

## Annual Report 2016







#### GIOVANNI RECORDATI (1949-2016)

#### Aptitude and ingenuity

From a young age, Giovanni Recordati had always loved a good challenge. Rather than seek out unattainable aims, however; he tended to focus on those he believed he could realistically achieve.

Graduating in Engineering from the Polytechnic University of Milan in 1974, Giovanni considered linear algebra as a rational and mathematical approach to solving problems. This innate attitude toward life would accompany and define him throughout his career.

Upon graduation, Giovanni joined Recordati as a researcher. In 1978, he went on to obtain a Master's in Management Science from the Imperial College in London, returning to his work at the company shortly after. To enhance his professional experience at Recordati and develop a better understanding of the company's dynamics, Giovanni underwent a comprehensive training process, in which he learned about the company's integrated research and development of new drugs, the production of active ingredients, the pharmaceutical production and logistics, as well as the promotion of its products.

It was this fundamental process of professional development that would later lead to his appointment as Chief Executive Officer in 1990, then Chairman in 1999, following the passing of his father Arrigo. It would also be the dawn to a new era of growth for Recordati, which after its initial success in the '60s, experienced a difficult period of transition lasting several decades. Starting in 2000, Giovanni drove the firm to become one of Italy's leading pharmaceutical companies. Introducing new impetus and entrepreneurial vision in the business, coupled with his strong leadership skills, Giovanni helped Recordati establish a fresh development strategy which, adhering to the company's mission and utilizing available resources, led to a spurt of acquisitions of 22 international businesses and pharmaceutical products across Europe, America and Africa in the span of 16 years.

Much of Recordati's success can be credited to Giovanni's inherent belief in research, a value instilled in him by his father. The company's development of lercanidipine, an innovative calcium channel blocker created in the Recordati laboratories, resulted in the strengthening of the group's cash flow generation, thus paving the way for the company's first acquisitions in France and Germany. This phase of rapid growth was founded on Recordati's traditional dedication to R&D, which had previously generated innovative drugs in the fields of urology and andrology, starting with Genurin® (flavoxate) – the first drug entirely developed by an Italian company to be approved by the FDA – and followed by further development of owned or licensed-in products for various urological disorders.

Constantly seeking new horizons, Giovanni continued to guide Recordati on a fruitful path of acquisitions and growth, penetrating the vast, lucrative markets of Europe and the United States, as well as emerging markets in Eastern Europe, such as Russia, and identifying opportunities in North Africa and Turkey. The peak of acquisitions throughout his 16 years of leadership resulted in significant growth in personnel, with the number of employees increasing from 1,566 to 4,116 and an expansion to eight pharmaceutical plants across Europe and North Africa. This extensive process of globalization transpired in Recordati's generation of 80% revenue outside its domestic market in 2016, distributing an overall dividend for the 16-year period of €755.7 million and increasing its capitalization from €172 million to €6 billion.

Recordati's traditional expertise and business had historically been based in the field of primary care, in which most of the

acquisitions under Giovanni's leadership were made. However, Giovanni had extended the company's mission to also become a leader in the rare diseases and orphan drugs sector, a fast-growing and promising market of the future at the time. At the end of 2007, Recordati acquired Paris-based firm Orphan Europe, present in a number of European and Middle East countries. This move served as a stepping stone for further growth in the field of rare diseases, resulting in the establishment of Recordati Rare Diseases in the United States with the acquisition of Lundbeck's rare disease business, in addition to further expansion in Mexico, Brazil, Colombia and Canada.

Recordati's expansion into the field of rare diseases was a product of Giovanni's ingenuity and brilliant intuition. He was a true visionary who, rather than be distracted by lofty business goals, chose to dedicate himself to the achievement of realistic ambitions. His pragmatic approach drove the company's orphan drug segment in 2016, resulting in revenues amounting to €186.8 million and generating 25.5% of Recordati's operating income. In this pharmaceutical area, accounting for 16.2% of the group's overall revenue, Recordati has established a global presence.

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The substantial commitment, impetus and perseverance Giovanni put into his successful career was balanced by his passion for life and all its nuances and challenges. Per family tradition, he took a profound interest in sports cars and racing, in which he actively participated. What initially began as an adrenaline-packed hobby of hair-pin turns, dirt road excursions and power shifting quickly turned into a genuine talent. Over the course of 40 years of high-level amateur activity across Europe, Giovanni distinguished himself as a skilled pilot in the gentleman drivers category; often resulting the victor of competitions, he accumulated a number of prestigious achievements, trophies and memorabilia in the sport, which he often kept in his office.

Harmonizing Giovanni's stimulating extracurricular activity was his love for yachting and the sea, where he could unwind after a hard day's work. Though he tended to treat his nautical experiences with irony, in order to avoid getting caught up in excessive exuberance.

Giovanni Recordati represented the third generation of a successful entrepreneurial family, who proved himself capable of leading and expanding Recordati with his inherent genius, passed down from his father Arrigo and his grandfather Giovanni before him. As all great entrepreneurs do, Giovanni demonstrated extraordinary strategic vision and had the ability to see into the future without underestimating day-to-day activity. He had a modern take on entrepreneurial function, rooted in ethics based on equal interests between shareholders, employees, customers, suppliers and civil and institutional society to the point that Recordati, listed on the Italian stock exchange, has always benefited from a public company corporate governance.

Giovanni was also exceptionally skilled in motivating his staff – one he partly inherited from Arrigo and which he was able to effectively lead, inspire and, if necessary, renew. He had a particular way of going about things and never felt completely satisfied, ultimately feeding his ambitions, which were neither presumptuous nor vain and always convincing. Giovanni's managers supported him wholeheartedly in an environment inspired by the principle of delegation of authority and operational autonomy, in which ultimate responsibility was always placed on the superior.

\* \* :

The greatest success of Giovanni's life, however; was his dedication to keeping the family together and guiding it with the utmost mutual respect, in a community of pride and affection.

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THE RECORDATI SHARE



# Recordati, an international group

**REVENUE** 

(Million Euros)

1,153.9

**NET INCOME** 

(Million Euros)

237.4

**EMPLOYEES** 

exceed 4,100

Recordati is a growing international pharmaceutical group. It actively seeks new opportunities and faces the challenges of a constantly changing marketplace with determination. In 2016 the group generated revenues of € 1,153.9 million and has a staff of more than 4,100 employees.

ecordati is a well-established 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.

Today Recordati 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 Czech Republic and Slovakia, in Romania, Poland, Russia and the other C.I.S. countries, Ukraine, Georgia, Turkey, Tunisia, in the U.S.A., Mexico and in some South American countries. Recordati sells its products in 135 markets both directly and through license agreements. In addition to its geographical expansion

the Group has enriched its product portfolio by developing its own pipeline of products and by entering the segment dedicated to rare diseases.

Recordati develops, produces and sells drugs for the treatment of rare diseases through Orphan Europe and Recordati Rare Diseases, two companies dedicated mainly to metabolic deficiencies of a genetic nature.

Among its most important products in the cardiovascular therapeutic area are those 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.

Recordati's commitment in the uro-genital therapeutic area and its know-how and expertise accumulated over 40 years of research and study has led to its being the European partner of established international pharmaceutical companies such as the Japanese company Kissei among many others.

Silodosin, a treatment for benign prostatic hyperplasia discovered by researchers at Kissei and developed for the European markets by Recordati, is one of the group's most important specialties. This product is now marketed successfully in 34 countries. Also pitavastatin, a latest generation statin for controlling hypercholesterolemia, discovered and developed by Kowa, was obtained under license for Europe.

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



# The future of the group

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

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

### Letter to our shareholders





The results obtained in 2016 confirm the sustained growth of the group, with a significant increase of both revenues and profitability.

#### To Our Shareholders,

In 2016, following a long illness, the Chairman and Chief Executive Officer of the company, Mr. Giovanni Recordati, passed away on August 15. Mr. Giovanni Recordati has been Chief Executive Officer of the company since 1990 as well as Chairman of the Board of Directors since 1999. Under his management the group grew vigorously becoming a well-known international pharmaceutical player with subsidiaries in Europe, North America, South America and North Africa as well as developing a presence in the rare disease segment.

The Board of Directors, at a meeting convened urgently, resolved to appoint Alberto Recordati Chairman of the Board of Directors of the company and Andrea Recordati Vice Chairman and Chief Executive Officer. In particular, Andrea Recordati, Chief Operating Officer since 2013 in charge of all the commercial and production activities of the group, has been granted all the powers for the ordinary and extraordinary management of the company, including the direction and coordination activities regarding all companies belonging to the group. It is the intention of the Directors to proceed along the lines of the development strategy outlined by Giovanni Recordati with the objective of continuing the growth of the group.

Regarding the group's financial performance, the results obtained in 2016 confirm the sustained growth of the group, with a significant increase of both revenues and profitability. All business segments and the main corporate products, as well as the consolidation of the two acquired companies, contributed to these results. Group consolidated revenue for 2016 is € 1,153.9 million, up 10.1% over the preceding year. International sales are € 916.3 million, up 9.6% and now represent 79.4% of total revenue. Operating income, at 28.4% of sales, is € 327.4 million, a growth of 17.6% compared with the preceding year. This result includes non recurring expenses of € 12.8 million due to charges for organizational restructuring and ancillary costs related to the recent acquisitions of Italchimici S.p.A. and Pro Farma AG as well as the write-down of certain intangible assets. Net income is € 237.4 million, an increase of 19.4%, with a further improvement as margin on sales which is now 20.6%. At 31 December 2016 the group's net financial position records net debt of € 198.8 million compared to net debt of € 88.7 million at 31 December 2015, including the acquisition of Italchimici S.p.A. and Pro Farma AG, the distribution of dividends and share buy-backs that accounted for a total amount of more than € 300 million during the period. Shareholders' equity further increased to € 903.9 million.

In 2016 a number of initiatives were pursued in line with the group's strategy of continued growth and development.

In 2016 a number of initiatives were pursued in line with the group's strategy of continued growth and development.

During May 100% of the share capital of Italchimici S.p.A., an Italian pharmaceutical company with operational headquarters in Milan was acquired. The value of the transaction (enterprise value) was of around € 130 million and was be funded from existing liquidity. Italchimici, with over 40 years of history and revenues in 2015 of € 46 million, is a consolidated firm in the Italian pharmaceutical market with well-known products. The company offers therapeutical solutions mainly in the gastroenterological and respiratory areas which consist of both pharmaceutical products as well as food supplements and medical devices to improve the health and well-being of patients. The main brands in its extensive product portfolio are Reuflor® (lactobacillus reuteri), Peridon® (domperidone) and Lacdigest® (tilactase) in the gastroenterological offering and Aircort® (budesonide) among the respiratory products.

In July 100% of the share capital of Pro Farma AG, a Swiss pharmaceutical company with headquarters in Zug, was acquired. The value of the transaction (enterprise value) is of CHF 16 million and was funded from existing liquidity. Pro Farma, with 2016 revenues of around CHF 10 million, markets proprietary and in-licensed specialties in selected therapeutic areas which include both prescription and OTC drugs. The main brands are Lacdigest\* (tilactase), Tretinac\* (isotretinoin) and Urocit\* (potassium citrate). Furthermore, the company offers distribution and promotion services to other pharmaceutical companies. The acquisition of Pro Farma represents an excellent base on which to develop our operations in Switzerland where Recordati has recently started to sell its product portfolio directly to the market. Furthermore, the main product Lacdigest will contribute to the enhancement of our presence in gastroenterology.

Also during July, a partnership with AP-HP (Assistance Publique – Hopitaux de Paris) was finalized under which AP-HP will grant an exclusive world-wide license to Orphan Europe (a Recordati company) for the development and commercialization of an innovative product for the treatment of acute decompensation episodes in patients affected by Maple Syrup Urine Disease (MSUD), a severe metabolic disorder.

At the beginning of August Recordati and Gedeon Richter signed an exclusive license agreement to commercialize cariprazine, a novel atypical antipsychotic in Western Europe and in Algeria, in Tunisia and in Turkey. Cariprazine was discovered by Richter scientists and was launched in the U.S.A. in March 2016 under the trademark of Vraylar<sup>TM</sup>. In March 2016, the European Medicines Agency (EMA) started the evaluation of Richter's marketing authorization application for cariprazine for the treatment of schizophrenia. Schizophrenia is a chronic and disabling disorder that has a worldwide prevalence approaching 1%. It imposes significant burden on patients, their families, and society. Symptoms fall into three broad categories: positive symptoms (hallucinations, delusions, thought disorders, and movement disorders), negative symptoms (such as loss of motivation and social withdrawal), and cognitive symptoms (problems with executive functioning, focusing, and working memory). Cariprazine is an orally active and potent dopamine  $D_3/D_2$  receptor partial agonist with preferential binding to  $D_3$  receptors and partial agonist at serotonin 5-HT<sub>1A</sub> receptors.

The development of the segment dedicated to treatments for rare diseases and its expansion into new markets will continue to be a priority. Going forward we will continue to develop the business internationally, 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. and in some Latin American countries. 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.

We believe that the strict implementation of our strategy will enable us to be optimistic regarding the future, and we count, as always, on the entrepreneurship and determination of our management team, the professional skills of our employees and the trust of our shareholders. We would like to express our gratitude to all of them for their support during 2016.

#### **DIVIDENDS**

Based on the results obtained, the Board of Directors of the parent company will propose to the shareholders a dividend of € 0.35 per share, in full balance of the interim 2016 dividend of € 0.35, to be paid to all shares outstanding at ex-dividend date, excluding those in treasury stock, as from 26 April 2017 (record date 25 April 2017), with ex-dividend on 24 April 2017 (against presentation of coupon no. 19). The full 2016 dividend is therefore of € 0.70 per share (€ 0.60 per share in 2015).

Alberto Recordati

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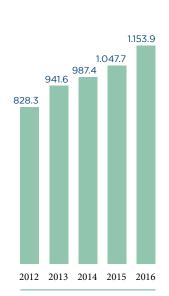
Chairman

Andrea Recordati

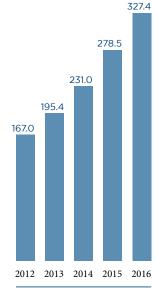
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Vice Chairman and Chief Executive Officer

# The group in figures



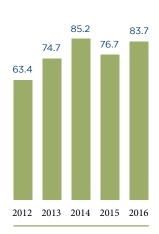
REVENUE Milions of Euro



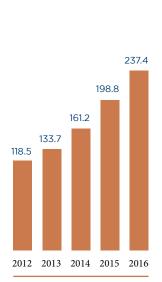
**OPERATING INCOME**Milions of Euro



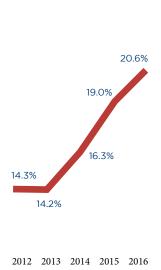
OPERATING INCOME AS % OF REVENUE



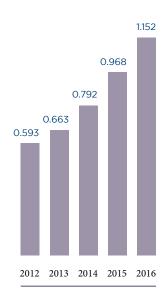
**R&D EXPENSES**Milions of Euro



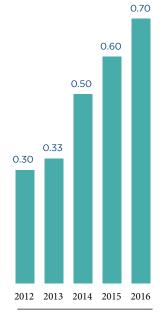
**NET INCOME**Milions of Euro



NET INCOME AS % OF REVENUE



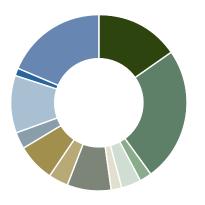
NET INCOME PER SHARE Euro



DIVIDEND PER SHARE Euro

#### GEOGRAPHICAL COMPOSITION OF PHARMACEUTICAL SALES

- 20.6% Italy
- 10.3% France
- 9.1% USA
- 9.1% Germany
- 7.8% Turkey
- 7.1%
  Russia, Ukraine and other CSI
- 6.9% Spain
- 3.8% North Africa
- 3.6% Portugal
- 3.6% Other West Europe
- 2.9% Other CEE
- 15.2% Other International sales



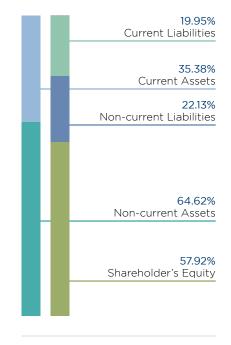
#### PHARMACEUTICAL SALES BY THERAPEUTIC AREA

- 15.4% Gastrointestinal and Metabolism
- 24.6% Cardivascular
- 2.3%
  Dermatology
- 3.6% Ginecology
- 1.9%
- Anti-infective 8.0%
- Muscolo-skeletal, Analgesia
- Central Nervous System
- Respiratory
- 3.1% Sense organs
- 10.6% Urology

7.1%

- 1.4% Others
- 18.4%

  Treatments for Rare Diseases



#### BALANCE SHEET At 31 December 2016

### SHAREHOLDER'S EQUITY

Milions of Euro

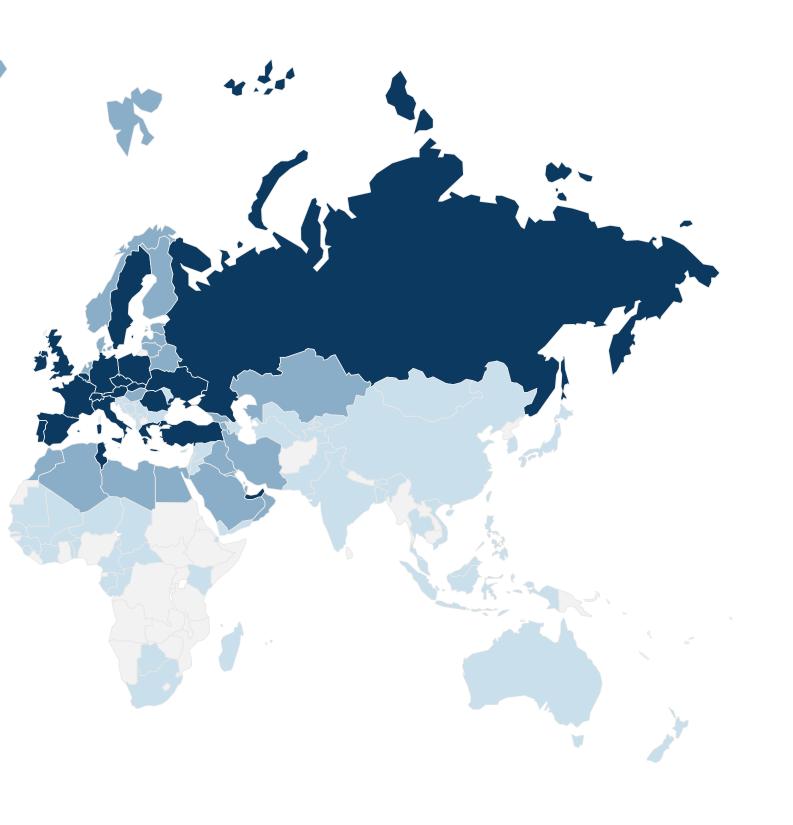
903.9

### NET FINANCIAL POSITION

Milions of Euro

(198.8)







### Group activities

In addition to being present in the field of cardiovascular disease, and in particular in hypertension, Recordati also operates in the area of urology with treatments for benign prostatic hyperplasia and in the area dedicated to treatments for rare diseases where the group researches, develops and markets a number of orphan drugs.

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

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

Is an antihypertensive drug discovered and developed entirely in the Recordati research laboratories. Lercanidipine, the Group's main product, is effective in gradually lowering blood pressure values to optimal levels avoiding episodes of reflex tachycardia and reducing the risk of cardiovascular events and their related mortality. It's lipofilicity 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.

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

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

antihypertensive drug to keep their blood pressure at desired levels. The use of fixed combinations of antihypertensive agents is growing and is expected to play a significant and increasing role in the treatment of hypertension.

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.

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

#### LIVAZO<sup>®</sup>/ALIPZA<sup>®</sup> (pitavastatin)

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

Pitavastatin is indicated for the reduction of elevated total cholesterol (TC) and LDL cholesterol (LDL-C), in adult patients with primary hypercholesterolemia and combined (mixed) dyslipidemia when response to diet and other non-pharmacological measures is inadequate.

In controlled clinical trials involving more than 1,600 patients it was shown that pitavastatin induces not only a reduction in LDL-cholesterol (the "bad" cholesterol that contributes to formation of atherosclerotic plaques) but also an increase in HDL-cholesterol (the "good" cholesterol that is removed from the arterial walls), a dual effect that should be regarded as highly relevant, since it appears to reduce the relative risk for cardiovascular complications.

Furthermore, it has been shown that pitavastatin is minimally metabolized by the enzymes of the Cytochrome P-450 family, enzymes that play a key role in the metabolism of many drugs, thus minimizing the potential risk for unpredictable responses to treatment or for interaction with drugs metabolized by this pathway. Pitavastatin therefore presents an excellent safety profile due to the lower likelihood of drug-drug interactions than that of most other statins.

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

#### **UROREC®** (silodosin)

Silodosin is a drug indicated for the treatment of benign prostatic hyperplasia (BPH), a widespread disease on the increase in aging populations. It manifests in males, generally after the age of fifty, with problems linked to urination, such as reduced urine stream, increased frequency and urgency and nocturia.

Silodosin is a powerful antagonist of the α1 adrenergic receptors with a high affinity for a1A receptors. Blocking of the a1A receptors leads to a rapid increase in urine flow and an improvement in both irritative symptoms (frequency, urgency, nocturia) and obstructive symptoms (hesitancy, incomplete emptying of the bladder, intermittency, weak stream). As demonstrated by a study conducted in Europe by Recordati on more than 800 patients, the administration of silodosin leads to an improvement in urine flow after only 2-6 hours and rapid relief from both obstructive and irritative symptoms in the course of 3-4 days. Symptom improvement is maintained during long term treatment. The safety and tolerability of silodosin has been assessed with positive results on 1,600 patients.

#### **EUROPEAN SOCIETY OF HYPERTENSION (ESH) CONGRESS**

European congress dedicated to the area of hypertension and is well recognized worldwide. It was held in Milan from the 27th to the 31st of August 2016 and was attended by 31,000 delegates. As usual Recordati was present with a large stand dedicated to the communication of its main cardiovascular products Zanidip®, Zanipress® and Livazo® and a number of scientific meetings – Meet the Expert - were organized with experts of high standing in the field.

On the first day Professor Athanasios Manolis (Asklepeion Hospital, Athens) discussed antihypertensive drugs and diabetes, and a session was dedicated to the theme "Fixed combinations, hypertension and organ protection: a focus on diabetes". Over the following days Professor Damiano Rizzoni (Brescia University) was invited to discuss the role of microcirculation as a parameter for the evaluation of cardiovascular risk and Professor Lorenzo Ghiadoni (Pisa University) the benefits of the fixed combination of lercanidipine and enalapril in effectively reducing high blood pressure while ensuring renal protection. During the meeting entitled "Not all the statins are the same: some guidance on how to manage high-risk patients" Professor Kausik K. Ray (Imperial College, London) illustrated the characteristics of the various statins.

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

In all the clinical studies conducted until now, Urorec® has been found to be highly effective, so much so that it is considered a valid and innovative alternative to treatments currently

Silodosin is the result of original research by the Japanese pharmaceutical company Kissei Pharmaceutical Co. Ltd. and was obtained under license by Recordati for the whole of Europe and a number of countries in the Middle East and Africa.

The clinical development of the product was conducted by Recordati for its own markets. Recordati has successfully launched the drug in 34 countries including France, Germany, Italy, Spain, Russia and other CIS markets, Tunisia, Turkey and Switzerland.

Recently Recordati published the results of the SIRE clinical trial, conducted on more than 1,000 patients, which confirmed, in clinical practice, the efficacy of silodosin in reducing the most bothersome symptoms associated with BPH. Following recent evidence in the literature describing silodosin as an alpha blocker which is highly effective in reducing bladder obstruction, a new clinical trial was initiated in order to confirm these observations in patients with BPH by using urodynamic evaluation methods.

#### VITAROS®/VIRIREC® (alprostadil)

Is the first topical cream for the treatment of erectile dysfunction. It is indicated for men at least 18 years old who are unable to achieve or maintain a penile erection sufficient for satisfactory sexual performance. Its innovative formulation with specific excipients enhances the rapid absorption in situ of the active ingredient alprostadil, a synthetic analogue of prostaglandin E1, a potent vasodilatory substance naturally present in the human body.

The product is characterized by fast onset of action, between 5 and 30 minutes, and its effect lasts between 1 and 2 hours. Its efficacy was

shown in extensive phase III trials conducted on more than 1,700 patients. The topical administration and local mechanism of action minimizes any systemic adverse reaction or interaction with other drugs, food or alcoholic beverages, and therefore Vitaros® can be considered an effective and safe alternative to existing orally administered products. The product was launched successfully in Spain and is now also available in Portugal, Poland, Ireland, the Czech and Slovak Republics and will soon also be lauched in Greece and Romania.

#### LOMEXIN®/FALVIN® (fenticonazole)

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

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

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

#### GENURIN®/URISPAS® (flavoxate)

Flavoxate, a Recordati original research product, is a muscle relaxant of the urinary tract. It is indicated for the symptomatic treatment of dysuria, urgency, nocturia, frequency and incontinency and the treatment of bladder and urethral spasms. It is able to control symptoms associated with urgency and hyper activity of the detrusor, thanks to its action on the transmission of the reflex impulse to empty the bladder. Flavoxate is the first Italian drug to be approved by the American Food and Drug Administration and to be marketed in the United States of America, and is widely used in many countries.

#### KENTERA® (oxybutynin transdermal patch)

Kentera® is an oxybutynin transdermal system indicated for the treatment of symptoms associated with disorders of the lower urinary tract, such as incontinence, frequency and urgency.

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

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

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

TransAct\*LAT is a transdermal patch containing flurbiprofen, a non steroidal antiinflammatory drug (NSAID), indicated for the symptomatic relief of localized pain involving the musculoskeletal system.

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

All these characteristics and the efficacy of flurbiprofen, demonstrated by numerous clinical studies, make TransAct®LAT a highly appreciated specialty among doctors and the patients themselves. It is available in a number of countries in Europe, among which Italy and Portugal where it is successfully marketed by Recordati.

#### RUPAFIN®/WYSTAMM® (rupatadine)

Rupatadine is a second generation antihistamine. It is a histamine antagonist with selective peripheral H1 receptor antagonist activity. It

effectively blocks the receptors of the platelet activating factor (PAF), a characteristic which distinguishes it from other specialties belonging to the same class of drugs.

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

It is marketed in Italy, Germany and France.

#### LOPRESOR® (metoprolol)

Lopressor® belongs to the beta-blocker class of drugs and is indicated for the treatment of hypertension either alone or in association with other antihypertensive agents. This selective beta blocker is also indicated for long term treatment of angina pectoris. Lopresor® is available in a number of European countries and is particularly successful in Greece and in Germany.

#### **TERGYNAN®**

A fixed combination of different active ingredients, this product is used for the topical treatment of vaginal infections and the prevention of gynecological infections thanks to its distinct antimicrobial, anti-inflammatory, antiprotozoal and antimycotic activity.

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

#### PROCTO-GLYVENOL® (tribenoside)

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

Procto-Glyvenol® is successfully marketed by Recordati in the Central and Eastern European markets as well as in Portugal and Turkey and by licensees in other territories.

#### CITRAFLEET® and PHOSPHOSODA®

Both brands are bowel cleansers used in preparation for any diagnostic procedure which requires emptying of the intestines, such as colonoscopy or x-rays and belong to the Spanish company Casen Recordati.

These products are sold mainly in Spain and in Germany. Thanks to the constant product portfolio integration process among the group's subsidiaries, starting 2015 Citrafleet® was reinforced in Ireland and introduced in Portugal, Greece, Italy, Romania and Russia while Phosphosoda® was launched in Russia and Germany.

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

The group's product portfolio integration process involves two other gastrointestinal products indicated for constipation belonging to Casen Recordati: the laxatives Casenlax® and Fleet Enema®. The first was successfully launched in Italy and france and under the brand Laxbene® in Germany. A new form in individual ready to drink liquid sachets is available in Spain. Fleet Enema® is also indicated for bowel cleansing in preparation for surgery.

#### The HEXA line of products

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

The main brand is Hexaspray®, a spray for sore throats and leader in its class in France where a new flavour was introduced in 2016.

#### **MUVAGYN®**

Muvagyn\* is a line of OTC gynecological gels developed by the Spanish subsidiary Casen Recordati. It is a regenerative non-hormonal treatment of the vaginal mucus indicated mainly for vaginal dryness that was also launched in Italy in 2015 to complement Recordati's gynecological offering.





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

#### **ITALY**

Successfully present on the Italian market since 1926, the Recordati group has grown constantly and in 2016 commemorated its 90th anniversary.

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

In addition to its historic and established presence in the cardiometabolic field, the Italian product portfolio also boasts quality medicines in urology, in gastroenterology and in pain control. In 2016 it was enriched with the Italchimici products.

Peptazol® (pantoprazole), a proton pump inhibitor frequently used for the treatment of gastro esophageal reflux disease and in the prevention of gastro duodenal ulcers caused by NSAIDs, belongs to a large and competitive market. It is one of the most important products in the portfolio and one of the most stable brands in its market segment. Its lower potential for pharmacological interactions is widely recognized by doctors because the greatest users of this class of drugs are patients who simultaneously take a number of different treatments.

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

Urorec\* (silodosin) is appreciated by physicians in Italy and reinforces the company's presence in the field of urology and in particular in benign prostatic hyperplasia. In 2016 a new product, Recoprox® was added to the Italian urology portfolio. It is a food supplement based on serenoa repens which is widely used in clinical practice to improve the urinary tract and prostate functions.

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

Cardicor® (bisoprolol), a drug belonging to the beta-blocker class indicated for the treatment of chronic, stable, moderate to severe heart failure, associated with reduced systolic ventricular function. Administered in addition to ACE inhibitors and diuretics, it is today considered a gold standard.

Rextat® (lovastatin), together with the brand Lovinacor® (lovastatin) marketed by Innova Pharma, a well-known and trustworthy statin, it has a favourable cost/benefit profile in first line pharmacological treatment of dyslipidemia and is supported by extensive scientific documentation and clinical trials.

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



Rupafin® (rupatadine) is a valid therapeutic solution for the treatment of rhinitis and rash caused by seasonal or perennial allergies due to its particular mechanism of action. In 2016 an oral suspension pediatric formulation was added to the adult solid administration form.

To complete the pharmaceutical portfolio in Italy Recordati offers three specific gastrointestinal products: Losipaco®, Citrafleet® and Casenlax®. Losipaco<sup>®</sup> is a fixed combination of loperamide and simeticone indicated in the treatment of diarrhoea attacks associated with abdominal cramps, swelling and flatulence, which was launched in 2016. Citrafleet\* (sodium picosulfate) is a bowel cleanser used in the preparation of colonoscopy procedures. Casenlax® (macrogol) is an osmotic laxative particularly indicated in chronic constipation as it is not absorbed in the intestine and therefore appropriate also for pediatric use.

Recordati has always been close to both family doctors and specialists and each year sponsors a number of educational projects and training courses in its areas of therapeutic interest.

In 2016 around 5,000 participants attended the training courses promoted by the company. The program of residential courses dedicated to professional risk in primary care generated much interest. This program alone involved 1,300 family doctors.

In urology Recordati supports a Master's program

for young urologists to incentivize scientific research projects and the study of particularly innovative methodology. In 2016 the company actively supported research conducted by the Italian Society of Urology.

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

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

The Alovex® line comprises Alovex® active protection, indicated for the treatment of aphthas and mouth sores, Alovex® dentizione, a product specifically created for newborns which provides rapid relief from pain and irritation caused by teething and Alovex® labiale, for the treatment of lip herpes.

In the antihaemorrhoids segment the Proctolyn® line reinforced its leadership.

In the oral care market Dentosan® is a brand well-known both by doctors and pharmacists mainly thanks to the chlorhexidine based mouthwash line which represents a benchmark in the treatment of bacterial plaque. The Dentosan® line also comprises toothpaste gel and toothbrushes as well as dental floss.

In the decongestant and antihistamine eve drops market, the Imidazyl® brand maintains its leading position.

In the natural eye drops segment the Eumill® line consolidates its position thanks to the performance of Eumill Protection®, the lubricating and moisturizing drops which help to counteract ocular dryness and fatigue, available alongside Eumill<sup>®</sup>, the freshening and soothing eye drops. In 2016 the line was further enhanced with the introduction of new formulations of Eumill Naso for adults and children based on sea water saline solution for daily nasal cleansing and protection from allergens and polution.

Recordati also offers an OTC line of cough medicines which comprises Recotuss® Sedativo, syrup and tablets containing dextromethorphan bromide, an effective active principle for the symptomatic treatment of dry cough, and Recofluid®, a fluidifying mucolitic syrup which does not contain saccharose nor glucose and can therefore be administered to diabetics.

ClismaFleet®, a rectally administered solution for occasional constipation, is well appreciated by clinicians.

In June 2016 Recordati acquired Italchimici S.p.a.. The company, with over 40 years of history, is a consolidated firm in the Italian pharmaceutical market which offers therapeutical solutions mainly in the gastroenterological and respiratory

In the field of gastrointestinal disorders, the probiotic Reuflor® (a dietary supplement based on lactobacillus reuteri) has become an important benchmark supported by robust clinical evidence which show real efficacy in rebalancing intestinal bacterial flora in adults and children.

Peridon® (domperidone) is a gastroprokinetic widely used in adults for the treatment of symptoms such as nausea, vomiting, disturbances of the upper gastrointestinal tract, regurgitation. In 2016 a new line of dietary supplements was introduced (PeridoNatural®), based on ginger, camomile and vitamin B, which has been positively received as a natural adjuvant for digestion disorders in children and adults due to its optimal safety profile.

In the field on dietary intolerance, Lacdigest® is a well-known product based on the enzyme tilactase for the symptomatic treatment of lactose intolerance due to primary and secondary lactase deficiency, a common disturbance growing progressively due to the ageing of the population.

Nalcrom® (sodium cromoglycate) is a consolidated pharmacological option for the treatment and prevention of food allergies.

In 2016 the Italian commercialization rights to Entocir® (budesonide), a potent and efficacious drug for the treatment of slight to moderate Crohn's disease, were obtained.

In the respiratory area, Aircort® (budesonide) is a line of products available in a number of formulations widely used in disorders of the upper and lower respiratory tract and in bronchial asthma and allergic or perennial rhinitis.

Cynazin® is a drug based on cinnarizine indicated for the treatment of balance problems, originated in the central and peripheral nervous system, associated with vertigo, tremors, tinnitus, nystagmus, nausea and vomiting.

Completing the pharmacological portfolio, the Unicexal™/Cexidal® (ciprofloxacin and corticosteroid for topical use) line represents a valid treatment option in primary care for ear, nose and throat infections.

#### **FRANCE**

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

The French subsidiary holds significant positions in a number of therapeutic areas, such as the the cardiovascular area with Zanextra® (lercanidipine+enalapril), the urology area with Urorec® (silodosin), the anti-allergy segment with Wystamm® (rupatadine) and more recently the gastrointestinal area with Citrafleet®, a bowel cleanser in preparation for diagnostic procedures such as colonoscopy.

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

Laboratoires Bouchara Recordati has a historical presence in the French OTC market. The Hexa line of products (Hexaspray®, Hexalyse® and Hexamer®) maintain their leadership and

notoriety in the segment of winter maladies and Exomuc\* is now the best-known and leading mucolytic containing N-acetyl cysteine.

The OCT portfolio was further enhanced with The recent launch of Aphtavea®, a line of products for the treatment of mouth sores.

The company has also developed an important international presence and continues to expand in the Maghreb area, in French-speaking Africa and in Asia. Through its dynamic export and promotion activities it distributes a number of specialties from its product portfolio in over 30 different countries.

#### **GERMANY**

Recordati Pharma is one of the most esteemed German pharmaceutical companies in the field of orthopedics. Over time it has developed a strong presence in orthopedics and offers first class products to specialists in this field. The most important of these includes Ortoton® (metocarbamol), a muscle relaxant used for back pain which is the main product of the subsidiary and is leader in its class, Recosyn® (hyaluronic acid), which is available in four different formulations for specific treatment regimens, Lipotalon® (dexamethasone palmitate) and SportVis<sup>TM</sup> (biocompatible hyaluronic acid adapted for soft tissues).

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

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

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





(oxybutynin transdermal patch), indicated for urinary incontinence.

The German subsidiary markets a line of OTC products with a specific sales organization which operates in a growing market and is dedicated to a number of brands the bestknown of which are: Rhinopront® for rhinitis, Mirfulan®, a leading brand for diaper rash and JHP-Rödler®, a cough and cold medicine.

Recently Laxbene® Junior, a product for the treatment of constipation in children over six months of age, was added to the portfolio and has created important synergies between the gastrointestinal specialist line and the OTC presence.

#### **PORTUGAL**

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

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

Jaba Recordati's main products are Livazo® (pitavastatin), an innovative and much appreciated statin for the treatment of dyslipidemia, Zanipress® the fixed combination of lercanidipine and enalapril, which today is the leading brand in the calcium channel blocker + ACE inhibitor market in units, and Urorec® (silodosin) second in its class for the treatment of benign prostatic hyperplasia. TransAct\* LAT (flurbiprofen transdermal

patch), is a leading product in the market for transdermal patches within the topical antirheumatic class of drugs and Egostar®, vitamin D3 launched in 2015, is a leading brand in the food supplements market.

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

Among the self-medication products Guronsan®, a leader in the market for detoxification therapies and tonics for fatigue, is the most important.

Aloclair®, for the treatment of mouth sores, has also achieved encouraging results.

Jaba Recordati is developing a promising export business to Portuguese speaking countries such as Angola, Cape Verde, Mozambique, Guinea Bissau and Nigeria.

#### **SPAIN**

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

The subsidiary's products for bowel cleansing and oral rehydration are well appreciated and belong to market segments in which the company is an undisputed leader with shares of 67% and 72%. Worth mentioning are the well-known brands Citrafleet®, a bowel cleanser used in preparation for diagnostic procedures that require emptying of the intestines, and the rehydrating solution Bi-OralSuero®, both leaders in their classes.

Other highly appreciated products that have contributed to the development of the Spanish subsidiary are the statin for hypercholesterolemia Livazo® (pitavastatin) and the treatment for benign prostatic hyperplasia Urorec® (silodosin), which continue to grow in growing markets.

Recently the subsidiary's product portfolio was enhanced with the introduction of three lactobacillus reuteri based products: Reuteri drops, a complete treatment in drops form for colic in infants, Casenbiotic® drops, indicated in cases of diarrhea in infants, and Gastrus®, a combination of two lactobacillus reuteri strains for the treatment of helicobacter pillory.

Completing Casen Recordati's portfolio is Virirec® (alprostadil), the first topical cream treatment for erectile dysfunction which was launched in May 2015.

#### RUSSIA, OTHER C.I.S. COUNTRIES, **UKRAINE, CENTRAL ASIA**

The success of Rusfic, Recordati Ukraine and FIC Médical, our organizations which operate in Russia, in other markets of the C.I.S. (Commonwealth of Independent States), in Ukraine and in Central Asia, is largely based on the success of Tergynan® a product indicated for the topical treatment of vaginal infections and of a well-known portfolio of self-medication products.

Tergynan<sup>®</sup> is a leading product in the class of gynaecological anti-infective and antiseptic drugs and is widely used in all the countries of the Commonwealth of Independent States and in Ukraine and was recently launched in Mongolia.

In Russia, Polydexa® and Isofra®, indicated for the treatment of ear, nose and throat (ENT) disorders and the dietary supplement Alfavit® continue to increase their market shares.

Corporate products Procto-Glyvenol® (tribenoside), Urorec® (silodosin) and Lomexin® (fenticonazole) are growing.

In Russia a dedicated sales organization markets five lines of self-medication products. These are mainly well-known dietary supplements such as Alfavit® which holds a leading position on the market for vitamins and minerals formulations and Qudesan®, based on coenzyme Q10, for the prevention and treatment of chronic fatigue and metabolic dysfunction. The oral cavity antibacterials belonging to the Hexa line of products,

Hexalyse® and Hexaspray® are also well appreciated brands.

#### **TURKEY**

Recordati Ilaç continues to strengthen its position on the Turkish pharmaceutical market thanks to the success in the medical community of a number of products. It has a strong consolidated presence in the fields urology, cardiology, gynecology and in physical medicine and rehabilitation.

Urorec<sup>®</sup> (silodosin) and Zanipress<sup>®</sup> (lercanidipine+enalapril) continue to perform

Substantial growth is recorded by the corporate products Lercadip® (lercanidipine), Gyno-Lomexin® (fenticonazole) and Procto-Glyvenol® (tribenoside) as well as by the local brands Aknetrent® (isotretinoin), a treatment for severe acne, Mictonorm® and Mictonorm SR® (propiverine hydrochloride), a treatment for hyperactive bladder and urinary incontinence, Kreval®/Kreval Forte® (butamirate citrate) indicated for the control of pre and post-operative acute cough, Prepagel® (escin, salicylic acid), for use in cases of bruises, sprains, hematoma, and by the antibiotic Ciprasid® (ciprofloxacin).

Recordati Ilaç completed an important investment program for the construction of a new production plant in Cerkerzkoy which was declared GMP compliant by the Turkish authorities in March 2016.

It has a production capacity of 80 million packs per year and will produce a number of different products for a total of 52 million packs per year and has entirely substituted the production site in Esenyurt.

#### **POLAND**

The subsidiary in Poland, Recordati Polska, operates in a dynamic market growing at twice the rate of the market itself. It markets a diversified and well positioned product portfolio in the urological, gynaecological and cardiovascular therapeutic areas as well as in self-medication.

The company's main products are Procto-Glyvenol® (tribenoside) for the treatment of haemorrhoids, Uprox<sup>®</sup> (tamsulosin) for lower urinary tract disturbances associated with enlargement of the prostate, Finxta® (finasteride) for benign prostatic hyperplasia and the antihypertensive Lercan® (lercanidipine).

In 2016 the subsidiary's portfolio was enriched with the launch of Veral® (diclofenac), a gel for muscular pain relief, Vitaros® (alprostadil), a topical cream for the treatment of erectile dysfunction and Uprox® XR, an extended release tablet formulation of tamsulosin for benign prostatic hyperplasia.

#### CZECH REPUBLIC AND SLOVAKIA

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

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

Urorec® (silodosin) showed significant growth in Slovakia.

#### **GREECE**

With a growing presence on the cardiovascular market, Recordati Hellas, in addition to Lercadip® (lercanidipine) and its fixed combination with enalapril Lercaprel®, successfully markets Lopresor® (metoprolol), a selective beta-blocker indicated for the

treatment of various cardiovascular diseases and in particular for hypertension and angina pectoris which has become the Greek subsidiary's main product. The subsidiary's growth is also due to the sales development of Livazo® (pitavastatin), Urorec\* (silodosin), Lomexin\* (fenticonazole) and to the recent launch of Citrafleet®, a bowel cleanser used in the preparation of any diagnostic procedure which requires emptying of the intestines.

#### **SWITZERLAND**

In 2016 Recordati reinforced its presence in Switzerland with the acquisition in July of the Swiss pharmaceutical company Pro-Farma AG. The company is headquartered in Zug and also operates in Austria. It markets proprietary and in-licensed specialties in selected therapeutic areas with include both prescription and OTC drugs as well as offering distribution and promotion services to other pharmaceutical companies.

The acquisition of Pro Farma represents an excellent base on which to develop the operations in Switzerland where Recordati has recently started to directly sell its product portfolio.

The main brands in the Pro Farma portfolio are Lacdigest® (tilactase), used in lactose intolerance, a product which will contribute to the enhancement of our presence in gastroenterology, Tretinac® (isotretinoin), a treatment for severe acne, and Urocit® (potassium citrate) for the prevention of kidney stones.

#### **ROMANIA**

Through Recordati Romania, Recordati is also present in this Eastern European country. The Romanian subsidiary promotes both prescription and OTC products successfully.

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

The subsidiary also markets Revada® (diosmin) which is prescribed for venous insufficiency and other indications and Caldefix® (calcium and vitamin D3) for the treatment of osteoporosis.

In 2016 two new products were added to the self-medication portfolio: Casenfibra®, an innovative solution based on vegetable fibre for the prevention and treatment of slight constipation, and Citrafleet®, a bowel cleanser used in preparation for diagnostic procedures which require emptying of the intestines.

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

#### U.S.A.

Recordati Rare Diseases, the Group's US subsidiary focused on rare disease treatments, makes available to patients a portfolio of products the most important of which are Panhematin® (haemin for injection) for the amelioration of recurrent attacks of acute intermittent porphyria, Carbaglu® (carglumic acid) for the treatment of hyperammonaemia due to NAGS deficiency, NeoProfen® (ibuprofen lysine injection) indicated to close

□ Avilut 3-forte □ Avilut



a clinically significant patent ductus arteriosus (PDA) in premature infants and Cosmegen® (dactinomycin for injection) used mainly in the treatment of three rare cancers.

Recordati Rare Diseases, committed to reducing the impact of these extremely rare and devastating diseases, works closely with specialists, healthcare professionals, patients' families and patient groups to spread the scarce knowledge available, improve diagnosis and relative treatments, help to ensure access to treatment meeting the needs of people affected by these diseases.

#### **TUNISIA**

Recordati has a direct presence in North Africa through its subsidiary Opalia Pharma in Tunisia and through the export of a number of products from its French subsidiary mainly into Algeria.

Opalia Pharma ranks high in the Tunisian pharmaceutical market and is one of the largest local pharmaceutical companies.

The company markets branded generic drugs with leading products in dermatology and in the gastrointestinal and respiratory therapeutic areas.

Recent additions to this portfolio include Urorec\* (silodosin), and in 2016 Goldix\* Duo, a medication for colds and flu which includes both daytime and night-time formulations in the same pack, the first based on dextromethorphan, paracetamol and phenylephrine and the second one on dextromethorphan, paracetamol and doxylamine. Furthermore, Psoriasone® (calcipotriol and betamethasone), a gel for topical use widely used in the Tunisian market for the treatment of psoriasis.

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

In 2015 the company received the FIPA Award (Foreign Investment Promotion Award) from the head of the Tunisian government Habib Essid for both the investment made in the country and for the great capability and flexibility shown in overcoming economic difficulties

Rare diseases and orphan drugs

- A healthcare priority, a Recordati priority
- Orphan Europe and Recordati Rare Diseases: the Recordati companies dedicated to orphan drugs
- Recordati Rare Diseases

  FONDATION D'ENTERPRISE:

  our commitment to the treatment

  of rare diseases

#### A HEALTHCARE PRIORITY, A RECORDATI PRIORITY

Rare diseases bring great suffering to millions of affected people worldwide and to their families. They are mostly genetic diseases that can affect patients of any age, sex or ethnic origin and involve any type of medical specialization.

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., and is fatal or severely debilitating. Over 30 million people are affected in Europe alone.

