Foreign tax rate differential	(1.1)	(2.3)
Provisions for risks deriving from ongoing tax audits	(0.2)	2.2
Other differences, net	0.1	(1.0)
Tax benefit provided by the so-called “patent box” in Italy	(8.0)	0
Effective tax rate on income	15.2	23.3
IRAP	1.8	2.0
Effective tax rate, including IRAP	17.0	25.3

During the period an agreement was signed with the Italian Revenue Agency covering the complete definition of all the disputes connected with the tax periods 2016 and 2017 (see Note 38). The overall cost, which was already accrued in the previous year, is of € 4.8 million, in addition to € 0.2 million of interest cost, with all penalties waived. The agreed amount was paid in June. The € 0.5 million accrued in excess over the amount paid was reversed and booked to provision for taxes.

IRAP is levied only on the Italian companies and is computed applying a 5.26% rate to a broader taxable base calculated before the deduction of interest.

In compliance with the Consob communication dated 28 July 2006, relative to events, operations and matters which are not recurrent and do not occur frequently in the normal course of business, we point out the abovementioned tax benefit provided by the so-called “patent box” in 2019.

7. PROPERTY, PLANT AND EQUIPMENT

In the following table the composition of property, plant and equipment, their variation in detail, including the valuation of right-of-use assets (see Note 2), is shown.

€ (thousands)	Land & buildings	Plant & machinery	Other equipment	Advances/ construction in progress	Total
Cost					
Balance at 1 January 2018	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)
Balance at 31 December 2018	77,204	227,870	68,033	14,751	387,858
IFRS 16 first time application	14,214	420	10,383	0	25,017
Balance at 1 January 2019	91,418	228,290	78,416	14,751	412,875
Additions	3,788	2,250	14,340	12,935	33,313
Disposals	(2,193)	(634)	(2,849)	(1,835)	(7,511)
Other changes	(251)	3,270	2,275	(6,255)	(961)
Balance at 31 December 2019	92,762	233,176	92,182	19,596	437,716
Accumulated depreciation					
Balance at 1 January 2018	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)
Balance at 31 December 2018	43,767	186,365	54,144	0	284,276
Depreciation for the year	6,237	8,113	10,820	0	25,170
Disposals	(2,236)	(625)	(2,604)	0	(5,465)
Other changes	248	53	92	0	393
Balance at 31 December 2019	48,016	193,906	62,452	0	304,374
Carrying amount at					
1 January 2018	35,513	45,055	14,132	8,309	103,009
31 December 2018	33,437	41,505	13,889	14,751	103,582
31 December 2019	44,746	39,270	29,730	19,596	133,342

Additions during the year of € 33.3 million, of which € 11.2 million related to right-of-use assets, refer mainly to investments made by the Parent Company (€ 15.0 million), to the Spanish subsidiary Casen Recordati S.L. (€ 5.3 million) and to the Turkish subsidiary Recordati İlaç (€ 2.1 million).

Other changes include the conversion into Euros of property, plant and equipment booked in different currencies resulted in a net decrease of € 1.4 million compared to their value at 31 December 2018, of which € 1.8 million is due to the devaluation of the Turkish Lira and € 0.4 million is due to the revaluation of the Tunisian Dinar.

The following table shows the valuation of the right to use the assets conveyed under leases, already included in the table above, determined as prescribed by IFRS 16 (see Note 2).

€ (thousands)	Land & buildings	Plant & machinery	Other equipment	Total
Cost				
Balance at 31 December 2018*	3,132	0	543	3,675
First time application IFRS 16	14,214	420	10,383	25,017
Balance at 1 January 2019	17,346	420	10,926	28,692
Additions	3,602	93	7,505	11,200
Disposals	(752)	(15)	(1,197)	(1,964)
Other changes	43	(2)	29	70
Balance at 31 December 2019	20,239	496	17,263	37,998
Accumulated depreciation				
Balance at 31 December 2018*	911	0	224	1,135
Depreciation for the period	3,896	255	6,702	10,853
Disposals	(631)	(7)	(1,141)	(1,779)
Other changes	20	(1)	19	38
Balance at 30 December 2019	4,196	247	5,804	10,247
Carrying amount at				
31 December 2018 ^(*)	2,221	0	319	2,540
31 December 2019	16,043	249	11,459	27,751

* Amounts at 31 December 2018 refer to property financial leases in accordance with IAS 17 requirements.

Right-of-use assets refer mainly to the office premises of a number of Group subsidiaries and of the cars used by medical representatives operating in their territories.

8. INTANGIBLE ASSETS

Intangible assets, net of accumulated amortization, at 31 December 2019 and 2018 amount to € 1,161.8 million and € 672.1 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
Cost					
Balance at 1 January 2018	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	1	137,120
Other changes	(1,624)	45,311	(921)	(45,483)	(2,717)
Balance at 31 December 2018*	582,461	413,510	18,948	30,211	1,045,130
Balance at 1 January 2019	213,066	64,218	347	257,633	535,264
Additions	0	(300)	(377)	(1)	(678)
Disposals	(453)	0	0	0	(453)
Other changes	6,328	25,102	2,846	(24,284)	9,992
Balance at 31 December 2019	801,402	502,530	21,764	263,559	1,589,255
Accumulated depreciation					
Balance at 1 January 2018	160,169	129,269	16,557	0	305,995
Depreciation 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)
Balance at 31 December 2018	187,418	168,918	16,688	0	373,024
Depreciation for the year	28,500	24,083	495	0	53,078
Disposals	0	(268)	(377)	0	(645)
Other changes	1,805	(2,365)	2,598	0	2,038
Balance at 31 December 2019	217,723	190,368	19,404	0	427,495
Carrying amount at					
1 January 2018	423,936	68,152	1,797	46,680	540,565
31 December 2018	395,043	244,592	2,260	30,211	672,106
31 December 2019	583,679	312,162	2,360	263,559	1,161,760

* Restated following the change in the allocation of the price of acquisition of Tonipharm S.a.s. (see Note 34)

Increases during the period refer to:

- 390.0 million U.S. dollars paid to Novartis AG for the acquisition of the worldwide rights to Signifor® and Signifor® LAR for the treatment of Cushing's disease and acromegaly in adult patients for whom surgery is not an option or for whom surgery has failed, and to Isturisa® (osilodrostat), an investigational innovative drug for the treatment of endogenous Cushing's syndrome.
- 120.0 million U.S. dollars for future payments due to Novartis AG as per the agreement for the acquisition of the worldwide rights to Isturisa® (osilodrostat). In particular, 20.0 million U.S. dollars at the approval, obtained in January 2020, of the product in Europe, 40.0 million U.S. dollars at the launch in the four main European countries and 60.0 million U.S. dollars at the approval, obtained in March 2020, of the product in the U.S.A..
- 30 million U.S. dollars paid to Aegerion Pharmaceuticals Inc. as per the license agreement for the exclusive commercialization rights in Japan for Juxtapid®, a product indicated for patients with

homozygous familial hypercholesterolemia;

- a further € 30.0 million as per the agreement, signed in 2018 with Helsinn, for the acquisition 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;
- € 6.7 million for the renewal of the agreement with Amdipharm covering the distribution rights to TransAct® LAT;
- € 4.8 million milestone to Gedeon Richter as per the license agreement for Reagila® (cariprazine).

