

# **ANNUAL REPORT 2015**



#### **REVENUE**

€ (thousands)	2015	%	2014	%	Change 2015/2014	%
TOTAL REVENUE	1,047,676	100.0	987,356	100.0	60,320	6.1
Italy	211,570	20.2	218,829	22.2	(7,259)	(3.3)
International	836,106	79.8	768,527	77.8	67,579	8.8

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

€ (thousands)	2015	% of revenue	2014	% of revenue	Change 2015/2014	%
Revenue	1,047,676	100.0	987,356	100.0	60,320	6.1
EBITDA <sup>(1)</sup>	317,000	30.3	273,818	27.7	43,182	15.8
Operating income	278,517	26.6	231,030	23.4	47,487	20.6
Net income	198,803	19.0	161,193	16.3	37,610	23.3

<sup>(1)</sup> Earnings before interest, taxes, depreciation and amortization.

## **KEY CONSOLIDATED BALANCE SHEET DATA**

€ (thousands)	31 December 2015	31 December 2014	Change 2015/2014	%
Net financial position <sup>(2)</sup>	(88,737)	(186,045)	97,308	(52.3)
Shareholders' equity	869,992	787,422	82,570	10.5

<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**

€	2015	2014	Change 2015/2014	%
Net income <sup>(3)</sup>	0.968	0.792	0.176	22.2
Shareholders' equity <sup>(3)</sup>	4.234	3.852	0.382	9.9
Dividend	0.60 (4)	0.50	0.10	20.0
SHARES OUTSTANDING:				
- average during the year	205,270,094	203,573,320		
- at December 31	205,439,798	204,417,486		

<sup>(1)</sup> Earnings before interest, taxes, depreciation and amortization.

<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 3,855,062 shares in 2015 and 5,551,836 shares in 2014. Shareholders' equity per share is based on total shares outstanding at year end net of treasury stock. Treasury stock amounted to 3,685,358 shares at 31 December 2015 and 4,707,670 shares at 31 December 2014.

(4) Proposed by the Board of Directors.



## LETTER FROM THE CHAIRMAN

To Our Shareholders,

2015 was another growth year for our group due both to the positive development of our revenues and to the further improvement of our profitability. All business segments and the main corporate products contributed to these results with a particularly positive performance of the segment dedicated to treatments for rare diseases. Group consolidated revenue for 2015 is € 1,047.7 million, up 6.1% over the preceding year. International sales are € 836.1 million, up 8.8% and now represent 79.8% of total revenue. Operating income, at 26.6% of sales, is € 278.5 million, a growth of 20.6% compared with the preceding year. Net income is € 198.8 million, an increase of 23.3%, with a further improvement as margin on sales which is now 19.0%. At 31 December 2015 the group's net financial position records net debt of € 88.7 million, an improvement compared to net debt of € 186.0 million at the end of 2014, and shareholders' equity further increased to € 870.0 million.

In 2015 the internationalization of our rare disease business went ahead with the establishment of subsidiaries in Brazil, Mexico and Colombia. Furthermore, Carbaglu® (carglumic acid) was authorized for sale by Health Canada as an adjunctive therapy for the treatment of acute hyperammonaemia or as maintenance therapy for chronic hyperammonaemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS) in pediatric and adult patients.

In May Virirec® (alprostadil) was successfully launched in Spain. Virirec®/Vitaros® is indicated for the treatment of erectile dysfunction and is a topically-applied cream formulation of alprostadil, a vasodilator, which directly increases blood flow to the penis, causing an erection. Alprostadil is an alternative to the PDE-5 inhibitors for difficult to treat patients and Virirec®/Vitaros® offers a patient-friendly form versus other alprostadil dosage forms.

In September Erytech Pharma, a French biopharmaceutical company with which Orphan Europe, Recordati group, established an exclusive agreement in 2012 for the commercialization and distribution in Europe of Graspa® (a treatment for hematological malignancies intended to satisfy the unmet medical needs of frail patients, patients suffering relapses and other patient groups for whom the current treatments are not suitable) submitted a centralized Marketing Authorization Application to the European Medicines Agency (EMA) for Graspa® for the treatment of patients with acute lymphoblastic leukemia (ALL).