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

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

The specificities of rare diseases – limited number of patients and scarcity of relevant knowledge and expertise - single them out as a distinctive domain in Europe of very high added value which ensures that scarce knowledge and available resources are shared through international cooperation channels.

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

To provide care for people with a rare disease and to encourage pharmaceutical and biotechnology companies to invest in treatments for rare diseases governments have created various legal and financial incentives. In 1983 the Orphan Drug Act was introduced in the U.S.A. and European legislation passed in 1999 explicitly recognized the unmet need for targeted treatments for orphan diseases and created regulatory pathways and incentives for manufacturers to develop orphan drugs. From April 2000, when the EU orphan drug regulation came in to effect, many hundreds of drugs received orphan drug designation from the European Medicines Agency (EMA). Of those designated drugs, over 90 have received marketing authorization (MA).

Reports show that orphan drugs are estimated

to account for between 1.7% and 4% of the total drugs expenditure.

40% of the orphan medicines were licensed for oncological and hematological conditions and about 30% of the orphan drug market consists of drugs for rare inborn errors of metabolism.

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

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

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

Our specialties indicated for the treatment of rare and orphan diseases are marketed directly all over Europe, in the Middle East, in the U.S.A., Canada and in some Latin American countries, and through selected partners in other parts of the world.

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-acetylglutamate 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, and Pedea®/ Neoprofen® (i.v. ibuprofen) used in the treatment of a serious congenital cardiac malformation, the persistence of patent ductus arteriosus (PDA).

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

The growth of Orphan Europe, the success of Recordati Rare Diseases in the U.S.A. and the establishment of dedicated companies in Brazil, Mexico and Colombia are confirmation of Recordati's commitment to becoming a worldwide player in the segment dedicated to rare diseases.

#### IN EUROPE

Orphan Europe is a leading orphan drug pharmaceutical company in Europe dedicated to the research, development and marketing of treatments for rare diseases. It is one of the companies with most orphan drugs on the European market.

The company has been operating for 25 years and markets treatments mostly for inborn errors of metabolism. Orphan Europe focuses on drugs for some of the most uncommon diseases.

NAGS deficiency for example, treated with Carbaglu®, is 4000 times rarer than the European limit of 5 in 10,000 inhabitants. In 2011 Carbaglu® received approval in Europe for an additional indication, the treatment of three of the most common organic acidurias. Organic acidurias disrupt normal amino acid metabolism causing a buildup of organic acids in the body.

These disorders can cause similar clinical symptoms to NAGS deficiency. These are life threatening diseases predominantly present in infancy. Children affected are at an increased risk of severe disability, impaired quality of life and reduced life expectancy.

Orphan Europe has worldwide coverage, through its dedicated subsidiaries and commercial agreements with qualified distributors. It also operates a direct distribution and packaging system able to efficiently deliver very small quantities of specialist products to people around the world at a moment's notice.

Orphan drug specialists visit clinicians from many disciplines that diagnose and/or treat patients suffering from rare diseases. Hospital pharmacists, specialist nurses, biochemists and dieticians who work to alleviate the suffering of these patients, are also key contacts in these highly specialized disease areas.

#### IN THE UNITED STATES OF AMERICA

Recordati has progressively intensified its commitment to treatments for rare diseases reinforcing its presence also in the U.S.A.. Recordati Rare Diseases, the group's American subsidiary offers a portfolio of products for the treatment of a number of rare diseases.

The main products in the portfolio are Panhematin® (haemin for injection) for the amelioration of recurrent attacks of acute intermittent porphyria, Carbaglu® (carglumic acid) indicated for the treatment of hyperammonaemia due to N-acetyl glutamate synthase deficiency (NAGS deficiency),

NeoProfen® (ibuprofen lysine injection), indicated to close a clinically significant patent ductus arteriosus (PDA) in premature infants and Cosmegen® (dactinomycin for injection) used mainly in the treatment of rare cancers.

Also in the U.S.A. the organization works closely with specialists, healthcare professionals, patients' families and patient groups to meet the needs of people affected by these diseases, spread the scarce knowledge available and facilitate patient access to treatment.







#### MAIN TREATMENTS FOR RARE DISEASES IN OUR PORTFOLIO

Normosang*/Panhematin*	human hemin	Treatment of acute attacks of hepatic porphyria
Carbaglu®	carglumic acid	Treatment of hyperammonemia due to N-acetylglutamate synthase deficiency (NAGS deficiency) and some organic acidaemias (isovaleric acidaemia, methylmalonic acidaemia and propionic acidaemia)
Cosmegen®	dactinomycin	Treatment of three rare cancers
Pedea® / NeoProfen®	ibuprofene iv	Treatment of patent ductus arteriosus (PDA)
Cystadane®	betaine anhydrous	Treatment of homocystinuria
Cystadrops®	cysteamine chlorhydrate	Treatment of the ocular manifestations of cystinosis
Cystagon®	cysteamine bitartrate	Treatment of nephropathic cystinosis
Vedrop®	tocofersolan	Treatment or prevention of vitamin E deficiency in paediatric patients and adolescents suffering from congenital or hereditary chronic cholestasis
Chemet®	dimercaptosuccinic acid (DMSA)	Treatment of heavy metals poisoning
Wilzin®	zinc acetate	Treatment of Wilson's disease







#### RECORDATI RARE DISEASES FONDATION D'ENTREPRISE

OUR COMMITMENT TO RARE DISEASES

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

The Recordati Rare Diseases Foundation (previously Orphan Europe Academy) was instituted to provide unconditional grants for training in rare diseases to the scientific community. High-level courses are organized under the supervision of an independent scientific committee. The overall aim is to share experience in the management and outcome of rare disorders where individual knowledge is by its nature limited. The Academy offers specialists the opportunity to enrich their knowledge, develop new ideas and establish scientific relationships.

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

The Foundation also provides online e-learning courses which aim to provide physicians

world-wide with clinically useful and the most up-to-date information concerning current knowledge and recommendations for care.

Furthermore, we work in partnership with recreational camps for children with serious debilitating disease through our staff volunteering program.

We also support the work of European Reference Networks in providing equal and equitable care for patients with rare disease in Europe



Research and development

In 2016 research and development activities were concentrated on programs in rare diseases and urology and a number of projects aimed at the further investigation of the clinical profile of our products were advanced.

n 2016 research and development activities were concentrated on programs in rare diseases and urology and a number of projects aimed at the further investigation of the clinical profile of our products were advanced. An agreement was signed with Gedeon Richter for the commercialization of cariprazine, an innovative antipsychotic drug. Regarding activities in treatments for rare diseases, marketing approval was received for Cystadrops®, cysteamine gel based eye drops for the ocular manifestations in patients suffering from cystinosis.

Furthermore, activities progressed for the pharmaceutical and clinical development of new formulations of carglumic acid and hemin. Partnerships were finalized for the development of therapies to benefit patients suffering from severe conditions such as Maple Syrup Urine Disease (MSUD) and cystic fibrosis. Collaborations with research institutes were initiated for the advancement of new projects, one of which is a new therapeutic approach in Retinopathy of Prematurity (ROP).

#### PRODUCT DEVELOPMENT PIPELINE

NAME	ORIGINATOR	INDICATION	DEVELOPMENT STATUS
CYSTADROPS*	Orphan Europe (Recordati)	Corneal cysteine crystal deposits in patients with cystinosis	Approved in EU in January 2017
FORTACIN™	Plethora Solutions	Premature ejaculation	Variation of EU approval completed
REAGILA®	Gedeon Richter	Schizophrenia	Filed in EU
methadone		Treatment of cancer-related pain in cases of resistance or intolerance to opioids	Filed in France
GRASPA*	Erytech	Acute lymphoblastic leukemia (ALL) in patients with first recurrence of Philadelphia chromosome negative ALL	Pre-filing in EU
		Acute myeloid leukemia (AML) in patients >65 unfit for chemotherapy	Phase II b
CARBAGLU®	Orphan Europe (Recordati)	Hyperammonaemia due to NAGS deficiency and to the main organic acidemias	Development of new formulations in EU and USA. Pre-filing in the USA for the organic acidemias indication
REC 0438	Recordati/UFPeptides	Overactive bladder in patients with spinal lesions	Phase I completed EU
REC 0545	Orphan Europe (Recordati)/AP-HP	Acute decompensation episodes in MSUD	Formulation development. Clinical development planning

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 2016 to enrich our pipeline and ensure the group's future growth. At the same time, important and intense registration and regulatory activities were carried out to obtain marketing approvals for Recordati products in new territories.

Research and development activities during 2016 are summarized in the following paragraphs.



#### **UROLOGY AND ANDROLOGY**

In-house urology projects

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

REC 0438 represents a class of compounds to be potentially used in these patients who require repeated daily treatment, often with brief and variable efficacy and therefore not easily tolerated. REC 0438 would be administered by intravesical means in patients who must repeatedly use self-catheterization methods to empty their bladder. The objective of the treatment is to reduce incontinence episodes which have an important impact of patients' quality of life. Following the completion of the study conducted in healthy volunteers to whom single doses of up to 4 mg were administered, in 2016 the compound was also tested in adult patients with spinal lesions of a post-traumatic nature to whom a dose of up to 1 mg was administered. The data confirmed the optimal tolerability of the product also in patients subject to self-catheterization. The drug is well tolerated locally, it is not absorbed and accumulation is not expected.

#### Urorec® (silodosin)

In 2016 a single center clinical trial was conducted at the Federico II university in Naples to evaluate, using urodynamic testing, the efficacy of silodosin in reducing bladder neck obstruction in patients with benign prostatic hyperplasia who are slated for surgery. Results are expected during 2017. Preliminary observations in Japan involving an analogous patient population showed a significant and long-lasting reduction of the obstruction, so much so that at the end of the trial 44% of the men with BPH decided against surgery and continued treatment with silodosin.

During the year the results of the extensive European phase IV study (SiRE: EudraCT number: 2011-000045-20), conducted on more than 1,000 patients suffering from benign prostatic hypertrophy, that confirmed the efficacy of silodosin in relieving the BPH symptoms considered to be the most annoying, in particular nocturia, through the evaluation of the patients' micturition diaries, were published (Int J Urol. 2016;23:572-9).

Registration in new markets of silodosin (Urorec® and Silodyx™) was an ongoing activity also in 2016. Marketing authorization was obtained in Switzerland and a marketing authorization request was filed in Australia.

#### Vitaros®/ Virirec® (alprostadil cream)

Vitaros<sup>®</sup> is the first topically applied cream formulation for the treatment of erectile dysfunction, indicated for men 18 and older who are not able to achieve or maintain an erection satisfactory for sexual intercourse. The product, on the market in Spain since 2015, was classified as reimbursable in this country in 2016. In 2016 it was launched in other European countries (Ireland, Czech Republic, Portugal, Slovacchia and Poland). The protocol for a post-authorization study to be initiated in 2017 is being defined by various marketing authorization holders in Europe.

#### Fortacin™ (lidocaine+prilocaine)

Fortacin™ is an easy-to-use fast acting topical spray formulation of lidocaine and prilocaine for the treatment of premature ejaculation. Premature ejaculation is a common form of sexual dysfunction in men. Epidemiological studies conducted in the U.S.A. and in Europe indicate a prevalence of 20% to 30% in men of all ages. In view of its upcoming commercialization in a number of European countries, during 2016 the protocol for a postauthorization study (Drug Utilization Study) was defined to evaluate the utilization of the drug in clinical practice through the monitoring of prescription databases.

### CARDIOLOGY AND METABOLIC **DISORDERS**

Zanidip®/Zanipress® (plain lercanidipine/lercanidipine+enalapril)

In confirmation of the continued clinical interest in our anti-hypertensive drug lercanidipine, an original calcium channel blocker fully developed by Recordati (used in monotherapy or in association with enalapril), during 2016 a cumulative analysis of the extensive clinical and postmarketing experience with this product was made with the objective of updating and harmonizing the information directed at the medical community in Europe and in extra European countries, while also taking into account the results of the important international study FELT ("FELT" study: EudraCT number: 2009-015988-13; https:// www.clinicaltrialsregister.eu/ctr-search/ search?query=FELT+Recordati). This study conducted in 1,039 patients with moderate hypertension, to whom doses of 20 mg of lercanidipine combined with 20 mg of enalapril were administered, demonstrated the efficacy of the combination of these two drugs.

### Livazo® (pitavastatin)

Pitavastatin is a latest generation statin indicated for the reduction of elevated total and LDL cholesterol in patients suffering from primary hypercholesterolemia and combined dyslipidemia. During 2016 a change in the Summary of Product Characteristics, to include the results of clinical trials which show the reduced potential of pitavastatin in inducing diabetes in patients treated chronically for hypercholesterolemia, was approved at European level. Both a prospective clinical trial conducted on 1,269 patients with glucose intolerance treated with doses of 1 mg and 2 mg for more than two years, as well as the meta-analysis of controlled clinical trials involving 4,815 non-diabetic patients treated for at least 12 weeks, were positively appraised.

#### **PSYCHIATRY**

Reagila® (cariprazine)

In 2016 an agreement was signed between Recordati and Gedeon Richter for the commercialization of cariprazine, a novel antipsychotic drug, in Western Europe and in Algeria, in Tunisia and in Turkey and for the development of a pediatric clinical program in Europe.

Cariprazine is an orally active and potent dopamine D<sub>3</sub>/D<sub>2</sub> receptor partial agonist with preferential binding to D<sub>3</sub> receptors and partial agonist at serotonin 5-HT<sub>1A</sub> receptors. It was approved by the Food and Drug Administration (FDA) in 2015 and launched in the United States in March 2016 and is currently under review by the European Medicines Agency (EMA) for the treatment of schizophrenia, including negative symptoms.

Schizophrenia is psychic disorder characterized by a severe alteration of behavior and perception (hallucinations) and thought (delusions) disturbances. The delusions and hallucinations are also referred to as positive or productive symptoms which are accompanied by negative symptoms, characterized by apathy, loss of affectivity and poor ideation which are responsible for the patient's loss of contact with reality and his or her withdrawal into a world incomprehensible to others.

### 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, an application was submitted to the French authorities for the approval of the use of methadone for this condition. The application is currently under review.

### Lomexin® (fenticonazole)

Fenticonazole is a topical antimycotic drug originated by Recordati. The validity of this original product for the treatment of candida vulvovaginitis was confirmed by the successful completion in 2016 of a new decentralized European approval process which involved a number of European countries. Recordati's production site in Campoverde di Aprilia (Italy) where the active ingredient fenticonazole nitrate is produced, obtained the Certification of Conformity in the European Pharmacopeia for this compound.

### TREATMENTS FOR RARE DISEASES

Recordati is expanding its commitment to the discovery and development of treatments for rare diseases, and has a number of projects in the pipeline in various phases, from new formulations to phase III and post-approval studies. Furthermore, various collaborations with the best Universities worldwide are in place with the objective of finding new therapeutic uses for the current treatments as well as to promote research and development in the more relevant areas (metabolic diseases, neonatology).

### Carbaglu® (carglumic acid)

This product is an orphan drug approved by the European Medicines Agency (EMA) and 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<sup>®</sup> 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 July 2014 Carbaglu® was granted Orphan Drug Designation (ODD) by the FDA for its use in the treatment or organic acidemias and is currently in a pre-filing phase in the U.S.A. for this indication.

Recordati is developing a new formulation of Carbaglu® to be administered intravenously for the treatment of patients in an acute decompensation phase when oral administration is not possible due to the critical condition of the patient. Currently a tolerability phase I study in healthy volunteers is ongoing testing increasing doses of the product administered intravenously. Furthermore, a new oral formulation is under development 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.

Following the positive outcome of the clinical development a Marketing Authorization

Application was filed with the European Medicines Agency (EMA) to obtain the new indication. The application was positively appraised and in January 2017 marketing approval in the European Union was received for Cystadrops® to treat patients aged over two years affected by cystinosis.

### Graspa® (L-asparaginase)

Asparagine is a tumor growth factor for some blood tumors, and the enzyme L-asparaginase has been shown to possess a powerful antitumor activity, due to its capacity to degrade asparagine in plasma thus making it unavailable to the neoplastic cells which are unable to produce it. As the enzyme is highly toxic, part of the patient population does not tolerate the treatment protocols that include the use of L-asparaginase well and thus is not able to receive appropriate treatment. For these patients (mainly relapsed patients, senior and elderly adults) an important medical need is currently not adequately met.

Graspa® is a new alternative for asparaginase administration originated by the French biotechnology company Erytech Pharma: it is L-asparaginase encapsulated in homologous (hemo-compatible) human red blood cells (erythrocytes). GRASPA® reduces the toxicity and hypersensitivity issues associated with L-asparaginase treatments, while effectively suppressing the plasmatic bioavailability of asparagine.

Following the completion of the phase III study GRASPALL, which investigated the efficacy and safety of Graspa® (L-asparaginase encapsulated in human hemocompatible erythrocytes) in the treatment of acute lymphoblastic leukemia (ALL) an initial Marketing Authorization Application was submitted to the European Medicines Agency (EMA). The agency requested further information and therefore, a second application is currently in preparation to include further data requested by the Agency that is expected to be submitted during 2017. Within the same clinical development program in onco-hematology the phase



II-b study GRASPA-AML for the evaluation of the efficacy and safety of Graspa® in the treatment of acute myeloid leukemia (AML) in association with chemotherapy, is ongoing.

### **REC 0545**

In July 2016 a partnership with AP-HP (Assistance Publique – Hopitaux de Paris) was finalized under which AP-HP for the development and commercialization of an innovative product for the treatment of acute decompensation episodes in patients affected by Maple Syrup Urine Disease (MSUD), a severe metabolic disorder.

Maple syrup urine disease (MSUD), also called branched-chain ketoaciduria, is a rare metabolic disorder affecting branchedchain amino acids (leucine, isoleucine and valine) which results in a build up of these amino acids and their metabolites. This build-up manifests with severe symptoms affecting all organs right from the beginning of a newborn's life which, if not adequately diagnosed and treated result in the child's death. Even when chronically treated, patients may be subject to acute metabolic decompensation episodes that manifest with severe neurological symptoms which if not addressed can be life-threatening.

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



Pharmaceutical chemicals and production plants Recordati's pharmaceutical chemicals business focuses on:

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









**PHARMACEUTICAL** CHEMICAL **PLANTS** 

SITES FOR **PHARMACEUTICAL PRODUCTION** 

**NEW SITE FOR THE DISTRIBUTION** OF PRODUCTS FOR THE TREATMENT OF RARE DISEASES



Recordati produces
a number of active
ingredients and
intermediates
for the
pharmaceutical
industry.
It has two
pharmaceutical
chemical plants
and six sites for
pharmaceutical
production

### Italy, Campoverde di Aprilia

The Campoverde plant mainly supplies the active ingredients used in the preparation of the various pharmaceutical specialties produced by the company, but is also an established independent producer of a number of active and intermediate ingredients for the pharmaceutical industry internationally.

It is one of the most important producers in the world of verapamil HCl, phenytoin, papaverine HCl and dimenhydrinate. Other pharmaceutical chemicals are produced on behalf of important pharmaceutical companies. The facility was one of the first European plants to be inspected by the American Food and Drug Administration. The United States is one of the main markets for its production, second only to Europe. The Campoverde site covers a surface area of 380,000 sq. m. with an installed area of 35,000 sq. m., and produces approximately 650 metric tonnes per year of finished goods with approximately 5,000 metric tonnes of semifinished goods handled internally each year. High-tech systems are employed for the management of particularly delicate processes such as the reactions which employ cyanides, high pressure hydrogenations, methylations, chloromethylations or those which involve substances which require very stringent safety measures.

Investments have been made for additional productions, 12 new reactors and a latest generation three stage distillation unit were installed to further enhance production capacity.

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

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

In 2016 a high containment HP-API pharmaceutical isolator (glove box) was installed in the plant's research laboratories.

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

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

#### Ireland, Cork

In order to guarantee adequate and continuous supplies of the active ingredient lercanidipine, an important original Recordati drug, in 2005 a new dedicated plant was built in Cork in Ireland.

The plant is certified according to cGMP (current Good Manufacturing Practices) standards and covers an area of around 44,000 sq. m. This facility boasts automated process control systems which ensure constant high quality production.

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

In 2013 the plant received the *European Energy Efficiency Award* promoted by the Chemical European Federation Industry Council (CEFIC).

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

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

### Italy

The Milan site occupies a surface area of 21,000 sq. m. and produces 58 million packages per year.

It is specialized in the manufacture and packaging of solid oral forms, liquids, injectables and products for topical use.

#### France

The plant at Saint Victor covers a surface area of 6,750 sq. m. and is specialized in the production and packaging of liquid, solid oral and spray formulations. It produces 35 million packages per year.

### Turkey

The Turkish site in Çerkezköy, built on 45,000 sq. m. of land, occupies a surface area of approximately 19,000 sq. m. and currently produces 52 million packages per year of solid oral and liquid formulations and products for topical use, of which 20% is dedicated to third party production.

The plant was declared GMP compliant by the Turkish authorities in March 2016 and has a production capacity of 80 million packs per year. It has substituted the production site in Esenyurt which was closed down in December 2016 after transferring all production to the new manufacturing site.

### Spain

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

In particular, the plant manufactures a line of gastroenterological products. The plant produces around 12 million packs a year.

#### Tunisia

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

The plant produces around 17 million packs a year.

### Czech Republic

The plant in the Czech Republic, situated in Pardubice, produces creams, gels and ointments for a total of 2.5 million packages per year, some of which for third parties.

Packaging and distribution center dedicated to products for rare diseases

A new site in Paris for the distribution of products for the treatment of rare diseases was recently inaugurated.

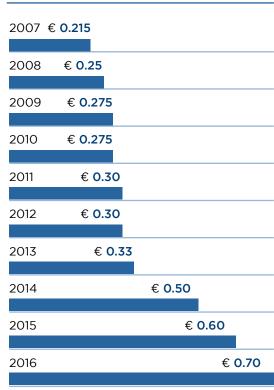
It occupies a surface area of 1,200 sq. m. and is entirely dedicated to the packaging, storage and shipping of rare disease products. An area of 400 sq. m. is office space.





# The Recordati share

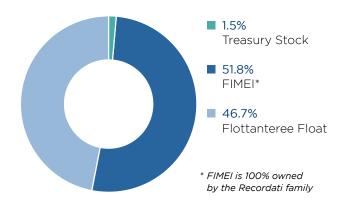
### **DIVIDEND** (per Share)



### THE RECORDATI SHARE **AT 31 DECEMBER 2016**

Listing:	Borsa Italiana, Blue Chip segment, healthcare
ISIN Code:	IT 0003828271
Ticker:	Bloomberg REC IM, Reuters RECI.MI
Index:	FTSE MIB FTSE Italia All-Share Pharmaceuticals & Biotechnology Index ICB Code 4570
Share Capital:	n. 209,125,156 common shares
Nominal value:	€ 0.125 per share
EPS (diluted):	€ 1.135
Dividend per share:	€ 0.70

### PRINCIPAL SHAREHOLDERS' **AT 31 DECEMBER 2016**



### **COMPARED TO** FTSE ITALIAN ALL-SHARE

Source: FactSet

•RECORDATI S.P.A. (L)

•FTSE ITALY ALL SHARE (IT) (R)



### **COMPARED TO** STOXX 600/HEALTHCARE

Source: FactSet

•RECORDATI S.P.A. (L)

•STOXX 600 / HEALTH CARE - SS (R)



## Financial highlights

### **REVENUE**

€ (thousands)	2016	%	2015	%	Change 2016/2015	%
TOTAL REVENUE	1,153,942	100.0	1,047,676	100.0	106,266	10.1
Italy	237,615	20.6	211,570	20.2	26,045	12.3
International	916,327	79.4	836,106	79.8	80,221	9.6

### **KEY CONSOLIDATED P&L DATA**

€ (thousands)	2016	% revenue	2015	% revenue	Change 2016/2015	%
Revenue	1,153,942	100.0	1,047,676	100.0	106,266	10.1
EBITDA <sup>(1)</sup>	371,217	32.2	317,000	30.3	54,217	17.1
Operating income	327,423	28.4	278,517	26.6	48,906	17.6
Net income	237,431	20.6	198,803	19.0	38,628	19.4

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

### KEY CONSOLIDATED BALANCE SHEET DATA

€ (thousands)	31 December 2016	31 December 2015	Change 2016/2015	%
Net financial position <sup>(2)</sup>	(198,771)	(88,737)	(110,034)	124.0
Shareholders' equity	903,940	869,992	33,948	3.9

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

### PER SHARE DATA

€	2016	2015	Change 2016/2015	%
Net income <sup>(3)</sup>	1.152	0.968	0.184	19.0
Shareholders' equity(3)	4.404	4.234	0.170	4.0
Dividend	0.70	0.60	0.10	16.7
SHARES OUTSTANDING:				
- average during the year	206,117,418	205,270,094		
- at December 31	205,233,894	205,439,798		

<sup>(3)</sup> Net income per share is based on average shares outstanding during the year net of average treasury stock. Average treasury stock amounted to 3,007,738 shares in 2016 and 3,855,062 shares in 2015. Shareholders' equity per share is based on total shares outstanding at year end net of treasury stock. Treasury stock amounted to 3.891.262 shares at 31 December 2016 and 3,685,358 shares at 31 December 2015.

# 2016 operational and financial reviews

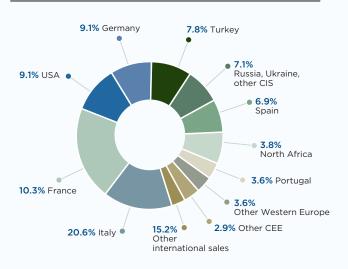
### Review of operations

Net consolidated revenue in 2016 is € 1,153.9 million, up 10.1% over the preceding year, with an increase in international sales of 9.6% to € 916.3 million, which represent 79.4% of total sales. Pharmaceutical sales are € 1,113.8 million, up by 10.1%. Pharmaceutical chemicals sales are € 40.2 million, up by 11.4%, and represent 3.5% of total revenues. The 2016 revenues include those generated by the Italian company Italchimici S.p.A. and the Swiss company Pro Farma AG, acquired in May and July and consolidated respectively as from 1 June and 1 July, for an amount of € 27.7 million. Excluding the new acquisitions sales growth would have been of 7.5%.

#### **SALES BY BUSINESS**



### PHARMACEUTICAL SALES



### **PHARMACEUTICALS**

The group's pharmaceutical business, which represents 96.5% of total revenue, is carried out in the main European markets, including Central and Eastern Europe, in Russia and other C.I.S., in Turkey, in Tunisia, in the

United States of America, in Mexico and in some South American countries through our own subsidiaries and, in the rest of the world, mainly through licensing agreements with pharmaceutical companies of high standing. We have gradually extended our international presence through the acquisition of existing marketing organizations with the aim to add our proprietary products, and those obtained under multi-territorial licenses, to the local portfolios.

#### Corporate products

The performance of products sold directly in more than one market (corporate products) during 2016 is shown in the table below.

€ (thousands)	2016	2015	Change 2016/2015	%
Zanidip® (lercanidipine)	113,999	115,707	(1,708)	(1.5)
Zanipress® (lercanidipine+enalapril)	69,075	65,675	3,400	5.2
Urorec® (silodosin)	85,197	68,275	16,922	24.8
Livazo® (pitavastatin)	35,130	28,418	6,712	23.6
Other corporate products*	215,546	199,289	16,257	8.2
Drugs for rare diseases	186,806	153,130	33,676	22.0

<sup>\*</sup> Include the OTC corporate products for an amount of € 61.4 million in 2016 and € 55.1 million in 2015 (+11.5%).

Zanidip® (lercanidipine) is Recordati's original calcium channel blocker for the treatment of hypertension available in 101 countries. 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)	2016	2015	Change 2016/2015	%
Direct sales	62,150	60,570	1,580	2.6
Sales to licensees	51,849	55,137	(3,288)	(6.0)
Total lercanidipine sales	113,999	115,707	(1.708)	(1.5)

Direct sales of lercanidipine based products are up by 2.6% mainly due to sales in Switzerland, previously out licensed and, since September 2016, handled directly by our subsidiary in this country. Sales increase in the U.K., in Turkey, Italy and Poland. Sales to licensees, which represent 45.5% of total lercanidipine sales, are down mainly due to the reduction of sales by our licensee in Venezuela and the change in Switzerland from licensed out to directly sold in the market.

Zanipress® is a specialty also indicated for the treatment of hypertension developed by Recordati which consists of a fixed combination of lercanidipine with enalapril. This product is marketed successfully by Recordati or by its licensees in 28 countries.

€ (thousands)	2016	2015	Change 2016/2015	%
Direct sales	51,815	47,808	4,007	8.4
Sales to licensees	17,260	17,867	(607)	(3.4)
Total lercanidipine+enalapril sales	69,075	65,675	3,400	5.2

Direct sales of Zanipress® in 2016 are up by 8.4% mainly due to the performance of the product in Italy, Turkey and Germany. This product is marketed in Italy by Recordati and Innova Pharma with the brands Zanipril® and Lercaprel® and by co-marketers Italfarmaco and Polifarma with the brands Coripren® and Atover® respectively. Sales recorded in 2016 by Zanipril® and Lercaprel® are € 16.2 million, up by 11.4%. Overall the product has achieved a market share of 33.1%. In France the lercanidipine/ enalapril fixed combination is marketed by Bouchara Recordati and by Pierre Fabre under their respective brands Zanextra® and Lercapress®. Sales of Zanextra® are € 10.5 million, up by 1.5%. Overall the product has achieved a market share of 25.4%. In Germany, Recordati Pharma sells Zanipress<sup>®</sup>, which recorded sales of € 9.1 million, up by 17.1%. The lercanidipine/ enalapril fixed combination is also sold by Berlin Chemie (Menarini group) as Carmen ACE® and by Meda as Zaneril®. Overall this product is the second largest in its class with a market share of 40.1%. In Portugal, where sales of Zanipress® are € 3.8 million (-7.0%), and in Spain where sales of Zanipress<sup>®</sup>, Lercapress<sup>®</sup> and Coripren<sup>®</sup> are € 3.8 million (+5.3%), generic versions of the product are present in the market. The lercanidipine/enalapril fixed combination is also sold by our marketing organizations in Turkey with sales of € 6.6 million (+13.3%), in Greece, Switzerland, Ireland, Russia and other C.I.S. and in North Africa. Sales to licensees, which represent 25.0% of total sales, are down by 3.4% and include the effect of the change in Switzerland from licensed out to directly sold in the market.

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 and the prevalence of the disorder is increasing with the ageing of the population, it is frequent in men over the age of fifty and its symptoms significantly reduce quality of life. 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. 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 34 countries and has achieved a share of 19.8% of the alpha blocker segment of the BPH market in the 17 main European countries. Silodosin based products are sold directly by our subsidiaries under the brand Urorec® and by licensees under the brand Silodyx<sup>™</sup> and generated sales in 2016 of € 85.2 million, up by 24.8%. Urorec® is doing particularly well in Italy achieving sales in 2016 of € 22.5 million (+16.5%). The product is also well accepted by physicians in France and in Spain where sales are € 13.8 million (+19.2%) and € 8.1 million (+11.8%) respectively. Urorec<sup>®</sup> is also growing significantly in Turkey where it was launched in 2012 and generated sales of € 8.9 million (+29.5%) in 2016.

Livazo® (pitavastatin) is a latest generation statin indicated for the reduction of elevated total and LDL cholesterol. 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 and Ukraine. Sales generated in 2016, including sales to co-marketers in Spain, Portugal and Greece, are € 35.1 million, up by 23.6%, and have achieved a share of 7.6% of the statins market in the four main countries.

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.

- Tergynan<sup>®</sup> 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 2016 are € 24.4 million, up by 7.8%, and are generated mainly in Russia where, in local currency, this product's sales grow by 20.7%.
- CitraFleet® and PhosphoSoda®, belonging to the Spanish company Casen
  Fleet acquired during 2013, are bowel cleansers used in preparation for
  any diagnostic procedure which requires emptying of the intestines, such
  as colonoscopy or X-rays. In 2016 sales of CitraFleet® are € 22.1 million
  and those of PhosphoSoda® are € 5.4 million. Fleet enema and Casenlax®,
  two other gastrointestinal products, generated sales of € 10.8 million and
  € 7.2 million respectively.
- Polydexa®, Isofra® and Otofa® are combination products for the treatment
  of ENT infections sold mainly in Russia. In 2016 sales of Polydexa® are €
  20.6 million, those of Isofra® are € 12.2 million while Otofa® generated
  sales of € 4.4 million. Overall sales are up compared to the preceding year
  despite the devaluation of the Russian rouble. In local currency sales of
  these products grow significantly in Russia.
- The Hexa line of products comprises biclotymol based antibacterial treatments of the oral cavity sold under the brands Hexaspray®, Hexalyse®, Hexapneumine® and Hexarhume®. Overall sales of these products in 2016 are € 18.6 million, an increase of 6.2%, and are generated mainly in France and North Africa.
- Procto-Glyvenol® (tribenoside), indicated for the treatment of internal and external hemorrhoids, 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 2016 are € 17.0 million, up by 17.8%.
- 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, mould, yeast
  and gram positive bacteria. Sales of this product for 2016 are € 16.9
  million, down by 2.4% over the preceding year.
- Flavoxate is an antispasmodic for the treatment of urinary incontinence, originated by Recordati, which is marketed under the brands Genurin® and Urispas®. Sales of this product in 2016 are € 10.7 million, up by 4.9%.
- TransAct<sup>®</sup> LAT, a transdermal patch containing 40 mg of flurbiprofen indicated for the symptomatic relief of localized pain involving the musculoskeletal system, obtained under license from Amdipharm, is sold on the Italian and Portuguese markets. Sales of this product are € 10.7 million (+2.3%) in 2016.
- 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 2016 total € 10.5 million (+4.5%).
- Kentera<sup>®</sup> 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 17 countries. Sales of Kentera<sup>®</sup> are € 8.6 million (+19.8%) in 2016.

- Lopresor<sup>®</sup> (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 2016 are € 6.1 million and are generated mostly in Greece and in Germany.
- Abufene® and Muvagyn® are gynaecological products indicated for menopausal symptoms. Sales of these products in 2016 are € 4.9 million and € 2.9 million respectively.
- Vitaros®/Virirec® (alprostadil) is a topically applied cream formulation of alprostadil for the treatment of erectile dysfunction obtained under license from the US pharmaceutical company Apricus Biosciences in 2014. The first launch took place in Spain in 2015 and during 2016 the product was launched in Portugal, Poland, the Czech Republic, Slovakia and Ireland. Sales generated in 2016 are € 1.3 million.

#### Treatments for rare diseases

The Recordati group operates in the rare disease segment worldwide through its dedicated subsidiaries Orphan Europe and Recordati Rare Diseases who share the conviction that each person with a rare disease has the right to the best possible treatment. Our organizations work closely with specialists, healthcare professionals, patients' families and patient groups to meet the needs of people affected by these diseases and to spread the scarce knowledge available.

Orphan Europe is a leading orphan drug pharmaceutical group in Europe dedicated to the research, development and marketing of treatments for rare diseases. It is one of the groups with the most orphan drugs on the European market. The group has been operating for 25 years and markets treatments mostly for inborn errors of metabolism. It has worldwide coverage through its subsidiaries and through the presence of dedicated highly trained representatives and commercial agreements. Furthermore, a direct distribution and packaging system is able to deliver very small numbers of specialist products to people around the world at short notice. Recordati has progressively and successfully intensified its commitment to treatments for rare diseases also in the U.S.A. where Recordati Rare Diseases Inc. offers a portfolio of products for the treatment of a number of rare diseases the most important of which is Panhematin® (haemin for injection) for the amelioration of recurrent attacks of acute intermittent porphyria.

Our specialties indicated for the treatment of rare and orphan diseases are marketed directly all over Europe, in Turkey, in the Middle East, in the U.S.A., Canada and in some Latin American countries, and mainly through partners in other parts of the world. 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-acetylglutamate 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); Pedea®/Neoprofen® (i.v. ibuprofen) used in the treatment of a serious congenital cardiac malformation, the persistence of patent ductus arteriosus (PDA); Cystadane® (betaine anhydrous) for the treatment of homocystinuria and Cystagon® (cysteamine bitartrate) for the treatment of proven nephropathic cystinosis.

Sales of these products in 2016 total € 186.8 million, an increase of 22.0% due to the good performance of the business in all markets.

### Pharmaceutical sales by geographical area

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

€ (thousands)	2016	2015	Change 2016/2015	%
Italy	229,920	204,847	25,073	12.2
France	115,052	110,590	4,462	4.0
U.S.A.	101,117	82,091	19,026	23.2
Germany	101,097	94,753	6,344	6.7
Turkey	86,321	74,073	12,248	16.5
Russia, other C.I.S. countries and Ukraine	79,512	72,382	7,130	9.9
Spain	76,441	71,981	4,460	6.2
North Africa	42,343	43,686	(1,343)	(3.1)
Portugal	40,279	39,346	933	2.4
Other Western European countries	40,064	28,502	11,562	40.6
Other C.E.E. countries	32,531	30,926	1,605	5.2
Other international sales	169,101	158,443	10,658	6.7
Total pharmaceutical sales	1,113,778	1,011,620	102,158	10.1

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

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

Local currency (thousands)	2016	2015	Change 2016/2015	%
Russia (RUB)	4,928,638	4,038,461	890,177	22.0
Turkey (TRY)	267,560	211,079	56,481	26.8
United States of America (USD)	114,983	91,118	23,865	26.2

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

#### **ITALY**

The Recordati group offers a broad range of medications in this country through its organizations Recordati S.p.A., Innova Pharma S.p.A., Orphan Europe Italy S.r.I. and as from 2016 Italchimici S.p.A.. 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.

€ (thousands)	2016	2015	Change 2016/2015	%
Prescription pharmaceuticals (a)	174,739	160,131	14,608	9.1
Self-medication pharmaceuticals (b)	55,181	44,716	10,465	23.4
Pharmaceuticals, Italy	229,920	204,847	25,073	12.2

- (a) Prescription pharmaceuticals include both reimbursable and non-reimbursable drugs.
- (b) Self-medication pharmaceuticals include OTC products and other pharmaceuticals not requiring a prescription.

The performance of the main products in Italy is the following:

€ (thousands) Indication 2016 2015 Change 2016/2015	%
Cardicor®         heart failure         23,411         20,250         3,161	15.6
Peptazol® gastric ulcers 22,563 23,651 (1,088)	(4.6)
benign prostatic Urorec® hyperplasia 22,489 19,308 3,181	16.5
Zanedip®/Lercadip® hypertension 18,762 18,407 355	1.9
Zanipril®/Lercaprel® hypertension 16,218 14,554 1,664	11.4
Rextat®/Lovinacor® hypercholesterolemia 13,098 11,953 1,145	9.6
Tora-Dol®         pain         12,514         12,202         312	2.6

Sales of prescription pharmaceuticals in Italy are up by 9.1%, as compared to the preceding year due to the good performance of the main products as well as the consolidation of sales generated by Italchimici S.p.A. as from 1 June. Urorec® and Zanipril®/Lercaprel® show strong growth and sales of both Cardicor® (bisoprolol) and the statins Rextat® and Lovinacor® (lovastatin) are developing significantly. Sales of Peptazol® (pantoprazole) were affected by generic competition. Sales of products for the treatment of rare diseases are up by 35.3%.

Sales of self-medication products are  $\in$  55.2 million, significantly up compared to the preceding year, and have benefited from the consolidation of Italchimici's self-medication products, in particular of Reuflor®, a lactobacillus based food supplement. Alovex<sup>TM</sup>, indicated for the treatment of oral cavity aphthae, is our best-selling self-medication product with sales of  $\in$  7.3 million and remains market leader with a share of 29.6%. Proctolyn® (treatment of haemorrhoids) with sales of  $\in$  6.8 million, up by 5.0%, also remains market leader. TransAct® LAT (a transdermal patch containing 40 mg of flurbiprofen indicated for the symptomatic relief of localized pain involving the musculoskeletal system) generated sales of  $\in$  6.5 million. Dentosan®, a line of oral care products, generated sales of  $\in$  5.1 million and sales of Eumill® (eye drops) at  $\in$  5.0 million are up by 28.5% thanks to the product line extension. Sales of Imidazyl® (eye drops) are down by 5.5%, mainly of the antihistamine formulation, due to a bland allergy season.

#### **FRANCE**

Laboratoires Bouchara Recordati S.A.S. is solidly established in the French pharmaceutical market thanks to a number of prescription drugs and a line of OTC products which are well-known in France. Orphan Europe S.A.R.L., the largest company in the Orphan Europe group dedicated exclusively to treatments for rare diseases, is based in France.

The 2016 revenue realized by our subsidiaries in France is  $\in$  115.1 million, up by 4.0% compared to the preceding year. Below is the performance of the main products:

€ (thousands)	Indication	2016	2015	Change 2016/2015	%
Methadone	drug addiction	29,903	28,139	1,764	6.3
Urorec®	benign prostatic hyperplasia	13,774	11,560	2,214	19.2
Zanextra®	hypertension	10,452	10,300	152	1.5
Hexa line	antibacterial	8,822	8,231	591	7.2
Neocodion®	cough	6,468	6,620	(152)	(2.3)
Zanidip®/lercanidipine	hypertension	5,480	5,623	(143)	(2.5)

Methadone, a synthetic opioid analgesic used as a substitute for heroin in somatic abstinence syndromes, in disintoxication from opiates and in maintenance programs, is Laboratoires Bouchara Recordati's most important product. In addition to methadone, sales of Urorec® are also growing significantly. The Hexa line, the main brand in the OTC line of products indicated for the treatment of ENT disorders, grows by 7.2%. Sales of drugs for the treatment of rare diseases, up by 28.1%, are growing significantly.

### **UNITED STATES OF AMERICA**

The group's pharmaceutical business in the U.S.A. is dedicated mainly 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, Cosmegen® (dactinomycin for injection) used mainly in the treatment of three rare cancers and Carbaglu® (carglumic acid), indicated for the treatment of acute hyperammonaemia associated with NAGS deficiency. Sales in 2016 are € 101.1 million, up by 23.2%, thanks to the good performance of the main products.

### **GERMANY**

Recordati Pharma GmbH is one of the most esteemed German pharmaceutical companies in the field of orthopedics. Over time it has developed a strong presence in orthopedics and offers first class product to specialists in this field. An important part of the Recordati Pharma operations is linked to its traditional presence in the gastroenterological area and in particular in the treatment of inflammatory intestinal diseases which consist mainly of Crohn's disease and ulcerative colitis. Operations in the segment dedicated to rare diseases in this country are carried out by Orphan Europe Germany GmbH.

Sales generated by our subsidiaries in Germany are € 101.1 million, an increase of 6.7% compared to the preceding year. The following table shows sales of the main products.

€ (thousands)	Indication	2016	2015	Change 2016/2015	%
Ortoton®	muscle relaxant	31,075	27,776	3,299	11.9
Claversal®	ulcerative colitis	12,487	12,588	(101)	(0.8)
Zanipress®	hypertension	9,110	7,777	1,333	17.1
Corifeo®/ lercanidipine	hypertension	7,247	7,137	110	1.5
Recosyn®	musculo-skeletal	6,148	6,271	(123)	(2.0)
Mirfulan®	healing ointment	6,202	5,992	210	3.5
Lipotalon®	anti-inflammatory	5,139	4,968	171	3.4

The significant sales increase is to be attributed to the growth of Ortoton® (methocarbamol) and to the success of our own generic version of lercanidipine. Sales of Zanipress® are also growing significantly thanks to the award of tenders for the supply of this product to the German regional health care schemes. The overall sales of self-medication products in Germany are € 17.2 million, up by 2.2% compared to the preceding year. Sales of the treatments for rare diseases in this country are up by 23.9%.

### **TURKEY**

Recordati Ilaç, the group's Turkish subsidiary, is one of the 30 leading pharmaceutical companies in Turkey and grows faster than the market. It continues to strengthen its position on the Turkish pharmaceutical market and has a strong consolidated presence in the fields of urology, cardiology, gynecology and in physical medicine and rehabilitation. Recordati Ilaç has undertaken an important investment program for the construction of a new production plant in Cerkezkoy which was declared GMP compliant by the Turkish authorities in March. The new production site will manufacture a number of different products with a total capacity of 80 million packs annually.

Sales in Turkey are  $\le$  86.3 million, up by 16.5%, and were impacted by the devaluation of the Turkish Lira which generated a negative currency exchange effect estimated at  $\le$  7.5 million. In local currency, sales in Turkey increase by 26.8%.

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

TRY (thousands)	Indication	2016	2015	Change 2016/2015	%
Mictonorm®	urinary incontinence	48,247	35,057	13,190	37.6
Cabral®	muscle relaxant	45,308	38,122	7,186	18.9
Lercadip®	hypertension	45,163	37,824	7,339	19.4
Urorec®	benign prostatic hyperplasia	29,623	20,698	8,925	43.1
Kreval®	cough	25,522	20,819	4,734	22.8
Zanipress®	hypertension	22,016	17,586	4,430	25.2
Ciprasid®	anti-infective	21,058	17,941	3,117	17.4
Procto-Glyvenol®	hemorrhoids	14,926	12,962	1,964	15.2

Worth mentioning is the good performance of the corporate products, mainly Urorec®, Lercadip® and Zanipress®.

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

The success of Rusfic LLC, Recordati Ukraine LLC and FIC Médical S.A.R.L., our organizations which operate in Russia, in Ukraine and in other markets of the C.I.S., is largely based on the success of Tergynan®, a product indicated for the topical treatment of vaginal infections which is market leader in the class of anti-infective and antiseptic gynecological drugs, and of a well-known portfolio of self-medication products.

Revenue generated in Russia, Ukraine and in the countries within the Commonwealth of Independent States (C.I.S.) is  $\in$  79.5 million, up by 9.9% compared to the preceding year despite an estimated negative currency exchange effect of  $\in$  6.0 million. Sales in Russia, in local currency, are RUB 4,928.6 million, up by 22.0% over the preceding year thanks to the growth of the main products in the portfolio.

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

RUB (thousands)	Indication	2016	2015	Change 2016/2015	%
Tergynan®	gynaecological infections	1,197,550	992,532	205,018	20.7
Polydexa®	ear infections	1,109,687	851,001	258,686	30.4
Isofra®	nasal infections	790,440	640,540	149,900	23.4
Alfavit®	food supplement	632,324	560,630	71,694	12.8

Sales in Russia, in local currency, grew significantly more than the market. The main product in the Russian portfolio is Tergynan®, leader in its class with a growing market share. Market shares of Polydexa® and Isofra® also increased. Sales of Alfavit®, the main brand of the five lines of self-medication products, grew significantly in 2016. Sales in Russia of the corporate products record significant growth, due mainly to Procto-Glyvenol® and Urorec® and to the introduction of Phosphosoda®.

Sales generated in the other C.I.S. countries, mainly Belarus, and in Ukraine are  $\in$  12.4 million, up by 5.4%.