“Other changes” includes the effect of the conversion into euros of the intangible assets booked in different currencies gives rise to a net increase of € 8.0 million as compared to 31 December 2018, mainly attributable to the revaluation of the Swiss franc (increase of € 4.9 million), the Russian ruble (increase of € 2.4 million) and of the U.S. dollar (increase of € 0.9 million).

9. GOODWILL

Goodwill at 31 December 2019 and 2018 amounted to € 578.0 million and € 577.8 million respectively and changed as follows:

€ (thousands)	Goodwill
Cost	
Balance at 31 December 2018*	615,450
Exchange rate adjustments	187
Balance at 31 December 2019	615,637
Accumulated amortization	
Balance at 31 December 2018	37,664
Changes during the year	0
Balance at 31 December 2019	37,664
Carrying amount at	
31 December 2018*	577,786
31 December 2019	577,973

* Restated following the change in the allocation of the price of acquisition of Tonipharm S.a.s.

As prescribed by IFRS 3, the recognition of the purchase price allocation associated with the acquisitions completed in 2018, of the Italian company Natural Point S.r.l. and of the French company Tonipharm S.a.s., are to be considered definite.

Regarding the Italian company, the process for the measurement of the fair value of the assets and liabilities at the date of acquisition confirmed the preliminary treatment in the financial statements for the year 2018: the fair value of the brand Magnesio Supremo® at the date of acquisition was higher than its book value and 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. Such goodwill was allocated to the specialty and primary care segment and is not tax deductible.

Regarding the acquisition of the French company Tonipharm S.a.s., acquired on 31 December 2018, the finalization of the process for the measurement of the fair value of the assets and liabilities at the date of acquisition resulted in some changes to the preliminary recognition in the financial statements for the year 2018. In addition to the identification of added value for the intangible assets Ginkor® and Alodont®, the € 0.4 million book value of an intangible asset was considered non recoverable and the deferred tax effect was recalculated in line with the tax reforms approved in France at the end of 2018 which include a gradual reduction in tax rates starting 2019 through 2022. Consequently, 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 the intangible assets Ginkor® and Alodont®, € 10.2 million to the relative deferred tax liabilities, while € 28.4 million were allocated to goodwill. Such goodwill has been allocated to the specialty and primary care segment and it is not tax deductible.

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 increase of € 0.2 million as compared to 31 December 2018 resulted. In particular, the goodwill associated with the acquisitions in Russia, Tunisia, Switzerland, the Czech Republic and Poland increased respectively by € 1.9 million, € 1.5 million, € 0.3 million, € 0.2 million and € 0.1 million, while the goodwill associated with the acquisition in Turkey decreased by € 3.8 million.

Net goodwill at 31 December 2019, amounting to € 578.0 million, relates to the following operational areas, which represent the same number of cash generating units:

- France: € 74.2 million;
- Russia: € 27.7 million;
- Germany: € 48.8 million;
- Portugal: € 32.8 million;
- Treatments for rare diseases business: € 110.6 million;
- Turkey: € 37.2 million;
- Czech Republic: € 14.0 million;
- Romania: € 0.2 million;
- Poland: € 15.4 million;
- Spain: € 58.1 million;
- Tunisia: € 17.3 million;
- Italy: € 133.2 million;
- Switzerland: € 8.5 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 assumptions 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 (2020-2022) are derived from the 2020 budget approved by the Board of Directors of the Parent on 19 December 2019 and, for the years 2021 and 2022, from specific forecasts prepared for the cash generating units subject to impairment testing approved by the Board of Directors of the Parent on 18 March 2020.

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	3.36%
Russia	10.80%
Germany	3.03%
Portugal	3.94%
Business dedicated to treatments for rare diseases	4.81%
Turkey	18.20%
Czech Republic	5.61%
Poland	5.69%
Spain	3.82%
Tunisia	12.13%
Italy	5.38%
Switzerland	3.81%

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 2019 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	
	31.12.19	31.12.18	31.12.19	31.12.18
PureTech Health p.l.c., United Kingdom	35,597	17,997	3.3%	3.4%
Erytech Pharma S.A., France	2,888	2,694	2.4%	2.4%
Codexis Inc., U.S.A.	73	72	n.s.	n.s.
Fluidigm Corp., U.S.A.	5	7	n.s.	n.s.
Others	3	3	n.s.	n.s.
Total equity investments	38,566	20,773		

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 2019 the overall fair value of the 9,554,140 shares held is of € 35.6 million. The € 17.6 million increase in value compared to that at 31 December 2018 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 listed 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 increased by € 0.2 million as compared to that at 31 December 2018 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 2019 are € 16.4 million, an increase of € 10.6 million compared to those at 31 December 2018. The increase is mainly attributable to the tax benefit provided by the so-called “patent box” agreed with the Italian tax authorities in December 2019 which can be used beyond 2020 (see Note 6).

12. DEFERRED TAX ASSETS

Deferred tax assets at 31 December 2019 and 2018 amount to € 71.5 million and € 81.2 million respectively. The main deferred tax assets and their change are analyzed below.

€ (thousands)	2019	2018
Balance at 1 January	81,227	73,297
Additions	6,763	16,968
Utilizations	(16,477)	(9,798)
Changes in reporting entities*	0	760
Balance at 31 December	71,513	81,227

* Restated following the change in the allocation of the price of acquisition of Tonipharm S.a.s (see Note 34)

€ (thousands)	Previous years' losses	Profit and loss temporary differences	Franking	Tax credits	Other	Total
Balance at 1 January	2,776	8,805	29,092	5,849	34,705	81,227
Additions	0	3,544	0	0	3,219	6,763
Utilization	(1,618)	(5,451)	(6,164)	(823)	(2,421)	(16,477)
Balance at 31 December	1,158	6,898	22,928	5,026	35,503	71,513

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 2019 the deferred tax assets corresponding to Italcimici's and the Parent Company's recognized tax benefits were utilized for an amount of € 6.2 million.

The tax credits relate to the tax incentives associated with the construction of the production plant in Turkey.

"Other" deferred tax assets refers mainly to temporary differences arising from the elimination of unrealized gains on intercompany transactions and includes also the effect of the application of IFRS 15 for an amount of € 2.5 million. Such caption also includes deferred tax assets related to components of the other comprehensive income amounting to € 2.0 million (€ 3.3 million at 31 December 2018).