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 markets with higher potential. The development of the segment dedicated to treatments for rare diseases will continue to be a priority. Our group already makes these treatments available through its own organizations throughout Europe, in the Middle East and in the U.S.A.. In coming years our objective is to continue to extend the presence of our rare disease operations to other important markets worldwide. 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 2015.

#### **DIVIDENDS**

Based on the results obtained, the Board of Directors of the parent company will propose to the shareholders a dividend of € 0.30 per share, in full balance of the interim 2015 dividend of € 0.30, to be paid to all shares outstanding at ex-dividend date, excluding those in treasury stock, as from 20 April 2016 (record date 19 April 2016), with ex-dividend on 18 April 2016 (against presentation of coupon no. 17). The full 2015 dividend is therefore of € 0.60 per share (€ 0.50 per share in 2014).

## RESEARCH AND DEVELOPMENT

In 2015 research and development activities involved programs in rare diseases and urology. During the year important progress was made in a number of clinical development programs.

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), was completed. The Marketing Authorization Application was submitted to the European Medicines Agency (EMA) in September 2015. 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 patients unfit for chemotherapy is ongoing.

The phase III study involving Citrafleet® conducted in Germany in 5 clinical centers, was completed. This study explored the preparatory condition prior to endoscopy in 320 patients at risk of intestinal polyps. At the beginning of 2015 the application for the addition of a split-dose administration regimen was submitted to the authorities and in December 2015 the European MRP (Mutual Recognition Procedure) variation was positively concluded.

Following the completion of the phase III-b study EQUIMETH2 conducted in France in 18 clinical centers specialized in the treatment of pain associated with tumours, in June 2015 the relative application was submitted to the French authorities for the approval of the use of methadone for this condition.

The following table shows the main projects and products in development.



#### PRODUCT DEVELOPMENT PIPELINE

NAME	ORIGINATOR	INDICATION	DEVELOPMENT STATUS
VITAROS®	Apricus	Erectile dysfunction	Approved by a number of health authorities in Europe
CARBAGLU®	Recordati	Organic acidemias (OA)	Approved in EU Phase III in U.S.A.
CARBAGLU®	Recordati	Hyperammonaemia	New formulations
CYSTADROPS®	Recordati	Ocular cystinosis	Filed in EU
FORTACIN™	Plethora Solutions	Premature ejaculation	Variation of EU approval
methadone		Cancer related pain in cases of resistance or intolerance to opioids	Filed in France
CITRAFLEET®	Recordati/Casen	Preparation for colonoscopy in patients at risk of intestinal polyps	MA variation approved in EU
GRASPA®	Erytech	Acute lymphoblastic leukemia (ALL) in patients with first recurrence of Philadelphia chromosome negative ALL	Filed in EU
		Acute myeloid leukemia (AML) in patients >65 unfit for chemotherapy	Phase II b
REC 0438	Recordati/UFPeptides	Overactive bladder in patients with spinal lesions	Phase I/II in EU

The introduction in the pipeline of new products, both through our discovery programs as well as through alliances with other companies, is of great importance for the group's future growth. During 2015 the product and project evaluation group was enlarged and consolidated. More than one hundred products in development or ready to be launched belonging to different therapeutic areas (urology, rare diseases, metabolism, oncology) were evaluated in order to assess their therapeutical potential.

This dynamic activity projected into the future emphasizes once more that the Recordati group maintains a high level of attention to all registration and regulatory activities regarding corporate products (silodosin, lercanidipine, pitavastatin, fenticonazole) and drugs for rare diseases (Carbaglu®, Cystadrops®, GRASPA®) following the vast and growing need for new product registrations, renewals and variations.

Research and development activities during 2015 are summarized in the following paragraphs.