### **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. The main product is CitraFleet®, a bowel cleanser used in preparation for diagnostic procedures. In Spain, Orphan Europe Spain S.L. markets the portfolio of products for the treatment of rare diseases.

Revenues in Spain are € 76.4 million, up by 6.2% compared to the preceding year. The following table shows sales of the main products.

€ (thousands)	Indication	2016	2015	Change 2016/2015	%
CitraFleet®	bowel cleansing	13.509	12.292	1.217	9.9
Livazo®	hypercholesterolemia	11.582	10.168	1,414	13.9
LIVULEO	benign prostatic	11,002	10,100	1,111	10.0
Urorec®	hyperplasia	8,083	7,233	850	11.8
Enema Casen	bowel cleansing	7,895	7,881	14	0.2
Cidine®	gastroprokinetic	5,429	5,077	352	6.9
Bi-OralSuero	rehydrating solution	5,328	4,798	530	11.0
Zanipress®	hypertension	3,057	2,906	151	5.2

The main product in the portfolio is CitraFleet®, a preparation for colonoscopy which is growing by 9.9%. Livazo® and Urorec® are performing well and the treatments for rare diseases record a 13.1% growth. Sales of Zanipress® grow despite competition from generic versions of the product helped by the promotion of the new higher dose formulation (lercanidipine 20mg+enalapril 20mg). Sales of Cidine® (cinitapride) are growing, despite the presence of generic competition, due to the strength of the brand.

### **NORTH AFRICA**

Recordati has established a direct presence in North Africa, where it already operated successfully through its export business from France, with the acquisition of the Tunisian pharmaceutical company Opalia Pharma S.A. in 2013.

Overall sales in North Africa are € 42.3 million, down by 3.1%, and comprise both the export sales from Laboratoires Bouchara Recordati S.A.S. into these territories, in particular Algeria, and the sales generated by Opalia Pharma mainly in Tunisia. Opalia Pharma markets branded generic drugs with leading products in dermatology and in the gastrointestinal and respiratory therapeutic areas. Sales in Tunisia, in local currency, grow by 9.2% in 2016.

### **PORTUGAL**

Jaba Recordati is well positioned in the Portuguese pharmaceuticals market, mainly in the cardiovascular, urological, gastrointestinal and pain control fields and in the market for OTC Products. In addition, the treatments for rare diseases are available through Orphan Europe Portugal LDA.

Revenue generated by our subsidiaries in Portugal is  $\in$  40.3 million, up by 2.4%. The performance of the main products is listed below.

€ (the	ousands)	Indication	2016	2015	Change 2016/2015	%
Livazo <sup>c</sup>	R	hunarahalaataralamia	7 400	7 007	170	0.4
LIVazo		hypercholesterolemia	7,400	7,227	173	2,4
TransA	ct® LAT	anti-inflammatory	4,131	3,924	207	5,3
Zanipro	ess®	hypertension	3,834	4,124	(290)	(7,0)
Microla	ax®	laxative	2,939	2,839	100	3,5
Urorec	®	benign prostatic hyperplasia	2,735	2,355	380	16,1

The corporate products Livazo®, TransAct® LAT and Urorec®, second product in the alpha-blocker market, are performing very well. The weakness of Zanipress® sales is due entirely to a reduction in price. Generic versions of the product are present in the Portuguese market as from 2014.

#### OTHER WESTERN EUROPEAN COUNTRIES

The Recordati group is also present with its own subsidiaries in the United Kingdom with Recordati Pharmaceuticals Ltd and Orphan Europe United Kingdom Ltd, in Ireland through its subsidiary Recordati Ireland Ltd, in Greece with Recordati Hellas Pharmaceuticals S.A. and in Switzerland through Recordati S.A. and the recently acquired Pro-Farma AG, present also in Austria, and with Orphan Europe Switzerland GmbH. Furthermore, Orphan Europe Nordic A.B. and Orphan Europe Benelux BVBA are present in the segment dedicated to treatments for rare diseases in Scandinavia and in the Netherlands.

Sales in the United Kingdom are € 8.9 million and relate mainly to products for the treatment of rare diseases which account for 62.6% of our revenues in this country. The other sales are generated mainly by lercanidipine based products.

Sales in Ireland recorded by Recordati Ireland are € 1.4 million, mainly generated by Urorec®, Kentera® and Zanidip®. Sales in Greece reported by Recordati Hellas Pharmaceuticals of € 11.3 million, up by 7.6% thanks to the good performance of Livazo®, Urorec®, Lopresor® and Lomexin®. Sales in Switzerland generated by Pro Farma AG and Recordati S.A. are € 8.2 million and refer mainly to Livazo®, Zanidip®, Lacdigest® (tilattase) e Tretinac® (tretinoin). Sales in other Western European countries also comprise sales of products for the treatment of rare diseases in a number of countries for a total of € 10.3 million.

### OTHER CENTRAL AND EASTERN EUROPEAN COUNTRIES

The subsidiary in Poland, Recordati Polska Sp z o.o., markets a diversified product portfolio with an emphasis on the cardiovascular and urology therapeutic areas, in particular as regards benign prostatic hyperplasia, as well as in gynecology. The company's main product is Procto-Glyvenol® for the treatment of hemorrhoids. In addition, it promotes many other established local brands in the self-medication and wellness segment. Sales in Poland in 2016 are € 13.1 million, up by 3.6% thanks mainly to the good performance of Lercan® (lercanidipine) and to the launch of Vytaros®, the new product for erectile dysfunction. The Polish subsidiary's main product Procto-Glyvenol® generated sales of € 4.0 million, up by 14.1%.

Herbacos Recordati S.r.o., the group's subsidiary present in the Czech Republic and in Slovakia, successfully markets pharmaceutical products belonging to a number of therapeutic areas, including analgesic, anti-inflammatory and dermatological medicines, mainly belonging to the self-medication segment. Sales generated by Herbacos Recordati are € 12.9 million, up by 3.4% compared to the preceding year, thanks to the good performance of Procto-Glyvenol® and of Urorec® as well as to the launch of Vitaros®.

Recordati Romania S.R.L. promotes both prescription and OTC products successfully and the company's main product is Procto-Glyvenol®. Sales in Romania are € 4.4 million, up by 24.0% thanks to the good performance of Tergynan®, Lomexin® and of Procto-Glyvenol® as well as to the introduction of CitraFleet®.

Sales in these markets of the specialty products indicated for the treatment of rare and orphan diseases amount to  $\in$  2.2 million.

#### OTHER INTERNATIONAL SALES

Other international sales comprise the sales to, and other revenues from, our licensees for our corporate products, Laboratoires Bouchara Recordati's and Casen Recordati's export sales and Orphan Europe's sales in all other countries.

€ (thousands)	2016	2015	Change 2016/2015	%
Sales to international licensees	117,506	109,484	8,022	7.3
Laboratoires Bouchara Recordati exports (excluding North Africa)	15,090	14,908	182	1.2
Casen Recordati exports	5,603	6,558	(955)	(14.6)
Orphan Europe sales to licensees and exports	23,541	20,297	3,244	16.0
Other income	7,361	7,196	165	2.3
Total	169,101	158,443	10,658	6.7

Sales to international licensees grow by 7.3% thanks to the sales performance of silodosin (+50.5%) and of pitavastatin (+34.6%).

Sales outside France by our French subsidiary Laboratoires Bouchara Recordati are up by 1.2% while sales outside Spain by our Spanish subsidiary Casen Recordati are down by 14.6% as exported brands, mainly Phosphosoda® and Fleet Enema, are being progressively sold directly by Recordati's subsidiaries.

Revenue generated by our treatments for rare diseases in other countries, mainly in the Middle East, either directly or through licensees, are  $\in$  24.9 million, up by 19.9%, and include other income of  $\in$  1.4 million deriving mainly from the Pedea® license in China and the Carbaglu® license in Japan.

Other income refers to royalties and up-front payments related to license agreements.

### 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, phenytoin, papaverine and dimenhydrinate. Other pharmaceutical chemicals are produced on behalf of important pharmaceutical companies. In order to guarantee adequate and continuous supplies of the active ingredient lercanidipine, an important original Recordati drug, in 2005 a new and dedicated plant was constructed in Cork in Ireland. This facility boasts automated process control systems which ensure constant high quality production.

Sales of pharmaceutical chemicals, which comprise active substances produced in the Campoverde d'Aprilia plant for the international pharmaceutical industry, increase by 11.4% as compared to 2015. In particular, the products verapamil, papaverine and benidipine performed well.

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

€ (thousands)	2016	%	2015	%	Change 2016/2015	%
Italy	3,027	7.5	2,870	8.0	157	5.5
Europe (Italy excluded)	15,017	37.4	13,976	38.8	1,041	7.4
United States of America	9,708	24.2	8,812	24.4	896	10.2
America (U.S. excluded)	2,461	6.1	2,435	6.7	26	1.1
Australasia	8,799	21.9	6,104	16.9	2,695	44.2
Africa	1,152	2.9	1,859	5.2	(707)	(38.0)
Total	40,164	100.0	36,056	100.0	4,108	11.4

### 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 2016 the Milan plant obtained an environmental authorization from the Municipality of Milan (for a duration of 15 years) for: atmospheric emission permits, discharge to underground permit for water used in the heating/cooling system and waste water permit for industrial water and rainwater.

In 2016 the Turkish site of Cerkezkoy officially obtained all necessary environmental permits for the start of production (atmospheric emissions, waste water, waste management) and during the same year the plant was successfully audited by the Technical Committee of the IFC (International Finance Corporation) on "Health, Safety and Environment".

### Financial review

### **INCOME STATEMENT**

The following table shows the profit and loss accounts, including their expression as a percent of sales and change versus 2015:

€ (thousands)	2016	% revenue	2015	% revenue	Change 2016/2015	%
Revenue	1,153,942	100.0	1,047,676	100.0	106,266	10.1
Cost of sales	(360,959)	(31.3)	(335,210)	(32.0)	(25,749)	7.7
Gross profit	792,983	68.7	712,466	68.0	80,517	11.3
Selling expenses	(304,435)	(26.4)	(293,204)	(28.0)	(11,231)	3.8
R&D expenses	(83,710)	(7.3)	(76,736)	(7.3)	(6,974)	9.1
G&A expenses	(64,784)	(5.6)	(58,980)	(5.6)	(5,804)	9.8
Other income (expense), net	(12,631)	(1.1)	(5,029)	(0.5)	(7,602)	151.2
Operating income	327,423	28.4	278,517	26.6	48,906	17.6
Financial income (expense), net	(10,141)	(0.9)	(13,080)	(1.2)	2,939	(22.5)
Pre-tax income	317,282	27.5	265,437	25.3	51,845	19.5
Provision for income taxes	(79,851)	(6.9)	(66,634)	(6.4)	(13,217)	19.8
Net income	237,431	20.6	198,803	19.0	38,628	19.4
Attributable to:						
Equity holders of the parent	237,406	20.6	198,792	19.0	38,614	19.4
Minority interests	25	0.0	11	0.0	14	127.3

In 2016 international revenues went from  $\in$  836.1 million to  $\in$  916.3 million, an increase of 9.6%, and represent 79.4% of total revenue. Their breakdown by geographic area is shown in the table below:

€ (thousands)	2016	%	2015	%
Europe (Italy excluded)	674,066	73.6	616,464	73.7
United States of America	111,897	12.2	91,467	10.9
America (United States				
excluded)	21,641	2.4	18,904	2.3
Australasia	55,770	6.1	53,731	6.4
Africa	52,953	5.8	55,540	6.6
Total	916,327	100.0	836,106	100.0

Gross profit is  $\in$  793.0 million with a margin of 68.7% on sales, an increase over that of the preceding year due to the significant growth of products with relatively higher margins.

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

R&D expenses are  $\in$  83.7 million, up by 9.1% compared to those recorded in 2015 due to the advancement of development programs.

G&A expenses are up by 9.8% but remain unchanged as percent of sales.

Overall, labor cost in 2016 is  $\in$  270.4 million, an increase of 12.1% over 2015, with the cost per employee up by 8.6%.

Personnel and other human resources data at 31 December 2016 and 2015 are shown in the following table:

	2016	2015
Employees at year-end	4,116	3,929
Average age	42	42
Average service (years)	7.3	7.3
Labor productivity:		
Labor cost on net sales	23.4%	23.0%
Sales per employee (€ thousands) (a)	293.3	274.7
Value added per employee (€ thousands) (a)	161.6	146.4

Labor cost includes wages, related charges and additional costs.

(a) Data per employee for both years are computed on the average number of personnel, 3,935 in 2016 and 3,813 in 2015.

The 2016 human resources data include the personnel of the two companies acquired during the year, Italchimici S.p.A. and Pro Farma AG. The strengthening of our corporate organization continued in order to ensure the integration, monitoring and coordination of the foreign subsidiaries in accordance with our internationalization strategy. Personnel training and development represented a substantial portion of the group's efforts also in 2016. During the year the project aimed at identifying and evaluating personnel competencies within the group, with the objective of improving staff development and career planning, continued and the first results were obtained.

Other expenses net of other income are € 12.6 million and include non recurring expenses of € 12.8 million due to ancillary costs and charges for organizational restructuring related to the recent acquisitions of Italchimici S.p.A. and Pro Farma AG as well as the write-down of certain intangible assets.

Net financial charges are  $\in$  10.1 million, a decrease of  $\in$  2.9 million compared to the preceding year due mainly to the reduction of interest charges related to medium/long-term loans and to net foreign exchange gains as opposed to losses in the previous year.

The effective tax rate during the period is 25.2%, substantially in line with that of the preceding year.

Net income at 20.6% of sales is  $\le$  237.4 million, an increase of 19.4% over the preceding year.

### **FINANCIAL POSITION**

The net financial position at 31 December 2016 records net debt of € 198.8 million compared to net debt of € 88.7 million at 31 December 2015.

€ (thousands)	31.12.2016	31.12.2015	Change 2016/2015	%
Cash and short-term financial investments	138,493	225,525	(87,032)	(38.6)
Bank overdrafts and short-term loans	(15,689)	(9,849)	(5,840)	59.3
Loans – due within one year	(40,428)	(34,469)	(5,959)	17.3
Net liquid assets	82,376	181,207	(98,931)	(54.5)
Loans – due after one year <sup>(1)</sup>	(281,147)	(269,944)	(11,203)	4.2
Net financial position	(198,771)	(88,737)	(110,034)	124.0

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

During the year dividends were distributed for an overall amount of € 133.7 million, of which € 61.5 million for the balance of the financial year 2015 dividend and € 72.2 for the interim financial year 2016 dividend. The acquisitions of the Italian pharmaceutical company Italchimici S.p.A. and the Swiss company Pro Farma AG accounted for € 128.1 million and € 14.4 million respectively. In addition, € 10 million were paid at the signing of an exclusive license agreement for the commercialization of cariprazine, a novel atypical antipsychotic drug. Share buy-backs during the year to service existing stock option plans accounted for an outlay of € 71.6 million.

An amount of  $\in$  20.9 million was invested in property, plant and equipment, mainly involving the Parent company's Milan headquarters and production sites ( $\in$  7.8 million) and in Turkey by Recordati Ilaç for the completion of the activities related to the construction of a new production plant ( $\in$  6.5 million).

Net working capital for operations at 31 December 2016 is € 149.7 million and is thus comprised:

€ (thousands)	31.12.2016	% revenue	31.12.2015	% revenue	Change 2016/2015	%
Trade receivables, net	205,988	17.9	177,219	16.9	28,769	16.2
Inventories	158,800	13.8	143,093	13.7	15,707	11.0
Other current assets	36,455	3.2	34,163	3.3	2,292	6.7
Current assets	401,243	34.8	354,475	33.8	46,768	13.2
Trade payables	124,644	10.8	106,597	10.2	18,047	16.9
Tax payable	20,432	1.8	14,592	1.4	5,840	40.0
Other current liabilities	106,496	9.2	102,710	9.8	3,786	3.7
Current liabilities	251,572	21.8	223,899	21.4	27,673	12.4
Net working capital for operations	149,671	13.0	130,576	12.5	19,095	14.6
Days of sales outstanding	61		59			
Inventories as % of cost of sales	43.7%		42.7%			

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

#### **RELATED PARTY TRANSACTIONS**

Tax liabilities include an amount of € 1.3 million, computed by Recordati S.p.A. based on estimated taxable income, payable to the controlling company Fimei S.p.A. consequent to the participation in a tax consolidation grouping under tax laws in Italy.

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

### SUBSIDIARIES OUTSIDE THE EUROPEAN UNION

Pursuant to articles 36 and 39 of the Financial Markets Regulation 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 2016 the provisions of art. 36 of the Financial Markets Regulation apply to the subsidiaries Recordati Ilaç, Recordati Rare Diseases Inc. and Rusfic LLC and that the conditions indicated in the abovementioned art. 36 are fulfilled.

### SIGNIFICANT OPERATIONS, PUBLICATION REQUIREMENTS DEROGATION

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

### **FOURTH QUARTER 2016**

€ (thousands)	IV quarter 2016	%	IV quarter 2015	%	Change 2016/2015	%
Revenue	291,572	100.0	263,244	100.0	28,328	10.8
Cost of sales	(93,658)	(32.1)	(83,562)	(31.7)	(10,096)	12.1
Gross profit	197,914	67.9	179,682	68.3	18,232	10.1
Selling expenses	(78,032)	(26.8)	(73,685)	(28.0)	(4,347)	5.9
R&D expenses	(23,512)	(8.1)	(21,513)	(8.2)	(1,999)	9.3
G&A expenses	(17,687)	(6.1)	(16,027)	(6.1)	(1,660)	10.4
Other income (expense), net	(3,666)	(1.3)	(2,987)	(1.1)	(679)	22.7
Operating income	75,017	25.7	65,470	24.9	9,547	14.6
Financial income (expense), net	(1,515)	(0.5)	(2,913)	(1.1)	1,398	(48.0)
Pretax income	73,502	25.2	62,557	23.8	10,945	17.5
Provision for income taxes	(18,388)	(6.3)	(16,259)	(6.2)	(2,129)	13.1
Net income	55,114	18.9	46,298	17.6	8,816	19.0
Attributable to:						
Equity holders of the parent	55,108	18.9	46,297	17.6	8,811	19.0
Minority interests	6	0.0	1	0.0	5	500.0

Revenues during the fourth quarter 2016 are  $\in$  291.6 million, an increase of 10.8% compared to the same period of the preceding year. Pharmaceutical sales are  $\in$  281.3 million, up by 11.0% compared to the fourth quarter 2015. Pharmaceutical chemicals revenue, at  $\in$  10.3 million, up by 4.2% compared to the same period of the preceding year.

Operating income, at 25.7% of sales, is  $\in$  75.0 million up by 14.6%. Other expenses net of other income are to be attributed to the write-down of certain intangible assets.

Financial charges decrease significantly due mainly to the revaluation of some currencies which have resulted in the realization net foreign exchange gains.

Net income increases by 19.0% and benefits significantly from the reduction of financial charges.

### Main risks and uncertainties

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

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

### RISKS ASSOCIATED WITH THE EXTERNAL CONTEXT

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

The pharmaceuticals sector is heavily regulated locally, nationally and internationally and this affects activities at all levels. Group sales consist mainly 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 exposed to national and international technical standards which regulate pharmaceutical research and development, production and promotion.

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

### Risks associated with business expansion into emerging markets

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

Recordati carefully assesses all growth opportunities in all geographies in order to mitigate exposure to these uncertainties and where possible it prefers to acquire local companies with a smaller outlay of capital, rather than other companies that are more exposed to country risk. Evaluations of new business opportunities undergo analysis and monitoring by top management with the further garrison by 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 as soon as possible, it also manages risk by pursuing a policy to progressively diversify and broaden the range of its product portfolio, in order to reduce dependency on a small number of strategic pharmaceuticals, and increase the presence in the product portfolio of OTC products and treatments for rare diseases.

### RISKS ASSOCIATED WITH STRATEGY AND OPERATIONS

### Risks associated with the internationalization of the Group

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

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

### Risks associated with the expiry of patents

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

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

### Risks associated with investments in research and development

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

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

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

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

In order to mitigate that risk Recordati pursues two policy lines. One is to broaden and balance its pipeline of products, implemented by acquiring pharmaceuticals that are already registered or are about to be registered, or of new products at different stages of development. The other is to pursue a plan of geographical diversification designed to limit dependence on the regulatory authorities of a single country.

#### Risks associated with pharmacovigilance

The Group, as a holder of drug marketing authorizations, must comply with regulations on pharmacovigilance. These regulations require that holders of marketing authorizations submit to the regulatory bodies information regarding drug safety, within the time limits and in the manner established by these, with particular regard to adverse reactions. The ascertainment of serious adverse drug reactions can expose the Group to the risk of restrictions being placed on the prescription of a drug, and in the most serious cases, authorization to market the product can be revoked.

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

### Risks associated with the production process

The Group has production plants which produce both intermediate products and active ingredients and also finished pharmaceutical products. Production activities are carried out in strict compliance with internationally established Good Manufacturing Practices (GMP) implemented through Standard Operating Procedures applicable to the pharmaceutical sector, and are submitted to monitoring and inspection by national and international relevant authorities. The Group's production sites are provided with adequate structures and qualified personnel 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, 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. 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.

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

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

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

#### **FINANCIAL RISKS**

#### Credit Risk

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

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

#### **Interest Rate Risk**

The Group raises funds using debt and invests excess cash in money market and other financial instruments. The fluctuation of market interest rates influences the cost and returns of the debt and investment instruments therefore affecting the Group's net financial charges. The significant expansion of the Group into countries with different economic dynamics from the Euro (for example Turkey, Russia and Tunisia) leads to an increase in risk. The Group's policy is to limit the risk arising from interest rate fluctuations by establishing medium/long-term fixed interest loans or variable interest loans. Variable interest loans are covered with derivative financial instruments (for example interest rate swaps) for the sole purpose of minimizing such fluctuations and not for speculation. This hedging policy limits the Group's exposure to the risk of fluctuations in interest rates.

### Foreign Currency Risk

The Group operates in an international context and has assets and transactions denominated in foreign currency other than euro. It is therefore exposed to risks of foreign currency fluctuations which can affect is 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 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 30 which address, respectively, short-term financial investments, cash and cash equivalents, loans and bank overdrafts. The Group believes that the funds and credit lines currently available, in addition to those generated by operations and financing activities, are enough to satisfy investment needs, working capital requirements and the repayment of debts at their natural due dates.

#### LEGAL AND COMPLIANCE RISKS

### Risks associated with product liability

Despite careful compliance with standards and regulations, like any company operating in the pharmaceuticals sector, the Group could be exposed to risks of claims for damages caused by its pharmaceuticals. In order to meet those potential liabilities, the Group has taken out insurance policies to cover all the products marketed and under development. The maximum liability limits are considered adequate and are constantly monitored with the help of analyses and market research conducted by leading insurance brokers.

#### Risks associated with compliance

All operating and marketing activities performed by the Group, both in Italy and abroad, are performed in compliance with the legislation and regulations that apply in the geographical areas in which it operates, including national and international technical standards that apply to the pharmaceuticals sector which regulate pharmaceutical research and development, production, distribution and promotion. As concerns the regulation of drug promotion activities, the Group has formulated a set of ethical rules of conduct. All company personnel are continuously informed of those rules and monitoring, both internally and by independent certifiers, is performed constantly to ensure that they are properly observed. In compliance with Legislative Decree 231/2001 on the administrative liability of legal entities, the Italian companies in the Group have an "Organisation, Management and Control Model" that is continuously updated to comply with the latest amendments to the relevant legislation.

Regarding the risk of corruption, the Group is implementing 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 and the relative provisions made to meet future liabilities is given in notes 28 and 37 to the financial statements.

# Subsequent events and business outlook

In January 2017 the European Union Commission granted the European marketing authorization for Cystadrops®, the first eye-drop solution containing cysteamine hydrochloride approved in the European Union for "the treatment of corneal cystine crystal deposits in adults and children from 2 years of age with cystinosis". The European Commission granted Cystadrops® orphan drug designation in November 2008.

In February the signing of an exclusive worldwide licensing agreement covering the know-how developed by the Meyer Hospital in Florence (Italy) for the development of a treatment for pre-term babies affected by retinopathy of prematurity (ROP) was announced. Furthermore, Recordati shall support, over a period of three years, other Meyer projects in the rare disease area based on a mutually agreed plan.

On 9 February 2017 the company announced its financial targets for 2017 and its three-year business plan. Including the contribution of further acquisitions which may be completed within the period under analysis, our financial performance expectations for the 2017-2019 period are the following:

For 2017, our targets are to achieve sales of around  $\in$  1,220 million, EBITDA of around  $\in$  410 million, operating income of around  $\in$  365 million and net income of around  $\in$  260 million.

For 2019, we expect to achieve sales of around  $\in$  1,450 million, EBITDA of around  $\in$  500 million, operating income of around  $\in$  450 million and net income of around  $\in$  325 million.

Group consolidated sales during the first two months of 2017 are particularly positive thanks to the good performance of all our business segments and thanks also to favourable seasonality factors in some countries.

Milan, 1 March 2017

Andrea Recordati
Vice Chairman and Chief Executive Officer

### Consolidated financial statements

### RECORDATI S.P.A AND SUBSIDIARIES CONSOLIDATED FINANCIAL STATEMENTS AT AND FOR THE YEAR ENDED 31 DECEMBER 2016

The consolidated financial statements are presented in accordance with the International Accounting Standards (IAS) and the International Financial Reporting Standards (IFRS) issued or revised by the International Accounting Standards Board (IASB) and the interpretations of the International Financial Interpretation Reporting Committee (IFRIC) previously named Standing Interpretations Committee (SIC). The financial statements comply with the European Union's guidelines on the preparation of consolidated financial statements. The same accounting standards were used in the preparation of the financial statements at 31 December 2015.

### RECORDATI S.p.A. AND SUBSIDIARIES CONSOLIDATED INCOME STATEMENT FOR THE YEAR ENDED 31 DECEMBER 2016

### **INCOME STATEMENT**

€ (thousands)	Note	2016	2015
Revenue	3	1,153,942	1,047,676
Cost of sales	4	(360,959)	(335,210)
Gross profit		792,983	712,466
Selling expenses	4	(304,435)	(293,204)
R&D expenses	4	(83,710)	(76,736)
G&A expenses	4	(64,784)	(58,980)
Other income (expense), net	4	(12,631)	(5,029)
Operating income		327,423	278,517
Financial income (expense), net	5	(10,141)	(13,080)
Pretax income		317,282	265,437
Provision for income taxes	6	(79,851)	(66,634)
Net income		237,431	198,803
Attributable to:			
Equity holders of the parent		237,406	198,792
Minority interests		25	11
Earnings per share			
Basic		€ 1,152	€ 0.968
Diluted		€ 1,135	€ 0.951

Earnings per share (EPS) are based on average shares outstanding during each year, 206,117,418 in 2016 and 205,270,094 in 2015, net of average treasury stock which amounted to 3,007,738 shares in 2016 and 3,855,062 shares in 2015.

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

### RECORDATI S.p.A. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEET AT 31 DECEMBER 2016

### **ASSETS**

€ (thousands)	Note	31 December 2016	31 December 2015
Non-current assets			
Property, plant and equipment	7	110,202	108,987
Intangible assets	8	279,884	246,450
Goodwill	9	556,566	453,285
Other investments	10	19,199	32,444
Other non-current assets	11	5,428	4,549
Deferred tax assets	12	37,231	30,500
Total non-current assets		1,008,510	876,215
Current assets Inventories	13	158,800	143,093
Trade receivables	14	205,988	177,219
Other receivables	15	30,974	28,883
Other current assets	16	5,481	5,280
Fair value of hedging derivatives (cash flow hedge)	17	12,497	12,671
Short-term financial investments, cash and cash equivalents	18	138,493	225,525
Totale attività correnti		552,233	592,671
Total assets		1,560,743	1,468,886

### **EQUITY AND LIABILITIES**

€ (thousands)	Note	31 December 2016	31 December 2015
Shareholders' equity			
Share capital		26,141	26,141
Additional paid-in capital		83,719	83,719
Treasury stock		(76,761)	(35,061)
Hedging reserve (cash flow hedge)		(7,420)	(3,290)
Translation reserve		(78,309)	(66,918)
Other reserves		35,295	42,543
Retained earnings		756,004	685,587
Net income for the year		237,406	198,792
Interim dividend		(72,245)	(61,606)
Group shareholders' equity	19	903,830	869,907
Minority interest		110	85
Shareholders' equity	20	903,940	869,992
Loans – due after one year Staff leaving indemnities Deferred tax liabilities Other non-current liabilities Total non-current liabilities	21 22 23 24	293,644 21,675 27,659 2,515 345.493	282,615 18,895 22,360 2,517 326,387
Current liabilities			
Trade payables	25	124,644	106,597
Other payables	26	77,957	72,351
Tax liabilities	27	20,432	14,592
Other current liabilities		562	959
Provisions	28	27,977	29,400
Fair value of hedging derivatives (cash flow hedge)	29	3,621	4,290
Loans – due within one year	21	40,428	34,469
Bank overdrafts and short-term loans	30	15,689	9,849
Total current liabilities		311,310	272,507
Total equity and liabilities		1,560,743	1,468,886

### RECORDATI S.p.A. AND SUBSIDIARIES STATEMENT OF COMPREHENSIVE INCOME FOR THE YEAR ENDED 31 DECEMBER 2016

€ (thousands)	2016	2015
Net income for the year	237,431	198,803
Gains/(losses) on cash flow hedges	(4,130)	(2,607)
Gains/(losses) on translation of foreign financial statements	(11,391)	(10,604)
Other gains/(losses)	(9,259)	11,137
Income and expense for the year recognized directly in equity	(24,780)	(2,074)
Comprehensive income for the year	212,651	196,729
Attributable to:		
Equity holders of the parent	212,626	196,718
Minority interests	25	11

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

€ (thousands)	Share capital	Add. paid-in capital	Treasury stock	Hedging reserve	Translation reserve	Other reserves	Retained earnings	Net income for the year	Interim dividend	Minority interest	Total
Balance at 31.12.2014	26,141	83,719	(30,727)	(683)	(56,314)	29,865	627,240	161,187	(53,080)	74	787,422
Allocation of 2014 net income:											
- Dividends							(13,318)	(88,926)	53,080		(49,164)
- Retained earnings							72,261	(72,261)			
Change in the reserve for share based payments						1,541	1,111				2,652
Purchase of own shares			(17,730)								(17.730)
Sale of own shares			13,396				(1,645)				11,751
Interim dividend							, . ,		(61,606)		(61,606)
Other changes							(62)		(- ,,		(62)
Comprehensive income for the year				(2,607)	(10,604)	11,137	, ,	198,792		11	196,729
Balance at 31.12.2015	26,141	83,719	(35,061)	(3,290)	(66,918)	42,543	685,587	198,792	(61,606)	85	869,992
Allocation of 2015 net income:											
- Dividends							2,425	(125,516)	61,606		(61,485)
- Retained earnings							73,276	(73,276)	01,000		(01,100)
Change in the reserve for share based payments						2.011	1,973	(* 5,=: 5)			3.984
Purchase of own shares			(71,605)			2,011	1,070				(71,605)
Sale of own shares			29,905				(7,186)				22,719
Interim dividend							, ,		(72,245)		(72,245)
Other changes							(71)				(71)
Comprehensive income for the year				(4,130)	(11,391)	(9,259)		237,406		25	212,651
Balance at 31.12.2016	26,141	83,719	(76,761)	(7,420)	(78,309)	35,295	756,004	237,406	(72,245)	110	903,940

### RECORDATI S.p.A. AND SUBSIDIARIES CONSOLIDATED CASH FLOW STATEMENT FOR THE YEAR ENDED 31 DECEMBER 2016

€ (thousands)	2016	2015
Operating activities		
Cash flow		
Net Income	237,431	198,803
Depreciation of property, plant and equipment	12,466	11,948
Amortization of intangible assets	25,466	26,535
Write-down of assets	5,862	(
Total cash flow	281.225	237,286
(Increase)/decrease in deferred tax assets	(5,637)	3,510
Increase/(decrease) in staff leaving indemnities	1,273	507
Increase/(decrease) in other non-current liabilities	(216)	(4,200
	276,645	237,103
Changes in working capital		
Trade receivables	(20,509)	1,810
Inventories	(9,982)	(1,870
Other receivables and other current assets	547	3,080
Trade payables	7,005	(5,939
Tax liabilities	5,191	2,05
Other payables and other current liabilities	194	7,52
Provisions	(3,655)	3,610
Changes in working capital	(21,209)	10,269
Net cash from operating activities	255,436	247,372
Investing activities		
Net (investments)/disposals in property, plant and equipment	(19,669)	(31,239
Net (investments)/disposals in intangible assets	(17,272)	(2,451
Acquisition of equity	(120,790) <sup>(1)</sup>	(2,101
Net (increase)/decrease in equity investments	121	(
Net (increase)/decrease in other non-current receivables	(879)	194
Net cash used in investing activities	(158,489)	(33,496
Financing activities		
Short-term financial position of companies acquired or disposed of	(21,675)	(
Medium/long term loans	50,128	52,043
Re-payment of loans	(33,977)	(66,234
Purchase of Treasury stock	(71,605)	(17,730
Sale of Treasury stock	22,719	11,75
Effect of application of IAS/IFRS	3,765	2,840
Other changes in equity	(71)	(62
Dividends paid	(133,730)	(110,770
Change in translation reserve	(5,373)	1,518
Net cash from/(used in) financing activities	(189,819)	(126,638
Changes in short-term financial position	(92,872)	87,238
Short-term financial position at beginning of year *	215,676	128,438
Short-term financial position at end of period *	122,804	215,676
onore torre mandral poolation at one or portor	122,007	210,07

<sup>\*</sup> Includes cash and cash equivalents net of bank overdrafts and short-term loans.

Acquisition of Pro Farma AG (14,496): Working capital (745), Short-term financial position\* (94), Fixed assets (5.447), Goodwill (8,485), Deferred tax liabilities 275.

<sup>(1)</sup> Acquisition of Italchimici S.p.A. (106,294): Working capital 2,859, Short-term financial position\* 21,769, Fixed assets (36,448), Goodwill (105,303), Personnel leaving indemnity 1,507, Deferred tax liabilities 9,322.

### Recordati s.p.a. and subsidiaries

## Notes to the consolidated financial statements for the year ended 31 december 2016

### 1. GENERAL

The consolidated financial statements at 31 December 2016 comprise Recordati S.p.A. (the Company) and subsidiaries controlled by the Company. The companies included in the consolidated accounts, the consolidation method applied, their percentage of ownership and a description of their activity are set out in attachment 1.

During the year the consolidation perimeter changed following two acquisitions. In May the Italian pharmaceutical company Italchimici S.p.A., which offers therapeutical solutions mainly in the gastroenterological and respiratory areas which consist of both pharmaceutical products as well as food supplements and medical devices to improve the health and well-being of patients, was acquired. The recognition of this company in the accounts is not yet definite, and could be subject to change, as allowed by IFRS 3. The profit and loss accounts of Italchimici S.p.A. are consolidated as from 1 June 2016 and the consolidated cash flow statement includes the effect of the balance sheet accounts at 31 May 2016. In July the Swiss company Pro Farma AG and its Austrian subsidiary Pro Farma GmbH, which market proprietary and in-licensed specialties in selected therapeutic areas which include both prescription and OTC drugs, were acquired. The recognition of this company in the accounts is not yet definite, and could be subject to change, as allowed by IFRS 3. The profit and loss accounts of Pro Farma AG and its Austrian subsidiary Pro Farma GmbH are consolidated as from 1 July 2016 and the consolidated cash flow statement includes the effect of the balance sheet accounts at 30 June 2016.

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

### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The financial statements have been prepared in accordance with International Accounting Standards and International Financial Reporting Standards (IAS/IFRS) issued by the International Accounting Standards Board (IASB) and in compliance with the European Union's guidelines on the preparation of consolidated financial statements. The same accounting policies applied in the preparation of the consolidated financial statements at 31 December 2015 were used in the preparation of the financial statements at 31 December 2016.

No significant changes in accounting policies were applied in the preparation of the consolidated financial statements.

The financial statements of the consolidated companies, prepared by the Board of Directors or the Sole Directors for submission to the respective Shareholders' meetings, have been reclassified and adjusted as required in accordance with International Accounting Standards and International Financial Reporting Standards (IAS/IFRS). The criteria applied is consistent with that of the consolidated financial statements at 31 December 2015.

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 IAS 39 and defined benefit plans for which the actuarial valuation was carried out as prescribed by IAS 19.

The preparation of the financial statements requires management to make estimates and assumptions 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, which are based on management's best judgment at the date of the financial statements, deviate from the actual circumstances, the original estimates and assumptions will be modified as appropriate in the period in which the circumstances change.

The principal accounting policies adopted are set out below.

### **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.
- Intercompany payables and receivables and transactions, as well as intragroup profits and losses not yet realized, are eliminated.
- Any excess of the cost of acquisition over the value of equity at the date of acquisition is recognized as goodwill.

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

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

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

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

#### **BALANCE SHEET**

**Property, plant and equipment** - Property, plant and equipment is stated at purchase cost less accumulated depreciation and any recognized impairment loss. Reviews are performed when events or situations occur which indicate that the carrying amount of the assets can no longer be recovered (see paragraph on Impairment). Depreciation is computed on a straight-line basis using rates which are held to be representative of the estimated useful life of the assets.

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

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

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

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

**Goodwill** - Goodwill arising on consolidation represents the excess of the cost of acquisition over the Group's interest in the fair value of the identifiable assets and liabilities of a subsidiary, associate or jointly controlled entity at the date of acquisition. Transaction costs associated with the aggregation of companies are not considered acquisition costs and are recognized as expenses in the year they are incurred. Goodwill is recognized as an asset and reviewed annually in order to determine any impairment loss.

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

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

Impairment - At each balance sheet date, the Group reviews the carrying amounts of its tangible and intangible assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss (if any). Where it is not possible to estimate the recoverable amount of an individual asset, the Group estimates the recoverable amount of the cash-generating unit to which the asset belongs.

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

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

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

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

**Other investments** - Other investments are those described by IAS 39 as available-for-sale financial assets. They comprise equity instruments and are measured at fair value. If their market value is not available and their fair value cannot be reasonably determined, these investments are valued at cost and adjusted for loss of value (impairment) if required. The impairment cost is recognized in the income statement.

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

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

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

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

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

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

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

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

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

**Loans** - Interest-bearing loans are recorded at the proceeds received, net of direct issue costs. Subsequently, loans are measured using the amortised cost method as prescribed by IAS 39. The amortised cost of a financial asset or financial liability is the amount at which the financial asset or liability is measured at initial recognition minus principal repayments, plus or minus the cumulative amortisation using the effective interest method of any difference between that initial amount and the maturity amount.

If the loans are covered using derivative instruments qualifying as fair value hedges, in accordance with IAS 39 these loans are measured at fair value as are their related derivative instruments.

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

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

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

Bank overdrafts and loans - Bank overdrafts and loans are recorded at the proceeds received, net of direct issue costs. Finance charges are accounted for on an accrual basis and are added to the carrying amount of the instrument to the extent that they are not settled in the period in which they arise.

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

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

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

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

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

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

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

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

### **INCOME STATEMENT**

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

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

**Selling expenses** - Include all expenses incurred in connection with the products sold during the year, such as payroll and other costs for sales and marketing personnel, promotional expenses and all distribution costs. Promotional expenses for the launch of new products are recognized in the income statement in proportion to the revenues obtained during the launch period.

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

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

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

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

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

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

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

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

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

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

#### 3. REVENUE

Net revenue for the years 2016 and 2015 is  $\in$  1,153.9 million and  $\in$  1,047.7 million respectively and can be broken down as follows:

€ (thousands)	2016	2015	Change 2016/2015
Net sales	1,139,444	1,032,447	106,997
Royalties	5,995	5,424	571
Up-front payments	4,158	5,748	(1,590)
Other revenue	4,345	4,057	288
Total revenue	1,153,942	1,047,676	106,266

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

Revenue from up-front payments refers to the licensing out of corporate products and in 2016 are mainly relative to agreements for the licensing of the lercanidipine+enalapril fixed combination ( $\in$  1.3 million), pitavastatin ( $\in$  1.1 million), ibuprofen ( $\in$  0.5 million), lercanidipine ( $\in$  0.5 million) and fenticonazole ( $\in$  0.4 million).

Other revenue includes commissions of € 1.5 million received by FIC Médical for promotion services rendered to third parties in the countries belonging to the Commonwealth of Independent States (C.I.S.).

### 4. OPERATING EXPENSES

Total operating expenses for the years 2016 and 2015 are € 826.5 million and € 769.2 million respectively and are analyzed by function as follows:

€ (thousands)	2016	2015	Change 2016/2015
Cost of sales	360,959	335,210	25,749
Selling expenses	304,435	293,204	11,231
Research and development expenses	83,710	76,736	6,974
General and administrative expenses	64,784	58,980	5,804
Other (income) expense, net	12,631	5,029	7,602
Total operating expenses	826,519	769,159	57,360

Labor cost in 2016 is  $\in$  270.4 million, an increase of 12.1% compared to 2015, and includes charges of  $\in$  4.0 million related to stock option plans determined in accordance with IFRS 2.

Depreciation and amortization charges are € 37.9 million. Depreciation of property, plant and equipment is € 12.5 million, up by € 0.5 million as compared to the preceding year. Amortization of intangibles is € 25.4 million, a decrease of € 1.1 million compared to 2015.

The following table summarizes the most significant components of other income (expense) which comprises mainly non-recurring events, operations and matters which are not often repeated in the ordinary course of business.

€ (thousands)	2016	2015	Change 2016/2015
Write-down of intangible assets	(5,862)	0	(5,862)
Organizational restructuring charges	(4,678)	(2,637)	(2,041)
Ancillary costs related to acquisitions	(2,272)	0	(2,272)
Other write-downs	0	(1,074)	1,074
Others	181	(1,318)	1,499
Total other income (expense), net	(12,631)	(5,029)	(7,602)

The write-down of intangible assets concerns mainly the amounts paid upfront for the acquisition of distribution rights for the products Fortacin<sup>TM</sup> (lidocaine/prilocaine) and Vitaros® (alprostadil) for which the expected returns from their future commercialization have been revised. In particular, the value of Fortacin<sup>TM</sup> was written down by  $\in$  5.3 million, following the approval of a dosage form different from that originally planned, and Vitaros® by e 0.6 million.

Organizational restructuring charges refer entirely to the recently acquired company Italchimici S.p.A.. Ancillary costs comprise those incurred for the acquisitions of Italchimici S.p.A. and Pro Farma AG in the amounts of  $\in$  2.0 million and  $\in$  0.3 million respectively.

#### 5. FINANCIAL INCOME AND EXPENSE

In 2016 and 2015 financial items recorded a net expense of € 10.1 million and € 13.1 million respectively which are comprised as follows:

€ (thousands)	2016	2015	Change 2016/2015
Exchange gains (losses)	1,708	(572)	2,280
Interest expense on loans	(8,086)	(8,700)	614
Net interest income (expense) on s/t financial position	(3,488)	(3,536)	48
Interest cost in respect of defined benefit plans	(275)	(272)	(3)
Total financial income (expense), net	(10,141)	(13,080)	2,939

The net exchange gains in 2016 as opposed to the losses in 2015 are mainly determined by the revaluation of some currencies, mainly the U.S. dollar and the Russian ruble.

The decrease in interest expense on loans is to be attributed mainly to the reimbursement of the notes due at the end of the preceding year and to the effect of the reduction in the cost of debt following the renegotiation of their conditions during the first half of 2015 (see Note 21).

#### 6. PROVISION FOR INCOME TAXES

The provision for income taxes amounts to  $\in$  79.9 million and includes income taxes levied on all consolidated companies as well as the Italian regional tax on production activities (IRAP) which is levied on all Italian companies.

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

	2016 %	2015 %
Standard income tax rate on pre-tax income of the parent company	27.5	27.5
Dividends from foreign subsidiaries	0.2	0.5
Consolidation effect	(4.3)	(4.3)
Other differences, net	0.7	0.4
Effective tax rate on income	24.1	24.1
IRAP	1.1	1.0
Effective tax rate, including IRAP	25.2	25.1

IRAP is levied only on the Italian companies and is computed applying a 4.14% rate to a broader taxable base calculated before the deduction of interest.

#### 7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment, net of accumulated depreciation, amounts to € 110.2 million and € 109.0 million at 31 December 2016 and 2015 respectively. The composition and variation of property, plant and equipment are shown in the following table:

€ (thousands)	Land & buildings	Plant & machinery	Other equipment	Advances/ construction in progress	Total
Cost					
Balance at 31.12.15	59,826	207,587	60,016	38,514	365,943
Additions	833	3,286	3,095	13,691	20,905
Disposals	0	(2,772)	(1,203)	(393)	(4,368)
Changes in reporting entities	0	0	525	0	525
Other changes	18,750	15,296	2,438	(44,805)	(8,321)
Balance at 31.12.16	79,409	223,397	64,871	7,007	374,684
Accumulated depreciati	ion				
Balance at 31.12.15	37,332	172,201	47,423	0	256,956
Depreciation for the year	2,299	6,667	3,500	0	12,466
Disposals	0	(2,493)	(979)	0	(3,472)
Changes in reporting entities	0	0	247	0	247
Other changes	(345)	(1,137)	(233)	0	(1,715)
Balance at 31.12.16	39,286	175,238	49,958	0	264,482
Carrying amount at					
31 December 2016	40,123	48,159	14,913	7,007	110,202
31 December 2015	22,494	35,386	12,593	38,514	108,987

Additions during the year of  $\le$  20.9 million refer mainly to investments made by the Parent in the Milan production plant and headquarters for an amount of  $\le$  7.8 million and by the Turkish subsidiary Recordati Ilaç for an amount of  $\le$  6.5 million for the completion of the construction of a new production plant.

The conversion into Euros of property, plant and equipment booked in different currencies resulted in a net decrease of  $\in$  6.3 million compared to their value at 31 December 2015, of which  $\in$  5.5 million is due to the devaluation of the Turkish Lira and  $\in$  0.8 million is due to the devaluation of the Tunisian Dinar.

At 31 December 2016 property, plant and equipment held under financial leases amount to  $\in$  0.4 million and are held by the company in Tunisia Opalia Pharma.