13. INVENTORIES

Inventories at 31 December 2019 and 2018 amount to € 226.9 million and € 206.1 million respectively, net of their respective obsolescence provisions for slow moving or expiring pharmaceutical products of € 4.7 million and € 3.8 million. Composition of inventories is as follows:

€ (thousands)	31.12.2019	31.12.2018	Change 2019/2018
Raw materials and supplies	66,286	54,403	11,883
Intermediates and work-in-process	35,067	27,546	7,521
Finished goods	125,532	124,135	1,397
Total inventories	226,885	206,084	20,801

The increase of € 20.8 million is due to the growth of the Group's business and to higher stocks in Russia in

order to properly handle the transition to serialized products in line with the deadlines established by local authorities.

14. TRADE RECEIVABLES

Trade accounts receivable at 31 December 2019 and 2018 amount to € 297.0 million and € 245.7 million respectively. These are shown net of the allowance for doubtful accounts which at 31 December 2019 is € 14.9million (€ 14.6 million at 31 December 2018) 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 63, a slight increase compared to 61 at 31 December 2018. The allowance for doubtful accounts increased by € 0.3 million (reduction of € 0.8 million in 2018). Such difference is classified in selling expenses.

The Group uses a matrix to measure the expected credit losses of trade receivable from individual customers, which comprise a very large number of small balances. Losses are estimated using a method based on the probability of a receivable progressing through successive stages of delinquencies calculated separately for exposures in different segments based on common credit risk characteristics, such as geographic region and age of customer relationship. The following table provides information about the exposure to credit risk for trade receivables as at 31 December 2019.

€ (thousands)	Gross carrying amount
Current (not past due)	265,677
1-30 days past due	15,379
31-60 days past due	5,289
61-90 days past due	5,208
More than 90 days past due	20,313
Total trade receivables	311,866

Additional information about how the Group assess the exposure to credit risk and the allowance for doubtful accounts is described in Note 33.

15. OTHER RECEIVABLES

Other receivables amount to € 79.9 million, an increase of € 41.5 million compared to those at 31 December 2018, and their breakdown is as follows:

€ (thousands)	31.12.2019	31.12.2018	Change 2019/2018
Tax receivable	71,302	30,375	40,927
Balances due from employees and agents	2,582	2,928	(346)
Other	6,065	5,159	906
Total other receivables	79,949	38,462	41,487

The increase in tax receivable is mainly attributable to the tax benefit provided by the so-called “patent box” agreed with the Italian tax authorities in December 2019 and which can be used in 2020, for an amount of € 25.6 million (see Note 6). Tax receivable also included value added tax (VAT) receivable (€ 13.9 million) and advance payments of income tax paid in excess. 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 2019 other current assets amount to € 7.7 million (€ 5.2 million at 31 December 2018) and relate mainly to prepaid expenses.

17. FAIR VALUE OF HEDGING DERIVATIVES

At 31 December 2019 the value of hedging derivatives included under this account is of € 9.9 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, gave rise to a € 9.9 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 € 6.7 million, and that covering the \$ 25 million tranche of the loan, provided by UniCredit, yielded a € 3.2 million positive value change.

The fair value of such hedging derivatives is measured at level 2. The fair value is calculated as the present value of the estimated future cash flows. Estimates of future floating-rate cash flows are based on quoted swap rates futures prices and interbank borrowing rates. Estimated cash flows are discounted using a yield curve which reflects the relevant benchmark interbank rate used by market participants for these purposes when pricing interest rate swaps.

18. SHORT TERM FINANCIAL INVESTMENTS, CASH AND CASH EQUIVALENTS

A break down is shown in the following table.

€ (thousands)	31.12.2019	31.12.2018	Change 2019/2018
Short term time deposits	46,539	25,615	20,924
Deposits in bank current accounts	141,346	172,350	(31,004)
Cash on hand	38	71	(33)
Total short term financial investments, cash and cash equivalents	187,923	198,036	(10,113)

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

At 31 December 2019 cash and cash equivalents are mainly denominated in Euros (99.5 million), in Pounds Sterling (13.3 million, mainly in the U.K. subsidiaries) and in U.S. dollars (63.9 million, mainly in the U.S. subsidiary Recordati Rare Diseases Inc.).

19. EQUITY ATTRIBUTABLE TO THE HOLDERS OF THE PARENT

Share capital – At 31 December 2019 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.

Additional paid-in capital – At 31 December 2019 additional paid-in capital is € 83.7 million, unchanged compared to the preceding year.

Treasury stock – At 31 December 2019, 3,308,571 shares are held as treasury stock, an reduction of 1,845,000 shares compared to those held at 31 December 2018. The change is due to the sale of 1,845,000 shares, for an amount of € 26.2 million, to service the exercise of options granted to company employees under the stock option plans. The total cost incurred for the purchase of current treasury stock is € 93.5 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 2019 this fair value measurement gives rise to a net liability, after-tax, of € 5.4 million.

Other reserves – These amount to € 64.7 million at 31 December 2019, an increase of € 21.6 million compared to those at 31 December 2018. 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 € 16.8 million and € 0.8 million respectively. The recognition of the gains associated with the investment in Puretech Health determined a positive after-tax effect of € 27.8 million while the recognition of the reduced value of the investment in Erytech Pharma determined an after-tax negative effect of € 1.4 million.

Retained earnings and net income for the year – These amount to € 999.7 million at 31 December 2019 and increase by € 101.7 million as compared to 31 December 2018. Net income for the year is € 368.8 million, an increase of 18.1% compared to the € 312.4 million 2018 net income. 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 2019 of € 0.48 per share, for a total amount of € 98.8 million.

Incentive plans – At 31 December 2019 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 2019 are analyzed in the following table.

	Strike price (€)	Options outstanding at 1.1.2019	Options granted during 2019	Options exercised during 2019	Options cancelled or expired	Options outstanding at 30.9.2019
Date of grant						
9 February 2011	6.7505	73,500	-	(73,500)	-	-
8 May 2012	5.3070	427,500	-	(185,000)	-	242,500
17 April 2013	7.1600	25,000	-	-	-	25,000
30 October 2013	8.9300	15,000	-	(10,000)	-	5,000
29 July 2014	12.2900	2,171,000	-	(1,032,500)	-	1,138,500
13 April 2016	21.9300	2,961,500	-	(544,000)	(199,500)	2,218,000
3 August 2018	30.7300	4,818,000	-	-	(239,500)	4,578,500
Total		10,491,500	-	(1,845,000)	(439,000)	8,207,500

During the year a number of Group employees were designated as beneficiaries of an incentive plan, with a vesting period of 5 years, under which they acquired shares of Rossini Luxembourg S.à r.l., indirect shareholder of Recordati S.p.A., at nominal value, and they will benefit from a return at termination of the vesting period.

20. NON-CONTROLLING INTERESTS

All consolidated companies are 100% owned except for Recordati Rare Diseases Italy 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%, in the amount of € 3.3 million, 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 non-controlling shareholders during the period until all capital shares are transferred.