## Lercanidipine

Regarding the fixed combination of enalapril and lercanidipine, the results of the European phase III study FELT (EudraCT number: 2009-015988-13; https://www.clinicaltrialsregister.eu/ctr-search/search?query=FELT+Recordati) conducted at high doses of both lercanidipine and enalapril (20mg/20mg) in 1,039 patients with moderate hypertension, demonstrated the efficacy of the combination of these two drugs. The results of this study were published in the Journal of Hypertension (2014; 32:1700-7). A second publication ("Effect of the Lercanidipine-Enalapril combination vs the corresponding monotherapies on home blood pressure in Hypertension: evidence from a large database", G. Mancia et al.) describes the importance of the FELT study results and was also published by the Journal of Hypertension in its January 2016 issue. This new dosage form of the fixed combination of the two antihypertensive drugs will allow patients to simplify their daily treatment of hypertension and increase compliance as encouraged by the scientific and



research associations. The results of the FELT study, significant due to the extensive patient case histories, allowed us to obtain the European Marketing Authorization for this new drug combination. Following the European approval in 2015 this new dosage form was also approved in Azerbaijan, Mexico, Nicaragua and Panama.

#### Silodosin

Regulatory activities for the approval of silodosin (Urorec® and Silodyx™) in new markets continued. In 2015 marketing authorization was obtained in Tunisia.

The European phase IV study SiRE (EudraCT number: 2011-000045-20; https://www.clinicaltrialsregister.eu/ctr-search/search?query=SIRE+Recordati) which was conducted in a cohort of almost 1,000 patients suffering from symptomatic benign prostatic hypertrophy (BPH) confirmed the efficacy of silodosin in relieving the BPH symptoms considered by the patients to be the most annoying, the good tolerability profile of this selective alpha blocker and the safety margin also in patients with cardiovascular disease. The results of the study were instrumental in obtaining a variation of the product's pharmacological profile (EU-SmPC) to include silodosin's efficacy data regarding specific BPH symptoms from the European medicines Agency (EMA).

During 2015 a phase IV open single center clinical trial was initiated and is still ongoing involving 30 patients at the Federico II university in Naples. The patients, who are slated for surgery for BPH, are placed on an eight week treatment schedule with silodosin. At the end of the treatment period the patients will undergo an indepth diagnostic evaluation, including urodynamic testing, to verify whether there is an improvement in bladder neck obstruction. Preliminary observations in Japan involving an analogous patient population showed a significant and long-lasting reduction of the obstruction. At the end of the Japanese trial 44% of the men with BPH decided against surgery and continued treatment with silodosin.

#### Pitavastatin

Clinical work and meta-analysis conducted by our Japanese partner Kowa have highlighted the reduced potential of pitavastatin in inducing diabetes in patients treated chronically for hypercholesterolemia. The data were submitted to the European agencies for inclusion in an updated version of the SmPC (Summary of Product Characteristics) of the product.

In 2015 pitavastatin was approved for marketing in Russia.

## Fenticonazole

Fenticonazole is an antimycotic product for topical use originated by Recordati. Considering the consolidated use of this product, a review of its safety and efficacy profile was effected with a view to obtaining OTC (Over the Counter) status. The procedure for obtaining this status was positively concluded in Romania. Procedures to obtain this authorization are ongoing in a number of countries.

## Procto-Glyvenol®

Procto-Glyvenol®, which contains tribenoside (a synthetic glucofuranoside) and the local anesthetic lidocaine, is a topical product indicated for the treatment of internal and external hemorrhoids. The Recordati plant in Campoverde di Aprilia has been approved for the production of tribenoside.



#### In-house urology projects

Recordati's discovery programs in Urology are primarily focused on the search for innovative treatments to address micturition disorders such as urgency and frequency, often associated with incontinence, which are frequent in the elderly but also afflict particular groups of patients suffering from rare conditions.