#### 8. INTANGIBLE ASSETS

Intangible assets, net of accumulated amortization, at 31 December 2016 and 2015 amount to  $\in$  279.9 million and  $\in$  246.5 million respectively. Their composition and variation are shown in the following table:

Cost						
Balance at 31.12.15         318,997         147,558         16,981         7,667         491,20           Additions         212         1,022         1,082         15,492         17,80           Write-downs         (550)         (58)         0         (5,254)         (5,86)           Disposals         (79)         (210)         (88)         (916)         (1,29)           Changes in reporting entities         4,790         42,057         118         1,074         48,03           Other changes         7,824         196         128         (1,331)         6,81           Balance at 31.12.16         331,194         190,565         18,221         16,732         556,71           Accumulated amortization         Balance at 31.12.15         122,768         105,905         16,080         0         244,75           Amortization for the year         15,651         9,192         623         0         25,46           Write-downs         0         0         0         0         0           Disposals         (46)         (101)         (270)         0         (41)           Changes in reporting entities         1,788         4,557         77         0         6,42	€ (thousands)	and marketing	license, trademark and similar	Other		Total
Additions         212         1,022         1,082         15,492         17,80           Write-downs         (550)         (58)         0         (5,254)         (5,86)           Disposals         (79)         (210)         (88)         (916)         (1,29)           Changes in reporting entities         4,790         42,057         118         1,074         48,03           Other changes         7,824         196         128         (1,331)         6,81           Balance at 31.12.16         331,194         190,565         18,221         16,732         556,71           Accumulated amortization           Balance at 31.12.15         122,768         105,905         16,080         0         244,75           Amortization for the year         15,651         9,192         623         0         25,46           Write-downs         0         0         0         0         0           Disposals         (46)         (101)         (270)         0         (41           Changes in reporting entities         1,788         4,557         77         0         6,42           Other changes         1,722         (976)         (142)         0         60	Cost					
Write-downs         (550)         (58)         0         (5,254)         (5,867)           Disposals         (79)         (210)         (88)         (916)         (1,293)           Changes in reporting entities         4,790         42,057         118         1,074         48,03           Other changes         7,824         196         128         (1,331)         6,81           Balance at 31.12.16         331,194         190,565         18,221         16,732         556,71           Accumulated amortization         Balance at 31.12.15         122,768         105,905         16,080         0         244,75           Amortization for the year         15,651         9,192         623         0         25,46           Write-downs         0         0         0         0         0           Disposals         (46)         (101)         (270)         0         (41)           Changes in reporting entities         1,788         4,557         77         0         6,42           Other changes         1,722         (976)         (142)         0         60           Balance at 31.12.16         141,883         118,577         16,368         0         276,82	Balance at 31.12.15	318,997	147,558	16,981	7,667	491,203
Disposals         (79)         (210)         (88)         (916)         (1,293)           Changes in reporting entities in reporting entities         4,790         42,057         118         1,074         48,03           Other changes         7,824         196         128         (1,331)         6,81           Balance at 31.12.16         331,194         190,565         18,221         16,732         556,71           Accumulated amortization         Balance at 31.12.15         122,768         105,905         16,080         0         244,75           Amortization for the year         15,651         9,192         623         0         25,46           Write-downs         0         0         0         0         0           Disposals         (46)         (101)         (270)         0         (41)           Changes in reporting entities         1,788         4,557         77         0         6,42           Other changes         1,722         (976)         (142)         0         60           Balance at 31.12.16         141,883         118,577         16,368         0         276,82	Additions	212	1,022	1,082	15,492	17,808
Changes in reporting entities         4,790         42,057         118         1,074         48,03           Other changes         7,824         196         128         (1,331)         6,81           Balance at 31.12.16         331,194         190,565         18,221         16,732         556,71           Accumulated amortization         Balance at 31.12.15         122,768         105,905         16,080         0         244,75           Amortization for the year         15,651         9,192         623         0         25,46           Write-downs         0         0         0         0         0           Disposals         (46)         (101)         (270)         0         (41)           Changes in reporting entities         1,788         4,557         77         0         6,42           Other changes         1,722         (976)         (142)         0         60           Balance at 31.12.16         141,883         118,577         16,368         0         276,82	Write-downs	(550)	(58)	0	(5,254)	(5,862)
in reporting entities         4,790         42,057         118         1,074         48,03           Other changes         7,824         196         128         (1,331)         6,81           Balance at 31.12.16         331,194         190,565         18,221         16,732         556,71           Accumulated amortization           Balance at 31.12.15         122,768         105,905         16,080         0         244,75           Amortization for the year         15,651         9,192         623         0         25,46           Write-downs         0         0         0         0         0           Disposals         (46)         (101)         (270)         0         (41)           Changes in reporting entities         1,788         4,557         77         0         6,42           Other changes         1,722         (976)         (142)         0         60           Balance at 31.12.16         141,883         118,577         16,368         0         276,82	Disposals	(79)	(210)	(88)	(916)	(1,293)
Balance at 31.12.16         331,194         190,565         18,221         16,732         556,71           Accumulated amortization           Balance at 31.12.15         122,768         105,905         16,080         0         244,75           Amortization for the year         15,651         9,192         623         0         25,46           Write-downs         0         0         0         0         0           Disposals         (46)         (101)         (270)         0         (41)           Changes in reporting entities         1,788         4,557         77         0         6,42           Other changes         1,722         (976)         (142)         0         60           Balance at 31.12.16         141,883         118,577         16,368         0         276,82	•	4,790	42,057	118	1,074	48,039
Accumulated amortization         Balance at 31.12.15       122,768       105,905       16,080       0       244,75         Amortization for the year       15,651       9,192       623       0       25,46         Write-downs       0       0       0       0         Disposals       (46)       (101)       (270)       0       (41)         Changes in reporting entities       1,788       4,557       77       0       6,42         Other changes       1,722       (976)       (142)       0       60         Balance at 31.12.16       141,883       118,577       16,368       0       276,82	Other changes	7,824	196	128	(1,331)	6,817
Balance at 31.12.15       122,768       105,905       16,080       0       244,75         Amortization for the year       15,651       9,192       623       0       25,46         Write-downs       0       0       0       0         Disposals       (46)       (101)       (270)       0       (41)         Changes in reporting entities       1,788       4,557       77       0       6,42         Other changes       1,722       (976)       (142)       0       60         Balance at 31.12.16       141,883       118,577       16,368       0       276,82	Balance at 31.12.16	331,194	190,565	18,221	16,732	556,712
Amortization for the year         15,651         9,192         623         0         25,460           Write-downs         0         0         0         0           Disposals         (46)         (101)         (270)         0         (41)           Changes in reporting entities         1,788         4,557         77         0         6,42           Other changes         1,722         (976)         (142)         0         60           Balance at 31.12.16         141,883         118,577         16,368         0         276,82	Accumulated amortiz	zation				
for the year         15,651         9,192         623         0         25,46           Write-downs         0         0         0         0           Disposals         (46)         (101)         (270)         0         (41)           Changes in reporting entities         1,788         4,557         77         0         6,42           Other changes         1,722         (976)         (142)         0         60           Balance at 31.12.16         141,883         118,577         16,368         0         276,82	Balance at 31.12.15	122,768	105,905	16,080	0	244,753
Disposals         (46)         (101)         (270)         0         (41)           Changes in reporting entities in reporting entities         1,788         4,557         77         0         6,42           Other changes         1,722         (976)         (142)         0         60           Balance at 31.12.16         141,883         118,577         16,368         0         276,82	/ IIII OI CILCICITI	15,651	9,192	623	0	25,466
Changes in reporting entities         1,788         4,557         77         0         6,42           Other changes         1,722         (976)         (142)         0         60           Balance at 31.12.16         141,883         118,577         16,368         0         276,82	Write-downs	0	0	0	0	0
in reporting entities         1,788         4,557         77         0         6,42           Other changes         1,722         (976)         (142)         0         60           Balance at 31.12.16         141,883         118,577         16,368         0         276,82	Disposals	(46)	(101)	(270)	0	(417)
Balance at 31.12.16 141,883 118,577 16,368 0 276,82	•	1,788	4,557	77	0	6,422
	Other changes	1,722	(976)	(142)	0	604
Carrying amount at	Balance at 31.12.16	141,883	118,577	16,368	0	276,828
	Carrying amount at					
31 December 2016 189,311 71,988 1,853 16,732 279,88	31 December 2016	189,311	71,988	1,853	16,732	279,884
31 December 2015 196,229 41,653 901 7,667 246,45	31 December 2015	196,229	41,653	901	7,667	246,450

All intangible assets have a finite useful life and are amortized over a period not exceeding 20 years.

The additions during the period include:

 € 10.0 million paid to Gedeon Richter at the signing of an exclusive license agreement for the commercialization of cariprazine, a novel atypical antipsychotic drug, in Western Europe, Algeria, Tunisia and Turkey.  € 4.0 million for the second milestone due under the license agreement entered into in 2014 with Plethora Solutions Limited and Plethora Solutions Holdings Plc covering the commercialization of Fortacin<sup>™</sup>, a topical spray formulation of lidocaine and prilocaine for the treatment of premature ejaculation.

Following the revision of the expected future benefits to be derived from the commercialization of the relative products, the value of some intangible assets were written down. The reduction in value involved mainly Fortacin<sup>TM</sup>, for an amount of  $\in$  5.3 million, and Vitaros® (alprostadil) for an amount of  $\in$  0.6 million (See Note 4).

The intangible assets belonging to the recently acquired company Italchimici S.p.A. at the date of acquisition are included under "Changes in reporting entities" for a net amount of  $\in$  36.3 million, of which  $\in$  35.0 million are relative to the Reuflor® brands, one of the company's main products for gastroenterological use.

"Changes in reporting entities" also include the value of Pro Farma AG's intangible assets for an amount of  $\in$  5.3 million. Of this amount  $\in$  2.3 million are relative to the allocation to Urocit®, a drug to prevent urinary calculosis, to bring its book value in line with its fair value calculated during the acquired assets and liabilities identification process. Based on the knowledge of the market in which the acquired company operates and taking into account the historical sales trend of the product, the useful life of the asset is estimated to be of 10 years.

The conversion into Euros of intangible assets booked in different currencies resulted in a net increase of  $\in$  5.9 million compared to their value at 31 December 2015, of which  $\in$  5.2 million is attributable to the revaluation of the Russian Ruble,  $\in$  2.1 million to the revaluation of the U.S. Dollar and  $\in$  1.4 million to the devaluation of the Turkish Lira.

#### 9. GOODWILL

Goodwill at 31 December 2016 and 2015 amounted to € 556.6 million and € 453.3 million respectively and changed as follows:

€ (thousands)	Goodwill
Cost	
Balance at 31.12.15	490,949
Change in reporting entities (Italchimici S.p.A.)	105,303
Change in reporting entities (Pro Farma AG)	8,485
Exchange rate adjustments	(10,507)
Balance at 31.12.16	594,230
Accumulated amortization	
Balance at 31.12.15	37,664
Changes during the year	0
Balance at 31.12.16	37,664
Carrying amount at	
31 December 2016	556,566
31 December 2015	453,285

As prescribed by IFRS 3, the value of the companies acquired during the year, Italchimici S.p.A. and Pro Farma AG, has been allocated.

The acquisition of Italchimici S.p.A. determined and increase of € 105.3 million. The entire difference between the amount paid and the book value of the assets and liabilities acquired was allocated to goodwill. The measurement of the fair value of the company's assets and liabilities at the date of acquisition did not result in the identification of any item to which allocate the amount paid the company. We believe that the value of the acquisition resides in its strategic nature and in the possibility of generating operating synergies. The allocation is not yet definite, as allowed by IFRS 3.

With respect to the Swiss company Pro Farma AG, the measurement of the fair value of the company's assets and liabilities at the date of acquisition resulted in the identification of an increased value of the intangible assets acquired, and in particular of Urocit®, the fair value of which is higher than its book value. Therefore, an amount of  $\in$  2.3 million of the difference between the amount paid and the book value of the assets and liabilities acquired was allocated to this intangible asset to bring its book value in line with its fair value (see Note 8.). An amount of  $\in$  0.3 million was allocated to the relative deferred tax liabilities and the remaining  $\in$  8.5 million were allocated to goodwill. The allocation is not yet definite, as allowed by IFRS 3.

The exchange rate adjustments are related to the goodwill associated with the acquisitions made in countries having currencies different from the euro: goodwill calculated in local currency is translated into euros for the preparation of the consolidated financial accounts using the year-end exchange rates. An overall decrease of  $\in$  10.5 million as compared to 31 December 2015 resulted. In particular, the goodwill associated with the acquisitions in Turkey, Tunisia and Poland decreased respectively by  $\in$  11.2 million,  $\in$  2.4 million and  $\in$  0.5 million, while the goodwill associated with the acquisitions in Russia and in Switzerland increased respectively by  $\in$  3.5 million and  $\in$  0.1 million.

Net goodwill at 31 December 2015, amounting to  $\in$  556.6 million, relates to the following operational areas, which represent the same number of cash generating units:

- France: € 45.8 million;
- Russia: € 29.1 million;
- Germany: € 48.8 million;
- Portugal: € 32.8 million;
- Treatments for rare diseases business: € 110.6 million;
- Turkey: € 67.1 million;
- Czech Republic: € 13.1 million;
- Romania: € 0.2 million;
- Poland: € 14.9 million;
- Spain: € 58.1 million;
- Tunisia: € 22.2 million;
- Italy: € 105.3 million;
- Switzerland: € 8.6 million.

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

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

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

Operating cash flow forecasts for the explicit period assumed for the calculation were taken from the 2017-2019 Business Plan approved by the Board of Directors of the Parent on 9 February 2017.

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	4.34%
Russia	10.99%
Germany	3.80%
Portugal	8.82%
Business dedicated to treatments for rare diseases	4.34%
Turkey	12.48%
Czech Republic	4.31%
Poland	7.30%
Spain	5.30%
Tunisia	14.13%
Italy	6.53%
Switzerland	3.57%

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 2016 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:

	Balance sheet value		Percentage of equity owned	
€ (thousands)	31.12.16	31.12.15	31.12.16	31.12.15
PureTech Health p.l.c., United Kingdom	13,216	21,218	4.0%	4.0%
Erytech Pharma S.A., France	5,922	11,043	4.9%	5.4%
Tecnofarmaci S.p.A., Italy	27	87	4.2%	4.2%
Codexis Inc., U.S.A.	22	5	n.s.	n.s.
Fluidigm Corp., U.S.A.	7	10	n.s.	n.s.
Consorzio C4T, Italy	1	77	n.s.	n.s.
Others	4	4	n.s.	n.s.
Total equity investments	19,199	32,444		

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 2016 the overall fair value of the 9.554.140 shares held is of  $\in$  13.2 million. The  $\in$  8.0 million decrease in value compared to that at 31 December 2015 is booked as a loss for the period recognized directly in equity, net of the relative tax effect, and shown on the statement of comprehensive income.

Erytech Pharma S.A. is a French biopharmaceutical company focused on orphan oncology and rare diseases. The original investment of  $\in$  5.0 million consisted of a non-interest bearing loan which was converted into 431,034 shares in May 2013. The value of the investment was decreased by  $\in$  5.1 million as compared to that at 31 December 2015 to take into account its fair value. The after-tax difference was booked to equity and recognized in the statement of comprehensive income.

#### 11. OTHER NON CURRENT ASSETS

Receivables included in non-current assets at 31 December 2016 are  $\in$  5.4 million and refer mainly to guarantee deposits on rental and service contracts.

#### 12. DEFERRED TAX ASSETS

Deferred tax assets at 31 December 2016 and 2015 amount to  $\leqslant$  37.2 million and  $\leqslant$  30.5 million respectively. The main deferred tax assets and their change are analyzed below.

€ (thousands)	2016	2015
Balance at 1 January	30.500	33,021
Additions	11.941	6,417
Utilizations	(5.210)	(8,938)
Balance at 31 December	37.231	30.500

€ (thousands)	Previous years' losses	Profit and loss temporary differences	Other	Total
Balance at 31.12.2015	4,377	13,799	12,324	30,500
Additions	1,444	5,536	4,961	11,941
Utilization	(3)	(4,658)	(549)	(5,210)
Balance at 31.12.2016	5,818	14,677	16,736	37,231

"Other" deferred tax assets refers mainly to temporary differences arising from the elimination of unrealized gains on intercompany transactions.

#### 13. INVENTORIES

Inventories at 31 December 2016 and 2015 amount to  $\in$  158.8 million and  $\in$  143.1 million respectively, net of their respective obsolescence provisions of  $\in$  4.4 million and  $\in$  4.9 million. Composition of inventories is as follows:

€ (thousands)	31.12.2016	31.12.2015	Change 2016/2015
Raw materials and supplies	43,185	41,242	1,943
Intermediates and work-in-process	26,606	28,231	(1,625)
Finished goods	89,009	73,620	15,389
Total inventories	158,800	143,093	15,707

The increase is partly due the consolidation of the recently acquired companies, the effect of which is overall of  $\leqslant$  5.7 million, at their respective consolidation dates.

#### 14. TRADE RECEIVABLES

Trade accounts receivable at 31 December 2016 and 2015 amount to € 206.0 million and € 177.2 million respectively. These are shown net of the allowance for doubtful accounts which at 31 December 2016 is € 14.8 million (€ 13.3 million at 31 December 2015) and is considered to be sufficient to cover potential losses of certain receivables which, due to the nature of the customers in question or the destination markets, may be difficult to collect. Average days of sales outstanding are 61, compared to 59 at 31 December 2015.

Trade accounts receivable in the accounts of Italchimici S.p.A. and Pro Farma AG at their initial consolidation dates are of  $\in$  7.2 million and  $\in$  1.0 million respectively.

#### 15. OTHER RECEIVABLES

Other receivables amount to € 31.0 million, an increase of € 2.1 million compared to those at 31 December 2015, and their breakdown is as follows:

€ (thousands)	31.12.2016	31.12.2015	Change 2016/2015
Tax receivable	18.756	22.278	(3.522)
Balances due from employees and agents	8.062	2.500	5.562
Other	4.156	4.105	51
Total other receivables	30.974	28.883	2.091

Tax receivable comprises value added tax (VAT) receivable (€ 10.3 million) and advance payments of income tax. Receivables from employees and agents comprise advances on expense accounts and other credits. Under "Other" are included advances paid to suppliers and other parties and to computed credits under licensing-in agreements. The initial consolidation of the companies recently acquired accounts for an overall amount of €.2.3 million.

#### 16. OTHER CURRENT ASSETS

At 31 December 2016 other current assets amount to € 5.5 million (€ 5.3 million at 31 December 2015) and relate mainly to prepaid expenses.

## 17. FAIR VALUE OF HEDGING DERIVATIVES

At 31 December 2016 the value of hedging derivatives included under this account is of  $\in$  12.5 million.

The cross currency swaps covering the cash flows related to the notes issued and privately placed on 30 September 2014, for an amount of \$75 million, measured at fair value at 31 December 2016 give rise to a  $\in$  12.0 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  $\in$  8.0 million, and that covering the \$25 million tranche of the loan, provided by UniCredit, yielded a  $\in$  4.0 million positive value change.

In November 2016, following two loan agreements undersigned by the U.S. company Recordati Rare Diseases and the Parent for a nominal total of \$ 70 million (corresponding to the two tranches of the notes issued by Recordati Rare Diseases in 2013), two cross currency swaps were provided by Unicredit which effectively convert the loan into a total of  $\in$  62.9 million, of which  $\in$  35.9 million at a fixed interest rate of 1.56% per year corresponding to the tranche expiring in 2023 and  $\in$  27.0 million at a fixed interest rate of 1.76% per year for the tranche expiring in 2025. At 31 December 2016 the fair value of the hedging instruments is of  $\in$  0.5 million, recognized directly in equity.

## 18. SHORT TERM FINANCIAL INVESTMENTS, CASH AND CASH EQUIVALENTS

A break down is shown in the following table.

€ (thousands)	31.12.2016	31.12.2015	Change 2016/2015
Short term time deposits	21,323	52,520	(31,197)
Deposits in bank current accounts	117,130	172,965	(55,835)
Cash on hand	40	40	0
Total short term financial investments, cash and cash equivalents	138,493	225,525	(87,032)

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

At 31 December 2016 cash and cash equivalents are denominated in euro (92.8 million), in pounds sterling (19.0 million, mainly in the U.K. subsidiaries) and in U.S. dollars (12.1 million, mainly in the U.S. subsidiary Recordati Rare Diseases).

#### 19. SHAREHOLDERS' EQUITY

**Share capital** - At 31 December 2016 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.

As at 31 December 2016 the Company has two 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 and the 2014-2018 plan under which options were granted on 29 July 2014 and on 13 April 2016. 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 2016 are analyzed in the following table.

		Options outstanding at 1.1.2016	Options granted during 2016	Options exercised during 2016		Options outstanding at 31.12.2016
Date of grant						
9 February 2011	6.7505	1,372,500	-	(770,000)	(5,000)	597,500
8 May 2012	5.3070	*2,285,000	-	(850,000)	(10,000)	1,425,000
17 April 2013	7.1600	142,500	-	(22,500)	-	120,000
30 October 2013	8.9300	270,000	-	(90,000)	(25,000)	155,000
29 July 2014	12.2900	5,735,000	-	(980,000)	(225,000)	4,530,000
13 April 2016	21.9300	-	3,973,000	-	-	3,973,000
Total		9,805,000	3,973,000	(2,712,500)	(265,000)	10,800,500

<sup>\*</sup> An increase of 25,000 options compared to those at 31 December 2015 following the recalculation of options cancelled.

**Additional paid-in capital** - At 31 December 2016 additional paid-in capital is € 83.7 million, unchanged compared to the preceding year.

**Treasury stock** – At 31 December 2016, 3,891,262 shares are held as treasury stock, an increase of 205,904 shares compared to those held at 31 December 2015. The change is due to the sale of 2,712,500 shares, for an amount of € 22.7 million, to service the exercise of options granted to company employees under the stock option plans, and to the purchase of 2,918,404 shares for an amount of € 71.6 million. The total cost incurred for the purchase of current treasury stock is € 76.8 million and the average purchase price per share is € 19.73.

Hedging reserve – In accordance with IAS 39, 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 2016 this fair value measurement gives rise to a net liability, after-tax, of € 7.4 million.

**Other reserves** – These amount to € 35.3 million at 31 December 2016, a decrease of € 7.2 million compared to those at 31 December 2015. 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 € 15.4 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 € 7.9 million and € 0.5 million respectively. The recognition of the after-tax gains associated with the investments in Puretech Health and in Erytech Pharma determined an overall positive effect of € 6.3 million (of which € 5.7 million attributable to Puretech Health and € 0.6 million to Erytech Pharma).

Retained earnings and net income for the year – These amount to € 756.0 million at 31 December 2016 and increase by € 70.4 million as compared to 31 December 2015. Net income for the year is € 237.4 million, an increase of 19.4% compared to the € 198.8 million 2015 net income.

The shareholders' equity of the Italian companies includes untaxed reserves of  $\in$  101.1 million, net of  $\in$  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 2016 of  $\in$  0.35 per share, for a total amount of  $\in$  72.2 million.

#### **20. MINORITY INTEREST**

All consolidated companies are 100% owned except for the Italian subsidiary of Orphan Europe which is 99% owned and the Tunisian company Opalia Pharma which is 90% owned. The latter has however been 100% consolidated by applying the anticipated acquisition method allowed by IAS 32. Consequently, the amount estimated for the acquisition of the remaining 10% (€ 2.5 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 minority shareholders during the period until all capital shares are transferred.

#### **21. LOANS**

At 31 December 2016 medium and long-term loans total  $\in$  334.1 million. The net increase of  $\in$  17.0 million compared to 31 December 2015 was determined by the granting of new loans for an amount of  $\in$  50.1 million, reimbursements during the year of  $\in$  34.0 million and the effect of the conversion of loans in foreign currency which generated an increase of  $\in$  0.9 million.

The composition of medium and long-term loans at 31 December 2016 and 2015 is shown in the following table:

€ (thousands)	31.12.2016	31.12.2015
Loans granted to Recordati S.p.A.:		
Guaranteed senior notes issued by Recordati S.p.A. privately placed with international institutional investors in 2014: \$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%.	*70,860	68,571
Loan granted by Centrobanca, at variable interest rate covered by an interest rate swap, repayable in semi-annual installments starting 2012 through 2022	*40,778	47,574
Loan granted by UniCredit, at variable interest rate partly covered by an interest rate swap, repayable in semi-annual installments starting 2015 through 2020	*34,669	44,557
Loan granted by Banca Nazionale del Lavoro, at variable interest rate covered by an interest rate swap, repayable in semi-annual installments starting 2015 through 2018	*24,781	37,156
Loan granted by ING Bank, at variable interest rate covered by an interest rate swap, repayable in semi-annual installments starting 2016 through 2020	*26,160	29,880
Loan granted by Banca Nazionale del Lavoro, at variable interest rate covered by an interest rate swap, repayable in semi-annual installments starting 2019 through 2020	*24,950	-
Loan granted by Intesa Sanpaolo, at variable interest rate covered by an interest rate swap, repayable in semi-annual installments starting 2019 through 2021	*24,925	-
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)	*65,896	63,744
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	*18,215	22,197
Loan granted by ING Bank to Recordati llaç for an amount of TRY 5.9 million, at a fixed interest rate of 13.25%, repayable in a single installment in 2018	1,586	1,851
Various loans granted to Opalia Pharma S.A. due within 2019	890	1,167
Various interest-free loans granted to Casen Recordati due within 2021	335	387
Loan granted to Opalia Recordati due within 2021	27	-
Total amortized cost of loans	334,072	317,084
Portion due within one year	40,428	34,469
Portion due after one year	293,644	282,615

<sup>\*</sup> Net of direct issue costs for a total of € 2.0 million amortized using the effective interest method (private placement by Recordati S.p.A. € 0.3 million, Centrobanca € 0.1 million, Banca Nazionale del Lavoro € 0.2 million, UniCredit € 0.3 million, ING Bank € 0.1 million, Banca Nazionale del Lavoro € 0.1 million, Intesa Sanpaolo € 0.1 million, private placement by Recordati Rare Diseases € 0.5 million, IFC-World Bank € 0.3 million).

At 31 December 2016, the repayment schedule of long-term debt due after 31 December 2017 is as follows:

€ (thousands)	
2018	41,771
2019	48,583
2020	39,312
2021	18,414
2022 and subsequent years	145,564
Total	293,644

The average effective interest rate at 31 December 2016, applying the rates resulting from the hedging instruments, is 2.68%.

In December 2016 a loan agreement with Banca Nazionale del Lavoro was undersigned by the Parent company for an amount of € 25.0 million, disbursed net of expenses and commissions of € 0.1 million. The main terms and conditions provide for variable interest rate fixed at the six months Euribor plus a spread of 40 basis points and a duration of 4 years with semi-annual repayments of capital from March 2019 through September 2020. The loan is entirely covered with an interest rate swap, qualifying as a cash flow hedge, effectively converting the interest charges from variable to a fixed rate of 0.41%. The measurement at fair value at 31 December 2016 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 29). 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 were amply fulfilled.

Also in December 2016 a loan agreement with Intesa Sanpaolo was undersigned by the Parent company for an amount of € 25.0 million, disbursed net of expenses and commissions of € 0.1 million. The main terms and conditions provide for variable interest rate fixed at the six months Euribor plus a spread of 60 basis points and a duration of 5 years with semi-annual repayments of capital from June 2019 through December 2021. The loan is entirely covered with an interest rate swap, qualifying as a cash flow hedge, effectively converting the interest charges from variable to a fixed rate of 0.68%. The measurement at fair value at 31 December 2016 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 29). 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 were amply fulfilled.

The other main long-term loans outstanding are:

- a) A loan agreement with ING Bank undersigned by Recordati Ilaç on 30 November 2015 for an amount of 5.9 million Turkish lira to be repaid on 22 March 2018. Main terms are: fixed interest rate of 13.25%, quarterly payment of interest accrued and reimbursement of the entire principal at expiry date. The conversion of the loan into euros at 31 December 2016 resulted in an amount of € 1.6 million, a reduction of the liability by € 0.3 million as compared to that at 31 December 2015 due to the devaluation of the Turkish lira with respect to the currency exchange rate at consolidation.
- b) A loan agreement with UniCredit undersigned by the Parent company in May 2015 for an amount of € 50.0 million. The main terms and conditions provide for variable interest rate fixed at the six months Euribor plus a spread of 80 basis points and a duration of 5 years with semi-annual repayments of capital from November 2015 through May 2020. The residual amount of the loan at 31 December 2016 is of € 34,7 million. The loan is partly covered with an interest rate swap, qualifying as a cash flow hedge, effectively converting the interest charges on a portion of the debt from variable to a fixed rate of 1.734%. The measurement at fair value at 31 December 2016 of the swap covering € 25.0 million 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 29). 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 were amply fulfilled.

- c) A loan agreement with ING Bank for an amount of € 30.0 million, originally undersigned by the Parent company on 8 January 2014, was re-negotiated on 12 June 2015 with only the interest rate being changed. Main terms are: variable interest rate equivalent to the six months' euribor plus a spread of 85 basis points (as opposed to the 190 basis points in the previous agreement), and reimbursement of principal at the end of every six months starting July 2016 through January 2020. The debt outstanding at 31 December 2016 is of € 26.2 million. The loan was simultaneously covered with an interest rate swap qualifying as a cash flow hedge transforming the interest payable on the entire debt to a fixed interest rate of 1.913% following the above mentioned re-negotiation. The fair value measurement of the swap at 31 December 2016 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 29). The ING Bank loan agreement contains covenants which, if not met, could lead to a request for immediate repayment of the loan. The financial covenants are the following:
  - the ratio of consolidated net debt to consolidated EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;
  - the ratio of consolidated operating income to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions are amply fulfilled.

- d) A loan agreement with IFC-World Bank undersigned by the subsidiary Recordati Ilaç on 16 October 2014 for an amount of 71.6 million Turkish lira to finance the construction of a new production plant. Main terms are: variable interest rate equivalent to the three months' trlibor plus a spread of 162 basis points, 8-year duration and reimbursement of principal at the end of every three months starting November 2016 through August 2022. The debt outstanding at 31 December 2016 is of € 18.2 million, a reduction of € 4.0 million compared to that at 31 December 2015, of which € 3.1 million due to the devaluation of the Turkish Iira with respect to the currency exchange rate at 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 amply fulfilled.

e) Privately placed guaranteed senior notes privately placed 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 2016 resulted in an increase of the liability by € 2.3 million as compared to that at 31 December 2015 due to the revaluation of the U.S. dollar with respect to the currency exchange rate at consolidation. The loan was simultaneously covered with two cross currency 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 15year tranche. At 31 December 2016 the measurement at fair value of the hedging instruments generated an overall positive amount of € 12.0 million recognized directly to equity and stated as an increase of the 'Fair value of hedging derivatives (cash flow hedge)' under current assets (see Note 17).

The note purchase agreement covering the senior guaranteed notes issued by Recordati S.p.A. includes covenants which, if not met, could lead to a request for immediate repayment of the loan. The financial covenants are the following:

- the ratio of consolidated net debt to consolidated EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;
- the ratio of consolidated operating income to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions were amply fulfilled.

f) A loan agreement with Banca Nazionale del Lavoro undersigned by the Parent Company on 30 September 2013 for an amount of € 50 million, cashed-in net of expenses and commissions of € 0.6 million. Main terms are: variable interest rate equivalent to the six months' euribor plus a spread (which following a re-negotiation of the agreement was reduced from 200 to 70 basis points as from 1 April 2015) and 5-year duration with reimbursement of principal in 8 installments due at the end of every six months starting March 2015 through September 2018. The residual amount of the loan amounts to € 24.8 million at 31 December 2016. 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 which now stands at 1.6925% following re-negotiation. The measurement at fair value of the swap at 31 December 2016 generated a liability of € 0.3 million recognized directly in equity and under current

liabilities as 'Fair value of hedging derivatives (cash flow hedge)' (see Note 29). The loan agreement contains covenants which, if not met, could lead to a request for immediate repayment of the loan. The financial covenants are the following:

- the ratio of consolidated net debt to consolidated EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;
- the ratio of consolidated operating income to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions are amply fulfilled.

- g) Senior guaranteed notes issued by Recordati Rare Diseases Inc. privately placed with U.S. investors on 13 June 2013 to fund the acquisition of a portfolio of products for the treatment of rare and other diseases sold mainly in the United States of America. The loan comprises two series of notes for a total of \$ 70 million, of which \$ 40 million ten-year bullet and 4.55% coupon and \$ 30 million twelve-year bullet and 4.70% coupon. The conversion of the loan into euros at 31 December 2016 resulted in an increase of the liability by € 2.1 million as compared to that at 31 December 2015 due to the revaluation of the U.S. dollar. The note purchase agreement covering the senior guaranteed notes issued by Recordati Rare Diseases Inc. includes covenants which, if not met, could lead to a request for immediate repayment of the loan. The financial covenants are the following:
  - the ratio of consolidated net debt to consolidated EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;
  - the ratio of consolidated operating income to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.

The above conditions were amply fulfilled.

- h) A loan agreement with Centrobanca undersigned by the Parent company on 30 November 2010 to fund a three-year research and investment program. The loan, for which Centrobanca received funding from the European Investment Bank, amounts to € 75.0 million of which € 30.0 million were cashed in during 2010 and € 45.0 million in the first quarter of 2011, net of the € 0.3 million expenses. The main terms and conditions provide for a variable interest rate and a duration of 12 years with semi-annual repayments of capital from June 2012 through December 2022. The residual amount of the loan amounts to € 40.8 million at 31 December 2016. 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 2016 generated a liability of € 2.0 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 29). The loan agreement includes covenants which, if not met, could lead to a request for immediate repayment of the loan. The financial covenants are the following:
  - the ratio of consolidated net debt to consolidated net equity must be less than 0.75;
  - the ratio of consolidated net debt to consolidated EBITDA (for a period of twelve consecutive months) must be less than 3.00 to 1.00;
  - the ratio of consolidated EBITDA to consolidated net interest expense (for a period of twelve consecutive months) must exceed 3.00 to 1.00.
     The above conditions were amply fulfilled.

#### 22. STAFF LEAVING INDEMNITIES

This provision at 31 December 2016 and 2015 is € 21.7 million and € 18.9 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)	2016	2015
Balance at 1 January	18,895	18,388
Additions	1,660	1,914
Utilization	(688)	(1,138)
Change in reporting entities	1,507	-
Change in fair value	301	(269)
Balance at 31 December	21,675	18,895

The main part of this liability is to be attributed to the staff leaving indemnity fund *(TFR, trattamento fine rapporto)* in the Italian companies. The value of this fund as measured in accordance with IAS 19 amounts to  $\in$  14.3 million. The remaining part of this provision comprises employee benefit plans in the French subsidiary Laboratoires Bouchara Recordati ( $\in$  3.4 million), in the U.S. subsidiary Recordati Rare Diseases ( $\in$  1.9 million) and in the Orphan Europe group companies ( $\in$  0.9 million). The fair value calculation made using actuarial parameters updated at 31 December 2016 determined an adjustment of  $\in$  0.3 million compared to the value of the funds at 31 December 2015 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 2016 are  $\in$  27.7 million, a net increase of  $\in$  5.3 million over the balance at 31 December 2015. The roll forward of this account is as follows:

€ (thousands)	2016	2015
Balance at 1 January	22,360	21,553
Additions	1,094	5,056
Utilization	(5,392)	(4,249)
Changes in reporting entities	9,597	-
Balance at 31 December	27,659	22,360

Utilization during the year includes the deferred tax liability reductions of  $\in$  2.3 million and  $\in$  1.8 million resulting from the decrease in value of the holdings in Puretech Health plc and Erytech Pharma S.A. respectively as compared to that at 31 December 2015.

Changes in reporting entities refer mainly to the tax effect of € 10.1 million relative to the value allocated to the products sold under the Reuflor® brand.

At 31 December 2016 no deferred tax liabilities were calculated on subsidiaries' undistributed earnings because no significant additional tax would have to be paid by the group in the event of these dividend distributions as they are essentially exempt from dual income taxation.

#### 24. OTHER NON-CURRENT LIABILITIES

Other non-current liabilities as at 31 December 2016 are  $\leqslant$  2.5 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 2018.

#### 25. TRADE PAYABLES

Trade accounts payable, which are entirely of a commercial nature and include allocations for invoices to be received, at 31 December 2016 and 2015 amount to  $\in$  124.6 million and  $\in$  106.6 million respectively. The initial consolidation of the recently acquired companies accounts overall for an amount of  $\in$  11.0 million.

#### **26. OTHER PAYABLES**

Other accounts payable at 31 December 2016 and 2015 amount to  $\in$  78.0 million and  $\in$  72.4 million respectively. Their composition is as follows:

€ (thousands)	31.12.2016	31.12.2015	Change 2016/2015
Personnel	28,554	25,982	2,572
Social security	14,253	13,530	723
Agents	963	846	117
Balance due for the acquisition of equity	0	586	(586)
Other	34,187	31,407	2,780
Total other payables	77,957	72,351	5,606

The line "Other" includes:

- € 6.6 million due by Recordati Rare Diseases Inc. to the U.S. healthcare insurance schemes;
- € 3.5 million to be paid to the "Krankenkassen" (German healthcare schemes) by Recordati Pharma GmbH;
- € 4.4 million which results from a mandatory discount of 1.83% on the retail selling price of reimbursed medicines and the contribution in substitution of a 5% price reduction on selected products to be paid by the Italian companies to the Italian regional healthcare systems.

In July the last price installment of  $\in$  0.6 million for the acquisition of the Polish company Farma Project was paid. The effect arising from the consolidation of Italchimici S.p.A. and Pro Farma AG is overall of  $\in$  5.0 million.

#### 27. TAX LIABILITIES

Tax liabilities at 31 December 2016 and 2015 amount to € 20.4 million and € 14.6 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.

#### 28. PROVISIONS

Provisions in place at 31 December 2016 amount to  $\in$  28.0 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)	31.12.2016	31.12.2015	Change 2016/2015
Tax	4,852	4,362	490
Other	23,125	25,038	(1,913)
Total provisions	27,977	29,400	(1,423)

€ (thousands)	2016	2015
Balance at 1 January	29,400	25,784
Additions	3,281	10,237
Change in reporting entities	2,232	-
Utilization	(6,936)	(6,621)
Balance at 31 December	27,977	29,400

The additions during the year are related mainly to accruals for organizational restructuring following the acquisition of Italchimici S.p.A.. Total provisions at year end are mainly comprised by those booked by the Parent and the other Italian companies ( $\in$  16.9 million), by the companies in France ( $\in$  3.2 million), in Spain ( $\in$  2.7 million) and in the U.S.A. ( $\in$  2.0 million).

## 29. 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 2016 give rise to a  $\in$  3.6 million liability which represents the unrealized benefit of paying the current expected future rates instead of the rates agreed for the duration of the loans. The liability refers to the interest rate swaps covering the interest rate risk on loans granted by Centrobanca (€ 2.0 million), Banca Nazionale del Lavoro (€ 0.3 million), lNG Bank (€ 0.6 million), by UniCredit (€ 0.5 million), by Intesa Sanpaolo (€ 0.1 million) and by the new loan of € 25 million granted by Banca Nazionale del Lavoro (€ 0.1 million).

## 30. BANK OVERDRAFTS AND SHORT-TERM LOANS

Bank overdrafts and short-term loans at 31 December 2016 are € 15.7 million and comprise mainly overdrafts, temporary use of lines of credit by foreign subsidiaries and by interest due on existing loans. At 31 December 2016, a total of 20 million Turkish Lira, for an equivalent amount of € 5.4 million, were drawn down on the revolving line of credit obtained in July 2015 by Recordati llaç, the subsidiary in Turkey, for a maximum amount of 40 million Turkish Lira. This short-term financing instrument, which has 24 months maximum duration, provides flexibility by combining the fact that it's non-revocable with the variability of the draw-downs based on specific financial needs. The agreement contains financial covenants in line with those already in place for other loans.

#### 31. ACQUISITION OF COMPANIES

The following table summarizes the effects of the consolidation at the date of acquisition of Italchimici S.p.A., the Italian company of which the group acquired 100% of the share capital on 31 May 2016.

€ (thousands)	Book value	Fair value adjustments	Fair value of assets and liabilities acquired
Non-current assets			
Property, plant and equipment	126	0	126
Intangible assets	36,322	0	36,322
Current assets			
Inventories	4,919	0	4,919
Trade receivables	7,227	0	7,227
Other receivables	2,099	0	2,099
Tax receivable	156	0	156
Other current assets	215	0	215
Short-term financial investments, cash and cash equivalents	25,681	0	25,681
Non-current liabilities			
Loans – due after one year	(1,507)	0	(1,507)
Deferred tax liabilities	(9,322)	0	(9,322)
Current liabilities			
Trade payables	(9,890)	0	(9,890)
Other payables	(4,775)	0	(4,775)
Tax liabilities	(578)	0	(578)
Provisions	(2,232)	0	(2,232)
Bank overdrafts and short-term loans	(47,450)	0	(47,450)
	991	0	991
Goodwill			105,303
Cost of the acquisition			106,294

The entire difference between the amount paid, adjusted contractually by  $\in$  1.3 million over the  $\in$  105,0 million paid at the closing, and the book value of the assets and liabilities acquired was allocated to goodwill. The measurement of the fair value of the company's assets and liabilities at the date of acquisition did not result in the identification of any item to which allocate the amount paid and it is deemed that the value of the acquisition resides in its strategic nature. The allocation is, however, not yet definite as allowed by IFRS 3.

Intangible assets acquired include the brands of Reuflor®, one of the main products in the portfolio, to which, following a recent extraordinary operation and based on independent third party estimates, the company allocated a value of  $\in$  36.0 million, of which  $\in$  35.0 million remained at the time of acquisition.

Bank loans acquired refer to short-term financing, which were immediately reimbursed following the acquisition using available liquidity and an intercompany loan.

The following table summarizes the effects of the consolidation at the date of acquisition of Pro Farma AG, the Swiss company of which the group acquired 100% of the share capital on 14 July 2016 and its Austrian subsidiary Pro Farma GmbH.

€ (thousands)	Book value	Fair value adjustments	Fair value of assets and liabilities acquired
Non-current assets			
Property, plant and equipment	152	0	152
Intangible assets	3,002	2,293	5,295
Current assets			
Inventories	806	0	806
Trade receivables	1,033	0	1,033
Other receivables	175	0	175
Tax receivable	160	0	160
Other current assets	34	0	34
Short-term financial investments, cash and cash equivalents	1,929	0	1,929
Non-current liabilities			
Deferred tax liabilities	0	(275)	(275)
Current liabilities			
Trade payables	(1,152)	0	(1,152)
Other payables	(240)	0	(240)
Tax liabilities	(71)	0	(71)
Bank overdrafts and short-term loans	(1,835)	0	(1,835)
	3,993	2,018	6,011
Goodwill			8,485
Cost of the acquisition			14,496

An amount of  $\in$  2.3 million from the difference between the amount paid and the book value of the assets and liabilities acquired was allocated to Urocit®, one of the company's main products. The remainder amounts to  $\in$  8.5 million, after deferred taxes of  $\in$  0.3 million arising from the value allocated to intangible assets, and was allocated to goodwill. The allocation is not yet definite, as allowed by IFRS 3.

Bank loans acquired refer to financing which at 31 December 2016 is fully reimbursed.

## 32. FAIR VALUE OF FINANCIAL INSTRUMENTS

As prescribed by IFRS 7 hereunder are stated the balance sheet values and fair values at 31 December 2016 of financial assets and liabilities:

€ (thousands)	Book value	Fair value
Financial assets		
Short-term financial investments, cash and cash equivalents	138,493	138,493
Trade receivables	205,988	205,988
Equity investments	19,199	19,199
Other receivables	30,974	30,974
Fair value of hedging derivatives _(cash flow hedge)  Financial liabilities	12,497	12,497
Borrowings		
- loans at variable interest rates	18,214	18,214
- loans at variable interest rates covered with interest rate swaps	176,263	176,263
- loans at fixed interest rates	2,838	2,855
<ul> <li>loans at fixed interest rates covered with cross currency swaps</li> </ul>	136,757	130,844
Trade payables	124,644	124,644
Other payables	98,389	98,389
Fair value of hedging derivatives (cash flow hedge)	3,621	3,621
Bank overdrafts and short-term loans	15,689	15,689

#### 33. DISCLOSURE OF FINANCIAL RISKS

The Group constantly monitors the financial risks to which it is exposed in order to take immediate mitigating action when necessary. The objective of group financial policy is to achieve a balanced and prudent financial structure in order to fund growth, both organic and through business expansion.

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 2016 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 2016, total trade receivables of € 220.8 million include € 20.4 million of receivables overdue by more than 90 days. Of these, € 1.1 million are receivables from Italian public hospitals which, despite their very long payment times, do not represent a significant risk situation. An allowance for doubtful accounts of € 14.8 million, which is considered to be sufficient to cover potential losses on collection, is in place.

Interest Rate Risk — The Group raises funds using debt and invests excess cash in money market and other financial instruments. The fluctuation of market interest rates influences the cost and returns of the debt and investment instruments therefore affecting the Group's net financial charges. The Group's policy is to limit the risk arising from interest rate fluctuations by establishing fixed interest loans or variable interest loans covered by derivative financial instruments, which are used to hedge risk and are never of a speculative nature, to minimize such fluctuations, as described in note 21. As a result of this policy and considering the current amount of net debt, it is believed that the change in current interest rates would not have a significant impact on net financial expenses.

**Foreign Currency Risk** – The Group is exposed to foreign currency exchange rate fluctuations which can affect its operating results and the value of its equity. All companies are subject to exchange rate fluctuations affecting trade and financial balances in currencies different from their own. In order to limit this risk, in some cases non speculative hedging instruments are negotiated.

As at 31 December 2016 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 1,570.9 million in Russian roubles; net receivables of 5.0 million in U.S. dollars; net receivables of 8.5 million in Tunisian dinars; net receivables of 2.2 million in Swiss francs; net receivables of 8.3 million in Romanian ron; net receivables of 3.1 million in Polish zloty.

Among the companies in countries outside the European Monetary Union, at 31 December 2016 the main net exposure in currencies different from their own, and not covered by hedging instruments, is in Euros and is referred to the companies in the Czech Republic (net receivables of 3.2 million), in Tunisia (net receivables of 1.2 million), in Sweden (net receivables of 1.2 million) and in Turkey (net debt of 2.9 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 2016 the net equity values of these companies are denominated mainly in U.S. dollars (108.7 million), in pounds sterling (18.3 million), in Swiss francs (8.8 million), in Turkish lira (166.7 million), in Czech crowns (306.3 million), in Romanian ron (5.1 million), in Russian roubles (2,016.7 million), in Polish zloty (4.3 million) and in Tunisian dinars (26.5 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 2016, is negative by  $\ensuremath{\in}$  78.3 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 2016 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 30 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. 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 pharmaceutical segment and the segment dedicated to treatments for rare diseases. The following table shows financial information for these two business segments as at 31 December 2016 and includes comparative data.