21. LOANS

At 31 December 2019 loans total € 1,087.2 million. Loans include the liability, determined by the application of the new accounting principle IFRS 16, that represents the obligation of making the payments provided for in the existing lease contracts (see Note 2). The net increase of € 315.9 million compared to 31 December 2018 was determined by the granting of new loans for an amount of € 418.8 million, the effect of the first time application of IFRS 16 in the amount of € 25.0 million, new leasing liabilities for an amount of € 11.2 million and reimbursements of € 140.4 million. Reimbursements include € 61.3 million due to the early repayment of the privately placed notes issued by Recordati Rare Diseases on 13 June 2013 for a total of \$ 70 million, following the acquisition of FIMEI S.p.A. (shareholder of the Parent) by a Consortium of investment funds controlled by CVC Capital Partners, and € 10.3 million due to payments of lease liabilities. The conversion of loans in foreign currency gave rise to an increase of € 1.3 million.

The composition of medium and long-term loans at 31 December 2019 and 2018 is shown in the following table:

€ (thousands)	31.12.2019	31.12.2018
Loans granted to Recordati S.p.A.:		
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%.	*66,553	*65,266
Loan granted by Centrobanca, at variable interest rate covered by an interest rate swap, repayable in semi-annual installments starting 2012 through 2022	*20,389	*27,186
Loan granted by UniCredit, at variable interest rate partly covered by an interest rate swap, repayable in semi-annual installments starting 2015 through 2020	*4,997	*14,893
Loan granted by ING Bank, at variable interest rate covered by an interest rate swap, repayable in semi-annual installments starting 2016 through 2020	3,750	*11,220
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	*12,490	*24,977
Loan granted by Intesa Sanpaolo, at variable interest rate covered by an interest rate swap, repayable in semi-annual installments starting 2019 through 2021	*16,637	*24,955
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	*124,896	*124,888
Loan granted by Mediobanca, at variable interest rate covered by an interest rate swap, repayable in annual installments starting 2018 through 2024	54,000	64,500
Loan granted by UbiBanca, at variable interest rate covered by an interest rate swap, repayable in 2022	*49,972	*49,962
Loan granted by Unicredit, at variable interest rate covered by an interest rate swap, repayable in 2021	*49,967	*49,948
Loan granted by Intesa Sanpaolo, at variable interest rate covered by an interest rate swap, repayable in semi-annual installments starting 2019 through 2025	*64,122	*74,808
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	*14,996	*14,994
Loan granted by Medio Credito Centrale, at a reduced interest rate of 0.5%, repayable in semi-annual installments starting 2019 through 2021	*2,995	*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	*149,471	*149,337
Loan granted by Mediobanca, Natixis and Unicredit, syndicated involving a pool of Italian and international banks, at variable interest rate, repayable in semi-annual installments starting 2020 through 2024	*396,722	-
Loan granted by ING Bank, at variable interest rate, repayable in semi-annual installments starting 2021 through 2024	*22,395	-
Leasing liabilities associated with Recordati S.p.A.'s lease agreements	3,511	-
Loans granted to other Group companies:		
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
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	*4,763	*7,190
Various interest-free loans granted to Casen Recordati S.L. due within 2029	339	395
Loans granted to Opalia Pharma	-	41
Leasing liabilities associated with other Group companies lease agreements	24,196	1,626
Total amortized cost of loans	1,087,161	771,230

€ (thousands)	31.12.2019	31.12.2018
Portion due within one year	149,817	130,583
Portion due after one year	937,344	640,647

* Net of direct issue costs, amortized using the effective interest method. At 31 December 2019 overall residual costs are € 4.7 million mainly relative to the syndicated loan granted to Recordati S.p.A. by a pool of banks (€ 3.3 million), to the private placements by Recordati S.p.A. in 2014 and 2017 (€ 0.3 million) and to the loans granted by Mediobanca (€ 0.5 million), Intesa Sanpaolo (€ 0.2 million), IFC-World Bank (€ 0.2 million), ING Bank (€ 0.1 million) and Centrobanca (€ 0.1 million).

The repayment schedule of loans due after 31 December 2020, based on their amortization plans, is as follows:

€ (thousands)	
2021	160,097
2022	259,211
2023	162,082
2024	170,112
2025 and subsequent years	185,842
Total	937,344

The average effective interest rate at 31 December 2018, applying the rates resulting from the hedging instruments, is 1.52%.

In August the Parent undersigned a loan agreement with ING Bank for an amount of € 22.5 million. The main terms and conditions provide for variable interest rate fixed at the 6 months' Euribor plus a spread of 135 basis points with semi-annual interest payments and semi-annual repayment of principal starting December 2021 through December 2024. 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 fulfilled.

In June Recordati S.p.A. negotiated a loan for an amount of € 400.0 million aimed at supporting the Group's growth strategy. The loan, initially undersigned by Mediobanca, Natixis and Unicredit was subsequently syndicated involving a pool of Italian and international banks. The terms of the loan provide for a variable interest rate at the 6 months' Euribor (with a zero floor) plus a 135 basis points spread and a duration of 5 years with principal semi-annual repayment starting 30 June 2020 through June 2024. Funding, net of up-front commissions, took place on 30 July 2019. 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 fulfilled during the period.

The main other long-term loans outstanding are:

- a) A loan agreement undersigned with Mediobanca by the Parent in November 2018 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 principal 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 2019 of the swap generated a liability of € 2.2 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 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 fulfilled during the period.

- b) A loan of € 4.3 million granted to the Parent in July 2018 by the Banca del Mezzogiorno-Mediocredito Centrale to fund investments in research and development, 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. The debt outstanding at 31 December 2019 is of € 3.0 million.
- c) 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 principal 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 fulfilled during the period.

- d) 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 principal from June 2019 through October 2025. The debt outstanding at 31 December 2019 is of € 64.1 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 1.305%. The measurement at fair value at 31 December 2019 of the swap generated a liability of € 1.1 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 were fulfilled during the period.

e) A loan agreement with UniCredit undersigned by the Parent in September 2017 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 55 basis points with semi-annual payments of interest and the repayment of principal 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 2019 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 fulfilled during the period.

f) A loan agreement with UBI Banca undersigned by the Parent in September 2017 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 50 basis points with semi-annual payments of interest and the repayment of principal 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 2019 of the swap generated a liability of € 0.7 million. 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 fulfilled during the period.

g) 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 principal from July 2018 through July 2024. The debt outstanding at 31 December 2019 is of € 54.0 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 2019 of the swap 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 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 fulfilled during the period.

h) 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 fulfilled during the period.

i) A loan agreement with Banca Nazionale del Lavoro undersigned by the Parent company in December 2016 for an amount of € 25.0 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 principal from March 2019 through September 2020. The debt outstanding at 31 December 2019 is of € 12.5 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 0.41%. The measurement at fair value at 31 December 2019 of the swap generated a slight liability 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 fulfilled.

j) A loan agreement with Intesa Sanpaolo undersigned by the Parent company in December 2016 for an amount of € 25.0 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 principal from June 2019 through December 2021. The debt outstanding at 31 December 2019 is of € 16.6 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 0.68%. The measurement at fair value at 31 December 2019 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 fulfilled.

k) 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 6 months Euribor plus a spread of 80 basis points and a duration of 5 years with semi-annual repayments of principal from November 2015 through May 2020. The debt outstanding at 31 December 2019 is of € 5.0

million. 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 fulfilled.