REC 0438 represents a class of compounds to be potentially used in patients with unstable bladder who require repeated daily treatment, mainly systemic, often with brief and variable efficacy and therefore not easily tolerated. REC 0438 would be administered intravesically with the object of improving lower urinary tract stability. Following the optimal tolerability profile shown in pre-clinical trials and the positive opinion issued by the Italian health institute (Istituto Superiore di Sanità), phase I clinical trials were initiated in 2014. A first study was conducted in healthy volunteers to whom up to 4mg of the compound were administered resulting in optimal tolerability. In a second study the product was tested in patients with spinal lesions (spinal cord injury, SCI) mostly of a post-traumatic nature. Following the administration of a single dose in adult patients the data confirmed the optimal tolerability of the product and evidence was collected showing that the drug is well tolerated locally, it is not absorbed and accumulation is not expected. A phase I-II Proof of Concept (PoC) trial in adult patients with SCI is now planned. Treatment will be administered over a 4 week period with 1 to 2 mg per day, in addition to the pharmacological treatment already present, with the objective of providing significant improvement over the usual treatment.

#### Preparation for colonoscopy

In Germany Recordati conducted a phase III randomized, multi-center, single blind study on subjects at risk of intestinal polyposis to evaluate the effectiveness of two administration schedules of CitraFleet® (sodium picosulfate plus magnesium citrate) to cleanse the colon in preparation for endoscopy (EudraCT Number: 2013-001620-20; https://www.clinicaltrialsregister.eu/ctr-search/search?query=2013-001620-20). The study demonstrated the efficacy of the split-dose administration regimen and a request for MRP (Mutual Recognition Procedure) variation was submitted to the European authorities at the beginning of 2015. The European variation procedure was concluded positively in December 2015 and the national approval phases are ongoing in a number of European countries.

#### Palliative treatment of pain in patients suffering from tumors (cancer-related pain)

In France Recordati markets methadone as replacement therapy for opioid drugs dependence, in a framework of programs involving medical, social and psychological management. Furthermore, methadone is increasingly used by specialists of pain management and by teams in palliative care units when level 3 analgesics (morphine, oxycodone, fentanyl, hydromorphone) are no longer efficient or poorly tolerated for the palliative treatment of pain in cancer patients (cancer-related pain). Recordati conducted an open, multi-centre, randomized, national phase III-b clinical study in France on methadone for the treatment of cancer-related pain inadequately relieved by opioids (the EQUIMETH2 study: EudraCT Number 2011-004609-26; https://www.clinicaltrialsregister.eu/ctr-search/search?query=2011-004609-26). The study was completed successfully thus confirming the therapeutic approach with methadone in these patients. In June 2015 Recordati filed a Marketing Authorization Application with the French authorities (ANSM) for the use of methadone in the palliative treatment of cancer-related pain in patients resistant or intolerant to opioids.

## Onco-hematology, treatment of acute leukemias

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 senior and elderly adults or relapsed patients) 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 or eliminates the toxicity and hypersensitivity issues associated with L-asparaginase treatments, while effectively suppressing the plasmatic bioavailability of asparagine.

GRASPA® was granted Orphan Drug status in EU in 2006 and in US in 2010 for the treatment of Acute Lymphoblastic Leukemia (ALL). ALL represents 12% of all cases of leukemia, with an incidence of 1 to 5 cases in 100,000 people. The U.S.A., Costa Rica, Switzerland and Italy are the countries where incidence is highest. During the past 30 years the prognosis for ALL has significantly improved thanks to the intensification and improvement of treatments. With the current treatment protocols based on poli-chemotherapy, which includes L-asparaginase, the cure rate exceeds 80%.

In 2009 an open, multi-center, randomized, Phase II-III clinical study GRASPALL (EudraCT Number: 2009-012584-34; https://www.clinicaltrialsregister.eu/ctr-search/search?query=GRASPALL) to evaluate the efficacy and safety of GRASPA® vs. L-asparaginase in combination with standard poli-chemotherapy, was initiated involving a group of 80 patients (children aged 1 to 17 and adults aged 18 to 55) suffering from ALL after a first relapse. The trial was completed after a 12 month follow-up and showed favourable effects also in patients who had previously manifested allergies or intolerance to L-asparaginase. These results constitute the clinical basis for the Marketing Authorization Application filed with the European Medicines Agency (EMA) in September 2015.