€ (thousands)	Pharmaceutical segment*	Rare diseases segment	Non- allocated	Consolidated accounts
2016				
Revenues	967,136	186,806	-	1,153,942
Expenses	(723,075)	(103,444)	-	(826,519)
Operating income	244,061	83,362	_	327,423
2015				
Revenues	894,546	153,130	-	1,047,676
Expenses	(678,899)	(90,260)	-	(769,159)
Operating income	215,647	62,870	_	278,517

<sup>\*</sup> Includes the pharmaceutical chemicals operations

€ (thousands)	Pharmaceutical segment*	Rare diseases segment	Non-C allocated**	consolidated accounts
31 December 2016				
Non-current assets	788,083	201,228	19,199	1,008,510
Inventories	140,939	17,861	-	158,800
Trade receivables	174,540	31,448	-	205,988
Other current assets	32,782	3,673	12,497	48,952
Short-term investments, cash and cash equivalents	-	_	138,493	138,493
Total assets	1,136,344	254,210	170,189	1,560,743
Non-current liabilities	48,602	2,926	293,965	345,493
Current liabilities	213,723	37,848	59,739	311,310
Total liabilities	262,325	40,774	353,704	656,803
Net capital employed	874,019	213,436		
31 December 2015				
Non-current assets	649,934	193,837	32,444	876,215
Inventories	127,643	15,450	-	143,093
Trade receivables	150,600	26,619	-	177,219
Other current assets	28,857	5,306	12,671	46,834
Short-term investments, cash and cash equivalents	-	-	225,525	225,525
Total assets	957,034	241,212	270,640	1,468,886
Non-current liabilities	39,770	1,919	284,698	326,387
Current liabilities	192,761	31,139	48,608	272,508
Total liabilities	232,531	33,058	333,306	598,895
Net capital employed	724,503	208,154		

<sup>\*</sup> Includes the pharmaceutical chemicals operations.

The pharmaceutical chemicals operations are considered part of the pharmaceutical segment as they are prevalently dedicated to the production of active ingredients for this business, both from a strategic and organizational point of view.

The following table presents net revenues by geographic area:

€ (thousands)	2016	2015	Change 2016/2015
Europe	911,681	828,034	83,647
of which Italy	237,615	211,570	26,045
Australasia	55,770	53,731	2,039
America	133,538	110,371	23,167
Africa	52,953	55,540	(2,587)
Total revenue	1,153,942	1,047,676	106,266

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.

<sup>\*\*</sup> Non-allocated amounts include: other equity investments, short-term investments, cash and cash equivalents, loans, hedging instruments, bank overdrafts and short-term loans.

#### **35. NET FINANCIAL POSITION**

The following table summarizes the Company's net financial position:

€ (thousands)	2016	2015	Change 2016/2015
Deposits in bank current accounts and cash on hand	117,170	173,005	(55,835)
Short-term time deposits	21,323	52,520	(31,197)
Liquid assets	138,493	225,525	(87,032)
Bank overdrafts and short-term loans	(15,689)	(9,849)	(5,840)
Loans - due within one year	(40,428)	(34,469)	(5,959)
Short term borrowings	(56,117)	(44,318)	(11,799)
Net current financial position	82,376	181,207	(98,831)
Loans - due after one year	(156,887)	(150,301)	(6,586)
Loan notes issued (1)	(124,260)	(119,643)	(4,617)
Non-current loans	(281,147)	(269,944)	(11,203)
Net financial position	(198,771)	(88,737)	(110,034)

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

## 36. 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:

	Sharehol	ders' equity	Net incon	ne for the year
€ (thousands)	31.12.2016	31.12.2015	2016	2015
Recordati S.p.A.	316,717	389,571	110,102	125,516
Consolidation adjustments:				
Margin in inventories	(29,090)	(25,662)	(3,428)	5,620
Related deferred tax	7,857	8,142	(285)	(1,732)
Other adjustments	(5,005)	(3,186)	(1,821)	(901)
Retained earnings of consolidated subsidiaries at beginning of the year, net of amounts already booked by Recordati S.p.A.	495,022	400,781	-	-
Net income for the year of consolidated subsidiaries, net of amounts already booked by Recordati S.p.A.	196,638	167,179	196,638	167,179
Dividends received from consolidated subsidiaries	-	-	(53,021)	(90,018)
Revaluation of holdings in controlled companies	-	-	(10,779)	(6,872)
Translation adjustments	(78,309)	(66,918)	-	-
Consolidated financial statements	903,830	869,907	237,406	198,792

## 37. LITIGATION AND CONTINGENT LIABILITIES

The parent company and some subsidiaries are party to certain legal actions, the outcomes of which are not expected to result in any significant liability.

On 29 September 2006 the Company received a notice of tax assessment from the Internal Revenue Service stating certain additional taxes for the fiscal year 2003 in the amount of: corporate tax of € 2.3 million, IRAP of € 0.2 million and VAT of € 0.1 million and additional tax liabilities of € 2.6 million. The Company believed no amount was due as it considered the assessment flawed both from a legitimacy as well as a substantive point of view, and was supported in its position by professional opinion. An appeal was therefore filed with the Provincial Tax Commission of Milan. The first degree judgement before the Provincial Tax Commission was concluded partially in the Company's favour with decision n. 539/33/07 dated 11 October 2007, filed on 16 October 2007. An appeal was filed against that judgment with the Regional Tax Commission of Milan firstly by the Milan office of the Tax Authorities with notice served on 8 November 2008 and secondly by the Company with notice served on 7 January 2009. With a decision dated June 10, 2009 n. 139/32/09, filed on November 27, 2009 the Regional Tax Commission of Milan rejected the interlocutory appeal presented by the Company and accepted the principal appeal of the Agenzia delle Entrate di Milano (Inland Revenue of Milan). On the basis of that decision, the claims included in the above mentioned tax assessment for the year 2003 have been essentially fully confirmed and the Company has paid all amounts due. On 26 May 2010 the Company appealed that decision before the Corte Suprema di Cassazione (Supreme Court of Cassation).

On 24 September 2014 the Italian Tax Police (Guardia di Finanza) visited Recordati S.p.A. as part of the general tax inspection regarding IRES (corporate income tax) and IRAP (regional value added tax) for the years 2010 through 2012. The 2010 inspection was concluded with a formal notice of assessment issued on 23 September 2015 in which the tax inspectors considered a cost item for services rendered for an amount of € 50,000 not to be sufficiently documented and therefore not deductible for income tax purposes. On 19 October 2015 the Company applied for a voluntary assessment procedure, which ended with the payment of the taxes and penalties owed by the Company.

On 26 July 2016, on the basis of the same tax audit of the Company above mentioned, the Italian Tax Police issued a Tax Audit Report for the 2011 tax year, and subsequent notice of assessment issued by the Internal Revenue Service, which, based on the issues raised in the Tax Audit Report, disallowed costs for services rendered for an amount of € 50,000 - an issue with regard to which a notice of assessment was already issued for 2010 - being not sufficiently documented. On 15 December 2016 the Company settled the dispute by accepting the remark in the notice of assessment without any challenging.

In December 2015 the same Italian Tax Police (Guardia di Finanza) notified the Company of their intention to commence a general income tax inspection covering the years 2009 through 2014 involving the group companies which reside in Ireland and in Luxembourg, Recordati Ireland Ltd and Recordati S.A. Chemical and Pharmaceutical Company respectively. The declared intention of the inspection is to evaluate the operational context of the foreign companies in order to verify whether said companies are in reality only formally localized abroad but are substantially managed/administered from Italy. After having analysed the documents and completed the investigation process, the Italian Tax Police preliminarily revealed to Recordati Ireland Ltd., on 13 February 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 € 95 million, against taxes of € 44 million already paid in Ireland. Similarly, the Italian Tax Police preliminarily revealed to Recordati S.A. Chemical and Pharmaceutical Company, on 22 February 2017, their reasons for considering the Luxembourg company subject to tax in Italy for corporate tax purposes in the reference period, resulting in an assessment of taxes allegedly owed to Italy, in the amount of € 5.5 million. The Company, supported in its position by professional opinion, maintains that the companies under inspection operate in such a way as to justify the correctness of the fiscal policy adopted. Therefore, no provisions are made in the consolidated accounts as a result of the above mentions inspections, also in consideration of available information at this stage of the activity

## RECORDATI S.p.A. AND SUBSIDIARIES SUBSIDIARIES INCLUDED IN THE CONSOLIDATED ACCOUNTS AT 31 DECEMBER 2016

#### **ATTACHMENT 1.**

Consolidated Companies	Head Office	Share Capital	Currency	Consolidation Method
RECORDATI S.P.A.  Development, production, marketing and sales of pharmaceuticals and pharmaceutical chemicals	Italy	26,140,644.50	Euro	Line-by-line
INNOVA PHARMA S.P.A. Marketing and sales of pharmaceuticals	Italy	1,920,000.00	Euro	Line-by-line
CASEN RECORDATI S.L. Development, production, marketing and sales of pharmaceuticals	Spain	238,966,000.00	Euro	Line-by-line
RECORDATI S.A. Chemical and Pharmaceutical Company Holding company	Luxembourg	82,500,000.00	Euro	Line-by-line
BOUCHARA RECORDATI S.A.S. Development, production, marketing and sales of pharmaceuticals	France	4,600,000.00	Euro	Line-by-line
RECORDATI PORTUGUESA LDA Dormant	Portugal	24,940.00	Euro	Line-by-line
RECORDATI RARE DISEASES COMERCIO DE MEDICAMENTOS LTDA Dormant, holds pharmaceutical marketing rights in Brazil	Brazil	166.00	BRL	Line-by-line
RECORDATI RARE DISEASES INC. Development, production, marketing and sales of pharmaceuticals	U.S.A.	11,979,138.00	USD	Line-by-line
RECORDATI IRELAND LTD Development, production, marketing and sales of pharmaceuticals	Ireland	200,000.00	Euro	Line-by-line
RECORDATI S.A. Marketing and sales of pharmaceuticals	Switzerland	2,000,000.00	CHF	Line-by-line
LABORATOIRES BOUCHARA RECORDATI S.A.S. Development, production, marketing and sales of pharmaceuticals	France	14,000,000.00	Euro	Line-by-line
RECORDATI PHARMA GmbH Marketing and sales of pharmaceuticals	Germany	600,000.00	Euro	Line-by-line
RECORDATI PHARMACEUTICALS LTD Marketing and sales of pharmaceuticals	United Kingdom	15,000,000.00	GBP	Line-by-line
RECORDATI HELLAS PHARMACEUTICALS S.A. Marketing and sales of pharmaceuticals	Greece	10,050,000.00	Euro	Line-by-line
JABA RECORDATI S.A. Marketing and sales of pharmaceuticals	Portugal	2,000,000.00	Euro	Line-by-line
JABAFARMA PRODUTOS FARMACÊUTICOS S.A. Marketing of pharmaceuticals	Portugal	50,000.00	Euro	Line-by-line
BONAFARMA PRODUTOS FARMACÊUTICOS S.A. Marketing of pharmaceuticals	Portugal	50,000.00	Euro	Line-by-line
RECORDATI ORPHAN DRUGS S.A.S. Holding company	France	57,000,000.00	Euro	Line-by-line
ORPHAN EUROPE SWITZERLAND GmbH Marketing and sales of pharmaceuticals	Switzerland	20,000.00	CHF	Line-by-line
ORPHAN EUROPE MIDDLE EAST FZ LLC Marketing and sales of pharmaceuticals	United Arab Emirates	100,000.00	AED	Line-by-line
ORPHAN EUROPE NORDIC A.B. Marketing and sales of pharmaceuticals	Sweden	100,000.00	SEK	Line-by-line
ORPHAN EUROPE PORTUGAL LDA Marketing and sales of pharmaceuticals	Portugal	5,000.00	Euro	Line-by-line
ORPHAN EUROPE S.A.R.L. Development, production, marketing and sales of pharmaceuticals	France	320,000.00	Euro	Line-by-line

Consolidated Companies	Head Office	Share Capital	Currency	Consolidation Method
ORPHAN EUROPE UNITED KINGDOM LTD Marketing and sales of pharmaceuticals	United Kingdom	50,000.00	GBP	Line-by-line
ORPHAN EUROPE GERMANY GmbH Marketing and sales of pharmaceuticals	Germany	25,600.00	Euro	Line-by-line
ORPHAN EUROPE SPAIN S.L. Marketing and sales of pharmaceuticals	Spain	1,775,065.49	Euro	Line-by-line
ORPHAN EUROPE ITALY S.R.L. Marketing and sales of pharmaceuticals	Italy	40,000.00	Euro	Line-by-line
ORPHAN EUROPE BENELUX BVBA Marketing and sales of pharmaceuticals	Belgium	18,600.00	Euro	Line-by-line
FIC MEDICAL S.A.R.L. Marketing of pharmaceuticals	France	173,700.00	Euro	Line-by-line
HERBACOS RECORDATI s.r.o.  Development, production, marketing and sales of pharmaceuticals	Czech Republic	25,600,000.00	CZK	Line-by-line
RECORDATI SK s.r.o.  Marketing and sales of pharmaceuticals	Slovakia	33,193.92	Euro	Line-by-line
RUSFIC LLC Marketing and sales of pharmaceuticals	Russian Federation	3,560,000.00	RUB	Line-by-line
RECOFARMA İLAÇ Ve Hammaddeleri Sanayi Ve Ticaret L.Ş. Marketing of pharmaceuticals	Turkey	10,000.00	TRY	Line-by-line
RECORDATI ROMÂNIA S.R.L. Marketing and sales of pharmaceuticals	Romania	5,000,000.00	RON	Line-by-line
RECORDATI İLAÇ Sanayi Ve Ticaret A.Ş.  Development, production, marketing and sales of pharmaceuticals	Turkey	120,875,367.00	TRY	Line-by-line
RECORDATI-POLSKA Sp. z o.o.  Marketing and sales of pharmaceuticals	Poland	4,500,000.00	PLN	Line-by-line
ACCENT LLC Holds pharmaceutical marketing rights	Russian Federation	20,000.00	RUB	Line-by-line
RECORDATI UKRAINE LLC Marketing of pharmaceuticals	Ukraine	1,031,896.30	UAH	Line-by-line
CASEN RECORDATI PORTUGAL Unipessoal Lda Marketing and sales of pharmaceuticals	Portugal	100,000.00	Euro	Line-by-line
OPALIA PHARMA S.A. Development, production, marketing and sales of pharmaceuticals	Tunisia	8,738,000.00	TND	Line-by-line
OPALIA RECORDATI S.A.R.L. Marketing of pharmaceuticals	Tunisia	20,000.00	TND	Line-by-line
RECORDATI RARE DISEASES S.A. DE C.V. Marketing of pharmaceuticals	Mexico	50,000.00	MXN	Line-by-line
RECORDATI RARE DISEASES COLOMBIA S.A.S. (1) Marketing of pharmaceuticals	Colombia	150,000,000.00	COP	Line-by-line
ITALCHIMICI S.p.A. <sup>(2)</sup> Marketing of pharmaceuticals	Italy	7,646,000.00	EUR	Line-by-line
PRO FARMA AG (2) Marketing of pharmaceuticals	Switzerland	3,000,000.00	CHF	Line-by-line
PRO FARMA GmbH <sup>(2)</sup> Marketing of pharmaceuticals	Austria	35,000.00	EUR	Line-by-line

<sup>(1)</sup> Established in 2015 (2) Acquired in 2016

	_		_	_	PER	CENTAGE OF	OWNERSHIF	o .	_	_	_	_
Consolidated companies	Recordati S.p.A. (Parent)	Recordati S.A. (Lux)	Recordati Pharma GmbH	Bouchara Recordati S.A.S.	Casen Recordati S.L.	Recordati Orphan Drugs S.A.S.	Orphan Europe S.A.R.L	Herbacos Recordati s.r.o.	Recordati Ilaç A.Ş.	Opalia Pharma S.A.	Pro Farma AG	Total
INNOVA PHARMA S.P.A.	100.00											100.00
CASEN RECORDATI S.L.	68.447	31.553										100.00
RECORDATI S.A. Chemical and Pharmaceutical Company	100.00											100.00
BOUCHARA RECORDATI S.A.S.	99.94	0.06										100.00
RECORDATI PORTUGUESA LDA	98.00	2.00										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
RECORDATI S.A.		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	3.33	96.67										100.00
RECORDATI HELLAS PHARMACEUTICALS S.A.	0.95	99.05										100.00
JABA RECORDATI S.A.					100.00							100.00
JABAFARMA PRODUTOS FARMACÊUTICOS S.A.					100.00							100.00
BONAFARMA PRODUTOS FARMACÊUTICOS S.A.					100.00							100.00
RECORDATI ORPHAN DRUGS S.A.S.		90.00	10.00									100.00
ORPHAN EUROPE SWITZERLAND GmbH						100.00						100.00
ORPHAN EUROPE MIDDLE EAST FZ LLC						100.00						100.00
ORPHAN EUROPE NORDIC A.B.						100.00						100.00
ORPHAN EUROPE PORTUGAL LDA						100.00						100.00
ORPHAN EUROPE S.A.R.L.						100.00						100.00
ORPHAN EUROPE UNITED KINGDOM LTD							100.00					100.00

					PER	CENTAGE OF	OWNERSHIP	)				
Consolidated companies	Recordati S.p.A. (Parent)	Recordati S.A. (Lux)	Recordati Pharma GmbH	Bouchara Recordati S.A.S.	Casen Recordati S.L.	Recordati Orphan Drugs S.A.S.	Orphan Europe S.A.R.L	Herbacos Recordati s.r.o.	Recordati Ilaç A.Ş.	Opalia Pharma S.A.	Pro Farma AG	Total
ORPHAN EUROPE GERMANY GmbH							100.00					100.00
ORPHAN EUROPE SPAIN S.L.							100.00					100.00
ORPHAN EUROPE ITALY S.R.L.							99.00					99.00
ORPHAN EUROPE BENELUX BVBA						99.46	0.54					100.00
FIC MEDICAL S.A.R.L.				100.00								100.00
HERBACOS RECORDATI s.r.o.	0.08	99.92		-								100.00
RECORDATI SK s.r.o.								100.00				100.00
RUSFIC LLC				100.00								100.00
RECOFARMA ILAÇ Ve Hammaddeleri Sanayi Ve Ticaret L.Ş.									100.00			100.00
RECORDATI ROMÂNIA S.R.L.		100.00										100.00
RECORDATI ÌLAÇ 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.A.R.L.				1.00					99	9.00		100.00
RECORDATI RARE DISEASES S.A. DE C.V.		99.998					0.002					100.00
RECORDATI RARE DISEASES COLOMBIA S.A.S. (1)					100.00							100.00
ITALCHIMICI S.p.A. (2)	100.00											100.00
PRO FARMA AG (2)	100.00											100.00
PRO FARMA GmbH (2)										1	00.00	100.00

<sup>(1)</sup> Established in 2015 (2) Acquired in 2016

## RECORDATI S.p.A. AND SUBSIDIARIES DISCLOSURE OF AUDITORS' FEES FOR ACCOUNTING AUDITS AND OTHER SERVICES

#### **ATTACHMENT 2.**

Type of service	Provider of the service	Recipient	Fees Amounts in €
Accounting audit	Auditor of Parent Company	Parent Company	103,800
Accounting audit	Auditor of Parent Company	Subsidiaries	29,000
Accounting audit	Network of auditor of Parent Company	Subsidiaries	507,166
Due diligence	Auditor of Parent Company	Parent Company	76,000
Due diligence	Network of auditor of Parent Company	Parent Company	139,319
Tax compliance	Network of auditor of Parent Company	Subsidiaries	87,305
Signature on returns and attestations	Auditor of Parent Company	Parent Company	26,000
Signature on returns and attestations	Network of auditor of Parent Company	Subsidiaries	41,108
Other services	Network of auditor of Parent Company	Subsidiaries	907

# 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 Vice Chairman 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 or 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 2016

- 2. The undersigned moreover attest that:
- 2.1 the consolidated financial statements at 31 December 2016:
  - 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 Counsel, 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, 1 March 2017

Signed by Andrea Recordati Vice Chairman and Chief Executive Officer Signed by
Fritz Squindo
Manager responsible for preparing
the company's financial reports

## Auditors' report



KPMG S.p.A. Revisione e organizzazione contabile Via Vittor Pisani, 25 20124 MILANO MI Telefono +39 02 6763.1 Email it-fmauditaly@kpmg.it PEC kpmgspa@pec.kpmg.it

(Translation from the Italian original which remains the definitive version)

#### Independent auditors' report pursuant to articles 14 and 16 of Legislative decree no. 39 of 27 January 2010

To the shareholders of Recordati Industria Chimica e Farmaceutica S.p.A.

#### Report on the consolidated financial statements

We have audited the accompanying consolidated financial statements of the Recordati Group (the "group"), which comprise the balance sheet as at 31 December 2016, the income statement, statement of comprehensive income, statement of changes in shareholders' equity, cash flow statement and notes thereto.

#### Directors' responsibility for the consolidated financial statements

The parent's directors are responsible for the preparation of consolidated financial statements that give a true and fair view in accordance with the International Financial Reporting Standards endorsed by the European Union and the Italian regulations implementing article 9 of Legislative decree no. 38/05.

#### Independent auditors' responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with the International Standards on Auditing (ISA Italia) promulgated pursuant to article 11 of Legislative decree no. 39/10. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on our judgement, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, we consider internal control relevant to the entity's preparation of consolidated financial statements that give a true and fair view in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal controls. An audit also includes evaluating the appropriateness of accounting policies used and

Ancona Aosta Barr Bergamo Bologna Bolzano Brescia Caltania Como Firenze Genova Lecce Milano Napoli Novara Padova Palermo Parma Parugia Pescara Roma Tonno Treviso Trieste Varese Verona

Societa per azión:
Capítale sociale
Euro 9.26 8.50.00 iv .
Registro Impresa Milano e
Codice Fiscale N. 00708600159
R E A. Milano N. 512867
Partás IVA 00708600159
VAT number 170070890159
Sede legale: vià Villor Pisani, 25



the reasonableness of accounting estimates made by directors, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

#### Opinion

In our opinion, the consolidated financial statements give a true and fair view of the group's financial position as at 31 December 2016 and of its financial performance and cash flows for the year then ended in accordance with the International Financial Reporting Standards endorsed by the European Union and the Italian regulations implementing article 9 of Legislative decree no. 38/05.

#### Report on other legal and regulatory requirements

Opinion on the consistency of the directors' report and certain information presented in the report on corporate governance and ownership structure with the consolidated financial statements

We have performed the procedures required by Standard on Auditing (SA Italia) 720B in order to express an opinion, as required by the law, on the consistency of the directors' report and the information presented in the report on corporate governance and ownership structure required by article 123-bis.4 of Legislative decree no. 58/98, which are the responsibility of the parent's directors, with the consolidated financial statements. In our opinion, the directors' report and the information presented in the report on corporate governance and ownership structure referred to above are consistent with the consolidated financial statements of the Recordati Group as at and for the year ended 31 December 2016.

Milan, 17 March 2017

KPMG S.p.A.

(signed on the original)

Marco Ferrarini Director of Audit

# Corporate governance report and ownership structure

#### Financial year 2016

pursuant to article 123 *bis* of the Consolidated Finance Act and article 89 *bis* of Consob Issuers' Regulations

Approved 1st March 2017 by the Board of Directors

Website: www.recordati.it

#### **GLOSSARY**

**CG Code:** the Corporate Governance Code for listed companies approved in July 2015 by the Corporate Governance Committee and promoted by Borsa Italiana S.p.A., the Italian Banking Association, Ania (national insurance association), Assogestioni (national association of asset management companies), Assonime (assoication of joint stock companies) and Confindustria (Confederation of Italian Industry).

CC: the Italian Civil Code.

Board: the Board of Directors of the Recordati S.p.A.

Issuer: Recordati S.p.A.

Year: the financial year to which this Report relates (2016).

**Consob Issuers' Regulations:** regulations governing issuers as established by Consob regulation no. 11971 of 1999 (as subsequently amended).

**Consob Markets Regulations:** regulations governing markets as established by Consob regulation no. 16191 of 2007 (as subsequently amended).

**Consob related-party regulations:** the regulations issued by the Consob with Resolution No. 17221 of 12<sup>th</sup> March 2010 (as subsequently amended) concerning transactions with related parties.

**Report:** the corporate governance report and the ownership structure that issuers are required to prepare pursuant to article 123 *bis* of the TUF.

Company: Recordati S.p.A.

**TUF:** Legislative Decree No. 58 dated 24th February 1998, *(Testo Unico della Finanza)* the TUF.

## 1. PROFILE OF THE ISSUER AND GENERAL INFORMATION

Recordati S.p.A. (Reuters RECI.MI, Bloomberg REC IM) was founded in 1926 and is a joint stock company listed on the *Mercato Telematico Azionario* (electronic stock exchange) operated by Italian Borsa Spa (ISIN IT 0003828271).

The Company and the Group that it leads has approximately 4,000 employees. They perform research and development, production, marketing and sales of pharmaceuticals and pharmaceutical chemicals. They perform their activities in the principal countries of the European Union, in Russia and in other Central and Eastern European countries, in Turkey, in North Africa and in the United States of America.

As at 31st December 2016, the Group was composed of 45 subsidiaries (of which three Italian), in addition to the Parent Company, Recordati S.p.A..

The primary objective of Recordati's corporate governance system is the creation of value for shareholders, without, however, losing sight of the social importance of the activity performed and of all the stakeholders involved.

The corporate governance structure of the Company is based on a conventional organisational model and therefore consists of the following corporate bodies: (i) the Shareholders' Meeting, (ii) the Board of Directors, (iii) the Board of Statutory Auditors. Accounting control is delegated, in compliance with the relative legislation in force, to a firm of auditors registered in the special roll maintained by the Consob. A "231" (administrative liability) Supervisory Committee has also been appointed which oversees the proper functioning of the "231 Model" and is responsible for updating it.

The Board of Directors has formed two committees from among its members with consultative and proposal-making functions: the Remuneration Committee and the Audit and Risk Committee, both consisting exclusively of independent directors.

Recordati adheres to and complies with the Corporate Governance Code for listed companies as published in July 2015 with the additions and necessary amendments resulting from the characteristics of the Group as mentioned in this Report (this may be consulted on the website of Borsa Italiana: http://www.borsaitaliana.it).

On June 20<sup>th</sup> 2016, Recordati was admitted to the FTSE MIB share index. The Board of Directors was informed, in this respect, of the specific recommendations contained in the Corporate Governance Code for listed companies included in that index. It found that the Company already complied with most of these and decided to take decisions for compliance with the additional recommendations (more specifically the formation of a sustainability committee) during the course of 2017, in line with the time limit set by the transition measures contained in the CG Code<sup>1</sup>.

Unless otherwise indicated, the information contained in this report relates to the financial year ended 31st December 2016 and, in relation to specific subjects, to the date of its approval by the Board of Directors (1st March 2017).

Unfortunately the year 2016 was marked by the demise of *Ing.* Giovanni Recordati, the Chairman and Chief Executive Officer, on 15<sup>th</sup> August 2016 after a long illness.

Ing. Giovanni Recordati had been Chief Executive Officer since 1990 and also Chairman of the Board of Directors since 1999. Under his leadership the Group grew uninterruptedly to become an international pharmaceutical company with subsidiaries in Europe, North America, South America and North Africa, while it also developed in the rare diseases sector.

On 16th August 2016, the Board of Directors resolved to appoint *Dr.* Alberto Recordati as Chairman of the Board of Directors of the Company and *Dr.* Andrea Recordati as Vice Chairman and Chief Executive Officer. More specifically, Andrea Recordati, who had already been Chief Operating Officer since 2013 with responsibility for the Group's commercial and production activities, was granted full powers for the ordinary and extraordinary management of the Company including those for the management and coordination of Group companies, exception being made for certain transactions that exceed determined thresholds, reserved to a decision by the Board of Directors.

This report therefore illustrates the governance solutions adopted by Recordati following the demise of *Ing.* Giovanni Recordati, the essential aspects of which have already been reported in the preceding paragraph. In some cases the Report makes reference to documents and information which may be consulted on the corporate website (www.recordati.it).

#### 2. OWNERSHIP STRUCTURE

(pursuant to Art. 123-bis, paragraph 1 of the TUF)

## a) Structure of the share capital and rights attaching to shares (pursuant to Art. 123 bis, paragraph 1, letter a) of the Consolidated Finance Act)

The subscribed and paid up share capital amounts to € 26,140,644.5 and is represented by 209,125,156 ordinary shares each with a par value of € 0.125 as reported in the table at the end of this section. The shares are listed on the *Mercato Telematico Azionario* (electronic stock exchange) operated by Borsa Italiana and issued under a dematerialisation regime. The rights attaching to the shares are set out in the By-Laws. More specifically, each share entitles the holder to a proportional part of the profits allocated for distribution; Art. 28 of the By-Laws provides that the net profits on the balance sheet are to be distributed as follows: (a) 5%

(five percent) to the legal reserve fund up to the amount established by the law; (b) the remainder, unless the Shareholders' Meeting, as proposed by the Board, resolves to allocate funds for extraordinary reserves or for other purposes, or to postpone part or all of the distribution to all shares to successive years, to be distributed to all shares. The Board of Directors may resolve to distribute interim dividends, within the limits and according to the procedures established by law. Dividends not collected within five years following the day on which they became payable shall revert to the Company and are recognised in the extraordinary reserve.

As reported in the table below, there are no other categories of shares, nor other financial instruments that assign the right to subscribe to new share issues, with the exception of the conditions indicated below in the context of stock option plans.

As concerns outstanding stock option plans and any share capital increases there may be at the service of those plans, reference is made to the information documents prepared in accordance with Art. 84-bis of the Consob Issuers' Regulations relating to each outstanding stock option plan, available on the Company website at the address: http://www.recordati.it/en/corporate\_governance/remuneration/stock\_option\_plans/.

The Remuneration Report pursuant to 84-quater of the Issuers' Regulations may also be consulted, available on the Company website (http://www.recordati.it/en/corporate\_governance/remuneration/remuneration\_reports/).

#### STRUCTURE OF THE SHARE CAPITAL

	No. Shares	% of share capital	Listed/ unlisted
Ordinary shares	209,125,156	100	Listed
Shares with multiple voting rights	0	0	
Shares with limited voting rights	0	0	
Shares with no voting rights	0	0	

No other financial instruments exist which give the right to subscribe newly issued shares.

## b) Restrictions on transfer of securities (pursuant to Art. 123-bis, paragraph 1, letter b) of the TUF)

The shares of the Company are freely transferable.

### c) Significant holdings in share capital (pursuant to Art. 123-bis, paragraph 1, letter c) of the TUF)

On the basis of information received, in accordance with article 120 of Legislative Decree No. 58/1998, as at 28<sup>th</sup> February 2017, the following parties held shares, either directly or indirectly, amounting to more than 3% of the share capital ("significant holdings").

#### SIGNIFICANT SHAREHOLDINGS

Declarant	Shareholder	Percentage (%) of ordinary share capital	Percentage (%) of voting share capital*
FIMEI S.p.A.	FIMEI S.p.A.	51.791%	51.791%
	INDIRECT NON-DISCRETIONARY MANAGEMENT OF INVESTMENTS **		
	0.008% FIAM LLC 0.041%		
	FIDELITY INSTITUTIONAL ASSET MANAGEMENT TRUST COMPANY		
	3.886% FMR CO, INC 0.111%		
FMR LLC	FIDELITY MANAGEMENT & RESEARCH (JAPAN) LIMITED	4.046% %	4.046% %

- As is known treasury stock consists of shares on which voting rights are only temporarily suspended in accordance with the law.
- \*\* On the basis of a communication pursuant to article 120 of Legislative Decree No. 58/1998 submitted by FMR LLC on 1st July 2016 in order to update the investment control chain when amendments to the Issuers' Regulations, pursuant to Consob Resolution No. 19614 of 26th May 2016 came into force.

As at 28<sup>th</sup> February 2017, Recordati S.p.A. also held 1.53% of treasury stock on which voting rights are suspended in accordance with the law.

Significant shareholdings may be consulted on the Consob website (www. consob.it).

## d) Securities with special rights (pursuant to Art. 123-bis, paragraph 1, letter d) of the TUF)

No securities with special rights of control have been issued.

## e) Shareholding by employees: exercise of voting rights (pursuant to Art. 123-bis, paragraph 1, letter e) of the TUF)

No shareholding system exists for employees which involves the exercise of voting rights which is different from that provided for shareholders in general.

## f) Restrictions on voting rights (pursuant to Art. 123-bis, paragraph 1, letter f) of the TUF)

Each ordinary share gives the right to vote without any restrictions.

## g) Shareholders' agreements (pursuant to Art. 123-bis, paragraph 1, letter g) of the TUF)

The Company has no knowledge of the existence of shareholders' agreements pursuant to TUF Art. 122.

## h) Change of control clauses (pursuant to Art. 123 *bis*, paragraph 1, letter h) of the TUF) and by-law provisions concerning public tender offers to purchase (pursuant to Art. 104, paragraph 1-ter and 104-bis, paragraph 1)

The Company and some of its subsidiaries are, in relation to their business operations, parties to some licensing agreements that include a clause, which is a normal provision in international agreements, authorising the Licensor to dissolve the contracts in the event of change of direct or indirect control of the Licensee.

In addition, bonds have been issued by the American subsidiary Recordati Rare Diseases Inc (in 2013 and guaranteed by the Company) and by the Company itself (2014) – for totals of US\$145 million - both privately placed with international investors and major loan agreements have also been signed by the Company – for a total of €177 million. As is normal in financial

operations of this type, they include a clause, which authorises the creditors to obtain immediate repayment if the control of the Company changes.

The By-Laws of the company do not allow exceptions to the provisions concerning takeovers on the passivity rule pursuant to Art. 104, paragraphs 1 *ter* of the Consolidated Finance Act nor do they allow the application of neutralisation rules pursuant to Art. 104-*bis*, paragraphs 1 of the Consolidated Finance Act.

## i) Authorisations for increase of share capital and acquisition of treasury shares (pursuant to Art. 123-bis, paragraph 1, letter m) of the TUF)

The Board of Directors was authorised to increase share capital, pursuant to CC Art. 2443, by a Shareholders' Meeting of 19th April 2012.

The increase in the share capital may be performed in one or more tranches, free of charge or by payment, for a total maximum nominal amount of € 50,000,000 within a period of no more than five years from the date of the resolution, by issuing ordinary shares and/or warrants for the subscription to such shares, to assign or to offer as an option to shareholders, with the right pursuant to the joint provisions of CC Art. 2441, last paragraph and TUF Art. 134, second paragraph, to offer subscription to the shares to Recordati S.p.A. employees or to subsidiaries of the Company in relation to the stock option plans decided by the Shareholders' Meeting (and therefore with the possibility to exclude the option rights to one fourth of the new issue). The Board of Directors may also decide that the issue should be performed with a share premium, setting the amount and also specifying that if the issue decided is not fully subscribed within the time limits set from time to time, the share capital shall be increased by an amount equal to the subscriptions received by the time limit set.

To-date, the Board has not yet acted on this mandate, not even partially.

That same Shareholders' Meeting authorised Directors, in accordance with Art. 2420-ter of the C.C. to decide the issue in one or more tranches, for a total maximum nominal amount of € 80,000,000, of bonds convertible to ordinary shares, or valid warrants to subscribe to such shares, to offer in option to shareholders within a period of no more than five years from the date of resolution, in observance of applicable law and regulations concerning the issuing of bonds, and at the same time, deciding an increase of share capital for the amount that corresponds to the nominal value of the shares to be attributed in conversion.

To- date, the Board has not yet acted on this mandate not even partially.

Having considered that the current authorisations pursuant to Art. 2443 of the CC and to Art. 2420-ter of the CC will expire on 19th April 2017 the Board resolved to submit a proposal to the shareholders' meeting convened to approve the 2016 annual report to renew those authorisations in order to maintain the necessary operational flexibility over an appropriate time horizon. The Directors Report on the relative items on the agenda, which will be made available within the legal time limits on the Company website and elsewhere, may be consulted for further information.

The By-Laws do not authorise the Board to issue financial instruments of participation.

In ordinary session on 13th April 2016 a Shareholders' Meeting renewed the authorisation to purchase and assign treasury shares, pursuant to CC articles 2357 et seq., until approval of the financial statements at 31st December 2016, scheduled for 11th April 2017. In particular, the maximum number of shares that may be acquired, after accounting for the number of treasury shares already held in the Company's portfolio, is 15,000,000, which corresponds to a total potential payment of not more than  $\in$  300,000,000, at a minimum price not less than the nominal value of Recordati shares (€ 0,125) and a maximum price not greater than the average of official Borsa

prices during the five sessions prior to the acquisition, plus 5%. Purchases must be made on regulated markets, in observance of Art. 144bis, paragraph one, letter b), of the Consob Issuers' Regulations and according to standard practices recommended by the Consob in accordance with TUF article 180.

At year-end, the Company held 3,891,262 treasury shares in portfolio, which represent 1.861% of the share capital.

On the basis of that shareholders' resolution, on 2<sup>nd</sup> November 2016, a programme was commenced to purchase treasury stock to be used at the service of stock option plans already adopted by the Company and for those which may be adopted in the future, designed for employees of the companies in the Recordati Group. As part of the implementation of that programme, from 2<sup>nd</sup> November 2016 until the date of this report, the Company purchased 2,382,304 ordinary shares for a total payout of €60,602,023.

In consideration of the expiry of the current authorisation which will occur when the Shareholders' Meeting is held to approve the 2016 Annual Report, the Board resolved to submit a proposal to the Shareholders' Meeting convened to approve the 2016 annual report to renew the authorisation to purchase and assign treasury stock in order to maintain the necessary operational flexibility over an appropriate time horizon. The Directors Report on the relative item on the agenda, which will be made available within the legal time limits on the Company website and elsewhere, may be consulted for further information.

## j) Management and co-ordination (pursuant to Art. 2497 et seg of the CC)

Although controlled by Fimei S.p.A., the Company is not subject to management and co-ordination by the same, pursuant to CC articles 2497 *et seq.* 

Fimei S.p.A. is a mere financial holding company with no operations of any kind; no procedures exist to furnish authorisations or instructions to the Company in its relations with the Parent Company and therefore the Company sets its own strategic and operating policies in full autonomy.

The fully controlled Italian subsidiaries have acknowledged management and co-ordination by the Company and have fulfilled legal disclosure requirements in this respect.

#### k) Other information

The information required by Art. 123 *bis*, paragraph one, letter i) of the TUF ("agreements between the Company and directors, members of the board of directors or the supervisory board, which provide for the payment of indemnities in the event of resignation, dismissal without just cause or if the contract of employment is interrupted following a public tender offer") is given in the Report on Remuneration published in accordance with Art. 123-ter of the TUF.

The information required by Art. 123 bis, paragraph one, letter I) of the TUF ("regulations for the appointment and replacement of directors and for amendments to the By-Laws, if different from those applicable by law in the absence of alternative provision") are given in the section of the report on the Board of Directors (section 4.1).

#### 3. COMPLIANCE (pursuant to Art. 123-bis, paragraph 2, letter a) of the TUF)

As illustrated in section 1, in accordance with the procedures contained in this report, the Company adheres to the CG Code, which may be consulted on the website of Borsa Italiana at the address http://www.borsaitaliana.it/borsaitaliana/regolamenti/corporategovernance/codice2015.pdf. Reasons are given where it was decided not to follow those principles or operating criteria either in the corresponding section of this report or in the corresponding section of the Report on Remuneration.

Furthermore, as already reported, on June 20th 2016 Recordati was admitted to the FTSE MIB share index. In this respect, even if for the purposes of the application of the CG Code on which Recordati is required to give account in this report, the Company does not consider that it is included in the FTSE MIB share index (see note 1 at the foot of page 4), this report nevertheless also give details of that which is already in place — and of that which may need to be assessed — with reference to the specific recommendations formulated for companies belonging to that index.

The Company is not subject to foreign laws that influence the corporate governance structure of the Company itself.

The main characteristics of the risk and internal control management systems in relation to financial reporting, including consolidated reporting, requested by Art. 123-*bis* paragraph 2, letter b) of the TUF are illustrated in the report on internal control and risk management (Sect. 11a).

The procedures for the functioning of shareholders' meetings, its principal powers, the shareholder rights and the procedures for exercising them, required by Art. 123-*bis*, paragraph 2, letter C) of the TUF, are illustrated in the section of the Report on Shareholders' Meeting (Sect. 11a).

The composition and functioning of management and supervision bodies and their committees, required by Art. 123-*bis* paragraph 2, letter d) of the TUF, are illustrated in the section of the Report on the Board of Directors (Sect. 4) and, in more detail for the Committees, in the section of the Report on internal Board Committees (Sect. 6).

#### 4. BOARD OF DIRECTORS

## 4.1 APPOINTMENT AND SUBSTITUTION OF THE BOARD OF DIRECTORS (pursuant to Art. 123-bis, paragraph 1, letter I) of the TUF)

The appointment and replacement of Directors is regulated by articles 15, 16 and 18 of the By-Laws, the text of which, last amended by the Board of Directors on 8<sup>th</sup> May 2012 in order to make compulsory amendments to comply with legislation on the balance between genders on corporate bodies, is reproduced for your information in full below:

Art. 15) The Board of Directors shall be appointed from slates of candidates presented by shareholders, in compliance with the existing legislation in force on gender balance, according to the procedures as indicated below, in which the candidates are identified by progressive numbers.

The slates, signed by the shareholders who present them, must be deposited at the registered office of the Company at least twentyfive days prior to the date of the first convention of the Shareholders' Meeting, available to anyone who requests to see them and they will also be subject to other forms of publicity in accordance with laws and regulations in force at the time. Every shareholder, shareholders who participate in a significant shareholders'

agreement pursuant to TUF Art. 122, the parent company, subsidiaries and companies subject to joint control pursuant to TUF Art. 93, may not present or contribute to the presentation of more than one slate, not even by means of another person or trustee, nor may they vote for different slates, and each candidate may be listed in only one slate or will be disqualified. The subscriptions and votes expressed in violation of this prohibition will not be attributed to any slate.

Only shareholders individually or jointly possessing a total number of shares with voting rights representing at least 2.5% of capital stock with voting rights at ordinary meetings, or representing a lesser percentage as established by binding legislative or regulatory provisions which shall be specified in the notice of meeting, shall have the right to submit slates.

The following items must be filed for each slate within the respective deadlines set out above and as provided by applicable regulations: (i) statements by each candidate to the effect that each accepts candidacy and declares, assuming full responsibility, that there are no reasons preventing the candidate from being elected or rendering him unsuitable for the office, and that the candidate meets any specific requirements for the relevant office; (ii) a curriculum vitae detailing each candidate's personal and professional characteristics and indicating that the candidate may be considered independent.

The specific certification demonstrating title to the necessary number of shares for the presentation of the slate, issued by a legally authorised intermediary must also be deposited within the time limits set by the relative regulations at the time when the slates are deposited at the Company.

Slates containing a number of candidates equal to or greater than three must be composed of candidates belonging to both genders, so that a percentage equal to that required by the legislation in force at the time concerning gender balance for the composition of the Board of Directors belongs to the less represented gender.

Slates that are presented but are not in accordance with the provisions as above will be considered as not presented.

The Board of Directors will be elected as follows:

- a) all of the Directors to be appointed, except one, will be selected from the slate that obtained the greatest number of votes, following the progressive order in which they are listed on the slate;
- b) the remaining director shall be the candidate placed at the number one position on the minority slate, which shall not be connected in any way, even indirectly, with those who submitted or voted for the slate indicated in letter a) above, which obtains the second highest number of votes. For this purpose, slates that did not obtain a percentage of votes equal to at least half of that required for presentation of the slates as at the fourth paragraph of this article will not be considered.

For the purposes of the appointment of directors as indicated at point b) above, in the event of a tie between slates, the slate presented by shareholders possessing the larger shareholding, or subordinately the larger number of shareholders, shall prevail.

If the candidates elected by the method as above do not include an adequate number of independent Directors with the characteristics as established for statutory auditors at TUF Art. 148, third paragraph, equal to the minimum number established by the law in relation to the total number of Directors, the last non-independent candidate, according to the progressive numbering, of the slate that obtained the greatest number of votes as at letter a) of the paragraph above, will be substituted by the first independent candidate, according to the progressive numbering, of the non-elected candidates on the same slate, or if not possible, by the first independent candidate, according to the progressive numbering, of the non-elected candidates of the other slates, according to the number of votes obtained by each. This procedure of substitution will be followed until the board of directors is composed of a number of members who have the qualifications as at TUF Art. 148, third paragraph, equal at least to the minimum legal number. If this procedure does not produce the latter result, the substitution will be effected by resolution of the Shareholders' Meeting by relative majority, after

presentation of candidates who possess the qualifications as cited above. Furthermore, if with the candidates elected according to the above procedures the composition of the Board of Directors in compliance with the legislation in force at the time concerning gender balance is not ensured, the candidate of the gender most represented elected as last in order on the slate which obtained with the largest number of votes shall be replaced by the first candidate of the less represented gender not elected in order on the same slate. That replacement procedure shall be followed until the composition of the Board of Directors in compliance with the legislation in force at the time concerning gender balance is ensured. Finally, if this procedure does not produce the result just indicated, then the replacement shall be made by a resolution of the Shareholders' Meeting by relative majority, after presentation of candidates belonging to the less represented gender.

If only one slate is presented, all of the Directors will be selected from the same slate. If no slate is presented the Shareholders' Meeting will decide by legal majority, without following the procedure as above. All of the foregoing is subject to compliance with the legislation in force at the time concerning gender balance.

Any different or additional compulsory provisions of the law or regulations will form an exception to these provisions.

Article 16) - The fees to be paid to the Board of Directors shall be established by the Shareholders' Meeting for the entire period of their term, or for each financial year, and may take the form of profit-sharing.

Article 18) - Unless already provided for by the Shareholders' Meeting, the Board shall appoint a Chairman and may appoint a Vice-Chairman from among its members. The Board shall also appoint one or more Managing Directors from among its members. The Chairman shall have all the powers vested in him by law; in the case of his absence or inability to attend for any reason, the said powers shall be exercised by the Vice-Chairman, or in his absence, by the most senior Director.

Finally, the Board shall appoint a Secretary, who need not be a member of the Board.

It is also underlined that, on the basis of the By-Laws in force, the right to submit slates is only held by shareholders who, individually or together with other shareholders submitting slates, hold voting shares representing at least 2.5% of the voting capital in an Ordinary Meeting, or representing a lower percentage established by mandatory laws or regulations. In this respect, in accordance with articles 144-quater and 144-septies of the Issuers' Regulations adopted by Consob Resolution No. 19856 of 25th January 2017 with regard to the capitalisation of the Company in the last quarter of 2016, the percentage of the share capital required to present slates of candidates to the Board of Directors of the Company is currently 1%.

On the basis of Art. 147-*ter*, paragraph one of the TUF, the By-Laws also state that for the purposes of the distribution of votes among directors to be elected, no account is taken of slates that have not obtained a percentage of votes equal to at least half of that required for the presentation of slates.