- l) 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 6 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 2019 is of € 3.8 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 2019 generated a slight liability 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 fulfilled.

- m) 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 3 months' Trlibor plus a spread of 162 basis points, 8-year duration and reimbursement of principal at the end of every three months starting November 2016 through August 2022. The value in euros of the outstanding loan at 31 December 2019 is of € 4.8 million, resulting in a reduction of the liability by € 2.4 million as compared to that at 31 December 2018, of which € 0.6 million was due to the devaluation of the Turkish lira at the date of consolidation. 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 fulfilled.

- n) 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 2019 resulted in an increase of the liability by € 1.3 million as compared to that at 31 December 2018 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 2019 the measurement at fair value of the hedging instruments generated an overall positive amount of € 9.9 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 fulfilled during the period.

o) 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. The main terms and conditions provide for a variable interest rate and a duration of 12 years with semi-annual repayments of principal from June 2012 through December 2022. At 31 December 2019 the outstanding amount of the loan is € 20.4 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 2019 generated a liability of € 0.6 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 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 fulfilled during the period.

22. STAFF LEAVING INDEMNITIES AND OTHER BENEFITS

This provision at 31 December 2019 and 2018 is € 20.6 million and € 19.5 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)	2019	2018
Balance at 1 January	19,547	21,093
Additions	1,892	1,899
Utilization	(1,674)	(2,106)
Change in reporting entities	0	114
Change in fair value	792	(1,453)
Balance at 31 December	20,557	19,547

This liability is to be mainly 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 € 10.5 million. The remaining part of this provision comprises employee benefit plans in the French subsidiary Laboratoires Bouchara Recordati (€ 4.7 million), in the U.S. subsidiary Recordati Rare Diseases (€ 2.0 million), in the German subsidiary Recordati Pharma (€ 1.2 million) and in the other Recordati Rare Diseases companies (€ 1.0 million). The fair value calculation made using actuarial parameters updated at 31 December 2019 determined an increase of € 0.8 million compared to the value of the funds at 31 December 2018 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 2019 are € 43.2 million, a net decrease of € 0.3 million over the balance at 31 December 2018. The roll forward of this account is as follows:

€ (thousands)	2019	2018
Balance at 1 January	43,486	17,554
Additions	1,457	1,417
Utilization	(1,771)	(2,831)
Changes in reporting entities*	-	27,346
Balance at 31 December	43,172	43,486

* Restated following the change in the allocation of the price of acquisition of Tonipharm S.a.s (see Note 34)

At 31 December 2019 no deferred tax liabilities were calculated on subsidiaries' undistributed earnings as, considering the current dividend policy applied by the Group and thanks to the substantial exemption from dual income taxation, no significant additional tax would have to be paid by the Group in the event of these dividend distributions.

Deferred tax liabilities related to components of the other comprehensive income amount to € 0.6 million (€ 0.9 million at 31 December 2018).

24. OTHER NON-CURRENT LIABILITIES

Other non-current liabilities as at 31 December 2019 are € 22.3 million. They include mainly € 17.8 million of future payments due to Novartis AG upon commercialization of Isturisa® in some European countries and € 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 2022. The fair value of such purchase option is measured at level 2 as the valuation model considers the present value of expected payments.

25. TRADE PAYABLES

Trade accounts payable, which are entirely of a commercial nature and include allocations for invoices to be received, at 31 December 2019 and 2018 amount to € 175.5 million and € 165.0 million respectively.

26. OTHER PAYABLES

Other accounts payable at 31 December 2019 and 2018 amount to € 185.7 million and € 85.5 million respectively. Their composition is as follows:

€ (thousands)	31.12.2019	31.12.2018	Change 2019/2018
Personnel	30,048	27,336	2,712
Social security	15,219	14,953	266
Agents	649	716	(67)
Other	139,790	42,529	97,261
Total other payables	185,706	85,534	100,172

The line "Other" includes:

- € 89.0 million for future payments due to Novartis AG following the approval of Isturisa® (osilodrostat) and its progressive launch. In particular, 20.0 million U.S. dollars at the approval, obtained in January 2020, of the product in Europe, 20.0 million U.S. dollars at the launch in some European countries and 60.0 million U.S. dollars at the approval, obtained in March 2020, of the product in the U.S.A.;
- € 6.1 million due by Recordati Rare Diseases Inc. to the U.S. healthcare insurance schemes;
- € 4.4 million to be paid to the "Krankenkassen" (German healthcare schemes) by Recordati Pharma GmbH;
- € 1.8 million which results from a mandatory discount of 1.83% on the retail selling price of reimbursed medicines.

27. TAX LIABILITIES

Tax liabilities at 31 December 2019 and 2018 amount to € 21.1 million and € 42.1 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. The reduction compared to 31 December 2018 is a consequence of a different result from the compensation between tax credits and debits.

28. OTHER CURRENT LIABILITIES

At 31 December 2019 other current liabilities amount to € 12.5 million, a reduction of € 6.8 million as compared to those at 31 December 2018. An amount of € 11.9 million is attributable to the adoption of the accounting principle IFRS 15 and will be recognized in the income statement in variable installments based on the realization of the conditions for revenue recognition.

29. PROVISIONS

Provisions in place at 31 December 2019 amount to € 17.9 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)	31.12.2019	31.12.2018	Change 2019/2018
Tax	604	644	(40)
Other	17,329	20,802	(3,473)
Total provisions	17,933	21,446	(3,513)

€ (thousands)	2019	2018
Balance at 1 January	21,446	48,322
Additions	3,002	3,183
Utilization	(6,515)	(30,059)
Balance at 31 December	17,933	21,446

Total provisions at year end are mainly comprised by those booked by the Parent and the other Italian companies (€ 7.4 million), by the French companies (€ 3.4 million), by the Spanish company Casen Recordati (€ 2.2 million) and by Recordati AG in Switzerland (€ 1.4 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 2019 give rise to a € 6.2 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 Mediobanca (€ 3.2 million), Intesa Sanpaolo (€ 1.1 million), UBI Banca (€ 0.7 million), Centrobanca (€ 0.6 million), UniCredit (€ 0.5 million), and Banca Nazionale del Lavoro (€ 0.1 million).