In order to ensure the election of at least one minority director, the By-Laws state that all the directors to be elected except for one shall be drawn from the slate which obtained the greatest number of votes in the order in which they are slated on that slate. The remaining director is the candidate placed in the number one position on the minority slate, which shall not be connected in any way, even indirectly, with the shareholders who submitted or voted for the majority slate and which obtained the majority of votes from the shareholders. In the case of a tied vote between slates, the minority director shall be drawn from the slate presented by the shareholders in possession of the greater number of shares or, secondarily, with the greatest number of shareholders.

As concerns the mechanism adopted to ensure that a minimum number of independent directors are elected in compliance with Art. 147-ter, paragraph four of the TUF, the By-Laws state that if the number of independent directors is not reached, the non-independent candidate elected in last place on the majority slate shall be replaced by the first independent candidate in progressive order not elected on that slate, or, if there is none, by the first independent candidate in progressive order not elected on the other slates, according to the number of votes obtained by each.

Finally if this procedure does not lead to the aforementioned result, the directors shall be replaced by a resolution passed by relative majority of the Shareholders' Meeting upon presentation of candidates satisfying the above requirements of independence.

If only one slate is presented, the By-Laws also state that all of the Directors to be elected shall be selected from that slate. If no slate is presented the Shareholders' Meeting shall decide by legal majority, without following the procedures just described.

The By-Laws to not lay down any additional requirements for the independence of Directors with respect to those contained in Art. 148, paragraph 3, of Legislative Decree No. 58/1998, because the Company adheres to the CG Code and the Board of Directors verifies possession of the requirements of independence in accordance with the CG Code and consequently when a Shareholders' Meeting appoints Directors, the Board of Directors invites candidates to the position of Director contained on slates to declare also these requirements, as adopted by the Company.

The table at the end of this section may be consulted for details of those directors currently in office who meet the requirements for independence in accordance with the TUF and those that are independent in accordance with the CC.

With regard to the regulations on gender balance in corporate bodies (Law No. 120/2011, new articles 147-*ter* and 148 of the Consolidated Finance Act, new Art. 144-*undecies* of the Issuers Regulations), which apply to the renewal of corporate bodies subsequent to 18th August 2012, the Company made the necessary amendments to the By-Laws on 8<sup>th</sup> May 2012 in order to comply with the new regulations.

In particular, the Board of Directors shall be appointed in compliance with the existing legislation in force on gender balance (and in any case on the basis of slates of candidates presented by shareholders). We report that when the Board of Directors is renewed, which must be resolved by the Shareholders' Meeting convened to approve the 2016 Annual Report, since this is the second period of office subject to the application of Law No. 120/2011, a

proportion equal to at least one third of the directors must be reserved to the least represented gender, with the figure rounded up the next whole number.

Furthermore, the By-Laws set out the procedures to follow to ensure that the composition of the Board of Directors complies with the existing legislation in force concerning gender balance: the candidate of the gender most represented elected as last in order on the slate which obtained with the largest number of votes shall be replaced by the first candidate of the less represented gender not elected in order on the same slate. That replacement procedure shall be followed until the composition of the Board of Directors in compliance with the legislation in force at the time concerning gender balance is ensured. Finally, if this procedure does not produce the result just indicated, then the replacement shall be made by a resolution of the Shareholders' Meeting by relative majority, after presentation of candidates belonging to the less represented gender.

The Issuer reports that it is not governed by any further laws and regulations concerning the composition of the Board of Directors.

## 4.2 COMPOSITION (pursuant to Art. 123-bis, paragraph 2, letter d) of the TUF)

The By-Laws currently in force state that the Company is managed by a Board of Directors consisting of a number of members varying between six and sixteen.

The Board of Directors in office at the date of this report was appointed by a Shareholders' Meeting held on 17th April 2014 for three years, with the term of office expiring at the time of the Shareholders' meeting held to approve the 2016 Annual Report. The Shareholders' Meeting held on 17th April 2014 had appointed a board composed of ten directors, of which six independent, including two women, in compliance with the criteria laid down by the applicable provisions on the matters of gender balance (at least one fifth of the members must be of the least represented gender) and the minimum number of independent directors (at least two for a Board composed of more than seven members)<sup>2</sup>. One director is appointed from the minority through the adoption of slate voting. Furthermore, as already reported, when the current Board of Directors in office was appointed in the Ordinary General Meeting held on 17th April 2014, two slates of candidates were presented for the office of Director: one by the majority shareholder FIMEI S.p.A.3 which obtained 67.467% of the share capital with voting rights represented in the Shareholders' Meeting and one by the minority shareholder TORRE Società Semplice<sup>4</sup>, which obtained 31.187% of the share capital with voting rights represented in the Shareholders' Meeting. The voting share capital represented 77.4% % of the share capital of the Issuer.

<sup>2</sup> The Corporate Governance Code recommends (Application Criterion 3.C.3.) that for issuers included in the FTSE-MIB index, at least one third of the Board of Directors is comprised of independent directors. If that portion does not correspond to a whole number, the number is rounded down.

<sup>3</sup> The slate presented by FIMEI S.p.A., together with the relative additional documentation filed in accordance with the law and the applicable regulations may be consulted on the website www.recordati.it, (in the section Investors/Shareholders' Meetings/2014). The slate contained the following candidates: Ing. Giovanni Recordati, Dr. Alberto Recordati, Dr. Andrea Recordati, Dr. Fritz Squindo, Dr.ssa Rosalba Casiraghi, Avv. Michaela Castelli, Prof. Marco Vitale, Mario Garraffo, Avv. Carlo Pedersoli, Dr. Andrea De' Mozzi.

<sup>4</sup> The slate presented by TORRE Società Semplice, together with the relative additional documentation filed in accordance with the law and the applicable regulations may be consulted on the website www.recordati.it, (in the section Investors/Shareholders' Meetings/2014). The slate contained the candidate Dr. Paolo Fresia.

Subsequently on 8th March 2016, the non-executive independent director Avv. Carlo Pedersoli handed in his resignation, due to too many professional commitments.

Following the resignation of Aw. Carlo Pedersoli as a Director of the company, in a meeting held on 8<sup>th</sup> March 2016, the Board resolved not to replace him in accordance with article 2386, paragraph 1 of the CC, expressly referred to in article 17 of the By-Laws, in consideration of the fact that it was very close to the next Shareholders' Meeting and it was considered best to postpone decisions on the appointment of a director and the reduction in the number of directors until that meeting. On that same date, the Board of Directors resolved to appoint Aw. Michaela Castelli, a non-executive and independent director, as a member of the Control and Risk Committee, to replace Avv. Pedersoli.

On 13th April 2016, a Shareholders' Meeting resolved to reduce the number of directors from ten to nine.

Finally, as already mentioned in section 1, on 15<sup>th</sup> August 2016, Ing. Giovanni Recordati, Chairman and Chief Executive Officer of the Company, unfortunately passed away after a long disease.

On 16<sup>th</sup> August 2016, the Board of Directors resolved to appoint Dr. Alberto Recordati as Chairman of the Board of Directors of the Company and Dr. Andrea Recordati as Vice Chairman and Chief Executive Officer. Subsequently, the Board also resolved not to replace him in accordance with Art. 2386, paragraph 1, of the Italian Civil Code, explicitly mentioned by Art. 17 of the By-Laws and to postpone the decision until it could be made directly by the Shareholders' Meeting that will resolve on all matters concerning the renewal of the Board of Directors.

A summary of the composition of the Board of Directors as at 31st December 2016 and details of the type of Director on that date is given as follows:

Alberto Recordati	Chairman	Executive	-	*BoD meeting of 19.03.1986
Andrea Recordati	Vice Chair and CEO	Executive	-	*Shareholders' meeting of 29.04.1998
Rosalba Casiraghi	Director	Non-executive	Independent	*Shareholders' meeting of 17.04.2014
Micaela Castelli	Director	Non-executive	Independent	*Shareholders' meeting of 17.04.2014
Paolo Fresia	Director	Non-executive	Independent	*Shareholders' meeting of 17.04.2014
Mario Garraffo	Director	Non-executive	Independent	*Shareholders' meeting of 29.04.1999
Fritz Squindo	Director	Executive	-	*BoD meeting of 14.03.2013
Marco Vitale	Director	Non-executive	Independent	*Shareholders' meeting of 13.04.1997

<sup>\*</sup>Date first appointed to the BoD

The personal and professional characteristics of each Director are documented in Attachment 1 to this Report along with the offices held by Directors in other listed companies.

For an assessment of the independence of the Directors in office, the table at the end of this section and the information specifically given in Section 4.6 may be consulted for further details.

#### TABLES COMPOSITION AND STRUCTURE OF THE BOARD OF DIRECTORS AND COMMITTEES

	Board of Directors in Office							Audit and Risk Committee			Remuneration Committee				
Office	Members	Year of birth	In office since	In office until	Slate (M/m) *	Exec.	Non- Exec.	Indep. accord- ing to CG Code	Indip. Da TUF	% ***	Numero altri incarichi in società quotate	** **	% ***	***	% ***
Chairman <sup>5</sup>	ALBERTO RECORDATI	1953	17.4.2014	Approval of 2016 AR	M	X				10/11	0				
Vice-Chairman and CEO <sup>6</sup> ◊	ANDREA RECORDATI	1971	17.4.2014	Approval of 2016 AR	M	Χ				10/11	0				
Director	ROSALBA CASIRAGHI	1950	17.4.2014	Approval of 2016 AR	M		Χ	Χ	Χ	11/11	1			M	6/6
Director	MICHAELA CASTELLI	1970	17.4.2014	Approval of 2016 AR	M		Χ	Χ	Χ	11/11	1	$M^7$	3/3	M	6/6
Director	PAOLO FRESIA	1988		Approval of 2016 AR	m		Χ	Χ	Χ	9/11	0				
Director	MARIO GARRAFFO	1937	17.4.2014	Approval of 2016 AR	M		Χ	X (**)	Χ	9/11	1	M	5/5	Р	6/6
Director•	FRITZ SQUINDO	1956	17.4.2014	Approval of 2016 AR	M	Χ				10/11	0				
Director o	MARCO VITALE	1935	17.4.2014	Approval of 2016 AR	M		Χ	X (**)	X (**)	8/11	1	Р	5/5		
Directors who retired from office in 2016															
Chairman and CEO ◊	GIOVANNI RECORDATI	1949	17.4.2014	Passed away on 15.8.2016	M	Χ				4/7	0				
Director	CARLO PEDERSOLI	1953	17.4.2014	Resigned on 8.3.2016	M	,	Χ	Χ	Χ	2/2	0	M	2/2		

- This symbol indicates that the director is responsible for the internal control and risk management system.
- This symbol indicates the principal manager of the issuer (chief executive officer or CEO).
- O This symbol indicates the lead independent director (LID).
- (\*) M/m are given in this column where "M" indicates a member elected from the majority slate and "m" from a minority slate.
- (\*\*) The Board has qualified Prof. Marco Vitale and Dr. Mario Garraffo as independent, even though they have been directors of the Company for more than nine years during the past twelve, and in the case of Prof. Vitale even though he has been appointed as a professional consultant to the Company with an annual fee of € 50.000.00 (a non-significant amount), considering that by their specific expertise and professional commitment to constant control and stimulation of the Board, they have demonstrated that they have maintained their characteristics of independence and freedom of judgement in evaluating the operations carried out by management.
- (\*\*\*) This column contains the percentage attendance of directors at the relative board and committee meetings (number of presences/number of meetings held during the actual period office of the person concerned).
- (\*\*\*\*) This column gives the number of appointments as a director or statutory auditor held by the person concerned in other companies listed on regulated markets, including foreign markets. For a complete list of other appointments including those in financial, banking or insurance companies or in large companies, please see the list contained in Attachment 1 of this document.
- (\*\*\*\*\*) This column indicates the position of the director within the committee: "C" Chair and "M" member.

Information concerning the date of the first appointment of directors to the board is given on page 102.

<sup>5</sup> Appointed Chairman of the Board of Directors on 16.8.2016

<sup>6</sup> Appointed Vice Chairman and Chief Executive Officer on 16.8.2016

<sup>7</sup> Took office following the resignation of Avv. Pedersoli on 8.3.2016

#### INDICATE THE QUORUM REQUIRED FOR THE PRESENTATION OF SLATES WHEN DIRECTORS WERE LAST APPOINTED: 1%

Number of meetings held during 2016	Board meetings	Audit and Risk Committee	Remuneration committee	
	11	5	6	

#### 4.2.1. Succession Planning

In compliance with Principle 5.C.2. of the CG Code, the Board of Directors considered the situation when complying with amendments to that Code made in December 2011 and decided that it was not necessary to adopt an official succession plan for executive directors

## 4.2.2. Maximum number of offices held in other companies

The Board of Directors preferred not to set any general criterion for the maximum number of positions as director or statutory auditor in other companies that are considered compatible with performing duties as a director of the Company. It has done this because it feels that it is best to allow individual directors to assess this compatibility themselves.

The Board self-assessment process carried out in 2016 confirmed the positive assessment made of the functioning of the Board and its committees also with particular reference to this aspect.

#### 4.2.3. Induction Programme

In line with the provisions of the CG Code on each Director carrying out their duties effectively and knowledgeably, following the appointment of the Board of Directors on 17th April 2014, the Chairman and Chief Executive Officer, *Ing.* Giovanni Recordati, had delivered a special report on the development of the Recordati Group over the last 15 years, immediately in the first board meeting following the appointment of the new Board. He had therefore organised a specific induction session held on 27th May 2014 for new directors, during which they were furnished with details of the business and organisational structure of the Recordati Group and on the markets in which it operates. The induction programme had also involved the Board of Statutory Auditors and the new statutory auditor of the Company in particular.

Generally speaking, during the course of meetings of the Board of Directors, the Chief Executive officer gives information required to present the performance of the Company and the Group, constantly providing, amongst other things, information and the most important updates to the regulatory framework for the sector and their impact on the Company. Also with regard to principles for the proper management of risks, during the course of meetings of the Board of Directors, the Chief Executive Officer ensures that appropriate details are given in this respect, if considered appropriate, in addition to the annual analysis of the Recordati Risk Catalogue.

In consideration of the experience acquired by members of the Board of Directors with specific reference to the business sectors in which the company operates and to the information provided to them in individual Board meetings, the Chairman and the Chief Executive Officer did not organise, in 2016, specific additional induction sessions with respect to those organised following the renewal of the Board of Directors in 2014 (since no changes had been made to the composition of the board). In 2016, the Chairman invited directors to take part in the meeting that the Company organises annually with senior and middle managers of the Group for the purpose, not only of illustrating the results of the Group in the previous year, but also of looking carefully at the Group's operating and development activities, which are of value in terms of additional activity to update the induction programme.

## 4.3 ROLE OF THE BOARD OF DIRECTORS (pursuant to Art. 123-bis, paragraph 2, letter d) of the TUF)

During the course of the year, the Board of Directors met eleven times, with meetings lasting on average around an hour and a half, on the following dates: 11<sup>th</sup> February 2016, 8<sup>th</sup> March 2016, 13<sup>th</sup> April 2016, 5<sup>th</sup> and 30<sup>th</sup> May 2016, 30<sup>th</sup> June 2016, 28<sup>th</sup> July 2016, 16<sup>th</sup> August 2016, 27<sup>th</sup> October 2016, 16<sup>th</sup> November 2016 and 15<sup>th</sup> December 2016. Average attendance was approximately 89% of the Directors.

As regards the current year, seven meetings are scheduled and the Board has already met on 9<sup>th</sup> February 2017. The percentage attendance of each Director at Board meetings and in the relative committees is shown in the table contained at the end of section 4.2.

The promptness and completeness with which information is provided before board meetings is ensured by the Chairman with the distribution of documents relating to the items on the agenda to members a few days immediately preceding the date set for the meetings. On some occasions it has not been possible to provide information concerning some items on the agenda until the time of the board meeting itself for reasons of confidentiality and urgency. On these occasions, the arguments were in any case investigated by internal committees, the within the scope of their remits, and the Chairman took care to provide adequate and detailed information during the Board meetings themselves. When making amendments to the CG Code in December 2011, the Board of Directors generally considered notice of three days to be appropriate and that time limit has normally been complied with in the meetings that followed (during the year documents relating to periodic accounts were in fact delivered approximately four days before meetings on average). The Board self-assessment process essentially confirmed the appropriateness of this notice.

During the course of the year and in the meetings already held in 2017 various persons attended board meetings in order to provide additional information on the items on the agenda. These included the Chief of Administration, the Chief of Group Operational Control and Reporting, the Chief of Corporate Development, the Chief of the Legal Service and Corporate Affairs (who also acted as the Secretary to the Board) and the Chief of the Group Internal Audit Function (who in line with the provisions of the CG Code reports to the Board of Directors) and the Group Tax Manager.

The Board of Directors has the duty to set strategic policies for the Company and the Group it leads and it is responsible for overseeing its management. In accordance with article 22 of the By-Laws, the Board is the corporate body endowed with the broadest powers to handle ordinary and extraordinary management of the Company and it has the right to conclude all acts that it deems appropriate in order to conduct business and to achieve the corporate purposes, excluding only those reserved by the law exclusively for the Shareholders' Meeting. On the basis of the terms indicated below, the Board has assigned part of its management responsibilities to the Chief Executive Officer.

In accordance with CC. Art. 2365, paragraph 2, the Board of Directors is also authorised to decided on the following matters:

- mergers in the cases established by CC articles 2505 and 2505 bis;
- establishment or suppression of secondary offices;
- specification of the Directors who are entitled to represent the Company;
- · reduction of share capital in the event of withdrawal of a shareholder;
- alignment of the By-Laws to provisions of the law and regulations;
- transfer of the registered office from one municipality to another in national territory.

The Board is also entitled to appoint and dismiss, following an obligatory opinion from the Board of Statutory Auditors, the Financial Reporting Officer, pursuant to TUF Art. 154-bis.

The Board is also responsible, in compliance with the CG Code, for the following:

- examination and approval of strategic, industrial and financial plans of the Company and the Recordati Group and monitoring implementation of these;
- definition of the nature and level of risk that is compatible with the Company's strategic objectives, including in its assessments, all risks that might be significant with a view to sustainability of the Company's activities in the medium to long-term;
- the definition of the corporate governance system of the Company itself and of the structure of the Group itself, setting guidelines for the governance of subsidiaries;
- evaluation of whether the organisational, administrative and financial structures of the Company and its strategic subsidiaries, as defined herein and as configured by the responsible organs, are adequate, with particular reference to the internal control and risk management system;
- attribution and cancellation of mandates to CEOs and the Executive Committee, defining the extent, means and intervals (at least quarterly), with which the delegates must refer to the Board about the activities carried out in exercising their mandates;
- the establishment, after examination of the proposals from the Remuneration Committee, and heard the opinion of the Board of Statutory Auditors, of the remuneration of executive directors and other Directors with special mandates, as well as the performance objectives link to variable remuneration of the latter and the division, for the individual members, of the total allotment for compensation of the Board, if the Shareholders' Meeting has not already decided the matter;
- evaluation of business trends, in accordance, amongst other things, with the law and the By-Laws, especially in the light of information provided by the delegated bodies and periodic comparison of results with budget previsions;
- examination and approval prior to strategic economic or financial operations
  of the Company and its subsidiaries, with particular attention to situations
  in which one or more Directors have an interest, whether personal or on
  behalf of third parties, and in general, to operations with related parties in
  accordance with the Regulations for Related-Party Transactions approved
  by the Board of Directors itself on 24th November 2010 (and last revised in
  2017); establish guidelines to identify significant operations;
- conduct, once a year, an evaluation of the size, composition and functioning
  of the Board of Directors and its committees and possibly indicate the type
  of management and professional figures whose presence on the Board
  would be useful, before the appointment of a new Board;
- communication, in the Corporate Governance Report, of the means of application of the CG Code;
- subject to the opinion of the Audit and Risk Committee, the definition
  of the guidelines for the internal control and risk management system,
  so that the principal risks to which the issuer and its subsidiaries are
  exposed are correctly identified and adequately measured, managed and
  monitored. It also determines the degree to which risks are compatible
  with management of the Company that is consistent with its strategic
  objectives;
- the selection of one or more Directors who are given responsibility for the creation and maintenance of an effective internal control and risk management system (Director/s responsible for the internal control system);

- the selection of an Audit and Risk Committee, which by conducting appropriate fact-finding activity, has the task of supporting the Board of Directors in its assessments of the internal control and risk management system and also those relating to the approval of periodic financial reports;
- subject to the opinion of the Audit and Risk Committee, the assessment, at least annually, of the adequacy of the internal control and risk management system with respect to the nature of the company and its risk appetite and also of its effectiveness;
- subject to the opinion of the Audit and Risk Committee, the approval, at least annually, of the working plan drawn up by the Chief of the Internal Audit Function, after, amongst other things, consultation with the Board of Statutory Auditors and the Director with Responsibility for the internal control and risk management system;
- subject to the opinion of the Audit and Risk Committee, a description of the main characteristics of the internal control and risk management system in the Corporate Governance Report and a report on its assessment of its adequacy:
- after consultation with the Board of Statutory Auditors, and assessment
  of the results furnished by the external statutory auditor in its letter of
  recommendations (if provided) and in its report on basic issues arising
  from its external statutory audit;
- on the basis of a proposal submitted by the Director with Responsibility for
  the internal control and risk management system, subject to the approval
  of the Audit and Risk Committee and after consultation with the Board of
  Statutory Auditors, the appointment and removal of the Chief of the Internal
  Audit Function ensuring that he or she has adequate resources and sets
  their remuneration consistent with company policies;
- the appointment and removal of members of the Company's Supervisory Committee formed and functioning in accordance with Legislative Decree No. 231/2001;
- the adoption of an Organisation and Control Model drawn up in accordance with Legislative Decree No. 231/2001 and the approval of amendments to it for compliance with changes in legislation and regulations as they come into force from time to time.

The Company has decided to take advantage, with effect from 20th December 2012, of the right not to comply with obligations to publish the reports required when significant operations are performed consisting of mergers, demergers, share capital increases through contributions in kind, acquisitions and disposals, in accordance with Art. 70, paragraph 8 and with Art. 71, paragraph 1-bis of the Issuers' Regulations.

On the date of the approval of this Report, the Board took the following actions in relation to the above:

- at the end of 2016 it examined and approved the 2017 Group budget;
- it monitored, the implementation of the 2015-2017 Three-Year Business Plan, by comparing, amongst other things, actual with budgeted results taken from the approved 2016 budget, carried out as generally established practice when quarterly accounting reports are approved;
- at the beginning of 2017 it approved the 2017-2019 Three-Year Business Plan;
- it examined the "Catalogue of Risks" for 2016, as updated compared to that examined for 2015 in preparation for the approval of the 2017 budget and the 2017-2019 Three-Year Business Plan approved at the beginning of 2017. With assistance from the consulting company Deloitte S.p.A., the Group developed its own model to map, manage and monitor risks in the Company and Group. This is updated constantly to better identify risks connected with the achievement of the strategic objectives of the current business plan and, in general, to identify and manage the main internal and external risks of the Group as efficiently as possible. This model is based on international principles of Enterprise Risk Management (ERM);

- as part of the update of the Catalogue of Risks relating to 2016, it assessed
  whether the degree and nature of the risks as identified in the Group
  Catalogue of Risks presented to the Board (including in its assessments
  also risks which might be of significance with a view to the medium to
  long-term sustainability of the Company's activities) are compatible with
  the Group's strategic objectives contained in the 2015-2017 Three-Year
  Business Plan and following its approval at the beginning of 2017, with
  the Group's strategic objectives contained in the 2017-2019 Three-Year
  Business Plan;
- with the opinion in favour of the Audit and Risk Committee, it updated the
  guidelines for the Recordati Group internal control and risk management
  system in order to implement amendments made to Legislative Decree No.
  135/2016 in relation to the duties of the board of Statutory Auditors in its
  capacity as the Internal Audit and Accounting Committee;
- after consultation with the Board of Statutory Auditors and the Director with Responsibility for the Internal Control and Risk Management System, it approved the work plan drawn up by the Chief of the Internal Audit Function for 2017;
- it approved the most important company directives;
- it confirmed the following as the subsidiaries with strategic importance, based principally on criteria of size (revenues) or in consideration of the particular market on which the subsidiary operates (such as the orphan drugs market): Laboratoires Bouchara Recordati S.a.s, Recordati Ireland Ltd., Jaba-Recordati S.A., Recordati Pharma GmbH, Innova Pharma S.p.A., Orphan Europe SARL, Recordati Ilac, Recordati Rare Diseases Inc. Rusfic Llc and Casen Recordati SL;
- following the demise of *Ing*. Giovanni Recordati, the Chairman and Chief Executive Officer, on 16<sup>th</sup> August 2016, it appointed Dr. Alberto Recordati as Chairman and *Dr*. Andrea Recordati as Vice Chairman, Chief Executive Officer and General Manager, defining the powers; subsequently as a consequence, the Board updated the procedure for significant transactions in line with the new powers (also where these relate to subsidiaries, in order to submit these to them for their own prior approval);
- it studied and approved the strategic operations of the Company and its subsidiaries in advance, when such operations were strategically significant in operating, capital or financial terms for the Company (with particular reference to company acquisitions, specialty medicines and loan agreements):
- at the beginning of 2016 it issued a positive evaluation of the adequacy
  of organisational, administrative and general accounting structures of the
  Company and its strategic subsidiaries put in place by the Chairman and
  CEO, with the support of the Director with responsibility for the internal
  control system and risk management, with particular reference to the
  internal control system and management of conflicts of interest, on the
  basis of the information provided to the Board in specific reports and
  other documentation (such as organisation charts) presented by the Chief
  of Group Audit, the Internal Audit and Risk Committee, the Supervisory
  Committee pursuant to Legislative Decree No. 231/2001, by the Director
  with responsibility for the internal control system and risk management
  and by the Chairman and CEO himself;
- it assessed the general performance of operations, firstly by approving accounting reports each quarter. Furthermore, in each meeting of the Board of Directors and independently of the time elapsed since the previous meeting, the CEO provides a report on activities carried out and the main transactions performed by the Company and its subsidiaries, even if they do not require prior approval by the Board of Directors;

- at the beginning of 2017, the Board carried out a periodic review of the Related-Party Transactions Regulations, three years having passed since it came into force and, having taken note of the opinion given by the Audit and Risk Committee, it considered that those regulations were still adequate, not requiring substantial modifications. Section 12 of this report may be consulted for further information on regulations governing transactions with related parties;
- it set performance objectives ring to the variable component of the remuneration of the Chairman of the Vice Chairman, Chief Executive Officer and General Manager.

Finally, as already reported, having received a prior opinion in favour from the Audit and Risk Committee, in December 2014 the Board of Directors had approved specific guidelines on the subject of corporate governance for subsidiaries of the Recordati Group, designed to redefine the corporate governance system and rules for subsidiaries, bringing them into line with developments in the internal organisational framework and with the relative best practices. At the beginning of 2017, following the governance solutions adopted by Recordati subsequent to the demise of *Ing.* Giovanni Recordati, the Chief Executive Officer submitted new corporate governance guidelines for subsidiaries of the Recordati Group to the Board of Directors, for the purpose of redefining the corporate governance system and rules for subsidiaries (with particular reference to size, composition and the principles by which the relative management bodies function) bringing them into line with changes in the organisational structure.

#### Self-assessment of the Board and its Committees

As it does every year, the Board of Directors carried out an assessment of the functioning of the Board itself and its committees and of their size and composition, with account also taken of factors such as professionalism, experience, including management experience, and the gender of its members, as well as their length of service in the role, with support from the Group Legal Service and Corporate Affairs Department of the Company. This evaluation was conducted by asking each Director to compile a questionnaire prepared by the Group Legal and Corporate Affairs Department of the Company. More specifically, the Independent Directors returned those questionnaires to an independent director who subsequently took steps to submit them to the Company in anonymous form. The results of the compilation of that questionnaire were discussed in the Board meeting held on 9th February 2017 and in that held on 1st March 2017, with particular reference to certain recommendations for shareholders in view of the renewal of the management body relating to the size of the Board. An orientation emerged which considered a Board composed of nine members to be adequate, taking care to see that the new composition adequately represents, in relation to the activities carried out by the Company, the different types of member (executive, non-executive, independent) and the expertise and professional and managerial experience needed for the proper management of the company. Generally the results of the evaluation, as in previous years, were positive with recommendations just mentioned.

#### 4.4 EXECUTIVE OFFICERS AND BODIES

#### Chairman, Vice Chairman and Chief Executive Officer

As already stated, until 15<sup>th</sup> August 2016 *Ing.* Giovanni Recordati had filled the positions of Chairman and Chief Executive Officer. On 16<sup>th</sup> August 2016, *Dr.* Alberto Recordati was appointed Chairman of the Board of Directors and *Dr.* Andrea Recordati was appointed Vice Chairman and Chief Executive Officer.

In accordance with article 23 of the By-Laws, representation of the Company shall be attributed to the Chairman of the Board of Directors or, in the event of his absence or inability to attend for any reason, to the Vice-Chairman, with sole signing authority for implementation of all resolutions of the Board unless otherwise resolved. The Chairman or, in the event of his absence or impediment for any reason, the Vice-Chairman, shall represent the Company before the law, with the power to take legal action and institute judicial and administrative proceedings at all levels of jurisdiction, including with respect to revocation and cassation proceedings, and appointing lawyers and attorneys for lawsuits.

In accordance with article 24 of the By-Laws, the Board of Directors may delegate all or part of its powers and functions not only to the Chairman, but also to the Vice-Chairman and one or more executive directors and it may grant special mandates to individual Directors or managers of the Company, including the power of attorney, determining their functions and powers under the law. In accordance with article 25 of the By-Laws, the Board may also delegate all or part of its powers to an Executive Committee.

On 17th April 2014 the Board of Directors had appointed Ing. Giovanni Recordati not only to the position of Chairman of the Board of Directors, but also to that of Chief Executive Officer with the purpose, even if not in line with the provisions of the Corporate Governance Code<sup>8</sup>, of improving the efficiency of the management of the Company. In fact, it had been considered, that by combining his role with that of a manager in the organisation, the Chairman was able to fulfil the role assigned to him by law extremely effectively, being fully up-to-date on operating events. Nevertheless, following the demise of Ing. Giovanni Recordati (15th August 2016), the Board considered that in compliance, amongst other things, with the recommendations of the CG Code, it was best not to concentrate too many roles in the same person. Furthermore, again in line with the recommendations of the CG Code, it was decided not to assign specific individual management powers to the Chairman. Moreover, the Chairman contributes to the formulation of strategic Company policies to be submitted to the Board of Directors in the context of the Chairman's Committee, which he chairs and on which the other executive directors Dr. Andrea Recordati and Dr. Fritz Squindo sit as members with the duty of examining the main operational events relating to Recordati and its subsidiaries.

In his role as Chief Executive Officer, *Ing.* Giovanni Recordati had been authorised, within the limits permitted by law, to exercise the broadest powers for the ordinary and extraordinary management of the Company, expressly including the power to appoint directors and his agents, persons with specific duties, experts and agents of the Company in general for specific actions or types of action, with the sole, exclusive and mandatory exclusion of the following operations reserved to the Board of Directors, except for operations performed with or between other companies of the Recordati Group:

- a) assumption of financial liability of more than € 50 million for any single operation;
- b) transfer of real estate for amounts of more than € 25 million, where the industrial operations of the Company or its subsidiaries are conducted at the time of the transfer;
- c) the purchase or sale of intellectual property of the Company or its subsidiaries for amounts exceeding € 25 million for each transaction;

- d) acquisition, transfer or any other provision in relation to holdings in other companies, likewise the acquisition or transfer of companies or company branches, for amounts of more than € 25 million for any single operation;
- e) the purchase and sale of proprietary medicinal products and generic products, for amounts exceeding € 25 million each;
- f) the grant of real or personal guarantees for amounts of more than € 25 million for any single operation;
- g) investments and disinvestment, other than those specified at the letters above, for amounts of more than € 15 million for any single operation.

Since 16th August 2016, Dr. Andrea Recordati, in his capacity as Chief Executive Officer, has been granted, within the limits permitted by Law, all the broadest powers for the ordinary and extraordinary management of the Company, also in relation to performing activities of management and co-ordination by the Company of the companies of the Group, expressly including the power to appoint directors and special officers, persons with specific duties, experts and agents of the Company in general for specific actions or types of action, and also with the power to take legal action and initiate judicial and administrative proceedings before courts at all levels, including with respect to revocation and cassation proceedings, and to appoint lawyers with the sole, exclusion of the operations listed below (exhaustive and mandatory in nature), which, because they are to be carried out directly by the Company and/or indirectly through subsidiaries, are operations reserved to the responsibility of the Board of Directors (except for intragroup operations, and that is performed with or between other companies of the Recordati Group):

- a) the assumption of financial debt for an amount greater than €25 million for each transaction and the grant of secured or personal guarantees for amounts greater than €10 million for each transaction;
- b) the sale and purchase of real estate properties for amounts of greater than €10 million, in which industrial activities of the Company or its subsidiaries are carried out at the time of the sale;
- c) the purchase or provision of ownership, or the purchase or the grant of licences for, intellectual property rights and more specifically by way of example, but not limited to these, intellectual property rights regarding specialty medicines, dietary supplements and medical devices for amounts not greater than €10 million each;
- d) acquisition, disposal or any other provision in relation to holdings in other companies and similarly the acquisition and disposal of companies or company operations, for an amount greater than €10 million each;
- e) the stipulation of agreements, including settlement agreements, concerning matters not included in those above for an amount greater than €10 million for each agreement.

On 16<sup>th</sup> August 2016, Dr. Andrea Recordati was also appointed Vice Chairman of the Board of Directors, responsible for the functions provided for by the By-Laws in the case of the absence or impediment of the Chairman of the Board of Directors.

The Chairman also: (i) convenes the Board meetings and ensures that the members of the Board and the Board of Statutory Auditors are provided, with advance notice of three days before the Board Meeting, except for exceptional cases of urgency and particular confidentiality, with the documentation and information necessary to enable them to express an informed opinion about the matters submitted to their examination and approval, (ii) co-ordinates the activities of the Board and conducts the proceedings of Board meetings; (iii) continuously provides information about the frequent variations of the law and the regulations that govern the sector and their impact on the Company, in order to develop the awareness of all Directors in relation to the situation and dynamics of the Company.

The Chief Executive Officer of Recordati does not hold interlocking directorships pursuant to Implementation Criterion 2.C.5 of the CG Code.

#### **Executive Committee**

No Executive Committee has been formed as an internal committee of the Board of Directors.

#### Reporting to the Board

The Chief Executive Office reported to the Board in individual Board meetings on the activities performed in exercising the powers conferred on him by the Board. In fact as already mentioned, in each meeting, and independently of the time elapsed since the previous meeting, the CEO provides a report on activities carried out and the main transactions performed by the Company and its subsidiaries, even if these are transactions which do not require prior approval by the Board of Directors.

#### 4.5 OTHER EXECUTIVE DIRECTORS

Until 15<sup>th</sup> August 2016, in addition to the Chairman and CEO, the other Directors that qualified as executives were *Dr.* Alberto Recordati, *Dr.* Andrea Recordati and Dr. Fritz Squindo.

*Dr.* Alberto Recordati, Vice-Chairman of the Board of Directors, coordinated R&D and "Licensing-in" activities.

From July 2013, *Dr.* Andrea Recordati had held responsibility for Group production and sales activities of the Group (including logistics and, from 2015, purchases) and he had been appointed Chief Operating Officer.

*Dr.* Squindo, General Manager for co-ordination of operations and Chief Financial Officer (as well as financial reporting officer and Director with responsibility for the internal control and risk management system), holds responsibilities for Administration, Finance and Control, Human Resources and Investors Relations & Corporate Communications. Dr. Squindo is also a director of other Group companies.

Subsequent to the 16<sup>th</sup> August 2016, in addition to the Chairman, *Dr.* Alberto Recordati and the Chief Executive Officer, *Dr.* Andrea Recordati, the Director Dr. Fritz Squindo has also been classified as an Executive Director. *Dr.* Squindo's powers remained unchanged compared with the first part of 2016.

### **4.6 INDEPENDENT DIRECTORS**

The Board of Directors of the Company has a number of independent directors in office which constitute the absolute majority of the members (five directors out of eight), which is a more rigorous approach than that required by the TUF and the CG Code itself, even for issuers included in the FTSE-Mib index

The procedure followed by the Board for verifying independence involves satisfaction of the requirement being declared by directors when they submit their candidature's and also when they accept their appointments. The Board ascertains that satisfaction in the first meeting subsequent to the appointment and discloses the results to the market.

Subsequently, and without prejudice to independent directors' commitments to promptly communicate to the Board the development of situations which determine failure to satisfy the requirement, the Board requires the directors concerned to annually confirm satisfaction of the requirements, as required by law and by the CG Code. The Board of Directors and the Board

of Statutory Auditors then proceed to verify the contents and to verify the correct application of requirements and of the procedure to ascertain them respectively.

With reference to the Board in office $^9$ , following the appointment by a Shareholders' Meeting on  $17^{\rm th}$  April 2014, for five Directors, Dr.ssa Rosalba Casiraghi, Aw. Michaela Castelli, Dr. Paolo Fresia, Dr. Mario Garraffo and Prof. Marco Vitale, having taken account of the declarations issued by these directors, the Board of Directors confirmed their possession of the requirements of independence pursuant to Art. 148, paragraph 3 of the TUF and the requirements of independence set forth in the CG Code, except for that which has been already reported in the notes to the table on page 17 and for that which is specified below.

Subsequently, this verification has been carried out annually, the last time being on  $9^{th}$  February 2017.

On that occasion the Board confirmed its previous assessment concerning the relationship between the Company and Prof. Vitale, attributable to a professional engagement worth € 50,000.00 annually, considering the relationship cited as not significant for the purposes of independence in consideration of the small quantitative nature of the engagement. Furthermore, the Board of Directors decided not to include the requirement relating to a Director holding office for more than nine of the last twelve years among those pursuant to the CG Code on the basis of which the assessment of the independence of Directors is performed. This is because, with precise reference to Prof. Vitale, Dr. Garraffo and Avv. Pedersoli, the Board considered that because of their specific expertise and professionalism and for their constant work in supervising and stimulating the Board they have demonstrated that they have maintained their characteristics of independence and freedom of judgement in assessing the work of management intact. Furthermore, the Board of Directors noted that the continuation of a Director in office for more than nine years should not in itself be considered a negative requirement for qualification as independent if the other requirements of the CG Code are satisfied. This is because great experience of the specific affairs of the issuer, the stature and professionalism of the persons considered, the absence of interests and significant relations with the Company constitute a value to be considered positively and such as to consider their capacity to judge freely and without bias to be untarnished. The Board therefore considered that the requirements of independence were met by the said directors in accordance with the CG Code, confirming its opinion that consideration must be given to substance and not form in an assessment of independence requirements, with account taken also of a widespread orientation among listed companies.

The Board of Statutory Auditors verified that the criteria and procedures of evaluation adopted by the Board to evaluate the independence of its members were implemented correctly.

The independent directors, at and before the beginning of meetings of the Board of Directors, verified each time the absence of any specific matters that might be significant in relation to their roles as independent Directors.

The independent directors met once in 2016, in April, without the other directors on the initiative of the Lead Independent Director.

#### 4.7 LEAD INDEPENDENT DIRECTOR

The Board has designated independent Director Prof. Vitale to be the lead independent director, to guide the independent Directors, with particular reference to the independent Directors, in order to improve the activities and functioning of the Board.

That appointment had been appropriate, in compliance with the recommendations of the CG Code, in consideration of the existence of a situation where the roles of Chairman and CEO accumulated in same person, Ing. Giovanni Recordati.

The lead independent director collaborates with the Chairman in order to ensure that the Directors receive complete and timely information, and is also authorised to convene special meetings of the independent Directors only, at his own discretion or at the request of other Directors. As already stated, the Lead Independent Director convened a special meeting of independent directors only in 2016.

# 5. CONFIDENTIALITY OF CORPORATE INFORMATION

On 3<sup>rd</sup> July 2016 Regulation (EU) No. 596/2014 containing regulations governing market abuse ("Market Abuse Regulation" or "MAR") and Directive 2014/57/EU, which regards penalties in cases of market abuse ("Directive MAD2) came into force. These rules brought about rather significant changes compared with the market abuse rules previously in force.

Subject to the prior opinion in favour of the Supervisory Committee and the Audit and Risk Committee (because market abuse procedures fall under "Model 231" administrative liability rules) in a meeting held on 30<sup>th</sup> June 2016, on the basis of a proposal from the Chairman and the Chief Executive Officer, the Board of Directors approved an update of the corporate procedures in force for compliance with the new regulatory framework and more specifically it approved the "Procedure for internal management and public disclosure of inside information". That Procedure therefore updated the previous "Internal Regulation for Processing Inside Information", which had been in force since 2006 and which had in turn replaced the previous internal regulation adopted in 2001.

That Procedure regulates the internal management and public disclosure of inside information relating to Recordati S.p.A. and its subsidiaries.

The rules of conduct set by the Procedure are designed to put the necessary organisational controls in place for the following: proper management of reporting; the processing of Inside Information (inclusive of identifying those persons responsible for the assessment of that information); the proper triggering of a delay procedure; taking account of persons who have access to inside information; disclosure to third parties (under determined conditions); and disclosure to the market of said information.

The Board also approved an update to the "Procedure for keeping and managing the list of persons who have access to Inside Information", which is designed to ensure compliance with the obligations laid down by the legislation and regulations in force, by regulating procedures for keeping and regularly updating the list, in application of the "Inside Information Procedure".

More specifically, in compliance with the new rules, the Procedure requires the List also to have a section in which to register persons who are permanently in possession of knowledge of all Inside Information.

The rules contained in the procedures mentioned have been adopted in compliance with the provisions of current laws and regulations in force:

- to protect investors and the integrity of the market, because they are designed to prevent transactions harmful to their interests through the exploitation of information asymmetries, which is to say altering market variables by spreading untruthful or misleading information;
- to protect the Company from possible responsibilities that may attach to it for unlawful conduct committed by parties related to it.

The Procedure, as already specified, is in fact a fundamental component of the Company's and the Group's internal control and risk management system and it is also an integral part of the overall system for the prevention of unlawful behaviour pursuant to Legislative Decree No. 231/2001 (administrative liability).

The Directors and the Statutory Auditors have also acquainted themselves with changes to the legislation on insider dealing and the relative disclosure obligations, to be carried out through the Company. The Board of Directors has also approved an update to its "Procedure on insider dealing" to comply with the new rules on market abuse. On the basis of the organisational structure of the Issuer, no new persons significant for the application of the regulations have been identified.

Finally, in compliance with the new market abuse rules, the Board of Directors has introduced, effective from 3rd July 2016, an obligation to abstain, during specific periods of the year, from transactions involving financial instruments issued by the company and listed on regulated markets. In compliance with the provisions of the MAR, those periods have been identified as running from the thirtieth day prior to the date of the meeting of the Board of Directors convened to approve interim or end-of-year financial reports which the Company is required to publish according to the rules of the trading venue in which the shares are admitted for trading or according to national law until the publication of the relative reports (i.e. the "blackout period").

#### 6. INTERNAL COMMITTEES OF THE BOARD

The Board of Directors has formed a Remuneration Committee and an Audit and Risk Committee from among its members, both with consultative and proposal-making functions and consisting exclusively of independent directors.

The CG Code recommends that the boards of directors of companies belonging to the FTSE-Mib index assess whether they should form a special committee to supervise sustainability issues connected with running the company and the dynamics of its interaction with all stakeholders, or to group together or distribute these functions amongst committees that already exist. As already mentioned, on June 20th 2016, Recordati was admitted to the FTSE MIB share index. We report that the Board of Directors has been informed of that specific recommendation contained in the CG Code and has decided to make that assessment during the course of 2017.

#### 7. APPOINTMENTS COMMITTEE

Finally, following the appointment of the new Board of Directors on 17th April 2014, the Board did not consider it necessary to form an Appointments Committee<sup>10</sup>, but expressly reserved the duties assigned to the latter by the CG Code to itself sitting in plenary session. This is mainly because until now no difficulty has been encountered in making appointment proposals, partly due to the presence of a shareholder who holds legal control of the Company and also because it is therefore considered preferable to reserve the functions that the CG Code attributes to an Appointments Committee, and which the Board already performed, to the Board sitting in plenary session – it will be recalled that the Board is currently composed of five independent members out of a total of eight.

In this respect, at the beginning of 2017, in consideration of the coming renewal of the management body, on the conclusion of an analysis of the results of the process to self assess the board and its internal committees, the Board of Directors expressed its desire to provide recommendations to shareholders before appointing the new management body. An orientation emerged which considered a Board composed of nine members to be adequate, taking care to see that the new composition adequately represents, in relation to the activities carried out by the Company, the different types of member (executive, non-executive, independent) and the expertise and professional and managerial experience needed for the proper management of the company.

#### 8. REMUNERATION COMMITTEE

Please consult the relevant part of the Report on Remuneration published in accordance with Art. 123-ter of the TUF for information on this section.

## 9. DIRECTORS' REMUNERATION

Please consult the relevant part of the Report on Remuneration published in accordance with Art. 123-*ter* of the TUF for information on this section

#### 10. AUDIT AND RISK COMMITTEE

In a meeting of 17<sup>th</sup> April 2014, following its appointment by a Shareholders' Meeting, the Board formed an Audit and Risk Committee comprising the following non-executive and independent (within the meaning described above) Directors: *Prof.* Marco Vitale, Chairman, *Dr.* Mario Garraffo and *Avv.* Carlo Pedersoli.

Following the resignation of *Awv.* Pedersoli as a Director of the Company in a meeting held on 8<sup>th</sup> March 2016, on that same date the Board of Directors resolved to appoint Avv. Michaela Castelli, a non-executive and independent director, as a member of the Control and Risk Committee to replace *Avv.* Pedersoli.

This Committee was again assigned responsibility for analysing problems and defining important policies for the auditing of company activities, providing consultancy and making proposals to the Board of Directors with regard to assessments and decisions concerning the internal control and risk management system and also with regard to the approval of periodic financial reports.

The Committee met five times during the year (sessions lasted around one hour and twenty minutes on average). The Committee met twice during the current year. The percentage attendance of Committee members at meetings is shown in the table contained at the end of section 4.2 of this Report. Two of the three members of the Committee have experience in accounting and financial matters.

The entire Board of Statutory Auditors has been constantly invited to participate in the Committee's work.

Invited by the Chairman of the Committee and with regard to individual items on the agenda, various non-members have participated in some meetings, in particular the General Manager for the Co-ordination of Operations (who is also the Director with responsibility for the internal control and risk management system), the Chief of Group Audit, the Chief of Group Human Resources, the Supervisory Committee pursuant to Legislative Decree 231/01, representatives of the Audit Firm, the "Official Employers", the heads of the prevention and protection services for production sites in Italy, on matters concerning safety at the workplace and consultants who provided support to the Company on specific projects examined by the Committee.