The measurement at fair value of the cross currency swaps stipulated by the Parent Company in November 2016 with Unicredit, covering two intercompany loans granted by the U.S. company Recordati Rare Diseases Inc. for a total nominal amount of 70 million U.S. dollars, was negative by € 1.7 million.

In October Recordati S.p.A. stipulated forward exchange contracts to cover the intercompany loan granted to Recordati AG for an amount of 228.9 million Swiss francs. The fair value of the derivative at 31 December 2019 was negative by € 2.9 million, which were booked to profit and loss compensating the exchange gains determined by the valuation of the underlying loan at current exchange rates.

The fair value of such hedging derivatives is measured at level 2. The fair value is calculated as the present value of the estimated future cash flows. Estimates of future floating-rate cash flows are based on quoted swap rates futures prices and interbank borrowing rates. Estimated cash flows are discounted using a yield curve which reflects the relevant benchmark interbank rate used by market participants for these purposes when pricing interest rate swaps.

31. BANK OVERDRAFTS AND SHORT-TERM LOANS

Bank overdrafts and short-term loans at 31 December 2019 are € 13.4 million and comprise temporary use of lines of credit, overdrafts by foreign subsidiaries and interest due on existing loans. The revolving line of credit obtained in July 2017 by Recordati Ilaç, the subsidiary in Turkey, for a maximum amount of 40 million Turkish lira and a 24 months' maximum duration, was extinguished.

32. FAIR VALUE OF FINANCIAL INSTRUMENTS

As prescribed by IFRS 7 hereunder are stated the balance sheet values and fair values at 31 December 2019 of financial assets and liabilities:

€ (thousands)	Book value	Fair value
Financial assets		
Financial assets measured at fair value		
Equity investments	38,566	38,566
Fair value of hedging derivatives (<i>cash flow hedge</i>)	9,949	9,949
Financial assets not measured at fair value		
Short-term financial investments, cash and cash equivalents	187,923	187,923
Trade receivables	296,961	296,961
Other receivables	79,949	79,949
Financial liabilities		
Financial liabilities measured at fair value		
Fair value of hedging derivatives (<i>cash flow hedge</i>)	10,788	10,788
Other non-current liabilities	3,257	3,257
Financial liabilities not measured at fair value		
Borrowings		
- loans at variable interest rates	423,880	423,880
- loans at variable interest rates covered with interest rate swaps	443,787	443,787
- loans at fixed interest rates	125,234	132,896
- loans at fixed interest rates covered with cross currency swaps	66,553	64,631
- leasing liabilities	27,707	27,707
Trade payables	175,481	175,481
Other payables	206,800	206,800
Other non-current liabilities	19,035	19,035
Bank overdrafts and short-term loans	13,392	13,392

33. DISCLOSURE OF FINANCIAL RISKS

The Group constantly monitors the financial risks to which it is exposed in order to take immediate mitigating actions when necessary.

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 2019 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 2019, total trade receivables of € 311.9 million include € 20.3 million of receivables overdue by more than 90 days. Of these, € 6.1 million are receivables from public hospitals which, despite their long payment times, do not represent a significant risk situation. An allowance for doubtful accounts of € 14.9 million, which is considered to be sufficient to cover potential losses due to insolvency, 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 2019 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 1,345.4 million Russian roubles;
net receivables of 2.1 million Swiss francs;
net receivables of 2.5 million U.S. dollars;
net receivables of 5.4 million Polish zloty.

Among the companies in countries outside the European Monetary Union, at 31 December 2019 the main net exposure in currencies different from their own, and not covered by hedging instruments, is in euros and in U.S. dollars. Net exposure in euros refer to the companies in the Czech Republic (net receivables of 1.8 million), Tunisia (net receivables of 1.5 million), Turkey (net payables of 5.2 million) Sweden (net payables of 3.3 million), Switzerland (net payables of € 2.9 million), Ukraine (net payables of 2.1 million), Mexico (net payables of 1.7 million) and Canada (net payables of 0.9 million). Net exposure in U.S. dollars refer to the companies in Switzerland (net payables of 112.6 million), Japan (net payables of 10.4 million) and Canada (net payables of 1.5 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 2019 the net equity values of these companies are denominated mainly in U.S. dollars (232.5 million), in Pounds Sterling (14.8 million), in Swiss francs (167.6 million), in Turkish lira (401.8 million), in Czech crowns

(351.9 million), in Romanian ron (39.6 million), in Russian roubles (3,747.5 million), in Polish zloty (25.9 million) and in Tunisian Dinars (53.5 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 2019, is negative by € 146.9 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 2019 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 following table summarizes the effects of the first time consolidation of Tonipharm S.a.s., of which the Group acquired 100% of its share capital on 31 December 2018, following the completion of the process for the measurement of the fair value of the assets and liabilities at the date of acquisition, which resulted in some changes of the preliminary values identified in the financial statements at 31 December 2018.

€ (migliaia)	Book value	Fair value adjustments	Fair value of assets and liabilities acquired
Non-current assets			
Property, plant and equipment	40	0	40
Intangible assets	11,466	38,500	49,966
Non-current receivables	125	0	125
Deferred tax assets	760	0	760
Current assets			
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
Non-current liabilities			
Deferred tax liabilities	0	(10,153)	(10,153)
Current liabilities			
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)
	15,873	28,347	44,220
Goodwill			28,416
Cost of the acquisition			72,636

The completion of the process for the measurement of the fair value of the assets and liabilities at the date of acquisition resulted in some changes to the preliminary recognition in the financial statements for the year 2018. In addition to the identification of added value for the intangible assets Ginkor® and Alodont®, the € 0.4 million book value of an intangible asset was considered non recoverable and the deferred tax effect was recalculated in line with the tax reforms approved in France at the end of 2018 which include a gradual reduction in tax rates starting 2019 through 2022. Consequently, 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 the intangible assets Ginkor® and Alodont®, € 10.2 million to the relative deferred tax liabilities, while € 28.4 million were allocated to goodwill in the specialty and primary care segment. Such goodwill is mainly attributable to the future economic benefits expected from the integration of the company within the Group and is not tax deductible.

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 Recordati Rare Diseases, its dedicated group of subsidiaries, 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 Rare Diseases operates directly in Europe, the Middle East, North Africa, the U.S.A., Canada, Mexico, Brazil, Colombia, Japan and Australia through its subsidiaries and highly qualified distributors in the rest of the world.

During 2019, Recordati Rare Diseases announced that its strategy aimed at establishing a direct presence in the key markets across all continents has been successfully executed. Several companies formerly operating under the name of Orphan Europe were recently renamed Recordati Rare Diseases, which is today the global brand of Recordati's organization dedicated to treatments for rare diseases and orphan drugs. Orphan Europe, founded in 1990, pioneered the development of orphan drugs in Europe and became part of Recordati in 2007.

The Group's chief executive officer reviews the internal management reports of each segment at least quarterly.

The following tables show financial information for these two business segments as at 31 December 2019 and includes comparative data.