The Legal Service and Corporate Affairs Office is always involved for the minuting of meetings.

## **Duties assigned to the Audit and Risk Committee**

The functions of the Audit and Risk Committee are to advise and submit proposals to the Board of Directors: by conducting appropriate fact-finding activity, it provides support to the Board of Directors in its assessments of the internal control and risk management system and also those relating to the approval of periodic financial reports. More specifically, it expresses opinions on the following:

- a) on the guidelines for the internal control and risk management system, so that the principal risks to which the Company and its subsidiaries are exposed are correctly identified and adequately measured, managed and monitored, and on the determination of criteria to assess whether such risks are compatible with management of the Company that is consistent with its strategic objectives;
- b) on the selection of one or more Directors who are given responsibility for the creation and maintenance of an effective internal control and risk management system;
- c) an assessment, at least annually, of the adequacy of the internal control and risk management system with respect to the nature of the company and its risk appetite and also its effectiveness;
- d) the approval, at least annually, of the work plan drawn up by the Chief of the Group Audit Function;
- e) the description of the main characteristics of the internal control and risk management system and on the assessment of its adequacy in the Corporate Governance Report;
- f) the assessment of the results furnished by the external statutory auditor in its letter of suggestions (if provided) and in its report on basic issues arising from its external statutory audit;
- g) the appointment and removal of the Chief of the Group Audit Function (formerly the Internal Control Officer in accordance with Art. 150 of Legislative Decree No. 58/1998), on the assignment of adequate resources to the latter to fulfil his/her duties and on the remuneration set for him/her consistent with Company policy.

Furthermore, in its work to support the Board of Directors, the Audit and Risk Committee:

- shall assess, together with the Financial Reporting Officer appointed
  to prepare the corporate accounting documents and after consultation
  with the external statutory auditors and the Board of Statutory Auditors,
  the correct use of accounting policies and their consistency in the
  preparation of the consolidated financial statements, prior to approval of
  the consolidated financial statements by the Board of Directors;
- shall express opinions on specific aspects concerning the identification of the main corporate risks;
- shall examine periodic reports for the assessment of the internal control and risk management system and those of particular importance prepared by the Group Audit Function;
- shall monitor the independence, adequacy and effectiveness of the Group Audit Function;
- shall require the Group Audit Function to investigate specific operational areas, reporting promptly to the Chairman of the Board of Statutory Auditors;
- shall report to the Board, at least semi-annually, when annual and interim financial reports are approved, on its activities and also on the adequacy of the internal control and risk management system;
- shall make proposals to the Board of Directors regarding changes to be made to the Organisational Model established pursuant to Legislative Decree 231/01 adopted by the Company;
- shall make proposals to the Board of Directors regarding the appointment of members of the Supervisory Committee created pursuant to Legislative Decree No. 231/01 and regarding the allocation of an annual budget to that body;
- shall express an opinion on the appointment of the Financial Reporting Officer appointed to prepare the corporate accounting documents:
- shall express an opinion on the Regulations for Related-Party Transactions
  which the Company must adopt in compliance with Consob Regulation No.
  17221 of 12th March 2010 and also on any subsequent amendments to
  those regulations;
- shall express an opinion, either binding or non-binding, on Related-Party Transactions of Major Importance and on Related-Party Transactions of minor importance in compliance with the aforementioned regulations governing related-party transactions adopted by the Company, unless they consist of Related-Party Transactions which concern remuneration;
- shall assist the Board of Directors on the implementation of recommendations contained in the Corporate Governance Code for listed companies in relation to the internal control and risk management system.

At the meetings mentioned above, the Committee mainly carried out the following activities:

- after consultation with the firm of auditors and the Board of Statutory Auditors and together with the financial reporting officer, it examined the results of the audit of the accounts regarding the financial statements and the proper use of accounting policies and their consistency in the preparation of the consolidated financial statements;
- it examined the periodic reports of the Supervisory Committee pursuant to Legislative Decree No. 231/01 and of the Chief of Group Auditing;
- it examined the results of the audits conducted in 2016 and the proposed audit plan for 2017;
- on the subject of safety in the workplace, it examined the reports of the "Official Employers" and of the heads of the Prevention and Protection Service at the production plants in Milan and at Campoverde as well as reports on the Group's plants abroad;

- it examined the results of inspections for conformity with the protocols which form part of the Organisational Model pursuant to Legislative Decree No. 231/2001 on the subject of the environment and safety at the workplace:
- it formulated a proposal for submission to the Board concerning the expenditure budget of the Supervisory Committee for the operating expenses of the committee itself concerning the application of the Organisation, management and control model pursuant to Legislative Decree 231/01;
- it examined the adequacy of the guidelines for the internal control and risk management system;
- it examined the organisational structure of the Group Audit function;
- it examined the update of the risk catalogue and developments concerning the principal risks associated with business activities in 2014 and it expressed a favourable opinion on the risk limits set for 2017;
- in its capacity as the Committee for Related-Party Transactions, it carried out the three-year periodic review of the Related-Party Transactions Regulations, and found no necessity to propose any substantial modifications to the Board;
- at the beginning of 2016, it examined changes made to the Corporate Governance Code in July 2015, which listed companies are required to apply by the end of 2016 and for which it had received preliminary information during the course of 2015. In this regard, it took note that the company did not consider it necessary to propose further actions with respect to those already in place for compliance purposes (except for ensuring that in future Board meetings the chairman of committees inform the board of its meetings at the next following board meeting), without formulating any observations;
- it examined an update to company procedures concerning market abuse to comply with the new legislative and regulatory framework, in preparation for examination and approval by the Board. Those procedures, as already specified, are in fact a fundamental component of the Company's and the Group's internal control and risk management system and they are also an integral part of the overall system for the prevention of unlawful behaviour pursuant to Legislative Decree No. 231/2001 (administrative liability);
- · t also expressed its opinion to the Board on the following:
  - the adequacy of the guidelines for the internal control and risk management system;
  - the adequacy of the internal control system, at the time of approval of the 2015 Annual Report and the 2016 half yearly interim financial report;
  - the programme of work prepared by Chief of Group Audit for 2015;
- it reported to the Board twice on its activities, at the time of approval of the 2015 Annual Report and the 2016 half yearly interim financial report.
   Meetings of the Committee were properly minuted.

The Committee had the opportunity to access company information and access the units necessary to perform its duties; it did not make use of external advisors.

The committee did not incur any expenses in the performance of its duties during the Year.

# 11. INTERNAL CONTROL AND RISK MANAGEMENT SYSTEM

As already mentioned in point 4.3, the Board of Directors has examined the update of the "Catalogue of Risks" for 2016, drawn up with assistance from the consulting company Deloitte S.p.A., in order to obtain an up-to-date and formal picture of the main internal and external risks of the Recordati Group and of the various tools and processes in place to manage those risks. In this respect a procedure is in place to ensure periodic updating of the Catalogue of Risks already indentified.

On the basis, amongst other things, of that examination, the Board has assessed whether the degree and nature of the risks, as identified in the Group Catalogue of Risks presented to the Board in a meeting of 15th December 2016, are compatible with the Group's strategic objectives contained in the 2017 annual budget and also the 2017-2019 Three-Year Business Plan.

Furthermore, with the opinion in favour of the Audit and Risk Committee, the Board considered that the guidelines for the internal control and risk management system of the Company and the Recordati Group, approved the previous year (except for some changes made for compliance with the new version of Art. 19 of Legislative Decree No. 39/2010, as amended by Legislative Decree No. 135/2016 concerning the duties assigned to the committee for internal control and accounting audit) were still adequate, so that the principal risks to which the Company and its subsidiaries are exposed are correctly identified and adequately measured, managed and monitored.

The internal control and risk management system consists of a structured and organic set of procedures and organisational units designed to prevent or limit the consequences of unexpected results, to enable corporate objectives to be achieved and to ensure both compliance with the law and regulations and proper and transparent reporting internally and to markets. The internal control and risk management system permeates the whole Company, involving a variety of staff with specific roles and responsibilities. The Company has put special whistle blowing channels of reporting in place as part of its organisational models pursuant to Legislative Decree No. 231/2001 (administrative liability) and the Group's anti-bribery system<sup>11</sup>.

The Board positively assessed the adequacy, effectiveness and actual functioning of the internal control and risk management system on the basis of information provided in meetings in the form of reports presented by the Internal Audit Committee and by the Supervisory Committee pursuant to Legislative Decree 231/01.

The heads of each department are responsible for designing and managing the internal control system and for monitoring its effective functioning on the basis of the guidelines approved by the Board of Directors.

The structural components of the internal control and risk management system consist of: the Code of Ethics, which defines the principles and underlying values of the Company's ethical code and the rules of conduct that are based on those principles; the system of powers and delegations with general and specific authorisations and the internal delegation of powers, according to the responsibilities assigned; corporate operating procedures; IT systems to support both management and production activities and also accounting and financial processes. With regard to compliance, the Issuer has had an organisational model in place pursuant to Legislative Decree No. 231/2001 since April 2003 which is continuously updated and also a

control model pursuant to Law No. 262/2005 for financial reporting (further information is given below on the "Risk management and internal control systems in relation to financial reporting").

The control instruments described above are monitored by management and also independently by the Group Audit Function by means of auditing activities set out in the annual audit plan. The results of auditing activities are reported to the Chairman and Chief Executive Officer, the Director responsible for the internal control and risk management system and to company management and also periodically to the Board of Statutory Auditors, the Audit and Risk Committee and the Board of Directors.

# 11.a) Principal characteristics of the risk and internal control and risk management system in relation to the financial reporting process.

The internal control and risk management system, as just defined, covers financial reporting which forms an integral part of it, the preparation of which is governed by organisational procedures and instructions which ensure compliance with the general principles of control laid down by the Issuer (e.g. a proper separation of functions, a proper system of authorisations and powers, checks and balances, accountability, etc.). It is based on the main established reference models (e.g. CoSO Report) being subject at the same time to verification and periodic update by means of a review of the risks to which the Company is exposed.

The financial reporting process of the Issuer was subjected to a series of procedural and organisational initiatives with action taken to create an internal controls system for administrative and accounting activities designed to guarantee the reliability, accuracy, completeness and promptness of financial reporting and to regularly produce management, operating and financial reports to the board and to the statutory and external auditors.

A description is given below, in accordance with the regulations in force, of the characteristics of the system adopted, with particular reference to (a) the stages of the risk and internal control management system in relation to the financial reporting process and (b) the roles and functions involved and the procedures for co-ordination between the parties involved.

# (a) The stages of the risk and internal control management system in relation to the financial reporting process

The Issuer has implemented a model for the administrative and accounting control of the system (hereinafter also the "262 Control Model) for some time now in order to ensure the effectiveness of that system. It has also assigned responsibility for verifying proper application of that model and for monitoring the functioning and adequacy of the Internal Control System in relation to the model to the Manager appointed to prepare corporate accounting documents.

The 262 Control Model control model consists of a set of corporate rules and procedures designed to enable objectives of reliability, accuracy, completeness and promptness in financial reporting to be achieved by identification and management of the main risks attaching to the preparation and disclosure of financial information.

The 262 Control Model consists of

- · administrative and accounting risk assessment;
- · administrative and accounting manuals and procedures,

which are closely related one to the other and subject to continuous update and periodic assessment.

More specifically administrative and accounting risk assessment is a continuous process of identifying and assessing risks attaching to accounting and financial information and it is performed by the Manager appointed to prepare corporate accounting documents with the support of the Group Internal Audit Function. This process is performed annually by means of:

- the identification, by means of quantitative (size) and qualitative (importance) criteria, of items in the financial statements and in financial information which may be highly sensitive and significant or involve risks of error or omission, with reference to the financial statements of the Parent or to the consolidated financial statements of the Group;
- the identification of the relative processes and accounting information input for each significant item of the financial statements and of financial information and of the relative controls to manage the risks identified.

If control activities are not found to be adequately documented or regulated in relation to risk areas identified following periodic risk assessment, it is the responsibility of the function responsible for the process, to provide adequate support documentation, with the support of the Financial Reporting Officer and, if necessary, the Internal Audit Function, to enable the existing controls in the area subjected to analysis to be assessed.

When risks were identified as a result of annual risk assessment activities, the Company and the Group put procedures, protocols and documents in place to control administrative and accounting activities.

The body of the administrative and accounting manuals and procedures is comprised of the following principal documents:

- the Group Accounting and Reporting Manual, designed to ensure the application of uniform criteria in the Group with regard to the recognition, classification and measurement in the accounts of operating and financial events:
- a system of internal certification by the management and administrative chiefs (CEO and Financial Controller) of the subsidiaries of the Recordati Group with regard to the accuracy, reliability and completeness of accounting information and its compliance with Group accounting policies and local regulations. This system, set out in the Group Accounting and Reporting Manual, is designed, amongst other things, to support the signing of certifications and attestations required by law of the Financial Reporting Officer and of the Chief Executive Officer;
- administrative and accounting procedures and protocols for closing accounts at the end of accounting periods and preparing annual financial statements and reporting packages which define control responsibilities, activities and rules to follow for the administration and accounts of the Parent Company and its subsidiaries;
- procedures for preparation of the consolidated financial statements which
  regulate the operations and controls to be performed for the preparation
  of the consolidated financial statements, describing, amongst other things,
  the activities to be performed in the consolidation IT system adopted by the
  Group and used in its subsidiaries and which define the responsibilities of
  the various functions for the proper functioning of that system;
- calendar of end of period activities: a document which is updated and distributed monthly, which gives deadlines for the process of closing accounts and preparing financial statements, reporting packages and the consolidated financial statements:
- operational procedures which define the activities, responsibilities and management operations in terms of authorisation, implementation, control, official approval and recognition in the accounts for those accounting and reporting areas considered significant, in co-ordination with annual accounting and administrative risk assessment. Those responsible for the functions and for the subsidiaries involved in the process of preparing and managing accounting and financial information are responsible for the proper functioning and update of the administrative and accounting internal control system in relation to all the processes and accounting reporting under their control and they must constantly monitor those

- administrative and accounting procedures in order to ensure that they are properly applied and appropriate to the existing processes;
- tables of administrative and accounting controls, which describe the
  control activities implemented in each administrative and accounting
  process in relation to the risk identified and the related control objectives
  and which summarise the results of control testing activities performed
  by the Internal Audit Function. The controls described by those tables
  represent the application of control principles described in administrative
  and accounting control procedures. These tables are therefore used as
  a tool for the identification of the key controls in place, specific to each
  significant process, and for the identification of tests to be performed to
  assess the adequacy of the administrative and accounting internal audit
  system. These tables are constantly updated by the Internal Audit Function.

The Financial Reporting Officer appointed to prepare corporate accounting documents assesses and testifies to the adequacy of the 262 Control Model, which is the administrative and accounting internal control system just described and to the proper functioning of the procedures in place at least twice annually, when the interim half year and annual financial statements (consolidated financial statements of the Group and separate financial statements of the Parent Company) are approved. He is supported by the testing activity performed by the Group Internal Audit Function designed to assess the adequacy of the design and proper implementation and operational effectiveness of the controls in place.

Independent testing is performed continuously throughout the year on the basis of the annual audit plan drawn up by the Chief of Group Audit. The results of testing activities, assessments of possible areas for improvement and the relative corrective action are officially published in an annual report addressed to the Chief of Group Audit, the Financial Reporting Officer and the CEO.

The Financial Reporting Officer appointed to prepare corporate accounting documents is also responsible for monitoring the administrative and accounting internal control system on the basis of information received from the chiefs of corporate functions and reports on the activities performed by the Internal Audit Function, in order to ensure that the body of procedures is updated and that the controls identified by means of the administrative and accounting procedures are actually implemented.

## (b) Roles and functions involved in the system for the management of risks and internal control in relation to the financial reporting process

The roles involved with specific reference to financial reporting processes are: the Board of Directors, CEO, the Chief of Group Audit, the Audit and Risk Committee and the Financial Reporting Officer (as well as the Director with responsibility for the internal control and risk management system).

The Financial Reporting Officer in conjunction with the CEO is responsible for putting adequate administrative and accounting procedures in place for the preparation of the separate Parent Company and consolidated financial statements.

Finally, we report that Legislative Decree No. 135/2016 has been in force since 5th August 2016, even if it contains a series of transition measures to ensure gradual introduction of the new rules. This decree implements Directive 2014/56/EU in Italian law which in turn had amended the previous Directive 2006/43/EU which had been implemented by Legislative Decree No. 39/2010, commonly known as the "Consolidated statutory audit law".

Legislative Decree No. 39/2010 that came into force on  $7^{th}$  April 2010 and had introduced the assignment of functions to the Board of Statutory Auditors to act as a "Committee for internal control and accounting audit" (CICAA)

indicating in particular that this should oversee the financial reporting process and the efficacy of the internal control, internal audit and, if applicable, the risk management systems.

In this respect, within the meaning of the general spirit of this legislation (i.e. an update of account auditing regulations to strengthen instruments designed to prevent financial crises and to consolidate and improve controls put in place by regulations to support the reliability and accuracy of company financial reports), Legislative Decree No. 135/2016 defines more accurately the duties assigned to Boards of Statutory Auditors in their capacity as the CICAA in entities of public interest.

The new version of Art. 19 introduces new elements to the old version, no longer assigning a general oversight function, but defining a series of specific duties, although they nevertheless relate to the four areas indicated above. More specifically, the CICAA is required to monitor the efficacy of systems for the internal control of a company's quality and risk management and, if applicable, internal audit, as far as the financial reporting of the entity subject to audit is concerned, without violating its independence.

Further information is given in Section 14 on the Board of Statutory Auditors.

# 11.1 DIRECTOR WITH RESPONSIBILITY FOR THE INTERNAL CONTROL AND RISK MANAGEMENT SYSTEM

Following his appointment by a Shareholders' Meeting, on the 17th April 2014 the Board of Directors, confirmed the appointment as Executive Director with responsibility for the internal control system of Dr. Fritz Squindo, the General Manager for the Co-ordination of Operations and the CFO.

The Director with responsibility for the internal control and risk management system:

- has identified, with the help of the Chief of Group Audit, the principal business risks, taking account of the characteristics of the activities undertaken by the Company and by its subsidiaries and has reported on this to the Board. In detail, he has completed the update of the Recordati Catalogue of Risks for 2016 (again with the assistance of the outside company Deloitte S.p.A.) and he has reported on this in detail to the Audit and Risk Committee and the Board;
- has implemented the guidelines defined by the Board and, with the assistance of the Chief of Group Audit and other competent functions within the Company, has designed, constructed and managed the internal control and risk management system, while constantly checking its adequacy and effectiveness;
- has brought the system, again with the help of the Chief of Group Audit
  and other competent functions within the Company, into line with changes
  in operating conditions and in the legislative and regulatory framework.

The Executive Director responsible for monitoring the functionality of the internal control system:

- may request the Group Audit Function to investigate specific operational areas and compliance with internal rules and procedures in carrying out company operations, reporting promptly to the Board of Directors, to the Chairman of the Audit and Risk Committee and to the Chairman of the Board of Statutory Auditors;
- shall report promptly to the Audit and Risk Committee (or to the Board
  of Directors) with regard to problems and difficulties found in carrying
  out their activities or of which they have nevertheless learnt, so that the
  Committee (or the Board) make undertake appropriate initiatives.
- shall submit a proposal to the Board of Directors for the appointment and removal of the Chief of the Group Audit Function and also on the remuneration for him, consistent with Company policy.

#### 11.2 CHIEF OF THE GROUP AUDIT FUNCTION

When implementing amendments made to the CG Code in December 2011, on 20th December 2012, with specific reference to the Chief of the Group Audit Function, the Board of Directors acknowledged that it was the responsibility of the Board of Directors to appoint and remove the chief of that function on the basis of a proposal submitted by the Director Responsible for the internal control and risk management system, and also to ensure that he has adequate resources to carry out the relative functions and to set the remuneration consistent with Company policies.

It is underlined that the Group Audit Function, headed by Dr. Minora, has no connection with any operational area whatsoever and reports hierarchically from 20<sup>th</sup> December 2012 to the Board of Directors. The Board also delegated responsibility to the Chairman and Chief Executive Officer for the ordinary management of the employment relationship with the Chief of the Group Audit Function. Following the demise of Ing. Recordati and the consequent modifications to the Company's organisational structure, the ordinary management of employment relationships has been assigned to the Chairman. Additionally, the Board confirmed the Chief of the Group Audit Function as the Internal Control Officer pursuant to Art. 150 of Legislative Decree No. 58/1998.

When he was appointed, the Board, having consulted with the Audit and Risk Committee, assessed the appropriateness of the remuneration paid to the Chief of Group Audit as an employee of the Company with respect to the Company's policies.

The duties of the Chief of Group Audit are as follows:

- to oversee, both on a continuous basis and in relation to specific needs and
  in observance of international standards, the functioning and the adequacy
  of the internal control and risk management system, by carrying out an
  audit plan approved by the Board of Directors, based on a structured
  process to analyse and set priorities in relation to the main risks;
- to prepare periodic reports containing adequate information on his activities, on the procedures employed to manage risks and on compliance with the plans drawn up to mitigate them. These periodic reports contain an assessment of the appropriateness of the internal control and risk management system;
- he promptly prepares reports on events of particular importance;
- he submits periodic reports to the Board of Statutory Auditors, the Audit and Risk Committee, the Board of Directors and the Director with responsibility for the internal control and risk management system;
- as part of the audit plan, he oversees the reliability of IT systems, including those responsible for bookkeeping.

For the purposes of the above the Chief of Audit has direct access to all information useful for performing his/her duties.

Furthermore, the Chief of Group Audit:

- explains the proposed annual work programme to the Audit and Risk Committee in order to implement any recommendations that Committee intended to make;
- assists the Executive Director responsible for overseeing the functionality
  of the internal control and risk management system with the design,
  management and monitoring of the internal control and risk management
  system and with the identification of the various risk factors;
- schedules and carries out, consistent with the annual work plan, direct and specific audit activities at Recordati S.p.A. and in all the subsidiaries, with particular regard to companies of strategic importance, in order to detect any failings there may be in the internal control and risk management system, in the various risk areas.

- checks that the rules and procedures for auditing and risk management processes are observed and that all individuals involved act in accordance with the predetermined objectives;
- carries out checks on his own initiative or on the request of the Board of Directors, the Audit and Risk Committee, the Executive Director responsible for monitoring the functionality of the internal control and risk management system or the Board of Statutory Auditors.

In detail, during the course of the year and in meetings of the Board of Directors already held in 2017, the Chief of Group Audit:

- explained the annual work programme and the organisational structure of his function to the Audit and Risk Committee and to the Board of Directors;
- had direct access to all the necessary information to carry out his role;
- carried out direct and specific auditing tasks, in a manner consistent with the annual work plan;
- reported to the Executive Director responsible for monitoring the functionality of the internal control system on the results of the auditing activities undertaken during the Year;
- reported on his actions and on the results of the activities undertaken to the Audit and Risk Committee and to the Board of Statutory Auditors of the Company.

The Chief of Group Audit had an operating budget which was used to carry out the audits and checks performed during the Year.

The Board of Directors was informed by the Audit and Risk Committee of the organisational structure of the Group Audit Function and it agreed with the assessment of its adequacy in carrying out the responsibilities assigned to it and drawing up the audit plan approved for 2017.

# 11.3 ORGANISATIONAL MODEL pursuant to Legislative Decree 231/2001.

The Company has adopted and effectively implemented a model which represents an organisational and operational tool aimed at preventing the Company's employees and colleagues from committing the crimes specified in Legislative Decree 231/01.

The duties of monitoring the adequacy updating and effectiveness of the Model have been transferred by the Company to a Supervisory Board having collective form, comprising two external members and one Company employee.

When the new CG Code was examined in the meeting held on 20th December 2012, the Board of Directors, assisted by the Audit and Risk Committee, also assessed whether to assign the functions of the Supervisory Committee (pursuant to Legislative Decree No. 231/2001 in accordance with Law No. 183/2011 — the 2012 "Stability" Law), and decided in favour of Recordati continuing to maintain a Supervisory Committee as a highly specialised unit, dedicated entirely to the supervision of ethical, preventative, organisational and management procedures adopted to prevent incurring liability within the meaning of Legislative Decree No. 231/2001 and therefore with specific expertise on compliance with a particular area of law which applies to the Company. These functions were not therefore assigned to the Board of Statutory Auditors.

The organisation, management and control model is constantly updated and monitored with particular attention paid to preventing crimes and to risk assessment, following the new regulatory changes.

The Model consists of a general part and a specific part, arranged into different sections. The general part includes, *inter alia*, the Code of Ethics, the Disciplinary System and the By-Laws of the Supervisory Board. The specific part includes, *inter alia*, a "map" of the areas where the risk of crime is more marked and a significant number of "protocols" through which measures are

put in place to prevent the commission of offences in the areas identified in the map. A similar model has been adopted for the subsidiaries Innova Pharma S.p.A. and Orphan Europe Italia S.r.I.

A presentation of the Model adopted by the Company is available on the Company's website at http://www.recordati.it/en/corporate\_governance/compliance\_programmes.

The Supervisory Committee, which is of a collegial nature, is composed of the Chief of the Audit Function and two external professionals, one of whom acts as the Chair. It has its own internal regulations and operates on the basis of a specific programme. It reports to the Board of Directors, directly or through the Audit and Risk Committee or the Board of Statutory Auditors.

For subsidiaries of strategic importance located abroad, policies with a function similar to those of the Organisational Model pursuant to Legislative Decree 231/01 adopted by the Company have been implemented and are being implemented, where considered necessary, including with reference to new local regulations.

#### 11.4 AUDIT FIRM

KPMG S.p.A. is the firm of external auditors appointed to audit the Company. The appointment was formally made by a Shareholders' Meeting on 13<sup>th</sup> April 2011 for the years 2011-2019, as proposed by the Board of Statutory Auditors.

#### 11.5 THE FINANCIAL REPORTING OFFICER

On 3<sup>rd</sup> May 2007, the Board of Directors, having noted the favourable opinion of the Board of Statutory Auditors and of the Internal Audit Committee, appointed Fritz Squindo, General Manager for the co-ordination of operations, as the Financial Reporting Officer.

During that meeting, it was confirmed that he satisfied the requirements of respectability and professionalism laid down in the applicable legislation and in the Company's By-Laws, which stipulate, in Art. 25, that the Financial Reporting Officer must not only satisfy the requirements of respectability laid down by law for those performing administrative and managerial duties but also the requirements of professionalism characterised by specific competence in administrative and accounting matters. This competence, to be verified by the Board of Directors, must be acquired through working experience in a position of adequate responsibility over a suitable period of time.

The Financial Reporting Officer is given duties and powers to perform that assignment, which include the provisions of the operational guidelines for that manager approved by the Board of Directors on 3 May 2007.

# 11.6 CO-ORDINATION BETWEEN THOSE INVOLVED IN THE INTERNAL CONTROL AND RISK MANAGEMENT SYSTEM

The Company has specified the roles and responsibilities of those involved in the internal control and risk management system in detail, in the guidelines for the internal control and risk management system of Recordati S.p.A. and of the Recordati Group and also the procedures for co-ordination between the parties involved

In this respect, the Company encourages meetings between the different roles involved in order to exchange information and to co-ordinate. As already reported, the entire Board of Statutory Auditors in particular is constantly invited to participate in the proceedings of the Audit and Risk Committee and also the Director Responsible for the internal control and risk management system, the Chief of Group Audit, the Supervisory Committee pursuant to Legislative Decree No. 231/01, and senior representatives of the external audit firm have participated in various meetings on invitation of the Chairman of the Committee and on individual items on the agenda.

The Board of Statutory Auditors of the Company and the Supervisory Committee pursuant to Legislative Decree No. 231/01 have organised and held joint meetings during the year for the same purposes of co-ordination on matters of common interest.

Finally, the Board of Statutory Auditors meets periodically with the Financial Reporting Officer, the external auditors and the various corporate functions involved in the processes and procedures that must be subject to specific audit by the Board of Statutory Auditors, including those relating to the internal control and risk management system.

# 11.7 REGULATIONS FOR CONTROLLED FOREIGN COMPANIES LOCATED IN NON-EU COUNTRIES

In relation to the provisions of articles 36 and 39 of the Markets Regulations concerning the conditions for the listing of the parent companies of companies formed and regulated under the laws of countries that do not belong to the EU and which are of significant importance for the purposes of consolidated financial statements, since 31st December 2016 the regulatory provisions of Art. 36 of the Markets Regulations have applied to the Turkish subsidiary Recordati Ilaç Sanayi Ve Ticaret Anonim Sirketi, to the American subsidiary Recordati Rare Diseases Inc and to the Russian subsidiary Rusfic Llc.

With reference to those companies, the Company:

- publicly discloses its financial statements used for preparing consolidated financial statements;
- ensures that they regularly deliver information to the external auditor of the Parent Company needed to audit the annual and interim accounts of the Parent Company itself.

Finally the Company possesses continuous knowledge of the composition of the corporate bodies of the controlled companies with information on the company officers and on the By-Laws of the companies.

# 12. DIRECTORS' INTERESTS AND RELATED-PARTY TRANSACTIONS

Subject to the opinion in favour of the Audit and Risk Committee identified as the Committee Responsible pursuant to Art. 4 paragraph 3 of Consob Regulation No. 17221 of 12<sup>th</sup> March 2010, in a meeting held on 24<sup>th</sup> November 2010, the Board adopted "Regulations for related-party transactions" in accordance with Art. 2391-bis of the Italian Civil Code and with the Regulations just mentioned to replace the "Procedure for significant transactions with related parties or when a Director has an interest in the transaction" adopted in 2008.

The Regulations for Related-Party Transactions (the full text is available on the Company website at http://www.recordati.it/en/corporate\_governance/related\_parties/regulations\_for\_related-party\_transactions/), in force since 1st January 2011, defines the guidelines and the criteria for the identification of related-party transactions and it gives details of the roles, responsibilities and operating procedures designed to ensure adequate reporting transparency and the relative proper conduct in form and substance for those transactions. The Company has also issued internal rules in order to ensure that the Regulations are fully implemented.

At the beginning of 2017, the Board therefore carried out a periodic review of the Related Party Transactions Regulations, three years having passed since it was last updated and, having taken note of the opinion given by the Audit and Risk Committee, it considered that those regulations were still adequate, not requiring substantial modifications, but only modifications of a formal character.

The following was performed on the basis of those Regulations:

- the Audit and Risk Committee was identified as the Committee Responsible for issuing a reasoned opinion on both transactions of Major Importance and transactions of Minor Importance, except for related-party transactions concerning remuneration, for which the Committee Responsible would be the Remuneration Committee. As already reported both committees are composed exclusively of independent Directors;
- a related-party transaction is defined as any transfer of resources, services
  or obligations (i.e. any contractual commitment) between Recordati —
  either directly or through its subsidiaries and one or more Recordati
  Related Parties, independently of whether any consideration has been
  agreed upon;
- · a Recordati related-party is defined as:
  - (a) the parent of Recordati and its shareholders;
  - (b) any other party which, either directly or indirectly, including through subsidiaries, trust companies or intermediaries and/or jointly with other parties (also defined as related parties):
    - (i) exercises Control over Recordati, is controlled by it or is subject to Common Control;
    - (ii) holds an interest in the share capital of Recordati such that it is able to exert Significant Influence over it;
  - (c) an associate company of Recordati;
  - (d) a joint venture in which Recordati SpA is a venturer;
  - (e) an executive with strategic responsibilities of Recordati or its parent;
  - (f) a close member of the family of one of the parties referred to in letters (a), (b) or (e);
  - (g) an entity in which one of the parties referred to in letters (e) or (f) exercises Control, Joint Control or Significant Influence or holds, either directly or indirectly, a significant proportion, and in any case not less than 20%, of the voting rights;
  - (h) a collective or individual, Italian or foreign, supplementary pension fund, formed for the benefit of Recordati employees, or any other entity related to it, to the extent by which that fund has been formed or promoted by Recordati, or in the circumstance that Recordati may influence its decision-making processes.
- Key Management Personnel are those persons defined as such in accordance with the legislation and regulations in force from time to time. At present these are those persons who have power over and responsibility, either directly or indirectly, for the planning, management and control of the activities of the Company, including the Directors (executive and non-executive) of the company itself, full members of the Board of Statutory Auditors, the General Managers, the manager appointed to prepare corporate accounting documents (the "Financial Reporting Officer") and all those additional persons identified from time to time as such by the Board of Directors, and proposed by the Chief Executive of the Company.
- Transactions of Major Importance are defined as those related-party transactions for which at least one of the relevance indicators contained in the aforementioned Attachment No. 3 of the Consob Regulations and which are applicable according to the characteristics of each related-party transaction (i.e. value of the transaction in relation to shareholders' equity or, if greater, to capitalisation; total assets of the entity involved in the transaction compared to the total assets of the Company; total liabilities of the entity acquired compared to the total assets of the Company) exceeds 5%:
- Transactions of Minor Importance are defined as those related-party transactions which are not transactions of Major Importance and not transactions of negligible amount i.e. transactions for an individual amount of less than 150,000 euro.

The Regulations do not apply to:

 Transactions of Negligible Amount unless they are more than one Transaction of Negligible Amount performed as part of a single plan, the total value of which exceeds the sum of 150,000 euro;

- intercompany transactions provided that no Significant Interests of other related parties of the Company exist in the subsidiaries of Recordati or in associate companies of Recordati which are counterparties to the transaction. It is considered that the existence of "Significant Interests" of other related parties could be determined by:
  - the existence of a significant amount receivable by the Chief Executive Officer of the Parent from a subsidiary;
  - one or more directors or other executives with strategic responsibilities shared between companies who benefit from share based incentive schemes (or in any case variable remuneration) dependent on the results of subsidiaries or associate companies with which the transaction is performed;
  - an interest held in a subsidiary or associate company (even indirectly) by the party that controls the parent.
- shareholders' resolutions pursuant to Art. 2389, paragraph one of the Italian Civil Code, concerning the remuneration due to members of the Board of Directors and resolutions concerning the remuneration of Directors appointed to special positions which forms part of the total amount determined in advance by shareholders in accordance with Art. 2389, paragraph three of the Italian Civil Code;
- shareholders' resolutions pursuant to Art. 2402 of the Italian Civil Code, concerning the remuneration due to members of the Board of Statutory Auditors;
- remuneration schemes based on financial instruments approved by shareholders in accordance with Art. 114-bis of the TUF and the relative transactions to implement them;
- decisions (other than those referred to under the preceding letter c) concerning the remuneration of Directors, Directors appointed to special positions and other executives with strategic responsibilities, when (i) the Company has adopted a remuneration policy (the formulation of which involved a committee formed exclusively of non-executive directors, the majority of which are independent) (ii) the Company has submitted a report which illustrates the remuneration policy to a Shareholders' Meeting for approval or a consultative vote, and (iii) the remuneration actually assigned is consistent with that policy;
- decisions, to be taken when a professional arrangement is established with Recordati, concerning the remuneration of executives with strategic responsibilities, other than Directors and members of the Board of Statutory Auditors;
- transactions which fall within the ordinary performance of operating activities and the related financial activities concluded under conditions equivalent to market conditions or standards (i.e. conditions similar to those normally practiced with non-related parties for transactions of an analogous nature, magnitude and risk or based on regulated tariffs or on compulsory prices or those practiced for parties with which the Company is obliged by law to negotiate a determined consideration). The "ordinary performance" is identified by considering the contents, recurrence, function or purpose and timing of the transaction and also the nature of the counterparty, even if it is a related-party. Operating Activities are defined as the main revenue generating activities and all other normal activities of the Company that are not classifiable as investment or financial activities pursuant to International Financial Reporting standard seven adopted by EC Regulation No. 1126 of 2008, as subsequently amended from time to time. Should the exemption contained in this point apply, the Company is nevertheless required, without prejudice to Art. 114, paragraph 1 of the TUF, to comply with the provisions of Art. 13, paragraph 3, letter c), points i) and ii) of the Consob Regulation No. 17221 of 12th March 2010;
- demerger transactions in the strict sense of the proportional type, share
  issues with option rights reserved to shareholders and to any holders of
  financial instruments (therefore issuances which are performed without
  excluding their option rights) and transactions for the purchase/sale of
  treasury stock if performed, other conditions remaining the same, to the
  benefit of both related parties and all others holding rights;

transactions to be performed on the basis of instructions for the purposes
of stability issued by the supervisory authority, without prejudice to
disclosure obligations under Consob Regulations.

The Company Annual Report may be consulted with a regard to transactions with related parties carried out in 2016.

# 13. APPOINTMENT OF STATUTORY AUDITORS

The appointment of Statutory Auditors is regulated by article 26 of the By-Laws, the text of which, last amended by the Board of Directors on 8<sup>th</sup> May 2012 in order to make compulsory amendments to comply with legislation on the balance between genders on corporate bodies, is reproduced below:

"Art. 26) The Shareholders' Meeting shall appoint the Board of Statutory Auditors, comprising three statutory auditors and two alternate auditors, who may be re-elected, and shall determine their remuneration. Their powers, duties and term of office shall be as established by law.

Auditors shall satisfy the requirements laid down in current laws and regulations. As regards requirements of professionalism, the matters and sectors of activity strictly connected with that of the company are the research, production and sale of chemical and pharmaceutical products.

The minority shareholders shall elect one Statutory Auditor and one Alternate Auditor.

Unless otherwise provided for in laws or regulations, the Board of Statutory Auditors shall be appointed according to the procedures set out in the following paragraphs on the basis of slates submitted by Shareholders in which candidate are listed by means of a progressive number and in compliance with the existing legislation in force concerning gender balance. The slate must specify whether each candidate is nominated for the position of Statutory Auditor or for the position of Alternate Auditor.

Only Shareholders individually or jointly possessing a total number of shares with voting rights representing at least 2.5% of capital stock with voting rights or representing a lesser percentage as established or provided by binding legal or regulatory provisions which shall be specified in the notice of meeting shall have the right to present slates.

Each shareholder, including shareholders who have signed a shareholders' agreement pursuant to Art. 122 of Legislative Decree No. 58/1998, the holding entity, subsidiaries, and jointly controlled entities are not permitted to submit or help to submit more than one slate or vote for different slates, including through an intermediary or trust company. Each candidate may only be present on one slate failing which he will be ineligible. Votes cast in violation of the above prohibition shall not be attributed to any slate.

Submitted slates shall be deposited at the Company's registered office at least twentyfive days before the date scheduled for the Shareholders' Meeting at first call without prejudice to any further forms of disclosure required by any rules or regulations from time to time in force.

Without prejudice to all other rules prescribed by the rules and regulations in force the following documents shall be submitted together with each slate by the deadline specified above:

- a) information on the identity of the shareholders who have submitted the slates, indicating the total percentage of capital stock held;
- b) a declaration by shareholders other than those who hold, including jointly, a controlling interest or relative majority, attesting to the absence of any forms of association with such shareholders, as provided by applicable regulations;
- c) a thorough report of the personal characteristics of candidates and a declaration from the said candidates attesting that they possess the requirements established by law, together with their acceptance of the candidature.

Slates containing a total number of candidates equal to or greater than three must be composed of candidates belonging to both genders, so that a percentage of candidates to the position of Statutory Auditor and candidates to the position of Alternate Auditor equal to that required by the legislation in force at the time concerning gender balance for the composition of the Board of Statutory Auditors belongs to the less represented gender in a given slate. Slates not satisfying the requirements specified above shall be considered as not having been submitted.

Auditors shall be elected as follows:

- 1. from the slate which obtained the highest number of votes at the Shareholders' Meeting, two statutory auditors and one alternate auditor shall be elected, based on the progressive order with which they are listed in the sections of the slate:
- 2. from the second slate which obtained the highest number of votes at the Shareholders' Meeting and which, in accordance with regulations in force, has no connection, not even indirectly, with those who submitted and voted for the slate which obtained the highest number of votes, one statutory auditor, who shall chair the Board of Statutory Auditors, and one alternate auditor shall be elected, based on the progressive order with which they are listed in the slate.

In the event of a tie between slates for the appointment of the Auditors indicated in point 2 of the foregoing paragraph, the slate submitted by shareholders owning the largest shareholding or, alternatively, the slate submitted by the largest number of shareholders shall prevail.

If by following the above procedures, the composition of the full members of the Board of Statutory Auditors in compliance with the legislation in force at the time concerning gender balance is not ensured, the necessary replacements shall be made from the candidates to the position of full Statutory Auditor on the slate that obtained the majority of votes on the basis of the order of the names on the slate.

Should a single slate or no slate be submitted, all candidates for that position named on the aforesaid slate or those voted by a Shareholders' Meeting (as long as they receive a relative majority of the votes cast in the Shareholders' Meeting) shall be elected as Statutory and Alternate Auditors and provided the existing legislation in force on gender balance are complied with.

Should they no longer satisfy the requirements laid down by law and in the by-laws, the auditor shall leave office.

Should it become necessary to replace a statutory auditor, the alternate auditor belonging to the same slate as the outgoing auditor shall take the latter's place or, failing this, should the minority auditor leave office, he shall be replaced by the next candidate on the slate from which the outgoing auditor was elector, or, alternatively, by the first candidate on the minority slate that obtained the second highest number of votes.

It is understood that the Board of Statutory Auditors shall continue to be chaired by the minority auditor and the composition of the Board of Statutory Auditors must comply with the existing legislation in force on gender balance.

The procedure outlined below shall be followed when the Shareholders' Meeting is required to appoint statutory and/or alternate auditors to complete the board: if it is necessary to replace auditors elected on the basis of the majority slate, the replacements shall be appointed by relative majority vote without slate voting; if, however, it is necessary to replace auditors elected on the basis of the minority slate, the Shareholders' Meeting shall replace them by a relative majority vote by choosing them from the candidates on the slate from which the outgoing auditor was elected or on the slate that obtained the second highest number of votes.

Should the application of the above procedures not result in the replacement of the auditors designated by minority shareholders for whatever reason, the Shareholders' Meeting shall hold a relative majority vote, following the presentation of candidatures by shareholders that, individually or together with others, possess shareholdings with voting rights that represent at least the percentage indicated above in relation to the procedure for the presentation of slates. However, votes registered by shareholders who hold

the relative majority of voting rights that may be exercised in the meeting as identified in disclosures made in accordance with applicable regulations, whether directly, indirectly, or jointly with other shareholders who have signed a shareholders' agreement as indicated in article 122 of Italian Legislative Decree No. 58/1998, shall not be considered in establishing the outcome of said vote.

The replacement procedures set forth in the above paragraphs must in any event ensure compliance with the legislation in force at the time concerning gender balance.

Members of the Board of Statutory Auditors may participate in meetings remotely by means of audio-visual connection, video conferencing or telephone link-up systems.

In the above case:

- the following must always be established:
  - a) the identity of all members attending at each connection point shall be verified:
  - b) each member attending shall be permitted to express a personal opinion verbally, to view, receive or send any documentation and to participate simultaneously in the discussion of the points at issue and pass resolutions;
- meetings of the Board of Statutory Auditors shall be considered to be held at the place where both the Chairman and Secretary are located.

The legal audit of the Company's accounts shall be performed by the Audit Firm on the basis of applicable regulations".

It is underlined that the right to submit slates is only held by shareholders who, individually or together with other shareholders submitting slates, hold voting shares representing at least 2.5% of the voting capital in the Ordinary Meeting, or representing any lower percentage established by mandatory laws or regulations. In accordance with articles 144-quater and 144-septies of the Issuers' Regulations adopted by Consob Resolution No. 19856 of 25th January 2017 with regard to the capitalisation of the Company in the last quarter of 2016, the percentage of the share capital required to present slates of candidates to the Board of Statutory Auditors of the Company is currently 1%.

The minority slates shall elect one Statutory Auditor and one Alternate Auditor. As regards the appointment mechanism adopted for choosing the candidates on the various slates submitted, note that, again according to the above transcribed Art. 26 of the By-Laws, two statutory auditors and one alternate auditor are elected from the slate which obtained the highest number of votes in the Shareholders' Meeting, based on the progressive order with which they are listed in the sections of the slate; from the second slate which obtained the highest number of votes after the first slate and which has no connection, not even indirectly, with the shareholders who submitted or voted for the slate which obtained the highest number of votes, one statutory auditor, who will chair the Board of Statutory Auditors, and one alternate auditor are elected, based on the progressive order with which they are listed in the slate.

With regard to the new legislation on gender balance in corporate bodies (articles 147-ter and 148 of the Consolidated Finance Act, Art. 144-undecies of the Issuers Regulations, as amended by Law No. 120/2011), which apply to the renewal of corporate bodies subsequent to 18th August 2012, the Company made the necessary amendments to the By-Laws on 8th May 2012 in order to comply with the new regulations. Reference may be made in this respect to the text of article 26 reported above in full.

In particular, the Board of Statutory Auditors shall be appointed in compliance with the existing legislation in force on gender balance (and in any case on the basis of slates of candidates presented by shareholders).

Finally, we report that article 19, paragraph 3 of Legislative Decree No. 39/2010, as amended by Legislative Decree No. 135/2016, requires that members of the committee for internal control and the accounting audit — which for "public interest entities" is the Board of Statutory Auditors — are competent as a whole and also in the sector in which the company operates.

#### 14. STATUTORY AUDITORS

The composition of the Board of Statutory Auditors in office on the closing date of the Year is shown below. The Board was appointed by the Ordinary Shareholders' Meeting of 17<sup>th</sup> April 2014 and its term of office will expire at the Shareholders' Meeting called to approve the financial statements for the year ended 31 December 2016.

One single slate of candidates was presented for the office of Statutory Auditor in the ordinary Shareholders' Meeting of  $17^{th}$  April 2014 by the shareholder FIMEI S.p.A. The slate presented by FIMEI S.p.A. contained the following candidates to the Board of Statutory Auditors for the years 2014-2015-2016:

Dr. Marco Nava
 Dr. Marco Rigotti
 Dr.ssa Livia Amidani Aliberti
 Dr. ssa Patrizia Paleologo Oriundi
 Dr. Marco Antonio Viganò
 Statutory Auditor
 Alternate Auditor

All the candidates listed above were elected with 160,739,107 shares in favour out of 161,863,413 shares voting (99.305%). The voting share capital represented 77.4% of the share capital of the Issuer.

The composition of the Board of Statutory Auditors complies with the criteria indicated in the applicable provisions on balance between genders.

Curricula vitae providing information on the personal and professional characteristics of each candidate were attached to the slate presented by FIMEI, accompanied by a slate of the management and supervisory positions occupied in other companies and which are significant in accordance with the law and also by declarations made by each candidate that they accept their candidature and that there are no grounds for ineligibility or incompatibility and that they satisfy the requirements prescribed by law and in the By-Laws for the office of Statutory Auditor. The above documentation may be consulted on the website www.recordati.it (in the section Investor Relations, Shareholders' Meetings, financial year 2014).