€ (thousands)	Specialty & primary care segment*	Orphan drugs segment	Non-allocated	Consolidated accounts
2019				
Revenues	1,231,998	249,850	-	1,481,848
Expenses	(876,116)	(140,466)	-	(1,016,582)
Operating income	355,882	109,384	-	465,266
EBITDA inclusive of write-down of intangible assets⁽¹⁾	422,514	121,453	-	543,967
2018				
Revenues	1,137,403	214,832	-	1,352,235
Expenses	(798,465)	(111,551)	-	(910,016)
Operating income	338,938	103,281	-	442,219
EBITDA inclusive of write-down of intangible assets⁽¹⁾	390,571	108,508	-	499,079

* Includes the pharmaceutical chemicals operations

⁽¹⁾ Net income before provision for income taxes, financial (income) expenses, net, depreciation and amortisation and write-down of both property, plant and equipment and intangible assets.

The reconciliation of the net income and the EBITDA inclusive of write-down of intangible assets is reported below:

€ (thousands)	2019	2018
Net income	368,866	312,422
Provision for income taxes	75,278	105,513
Financial (income) expenses, net	21,122	24,284
Depreciation and amortization	78,248	56,860
Write-down of intangible asset	453	0
EBITDA inclusive of write-down of intangible assets⁽¹⁾	543,967	499,079

⁽¹⁾ Net income before provision for income taxes, financial (income) expenses, net, depreciation and amortisation and write-down of both property, plant and equipment and intangible assets

€ (thousands)	Specialty & primary care segment*	Rare diseases segment	Non-allocated **	Consolidated accounts
31 December 2019				
Non-current assets	1,213,146	747,868	38,566	1,999,580
Inventories	200,848	26,037	-	226,885
Trade receivables	234,788	62,173	-	296,961
Other current assets	76,352	11,280	9,949	97,581
Short-term investments, cash and cash equivalents	-	-	187,923	187,923
Total assets	1,725,134	847,358	236,438	2,808,930
Non-current liabilities	63,441	22,581	937,343	1,023,365
Current liabilities	265,343	147,414	173,997	586,754
Total liabilities	328,784	169,995	1,111,340	1,610,119
Net capital employed	1,396,350	677,363		
31 December 2018				
Non-current assets***	1,214,096	226,466	20,772	1,461,334
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
Total assets	1,647,844	288,199	225,222	2,161,265
Non-current liabilities***	63,638	2,652	640,647	706,937
Current liabilities	264,813	68,694	157,235	490,742
Total liabilities	328,451	71,346	797,882	1,197,679
Net capital employed	1,319,393	216,853		

* 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

*** Restated following the change in the allocation of the price of acquisition of Tonipharm S.a.s (see Note 34)

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.

No single customer contributed over 10% to revenue in 2019 (none also in 2018).

The following table presents net revenues by geographic area:

€ (thousands)	2019	2018	Change 2019/2018
Europe	1,191,474	1,101,925	89,549
<i>of which Italy</i>	<i>287,289</i>	<i>273,197</i>	<i>14,092</i>
Australasia	85,465	62,295	23,170
America	152,626	136,751	15,875
Africa	52,283	51,264	1,019
Total revenue	1,481,848	1,352,235	129,613

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)	31.12.2019	31.12.2018	Change 2019/2018
Deposits in bank current accounts and cash on hand	141,384	172,421	(31,037)
Short-term time deposits	46,539	25,615	20,924
Liquid assets	187,923	198,036	(10,113)
Bank overdrafts and short-term loans	(13,392)	(16,905)	3,513
Loans – due within one year	(140,963)	(69,591)	(71,372)
Loan notes issued ⁽¹⁾	-	(65,471)	65,471
Leasing liabilities – due within one year	(8,854)	(216)	(8,638)
Short term borrowings	(163,209)	(152,183)	(11,026)
Net current financial position	24,714	45,853	(21,139)
Loans – due after one year	(726,834)	(449,083)	(277,751)
Loan notes issued ⁽¹⁾	(181,708)	(183,740)	2,032
Leasing liabilities – due after one year	(18,853)	(1,410)	(17,443)
Non-current loans	(927,395)	(634,233)	(293,162)
Net financial position	(902,681)	(588,380)	(314,301)

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

37. RECONCILIATION BETWEEN THE PARENT COMPANY'S SHAREHOLDERS' EQUITY AND NET INCOME AND GROUP CONSOLIDATED SHAREHOLDERS' EQUITY AND NET INCOME

The reconciliation between the parent company's shareholders' equity and net income and the Group consolidated shareholders' equity and net income is as follows:

€ (thousands)	Shareholders' equity		Net income for the year	
	31.12.2019	31.12.2018	2019	2018
Recordati S.p.A.	435,426	336,058	241,092	217,330
Consolidation adjustments:				
- Margin in inventories	(59,066)	(58,411)	(655)	(23,361)
- Related deferred tax	16,618	16,296	322	6,577
- Other adjustments	(13,726)	(10,802)	(4,014)	(2,463)
Retained earnings of consolidated subsidiaries at beginning of the year, net of amounts already booked by Recordati S.p.A.	708,217	591,143	-	-
Net income for the year of consolidated subsidiaries, net of amounts already booked by Recordati S.p.A.	257,974	243,255	257,974	243,255
Dividends received from consolidated subsidiaries	-	-	(128,138)	(135,162)
Write-down of holdings in controlled companies	-	-	2,244	6,200
Translation adjustments	(146,866)	(154,146)	-	-
Consolidated financial statements	1,198,577	963,393	368,825	312,376

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 company in Ireland, Recordati Ireland Ltd. The declared intention of the inspection was to evaluate the operational context of the foreign company in order to verify whether said company is in reality only formally localized abroad but is 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. Recordati Ireland Ltd. filed its 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 S.p.A, reviewed the claims raised in the aforementioned audit report and carried out an in-depth analysis on the relations between Recordati S.p.A 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 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., with a view to avoid litigation, accepted and paid in November 2018. Finally, in relation to the same transactions occurred between Recordati S.p.A. and the Irish subsidiary in the tax periods 2016 and 2017, the Agency made a tax settlement proposal based on the same criteria applied in the previous years and requested payment of additional Ires and Irap – fully covered by existing provisions – for a total amount of € 4,8 million, in addition to € 0,2 million of interest, with no penalties imposed. Recordati S.p.A., again with a view to avoid litigation, accepted and paid the said amounts in June 2019. As from 2018 the same criteria defined by the Agency for the preceding years was applied and set out in a Commercial and Management Service Agreement.

39. RELATED PARTIES

The Group's direct controlling company is FIMEI S.p.A., which since 2018 is owned by a consortium of investors controlled by CVC Capital Partners. FIMEI S.p.A. has its headquarters in Milan, via Vecchio Politecnico 9, Italy and prepares the consolidated financial statements of which the Parent Company is a part.