The personal and professional characteristics of each auditor are in any case contained in Attachment 1 of this Report.

#### TABLE FOR THE COMPOSITION AND STRUCTURE OF THE BOARD OF STATUTORY AUDITORS

Office	Members	Year first appointed	Year of birth	In office since	In Office until	In Office until Slate (M/m)*	Indep. accor ding to CG Code	Indep. according to TUF	(%) **	Number of other offices ***
Chairman	MARCO NAVA	2008	1960	17.4.2014	Approval of 2016 AR	M	X	X	8/8	0
Statutory Auditor	LIVIA AMIDANI ALIBERTI	2014	1961	17.4.2014	Approval of 2016 AR	M	Χ	Χ	8/8	1
Statutory Auditor	MARCO RIGOTTI	2008	1967	17.4.2014	Approval of 2016 AR	M	Χ	Χ	6/8	1
Alternate auditor	Patrizia Paleologo Oriundi	2014	1957	17.4.2014	Approval of 2016 AR	M	X	X	N.A.	1
Alternate auditor	MARCO ANTONIO VIGANÒ	2008	1960	17.4.2014	Approval of 2016 AR	M	X	X	N.A.	0

- \* M/m are given in this column where "M" indicates a member elected from the majority slate and "m" from a minority slate.
- \*\* This column contains the percentage attendance of Auditors at the relative board meetings of Statutory Auditors (number of presences/number of meetings held during the actual period office of the person concerned).
- \*\*\* This column gives the number of positions as a director or statutory auditor held by the person in accordance with article 148 bis of the TUF and the relative provisions for implementation contained in the Consob Issuers' Regulations. The full list of appointments is published by the Consob on its website in accordance with Art. 144 quinquiesdecies of Consob's Issuers' Regulations, Furthermore, all positions held by Statutory Auditors are given in full in the section of this Corporate Governance Report containing the curricula vitae of the Statutory Auditors.

# INDICATE THE QUORUM REQUIRED FOR THE PRESENTATION OF SLATES WHEN DIRECTORS WERE LAST APPOINTED: 1%

#### Number of meetings held during 2016: 8

Statutory auditors fees' are set by a Shareholders' Meeting when they are appointed.

The fees for the Board of Statutory Auditors in office were set by a Shareholders' Meeting held on 17<sup>th</sup> April 2014, at the same amounts as previously set, with an annual fee of €50,000 for the Chairman of the Board of Statutory Auditors and of €35,000 for each Statutory Auditor, gross of withholding tax.

Details of the fees earned in 2016 are nevertheless given in detail in the Remuneration Report.

During the year the Board of Statutory Auditors met eight times, with meetings lasting approximately two hours and twenty minutes on average.

As regards the current year, seven meetings are scheduled and the Board of Statutory Auditors has already met twice in 2017. The percentage attendance of Auditors in these meetings in 2016 is shown in the table above.

In application of Art. 144-novies of the Issuers' Regulations and the Corporate Governance Code (as amended in July 2015), the satisfaction of the requirements mentioned above by members of the Board of Statutory Auditors is assessed by the latter, which submits the results to the board of directors which discloses them, after the appointment, by means of a press release, and subsequently on an annual basis in the corporate governance report.

The Board of Statutory Auditors conducted an internal verification of its independence after its appointment. It was found from the outcome of that verification that all the Statutory Auditors in office possessed the requirements for independence according to Art. 148 of the TUF and also with regard to independence requirements contained in the CG Code. That assessment was repeated, with positive results, on 22nd-24th February 2017.

The Board of Statutory Auditors has checked the independence of the audit firm KPMG S.p.A., checking both compliance with legislative provisions and the nature and extent of services other than financial auditing provided to a number of subsidiaries by the same audit firm and by the entities belonging to the latter's network. For information concerning services other than those of auditing the accounts provided by the audit firm to the Company and its subsidiaries, reference may be made to the relative attachment "Disclosure of auditors' fees for accounting audits and other services" to the consolidated financial statements at 31st December 2016 and the draft separate financial statements of Recordati S.p.A. at 31st December 2016.

The Board of Statutory Auditors, in the performance of its activities, liaised with the Chief of Group Audit and with the Risk Committee through the constant presence in Committee meetings, in which the Chief of Group Audit also usually participates. It also worked with the Supervisory Committee appointed in accordance with Legislative Decree No. 231/2001. The Board reported to the Director with Responsibility for the internal control and risk management system. Finally, it participated in the work of the Remuneration Committee.

As part of its oversight of procedures for the concrete implementation of corporate governance rules, the Board of Statutory Auditors verified that the criteria and procedures of evaluation adopted by the Board to evaluate the independence of its members were implemented correctly.

The Board of Statutory Auditors is also called upon to carry out the duties assigned by the legislation in force to the "Committee for internal control and accounting audit" (CICAA), set up by Legislative Decree No. 39/2010 (the "Consolidated Statutory Audit Act"), which implements Directive No. 2006/43/EC concerning the statutory audit of annual accounts which entered into force on 7th April 2010. As already stated in Section 11, Legislative Decree No. 39/2010 was amended by Legislative Decree No. 135/2016 (with which Directive 2014/56/EU was implemented in Italian law), which came into effect on 5th August 2016 (although it contains a series of transition measures to ensure gradual introduction of the new rules).

The new version of article 19 of Legislative Decree 39/2010 defines the duties of the Board of Statutory Auditors in its capacity as the CICAA more precisely, no longer assigning a general oversight function to it, but defining a series of specific duties, although they nevertheless relate to the four areas which the previous article 19 required the Board of Statutory Auditors to oversee (the financial reporting process; the efficacy of the internal control, internal audit (if applicable) and risk management systems; the statutory audit of the separate company and consolidated financial reports; the independence of the statutory auditor or the firm of statutory auditors, especially with regard to the provision of non-auditing services to the entities subject to statutory audit of its accounts).

More specifically, the CICAA is required to monitor the efficacy of systems for the internal control of a company's quality and risk management and, if applicable, internal audit, as far as the financial reporting of the entity subject to audit is concerned, without violating its independence.

Furthermore, from the specific viewpoint of the statutory audit, on the basis of the new article 19 of Legislative Decree No. 39/2010, the duties of the CICAA are as follows:

- to monitor the statutory audit of the annual separate company and consolidated financial reports;
- to report to the management body and the results of the statutory audit and to submit to it the additional report required by article 11 of Regulation No. 537/2014, accompanied by any remarks that there may be;
- to verify and monitor the independence of the statutory auditors or the firm of statutory auditors, especially with regard to the adequacy of nonauditing services provided;

 these activities also include responsibility for the procedure for the selection of the auditing firm as well as the indication of the firm to be appointed in the recommendation (in accordance with the provisions of article 16 of Regulation No. 537/2014).

Also for the auditing purposes indicated above concerning the efficacy of the systems for the internal control of the Company's quality and risk management, the Board of Statutory Auditors examined the model to map, manage and monitor risks in the Company and the Group (named the "Catalogue of Risks") updated to 2016 and developed by the Group with assistance from the consulting company Deloitte S.p.A.

The Board of Statutory Auditors attended an induction meeting held on 27th May 2014, designed to increase the new Directors' and the new Statutory Auditors' knowledge of the reality and the dynamics of the Company. In consideration of the experience acquired by members of the Board of Statutory Auditors with specific reference to the business sectors in which the Company operates and to the information provided to them in individual Board meetings, the Chairman did not consider it necessary during the year to organise further induction sessions, since no changes had been made to the composition of the Board of Statutory Auditors. Furthermore, the Board of Statutory Auditors takes part in meetings of the Board of Directors and therefore receives a periodic update on operating activities and developments in the relative regulatory framework.

Finally, the Board of Statutory Auditors holds meetings on a regular basis with the Senior Managers responsible for the main departments of the company, who provide details requested by the that the board.

#### 15. RELATIONS WITH SHAREHOLDERS

The Company has created a specific section on its website called "Investors", which is easily identifiable and accessible and which contains important information about the Company for its shareholders so that they can exercise their rights in an informed manner. The Company has also created a special section of its website dedicated to corporate governance containing full documentation, including this report and an archive of past reports.

With regard to the publishing and storage of regulatory information pursuant to article 113 of the TUF we report that the company:

- from 28<sup>th</sup> May 2012 uses the SDIR NIS network managed by Blt Market Services, a company belonging to the London Stock Exchange Group, located at 6 Piazza degli Affari, Milano, for the transmission of regulatory information;
- from 19<sup>th</sup> May 2014 uses the centralised storage system for regulatory information named "1Info" to store regulatory information. This can be consulted at the website www.1info.it and it is operated by Computershare S.p.A. with registered offices in Milan and is authorised by the Consob with Resolution No. 18852 of 9<sup>th</sup> April 2014.

As part of the Company's organisational structure, Marianne Tatschke has been identified as Investor Relations Manager. In addition, the tasks of the Group Legal Service and Corporate Affairs Office also include the task of looking after relations with shareholders in general.

The Investor Relations function of the Company is also responsible for relations with financial analysts who cover the Company and with institutional investors. That function organises periodic "conference call" meetings designed to provide periodic operational and financial information and the documentation presented in those meetings is disclosed to the public at the same time on the Company website and it is filed with Borsa Italiana.

#### 16. SHAREHOLDERS' MEETINGS

In accordance with Art. 9 of the By-Laws in force, Shareholders' Meetings are convened in the manner and within the legal time limits on the Company website and, where necessary due to mandatory provisions or decided by the directors, in the Official Gazette and in at least one of the following national newspapers: "Il Corriere della Sera", "La Repubblica", "La Stampa", "Il Giornale", "Milano Finanza", as well as according to other procedures provided for by the legislation and regulations currently in force.

Article 3 of Legislative Decree No. 91 of 18.6.2012 (the "Corrective Decree") has established that Shareholders' Meetings are convened by a notice published on the Company website by the thirtieth day prior to the date of the Shareholders' Meeting and also using other procedures and within the time limit set by the Consob with regulations issued in accordance with article 113-ter, paragraph 3 of Consolidated Finance Act, inclusive of the publication of extracts in daily newspapers. These provisions apply to Shareholders' Meetings for which the notice to convene is published after 1st January 2013.

Following amendments made by the Shareholders' Meeting of 13<sup>th</sup> April 2011 to the By-Laws, Art. 9 states that "notice to convene may also contain the date of meetings convened subsequent to the first. The Board of Directors may decide, if it considers it appropriate, to convene Ordinary and Extraordinary Shareholders' Meetings to be held following one single Notice of Meeting. In the case of a single call the legal majorities for that purpose apply."

Furthermore, that same Art. 9 of the By-Laws also states that: "Ordinary Shareholders' Meetings are called to approve the financial statements within one hundred and twenty days of the end of the company's financial year. Where permitted by the law, a Shareholders' Meeting may be convened within onehundredandeighty days from the end of the financial year. Directors shall indicate the reasons for the delay in the report required by Article 2428 of the Italian Civil Code.

Other than on the initiative of the Board of Directors, a Shareholders' Meeting may be called pursuant to the law by the Board of Statutory Auditors or by only two of its members, or upon the request of shareholders representing at least 5% of the capital stock."

In accordance with Art. 12 of the By-Laws in force, resolutions of ordinary and extraordinary meetings, on the first and successive calls, as well as for single calls, are valid if made in the presence of the required number of persons and the majorities required by law. Therefore an ordinary Shareholders' Meeting is validly constituted in first call with the attendance of shareholders accounting for at least half of the share capital with voting rights at the meeting itself and resolutions are passed by an absolute majority of those participating, including abstentions.

An ordinary Shareholders' Meeting is validly constituted in second call no matter what proportion of the share capital is represented and resolutions are passed by an absolute majority of those participating, including abstentions. An Extraordinary Shareholders' Meeting is validly constituted in first call with the attendance of shareholders accounting for at least half of the share capital and resolutions are passed with the vote in favour of shareholders representing at least two thirds of the share capital.

An extraordinary Shareholders' Meeting is validly constituted in second call with the attendance of shareholders accounting for at least a third of the share capital and resolutions are passed with the vote in favour of shareholders accounting for at least two thirds of the share capital present at the meeting.

In the case of a single call: an Ordinary Shareholders' Meeting passes resolutions with an absolute majority, whatever the percentage of the capital stock represented and an Extraordinary Shareholders' Meeting is validly constituted when at least one fifth of the capital stock is represented and it passes resolutions with the vote in favour of at least two thirds of the share capital represented in the Shareholders' Meeting.

In relation to the right to participate in Shareholders' Meetings and voting rights, on the basis of Art. 83-sexies of the TUF, legitimate authorisation to participate in Shareholders' Meetings and to exercise voting rights is certified by a communication to the issuer, performed by the intermediary, in compliance with its accounting entries, certifying the party entitled to vote on the basis of information relating to the end of the accounting day of the seventh trading day prior to the date set for the Shareholders' Meeting in first call or second call. Nevertheless the legitimate right to participate and vote remains, should the communications be received by the Company later than the aforementioned time limit, provided they are received before the commencement of the proceedings of each single session of the Shareholders' Meetings.

In accordance with Art. 10 of the By-Laws, those holding the right to vote may be represented by a written proxy, where no incompatibilities and limitations exist pursuant to the legislation and regulations in force. The Company may be notified of the proxy for participation in the Shareholders' Meeting by sending the document to the email address indicated in the Notice of Meeting.

Furthermore, Art. 135-undecies of the TUF, inserted by Legislative Decree No. 27/2010 introduced a "Designated representative of a listed company" "unless the By-Laws stipulate otherwise, listed companies designate a representative for each Shareholders' Meeting to which shareholders may grant an authorisation, by the end of the second day of market trading prior to the date set for the Shareholders' Meeting in first or second call, with voting instructions on all or some of the motions on the agenda. The proxy is valid solely for proposals in relation to which voting instructions have been given." At present Recordati's By-Laws contain no provisions in this respect, and this new provision is therefore considered applicable to future Shareholders' Meetings of the Company, until different provisions are introduced to the Company By-Laws.

The Board believes that there are no conditions that require the adoption of particular initiatives regarding attendance of Meetings and the exercise of voting rights by shareholders such as, for example, postal voting.

In accordance with Art. 127-ter of the TUF, shareholders may submit questions on the items on the agenda even before the Shareholders' Meeting. Answers are given to questions received prior to the Shareholders' Meeting, subject to verification of the relevance and the legitimacy of the asker, at the latest during the meeting itself and the Company has the right to give a single answer to questions having the same content.

In this respect article 127-ter of the Consolidated Finance Act, expressly allows the Company to set a time limit within which questions formulated prior to a Shareholders' Meeting must be received if they are to be considered. The time limit is at the discretion of the Company, but may not be greater than three days prior to the date of the Shareholders' Meeting (in first or single call) or five days prior to the Shareholders' Meeting with, however, the obligation of the Company to furnish a reply at least two days prior to the Shareholders' Meeting, which may be by publication on the Company website. Cases where a reply is not obligatory are then specified: when the information required is already available in the format "answer and reply" in the relevant section of the website and also when the reply has already been published on the website.

When implementing amendments made to the CG Code made in December 2011, the Board felt it would be advisable to draw up regulations for proceedings in Shareholders' Meetings, even though no particular difficulties had been encountered in past meetings. The objective is to further ensure that the proceedings in Shareholders' Meetings are well-organised and practical and to ensure that each shareholder is able to speak on the items on the agenda.

The Shareholders' Meeting held on 17th April 2013 approved the text of the Shareholders' Regulations proposed by the Board of Directors, which is available on the Company website at www.recordati.it, in the corporate governance section.

In 2016, the shareholders met once on 13th April 2016, in a single session, with the attendance of approximately 77.86% of the share capital, in which votes were cast to approve the 2015 Annual Report, authorisation to purchase and dispose of treasury stock and the reduction of the total number of members of the Board of Directors to nine. The Shareholders' Meeting also cast a non-binding vote on the first section of the Remuneration Report. During that Shareholders' Meeting, the Board of Directors reported through its Vice Chairman (attended in addition to the Vice Chairman, by Directors: Dr.ssa Rosalba Casiraghi, Avv. Michaela Castelli, Dr. Mario Garraffo - also in his capacity as Chairman of the Remuneration Committee, Dr. Andrea Recordati, Dr. Fritz Squindo and Prof. Marco Vitale - also in his capacity as Chairman of the Internal Control committee and lead independent Director - and the Statutory Auditors, Dr. Marco Nava, the Chairman, and Dr.ssa Livia Amidani Aliberti, a Full Auditor) on activities performed and programmed, partly in reply to questions posed by some of the shareholders. The volume containing a copy of the draft separate financial statements and consolidated financial statements, with the accompanying reports and the Directors' Reports on the proposals concerning items placed on the agenda was handed out at the entrance and also sent to shareholders who had taken part in recent meetings in order to ensure adequate disclosure of the necessary information so that they could take the decisions for which they are responsible with full knowledge of the facts. The above documentation, together with the results of the votes, has been made available and it may be consulted on the Company website www.recordati.it in the section: Investors, Shareholders' Meetings, 2016.

The Remuneration Committee considered that there was no need to report to the Shareholders' Meeting on how it had carried out its duties, because that information was already contained in the Remuneration Report made available to shareholders before the meeting.

During the year, there were no significant changes in the market capitalisation of the Company's shares or in the composition of its corporate structure sufficient to require consideration of a proposal to the Shareholders' Meeting for changes to the Corporate By-Laws concerning the percentages established for the exercise of the actions and prerogatives provided for the protection of minorities.

On 26th October 2010 the Board of Directors amended the By-Laws in order to make compulsory amendments to comply with Legislative Decree No. 27/2010 for the "Implementation of directive 2007/36/ EC, concerning the exercise of some rights by company shareholders" and as a consequence of Consob Resolution No. 17592 of 14th December 2010. The Shareholders' Meeting of 13th April 2011 therefore approved amendments of an optional nature, considered advisable by the Board of Directors, to the By-Laws in accordance with Legislative Decree No. 27/2010. In this respect the Directors' Report on the item disclosed to the public for that Shareholders' Meeting may be consulted on the Company website www.recordati.it (in the section Investor Relations, Shareholders' Meetings, financial year 2011).

# 17. ADDITIONAL CORPORATE GOVERNANCE PRACTICES (pursuant to Art. 123-bis, paragraph 2,

(pursuant to Art. 123-bis, paragraph 2, letter a) of the TUF)

The Issuer does not apply any additional corporate governance practices, other than those described in the preceding sections of this Report.

# 18. CHANGES OCCURRING SINCE THE END OF THE YEAR

No changes in the structure of the corporate governance of the company have occurred since the end of the Year.

Milan, 1st March 2017

On behalf of the Board of Directors The Vice Chairman and Chief Executive Officer *Dr.* Andrea Recordati

#### **ATTACHMENT 1**

# PROFESSIONAL OVERVIEW OF THE DIRECTORS

#### **ALBERTO RECORDATI**

Alberto Recordati graduated from University of London King's College in 1977 with a degree in biochemistry and in 1984 successfully completed a research PhD within the Biochemistry Department of Charing Cross Hospital Medical School part of that same university.

He joined Recordati in 1984 as a researcher in the biochemistry laboratories. In 1987 he was appointed Head of the Planning and Product Development Office. From 1990 to 1992, he worked for the US subsidiary Pharmetrix Corp as research project coordinator. In 1992 he was appointed Industrial Manager for Biochemicals with responsibility for biochemical/microbiological research and for the Cascina dè Pecchi biochemical/fermentation production site. In 1995, he became Head of the Chemical Research and Technologies Division. In 1999, he was appointed director in charge of the fine chemicals sector and in 2004 Deputy Chairman of Recordati S.p.A.. He has held responsibility for co-ordinating the "Drug Discovery" and "Drug Development" activities of the Company since 2008 and also for licensing-in activities since 2011. On 16 august 2016, he was appointed Chairman of the Board of Directors of Recordati S.p.A.. He is also Chairman of the Board of Directors and Managing Director of FIMEI S.p.A..

#### ANDREA RECORDATI

Andrea Recordati gained a Bachelor of Arts in medieval and modern history from the University of London Royal Holloway and Bedford New College. Between September 1995 and March 1998, he participated in the SmithKline Beecham Management Access Program, in the United Kingdom, starting off as Assistant Product Manager in Consumer Healthcare and then, for one year, occupying the role of medical representative in Essex before becoming Project Manager responsible for the development and implementation of an innovative SmithKline Beecham marketing initiative.

He joined Recordati in 1998 as Project Leader for a project aimed at improving Sales Force productivity and better use of marketing investments. In April 1998, he joined the Board of Directors of the Company. In 1999, he was given responsibility for Pharmaceutical Business Development.

In March 2002, the Lercanidipine Business Unit was set up and he was appointed head of that unit. Since November 2002, he has been responsible for setting up the subsidiary Recordati Ireland and its industrial plant and, subsequently, for setting up the UK subsidiary. In September 2006, he was appointed Sole Director of the German subsidiary Recordati Pharma GmbH. In August 2007, the Northern and Central Europe Subsidiaries Division was set up and he was appointed head of that division. That division was enlarged in 2010 to include all western European companies. In February 2011 he was appointed General Manager of the International Pharmaceuticals Division. In July 2013 he was appointed Chief Operating Officer, being responsible for all the commercial and production activities of the Group and sitting on several boards of directors within the Group. On 16 august 2016, he was appointed as Vice Chairman and CEO of Recordati S.p.A.. He is also Vice Chairman of FIMEI S.p.A..

#### **ROSALBA CASIRAGHI**

Degree: Business Administration, Faculty of Economics a L. Bocconi University.

Official Registered Auditor. She started her career as cost accountant in a subsidiary of a U.S. corporation and then she has been Chief Financial Officer. After these work experiences, she has undertaken business and professional activities. Director and auditor in companies operating in industrial and financial sectors, listed and unlisted.

Board member in companies and other institutions:

- Member of Board of Fondo Strategico Italiano, holding of Cassa Depositi e Prestiti;
- Member of Board of Recordati, pharmaceutical group (listed company);
- Member of Board of Luisa Spagnoli, clothing industry in Perugia;
- · Chairman of Statutory Auditors Board of Banca Popolare di Vicenza;
- Chairman of Statutory Auditors Board of NTV, passenger services on high-speed lines (Italo);
- · Member of statutory Auditors Indesit, domestic appliances;
- · Member of statutory Auditors F.I.L.A. (listed company);
- · Member of statutory Auditors Persidera (Telecom Group);
- · Auditor of TIM Foundation (Telecom Group);

Previous directorships:

- 2007 2016 Member of Supervisory Board of Banca IntesaSanpaolo (listed company):
- 2012 2016 Member of Board of Università degli Studi di Milano;
- 2012 2015 Chairman of Statutory Auditors Board Npl, Non Performing Loans;
- 2013 2015 Chairman of Statutory Auditors Board of Telecom Media (listed company);
- 2009 2014 Member of Board of NH Hotel S.A., hotels group (listed in Madrid Stock Exchange);
- 2008 2013 Chairman of Nedcommunity, the Italian Association of independent directors;
- 2008 2013 Chairman of Statutory Auditors Board of Banca CR Firenze;
- 2009 2012 Member of Board of Alto Partners Sgr, management firm of private equity funds;
- 2009 2012 Member of Board of Biancamano, waste management company (listed company);
- 2008 2012 Member of Statutory Auditors of Industrie De Nora;
- 2005 2006 Member of Statutory Auditors Board of BancaIntesa (listed company);
- 2003 2006 Member of Statutory Auditors Board of Telecom Italia (listed company);
- 2001 2003 Member of Board of Banca Primavera (ora Banca Generali);
- 1999 2003 Member of Statutory Auditors Board of Pirelli (listed company);
- 1986 2000 Member of Board of Gpf&Associati, institute of market research:
- 1994 2001 Member of Italian Commission on Privatization at the Italian Ministry of Economy and Finance.

#### MICHAELA CASTELLI

Born on 7 September 1970.

- 1. Positions and Qualifications
- · Of Counsel to NCTM Studio Legale Associato.
- Member of the Board of Directors and Chairman of the Internal Control Committee, of A2A S.p.A., a company listed in the Blue Chip segment of Borsa Italiana in the FTSE MIB index.
- Member of the Board of Directors and of the Compensation Committee of Recordati S.p.A. a pharmaceutical company listed on the MTA of Borsa Italiana S.p.A. and, as of 8<sup>th</sup> March 2016, also member of the Audit and Risk Committee.
- Member of the Board of Directors, Chairman of the Internal Control Committee, Chairman of the Related Parties Transaction Committee and Member of the Remuneration Committee of ICBPI S.p.A..
- Member of the Board of Statutory Auditors of Nuova Sidap s.r.l. (Autogrill Group).
- Chairman of the Supervisory Board of Teva s.r.l. (Teva Pharmaceutical Industries Ltd Group, listed in the NYSE).
- Member of the Supervisory Board of Becton Dickinsons S.p.A..
- Member of the Supervisory Board and the Nomination Committee, and independent member of the Internal Supervisory Board, of A2A S.p.A. from June 2012 to JUNE 2014.
- Member and Secretary of the Board of Directors, and member of the Nomination and Compensation Committee and of the Internal Control Committee (Chairman), of Seat Pagine Gialle S.p.A., a company listed on the MTA of Borsa Italiana S.p.A. from October 2012 to September 2015 under the bankruptcy agreement in continuity procedure (judicial composition with creditors on a going concern basis pursuant to Article 163 of the Italian Royal Decree n. 267/1942).
- Member of the Board of Auditors of River Holding S.p.A. (Delta Banking Group) from 2009 to September 2013.
- Chairman of the Supervisory Board of Interbrand S.r.I. from 2009 to 2012.
- Chairman of the Supervisory Board of Bellco s.r.l.. from 2014 to January 2016
- Chairman of the Supervisory Board of Lima S.p.A. from 2009 to February 2013
- Member of the scientific editorial board of the Corporate Governance Committee of Borsa Italiana, which reviewed the new edition of the Corporate Governance Code for listed companies of March 2006 (published by Borsa Italiana).

#### 2. Degree and postgraduate courses

- University of Milan, Degree in Law, 1994.
- Commercial University "L. Bocconi" of Milan, Specialisation course in financial law. 2001.
- · Course in leadership organised by INSEAD, 2004.

#### 3. Experience in the areas of expertise<sup>12</sup>

- Head of Legal Affairs Listing Department, Head of the Secretariat of the Institutional Committee (decision-making body) and Secretary of the Supervisory Board at Borsa Italiana S.p.A. (2001 - 2010):
- Advisor to the companies of the group (Monte Titoli, Cassa di Compensazione e Garanzia, Bit Systems) on corporate law, delegations and governance;
- Preliminary legal investigation of the procedures for continued suspension and removal of financial instruments from trading (Cirio, Parmalat; Lazio AS, Giacomelli, Argentine Bonds);
- Legal assistance with corporate information handling and issuers' extraordinary transactions;
- Preliminary legal investigation of sanction procedures against issuers, sponsors and specialists;
- Preliminary legal investigation of the procedures for admission to trading of shares, including as a result of mergers/demergers, and of any other instruments issued by listed companies (Lottomatica, Snam, dual listing of NovusPharma, Vicuron);
- Preliminary legal investigation of the procedures for admission to trading of bonds, warrants and fund units (Vittoria assicurazione, Fiat, Roncadin);
- Preliminary legal investigation of the procedures for admission to trading of financial instruments (covered warrants, certificates, ABSs, ETFs, etc.);
- Examination of the evolution, at both domestic and international level, of corporate law and corporate governance, update of the principles applicable to listed companies and participation in the drafting of documents relating to consultation procedures (parliamentary hearings, consultation documents at both national and EU level, etc.);
- Assistance with the procedures for amending the rules on listed issuers;
- Gap Analysis, drafting of the organisational model under Legislative Decree No 231/2001.
- · Advisor at international law firms (Chiomenti and Ughi Nunziante).
- Advisor at the London branch of Banca Commerciale Italiana S.p.A.
   on syndicated loans and conduit lending (plain vanilla and structured
   financing), loan securitisation transactions, umbrella facilities, the
   structuring of loans to support acquisitions, mergers, demergers and the
   sale of businesses or business units.

#### 4. Professional Skills

Expert in corporate and financial markets law.

Lecturer at several courses on continuous education in corporate and financial markets law, both in Italy and abroad; speaker at numerous conventions.

Author of specialist publications.

#### **PAOLO FRESIA**

Native from Turin, Italy, Paolo holds a First Class Joint Honours B.A. degree in Philosophy and Economics from UCL, University College London. Starting from 2008, he worked with Goldman Sachs as an intern and then full time as fixed income sales trader.

He left the City in 2010 to pursue an M.Phil. in Development Studies at Trinity Hall, University of Cambridge. From late 2011 to early 2013, Paolo worked with the humanitarian NGO Médecins Sans Frontières — Doctors Without Borders. He was posted to Haiti for a year as the mission's Financial Coordinator.

In spring 2013, he moved to Asia to study Mandarin Chinese and – since September 2013 – has been a sustainability and corporate social responsibility consultant at BSR, Business for Social Responsibility, in their Hong Kong office.

#### MARIO GARRAFFO

Mario Garraffo graduated in Economics from the "Bocconi" University in Milano in 1960.

From 1960 to 1970, he was Controller and Development Director at La Centrale Finanziaria Generale, a holding company mainly invested in public utilities (communication and energy). From 1970 to 1980, he was Investment Director at the IFI group; from 1980 to 1985 he was Chief Executive Officer of IFIL- Finanziaria di Partecipazioni and from 1985 to 1993 President of IFINT (now EXOR). In 1993, he was appointed Chief Executive Officer of Lazard Italia until the acquisition of Vitale, Borghesi & Co. in 1998. Thereafter, he was appointed Chief Executive Officer of UNIM — Unione Immobiliare, a post which he held until the year 2000, when he was appointed as Chairman of General Electric Italia until 2004. He was then a Senior Advisor for General Electric Europe from 2004 until 2007.

He is an Independent Director, a Member of the Audit and Risk Committee and Chairman of the Compensation Committee at Recordati S.p.A..

He has been a Trustee of the Johns Hopkins University of Baltimore and a Trustee of the Johns Hopkins School for Advanced International Studies (SAIS) in Bologna.

From 1995 to 2006 he was President of the Bocconi University Alumni Association and member of the Board of Directors of the Donna Javotte Bocconi Foundation (Bocconi University's founding Entity).

Dr. Garraffo holds the following additional positions:

- Independent Director, Member of the Audit and Risk Committee and of the Compensation Committee of ANSALDO STS SpA.
- Independent Director of Quadrivio Capital Sgr.

### FRITZ SQUINDO

Fritz Squindo graduated "cum laude" in Economics at the Bocconi University in Milan, Italy. He started his career in 1981 in Telettra S.p.A., a telecommunications company within the Fiat Group, where he was employed in the finance department. In 1986 he joined Sanofi S.p.A., the Italian subsidiary of the French pharmaceutical group Sanofi, where he was first Head of Finance and, as from 1990, Head of Management Accounting. In 1992 he joined Recordati S.p.A. as Head of the Management Accounting department. In 1995 he was appointed Chief Financial Officer and in 2008 also became Managing Director. Since 2013 Mr. Squindo is a member of the Board of Directors of Recordati S.p.A. and is also part of the managing bodies of several Recordati Group companies.

#### **MARCO VITALE**

Marco Vitale, business economist. He has been teaching for several years business economy at Pavia University (where he also studied at the famous Ghislieri College); Bocconi University, Milan; Libero Istituto Universitario Carlo Cattaneo (for which he was vice-president, President of the Scientific Committee, and responsible for management area and which he contributed to create). He has been chairman of Istud (Foundation for the business culture and management), which he also contributed to re-launch, and has been co-ordinator for management area of ISTAO, post-degree management school founded by the economist Prof. Giorgio Fuà.

Former partner of Arthur Andersen & Co., he is founding partner and president of Vitale–Novello & Co. S.r.l., top management consulting firm. In this context, he is consultant and member of the board of directors for many important companies.

He has been president from 1984 to 2003 of A.I.F.I. (Italian Venture Capital and Private Equity Association) and promoter and first president of Arca Group, the mutual fund company of popular banks.

He has been Vice-president, member of the board and of the Executive Committee of Banca Popolare of Milan from 2001 till 2009 and was Chairman of Bipiemme Gestioni S.G.R., the Asset Management Company of the BPM Group.

Member of the Board of Olivetti Foundation; member of the Board of FAI Foundation. He is a member of UCID Brescia.

He has been President from March 2010 to June 2013 of Fondo Italiano di Investimenti SGR SpA, constituted by the Treasure Ministry, Confindustria, ABI, Banca Intesa, Unicredit, Monte Paschi, Crediop and some popular banks, with a capital of 1.2 billion Euro, with the aim of sustaining development projects and internationalization of little medium companies.

He has been appointed to several important public tasks.

He contributes to important leading newspapers and business magazines. He published several books including: Società, bilanci e borse valori in un mercato mobiliare evoluto (Etas-Kompass); La riforma delle società per azioni (Giuffré); La lunga marcia verso il capitalismo democratico (Ed. Il Sole-24 Ore); Liberare l'economia: le privatizzazioni come terapia alla crisi italiana (Ed. Marsilio); Le Encicliche sociali, il rapporto fra la Chiesa e l'economia (Ed. Il Sole-24 ore); Sviluppo e Spirito d'Impresa (Ed. Il Veltro); America. Punto e a capo (Scheiwiller); Il Mito Alfa (Egea editore, Bocconi); Lezioni di Impresa, da tempi e luoghi diversi – I proverbi di Calatafimi (Piccola Biblioteca Inaz, 2008); Gli angeli nella città (ESD Edizioni); Passaggio al Futuro, Oltre la Crisi attraverso la Crisi (Ed. Egea, Bocconi); Corruzione (ESD Bologna 2010); Responsabilità nell'impresa (Piccola Biblioteca d'Impresa Inaz, 2011); Viaggio nello sport italiano (ESD Edizioni, 2011).

He was editor in Italy and USA of the bilingual version of the essay of Carlo Cattaneo: "Intelligence as a principle of public economy".

Good mountain-climber, he has covered great part of Italy by bicycle, a good way to observe the Italian economy as it really is and not as people say to be. Prof. Vitale holds the following additional positions:

- Director ERMENEGILDO ZEGNA HOLDITALIA SpA.
- Director LUVE SpA (listed company).
- Director SMEG SpA.
- · Director Banca Passadore SpA.

# MEMBERS OF THE BOARD OF STATUTORY AUDITORS

#### STATUTORY AUDITORS

#### **MARCO NAVA**

Marco Nava graduated in Economics and Commerce and in Jurisprudence at the Università *Cattolica del Sacro Cuore* of Milan. He started his career as an accountant in 1988. He has been registered as an auditor since the first publication of the register (1995). He performs his principal activity as an accountant with his own offices in a partnership of accountants and lawyers. He is a statutory auditor and external auditor for companies operating in various sectors.

Marco Nava holds positions in the following companies:

- 1. Chief Executive Officer of Nava Viganò Revisori Associati Srl.
- 2. Sole director of Tazat Srl.
- 3. Chairman of the Board of Statutory Auditors of Cavenaghi SpA.
- 4. Chairman of the Board of Statutory Auditors of Dott. G. Cavenaghi SpA.
- 5. Chairman of the Board of Statutory Auditors of Euclidea SIM SpA.
- 6. Chairman of the Board of Statutory Auditors of Fratelli Re SpA.
- 7. Chairman of the Board of Statutory Auditors of Italchimici srl.
- 8. Chairman of the Board of Statutory Auditors of LCS SpA.
- 9. Chairman of the Board of Statutory Auditors of Max Moda SpA.
- 10. Chairman of the Board of Statutory Auditors of Prodotti Naturali SpA.
- 11. Chairman of the Board of Statutory Auditors of Recordati SpA.
- 12. Chairman of the Board of Statutory Auditors of RBR Valvole SpA.
- 13. Chairman of the Board of Statutory Auditors of Synlab Italia srl.
- 14. External Auditor Associazione Italiana Medicina Nucleare (AIMN).
- 15. External Auditor Società Italiana di Biochimica Clinica (SIBIOC).
- 16. Accounting Auditor Musixmatch SpA.
- 17. Accounting Auditor Tensive srl.
- 18. Statutory Auditor Beaumanoir Italy srl.
- 19. Statutory Auditor Campo SpA.
- 20. Statutory Auditor Fimei SpA.
- 21. Statutory Auditor Giuseppe & Fratelli Bonaiti SpA.
- 22. Statutory Auditor Innova Pharma SpA.
- 23. Statutory Auditor J Colors SpA.
- 24. Statutory Auditor Junionfin SpA.
- 25. Statutory Auditor National Instruments Italy srl.
- 26. Statutory Auditor S.I.S.A. Società Italiana Spalmature ed Affini SpA.
- 27. Statutory Auditor Twister Communications SpA.
- 28. Statutory Auditor Yazaki Europe Limited Italia srl.
- 29. Statutory Auditor Avio San Michele srl.
- 30. Member of Compliance Committee Giuliani SpA
- 31. Member of Compliance Committee CM Engineering srl.
- 32. Director Sifact Ricerca e Servizi srl.

#### LIVIA AMIDANI ALIBERTI

Livia Amidani Aliberti graduated in Economics and Commerce at LUISS (Rome, Italy) and holds a Master level Diploma from FT-Pearson (UK). She holds FCA status (CF1, 10, 11, 30); registered with the *Albo dei Dottori Commercialisti* (Association of Chartered Accountants) of Rome and a member of the Scientific Committee of NedCommunity. Executive director in charge of compliance and controls in FCA regulated entities. With more than ten years of consulting and research in corporate governance, her specialties include AIM Listings, Corporate Governance Assessment and Redesign, Strategic Evaluation of Boards; she is also engaged in gender diversity research and consulting. She is the author of several publications on gender diversity and directors.

Livia Amidani Aliberti occupies the following positions as corporate director:

- LVenture Group S.p.A. (listed company: Italy, MTA): independent director, chair of the Control and Risk Committee and Chair of the Related Party Transactions Committee.
- Amnesty International Charitable Trust UK (Company Limited by Guarantee):
   non- executive director, member of the Finance Audit and Risk Committee.
- · Bayes Investments Ltd, UK: executive director.
- · NAD Ltd, UK: executive director
- · Quantyx UK Ltd: executive director
- · Industrie De Nora SpA: independent director

#### **MARCO RIGOTTI**

Marco Rigotti was born in Milan on 16<sup>th</sup> June 1967. He graduated in Corporate Economics at the Bocconi University of Milan in 1992, and registered with the Albo dei Dottori Commercialisti (association of chartered accountants) of Milan in 1993 and in the register of auditors in 1999. Between 1995 and 1998, he worked at Consob for the insider trading and share price manipulation unit. Presently he practices as a consultant in Milan and holds monitoring positions in important listed groups. He is Chairman of the Boards of some companies of Alisarda Group, where he represents the controlling shareholder Aga Khan Fund for Economic Development (AKFED). He also performs research at the A. Sraffa Department of Legal Studies at the Bocconi University where he is a lecturer in commercial law. He is the author of numerous academic publications on company law and financial markets. Dr. Marco Rigotti occupies the following management and supervisory positions in other companies:

- · Chairman of the Board of Directors of Air Italy Holding Srl
- Chairman of the Board of Directors of Air Italy SpA
- · Chairman of the Board of Directors of Gestione Aeroporti Sardi SpA
- · Chairman of the Board of Directors of Eccelsa Aviation Srl
- Chairman of the Board of Directors of Meridiana Fly SpA
- Chairman of the Board of Directors of Meridiana Maintenance SpA
- · Chairman of the Board of Directors of Alisarda SpA
- Chairman of the Board of Statutory Auditors of Autogrill SpA
- Statutory Auditor of Recordati Industria Chimica e Farmaceutica SpA.

#### **ALTERNATE AUDITORS**

#### PATRIZIA PALEOLOGO ORIUNDI

Born in Milan on January 24<sup>th</sup> 1957, she is a 1980 Business Administration graduate of Università Commerciale L. Bocconi. She is a member of the Milan Association of Certified Public Accountants since 1983 and a financial auditor since 1995.

She has been built up her career working for renowned law firm specialized in tax regulation, becoming an expert in consulting for multinational and for non-commercial companies, tax litigations, in addition to legal and administrative control of companies, foundations and associations. She also deals with real estate, insurance and energy companies.

She has 30-years of experience as legal controller and member of the Supervising Body established by Legislative Decree no. 231/01.

Foreign Languages: English, Spanish and French.

She occupies the following management and supervisory positions in other companies:

- Chairman of Auditors' of the Associazione "Valore D Donne al vertice per l'Azienda di Domani";
- · Chairman of the Board of Statutory Auditors of Chiara Assicurazioni spa;
- · Chairman of the Board of Statutory Auditors of Close up spa;
- Chairman of Auditors' of Consorzio Universitario per l'Ingegneria nelle Assicurazioni;
- · Statutory Auditor of Esprinet spa;
- Statutory Auditor of Ge.si.ass scarl;
- External Auditor of Fondazione Antonio e Giannina Grillo Onlus;
- Chairman of the Board of Statutory Auditors of Helvetia Vita spa;
- Statutory Auditor of ICIM spa;
- Chairman of the Board of Statutory Auditors of Helvetia Italia spa;
- Shareholder Director of Quisi snc di Patrizia Paleologo & C;
- · Sole Auditor of Simoro srl;
- Statutory Auditor of Virgin Active spa;
- Statutory Auditor of Banca Farmafactoring spa.

#### MARCO ANTONIO VIGANÒ

Marco Antonio Viganò graduated in Corporate Economics, specialising in freelance professionals, at the Bocconi University of Milan in 1984. He passed state examinations and qualified to practice as an accountant in 1986 when he registered with the *Albo dei Dottori Commercialisti* (association of chartered accountants) of Milan. He has been registered as an auditor since the first publication of the register (1995). An expert in commercial and tax law, he practices as an accountant and advises companies, groups and organisations operating in a variety of economic sectors. He has been a lecturer at the Scuola di *Formazione del Praticantato* for accounting students and accountant and auditor for the *Università Cattolica del Sacro Cuore* of Milano

Marco Antonio Viganò holds positions in the following companies:

- · Sole Director Chem Investment Consulting Srl.
- · Sole Director QE Qualità Europa Srl.
- · Director R.B.R. Valvole SpA.
- · Chairman of the Board of Statutory Auditors Beaumanoir Italy Srl.
- · Chairman of the Board of Statutory Auditors J Colors SpA.
- Chairman of the Board of Statutory Auditors Junionfin SpA.
- Chairman of the Board of Statutory Auditors Twister Communication Group SpA.
- · Chairman of the Board of Statutory Auditors Vibro-mac Srl.
- · Chairman of the Board of Statutory Auditors Xilografia Nuova Srl.
- Chairman of the Board of Directors Masseria Giancamisa Soc. Agr. Srl.
- Chairman of the Board of Directors Nava Viganò Revisori Associati Srl.
- · Auditor ADMO.
- · Auditor Assovernici.
- · Auditor Ilas.
- · Auditor Progetto DDD Onlus.
- Statutory Auditor A-Tono Payment Institute SpA.
- · Statutory Auditor Euclidea SIM SpA.
- · Statutory Auditor Fratelli Re SpA.
- Statutory Auditor Immobiliare Parabiago SpA.
- · Statutory Auditor Immobiliare Risanamento Quartiere Caminadella SpA.
- · Statutory Auditor Torciture Fibre Sintetiche SpA.
- Sole Statutory Auditor Marionnaud Parfumeries Italia SpA.
- Sole Statutory Auditor Tecmec srl.

This booklet is a summary of the 2016 Report of Board of Directors of Recordati SpA, which has been publicly filed in accordance with Italian law.

All mentions and descriptions of Recordati prescription products are intended solely to inform the reader of the general nature of the Company's activities with the sole objective of presenting the Annual Report. They are not intended to promote the use, or to indicate the advisability of using, Recordati prescription products, in compliance with existing law.

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#### **BOARD OF DIRECTORS**

(elected by the Shareholders' Meeting of April 11, 2017)

#### Alberto Recordati

Chairman

#### Andrea Recordati

Vice Chairman

and Chief Executive Officer

#### Rosalba Casiraghi

Independent Director

Business consultant and external auditor

#### Michaela Castelli

Independent Director Of Counsel studio NCTM

#### Elisa Corghi

Independent Director Non-executive Director

#### Paolo Fresia

Independent Director Advisory Services Associate, **Business for Social Responsibility** 

### Mario Garraffo

Independent Director Former Senior Adviser GE Europe

### Fritz Squindo

Chief Financial Officer General Manager for the Coordination of Group Operations

#### Marco Vitale

Independent Director

Economist and Business Consultant

#### **AUDIT, RISK AND** SUSTAINABILITY COMMITTEE

#### Marco Vitale

Chairman

Michaela Castelli Elisa Corghi

#### **REMUNERATION COMMITTEE**

#### Mario Garraffo

Chairman

Rosalba Casiraghi Michaela Castelli

#### STATUTORY AUDITORS

## Antonio Santi

Chairman

## Livia Amidani Aliberti

Marco Nava Auditors

#### Andrea Balelli

Patrizia Paleologo Oriundi

Alternate auditors

#### **EXTERNAL AUDITORS**

KPMG S.p.A.

#### **MANAGEMENT**

#### Alberto Recordati

Chairman

#### Andrea Recordati

Vice Chairman and Chief Executive

Officer

### Enrico Baroncia

Pharmaceuticals, Italy

#### Luca Bolliger

Licensing

### Corrado Castellucci

Orphan Drugs

#### Gabriele Finzi

Corporate Development

#### Daria Ghidoni

Legal Affairs

#### Antoine Grouès

International Licensees Sales

## Giuseppe Gualazzini

**Human Resources** 

## Miguel Isla

International Specialty and Primary Care and Western Europe Subsidiaries

### Luisa Mainoli

Finance

#### Giovanni Minora

Auditing

#### Paolo Romagnoli

Pharmaceutical Chemicals

# Fritz Squindo

Chief Financial Officer General Manager for the Coordination of Group Operations

### Marianne Tatschke

Investor Relations

& Corporate Communications

#### Roberto Teruzzi

**Industrial Operations** 

#### Witold Urban

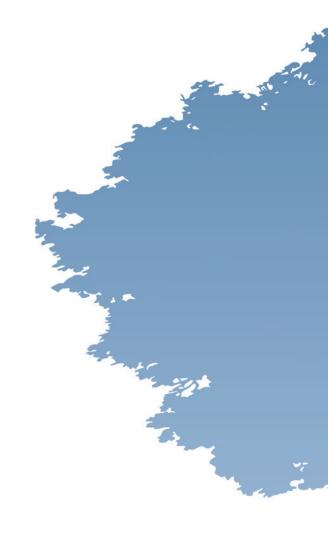
Central and Eastern Europe Subsidiaries

#### Ismail Yormaz

South Eastern Europe

and North Africa Subsidiaries





# **HEADQUARTERS**

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