Tax credits shown in the consolidated balance sheet at 31 December 2019 include those receivable from the controlling company FIMEI S.p.A. for an amount of € 40.6 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. The amount includes the effect of the so-called "patent box" agreed with the Italian tax authorities in December 2019, for the part related to corporate tax.

During 2018, a majority of the Company's share was acquired by CVC Fund VII through the acquisition of FimeI S.p.A.. As a result, the new ultimate controlling party of the Group is CVC Capital Partners. The previous ultimate controlling party was FimeI S.p.A..

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 specific functions, including those in other Group companies, during 2019 amount to € 2.6 million and € 0.1 million respectively.

Key management personnel compensation comprised the following.

€ (thousands)	2019	2018
Fixed remuneration	4,690	4,252
Non monetary benefits	57	56
Bonuses and other incentives	2,071	721
Share-based payments	1,390	849
Total	8,208	5,878

Compensation of the Group's key management personnel includes salaries and non-cash benefits. Executive officers also participate in the Group's stock option plans.

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

At the date of preparation of the financial statements no significant events occurred subsequent to the closing of the fiscal year that would require changes to the values of assets, liabilities or the profit and loss.

In January 2020 the European Commission has granted marketing authorisation for the orphan medicinal product Isturisa[®] (osilodrostat), indicated for the treatment of endogenous Cushing's syndrome (CS) in adults. The active substance of Isturisa[®] is osilodrostat, a cortisol synthesis inhibitor. Osilodrostat works by inhibiting 11-beta-hydroxylase, an enzyme responsible for the final step of cortisol biosynthesis in the adrenal gland. Isturisa[®] will be available as 1-mg, 5-mg and 10-mg film-coated tablets.

In March 2020 the FDA approved Isturisa[®] (osilodrostat) for the treatment of patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. Isturisa[®] is the first and only FDA-approved inhibitor of 11-beta-hydroxylase that has demonstrated normalization of cortisol levels in a significant portion of adult patients with a manageable safety profile, making this a novel treatment option for patients with Cushing's disease.

As from the month of February Italy and all the main countries in which the Group operates are impacted by the epidemiologic emergency due to the COVID-19 virus, declared a pandemic by the OMS in March. To face the emergency, in Italy, and subsequently also in other countries, restrictions to the circulation of people and provisions to support companies' economic activities have been introduced. The Group is implementing all possible measures and initiatives to guarantee the supply of medicines to its patients and the safety of its employees. Given the complex and constantly evolving situation it is not possible to predict possible future impacts at this time.

Except for the above, no significant events occurred subsequent to 31 December 2019.

41. SUBSIDIARIES INCLUDED IN THE CONSOLIDATED ACCOUNTS AT 31 DECEMBER 2019

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
RECORDATI RARE DISEASES 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
RECORDATI RARE DISEASES S.à r.l. <i>Development, production, marketing and sales of pharmaceuticals</i>	France	320,000.00	EUR	Line-by-line
RECORDATI RARE DISEASES UK Limited <i>Marketing and sales of pharmaceuticals</i>	United Kingdom	50,000.00	GBP	Line-by-line
RECORDATI RARE DISEASES GERMANY GmbH <i>Marketing and sales of pharmaceuticals</i>	Germany	25,600.00	EUR	Line-by-line
RECORDATI RARE DISEASES SPAIN S.L. <i>Marketing and sales of pharmaceuticals</i>	Spain	1,775,065.49	EUR	Line-by-line
RECORDATI RARE DISEASES 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
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

Consolidated Companies	Head Office	Share Capital	Currency	Consolidation Method
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	15,000,000.00	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. <i>Marketing of pharmaceuticals</i>	Canada	350,000.00	CAD	Line-by-line
RECORDATI RARE DISEASES JAPAN K.K. ⁽¹⁾ <i>Marketing of pharmaceuticals</i>	Japan	10,000,000.00	JPY	Line-by-line
NATURAL POINT S.r.l. ⁽²⁾ <i>Marketing of pharmaceuticals</i>	Italy	10,400.00	EUR	Line-by-line
RECORDATI RARE DISEASES AUSTRALIA Pty Ltd ⁽¹⁾ <i>Marketing of pharmaceuticals</i>	Australia	200,000.00	AUD	Line-by-line
TONIPHARM S.a.s. ⁽²⁾ <i>Marketing of pharmaceuticals</i>	France	257,700.00	EUR	Line-by-line
RECORDATI BULGARIA Ltd ⁽³⁾ <i>Marketing of pharmaceuticals</i>	Bulgaria	50,000.00	BGN	Line-by-line

⁽¹⁾ Established in 2018

⁽²⁾ Acquired in 2018

⁽³⁾ Established in 2019

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.	Recordati Rare Diseases 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
RECORDATI RARE DISEASES MIDDLE EAST FZ LLC					100.00						100.00
RECORDATI AB					100.00						100.00
RECORDATI RARE DISEASES S.à r.l.					100.00						100.00
RECORDATI RARE DISEASES UK LIMITED						100.00					100.00
RECORDATI RARE DISEASES GERMANY GmbH						100.00					100.00
RECORDATI RARE DISEASES SPAIN S.L.						100.00					100.00
RECORDATI RARE DISEASES 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
RECORDATI SK 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.	Recordati Rare Diseases S.à r.l.	Herbacos Recordati s.r.o.	Recordati İlaç A.Ş.	Opalia Pharma S.A.	Recordati AG	
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.	100.00										100.00
RECORDATI RARE DISEASES JAPAN K.K. ⁽¹⁾						100.00					100.00
NATURAL POINT S.r.l. ⁽²⁾	100.00										100.00
RECORDATI RARE DISEASES AUSTRALIA Pty Ltd ⁽¹⁾						100.00					100.00
TONIPHARM S.a.s. ⁽²⁾	100.00										100.00
RECORDATI BULGARIA Ltd ⁽³⁾	100.00										100.00

⁽¹⁾ Established in 2018

⁽²⁾ Acquired in 2018

⁽³⁾ Established in 2019

DISCLOSURE OF AUDITORS' FEES FOR ACCOUNTING AUDITS AND OTHER SERVICES

Type of service	Provider of the service	Recipient	Fees Amounts in €
Accounting audit	Auditor of Parent Company	Parent Company	130,700
Accounting audit	Auditor of Parent Company	Subsidiaries	78,100
Accounting audit	Network of auditor of Parent Company	Subsidiaries	633,679
Due diligence	Auditor of Parent Company	Parent Company	115,349
Tax compliance	Network of auditor of Parent Company	Subsidiaries	18,651
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	25,450
Other services	Auditor of Parent Company	Parent Company	70,000

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 2019.

2. The undersigned moreover attest that:

2.1. the consolidated financial statements at 31 December 2019:

- 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, 18 March 2020

Signed by
Andrea Recordati
Chief Executive Officer

Signed by
Fritz Squindo
Manager responsible for preparing
the company's financial reports