There is a solid clinical and experimental basis to evaluate the use of GRASPA® in other indications in oncohematology and in oncology (solid tumors). GRASPA® was granted Orphan Drug Designation in EU in 2013 and in US in 2014 for the treatment of Acute Myeloid Leukemia (AML). AML starts in the blood-forming cells of the bone marrow (myeloid) and progresses rapidly (acute) profoundly affecting the normal production of circulating blood cells. The symptoms of the disease are in fact due to the progressive substitution of the normal bone marrow cells with immature leukemic cells which causes a significant reduction of red blood cells (erythrocytes), white blood cells (leucocytes) and platelets. In Europe the incidence of the disease is estimated to be of 3 to 5 cases in 100,000 people, with areas where the incidence of AML is double that of ALL. In Italy the estimate is of 2,000 new cases of AML every year. The disease is infrequent before the age of 45 and more frequent in adults over the age of 65 and is more frequent in men than in women. The choice of treatment for AML depends on a number of factors, the first of which are the characteristics of the disease and the characteristics of the patient. In practice, the majority of patients with AML (mostly elderly men) are fragile and difficult to treat and therefore the unmet medical need for these patients is high. Treatment of younger patients (under the age of 60) consists of systemic cytotoxic chemotherapy with high doses of cytarabine. Drugs are used both in the induction phase as well as the consolidation (or maintenance) phase with a number of new chemotherapy agents today available. The success rate can vary widely, between 20% and 75%, but is low (around 10%) in the older patients who are unable to withstand the effects of the therapy. Recent clinical data indicates that asparaginase may have a synergic effect with cytarabine based treatment but asparaginase is not yet a recommended treatment for elderly patients due to its toxicity.

Recently a phase II-b international, multicenter, randomized and controlled clinical trial was initiated (GRASPA-AML EudraCT Number: 2012-002026-78; https://www.clinicaltrialsregister.eu/ctr-search/search?query=Graspa+AML) to evaluate the efficacy and safety of GRASPA® in the treatment of acute



myeloid leukemia (AML). The objective of the study is to evaluate the efficacy and tolerability of GRASPA® plus cytarabine vs. cytarabine alone in the treatment of newly diagnosed acute myeloid leukemia (AML) in patients over 65 years of age and unfit for intensive chemotherapy. The enrolment of patients in this European study with GRASPA® by a number of investigational centers in Finland, France, Germany, Italy and Spain is almost complete.

## 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).

#### Carglumic acid (Carbaglu®)

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® 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 phase III clinical development in the U.S.A. for this indication.

Recently the Recordati group has developed a new formulation of Carbaglu® to be administered intravenously (IV) for the treatment of patients with organic acidemias (OA) in an acute decompensation phase when oral administration is not possible.

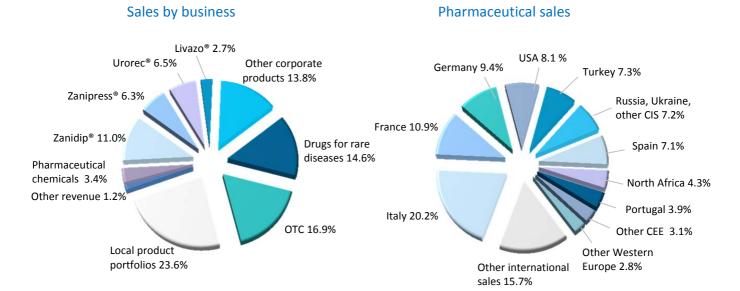
## Cysteamine (Cystagon®) and its derivatives

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, resulting in progressive blurred vision, pain, photophobia and frequent corneal ulceration and eye infections. Orally administered cysteamine does not adequately address ocular cystinosis. Cystadrops® are eye drops containing cysteamine chlorhydrate developed by Recordati for the specific treatment of the ocular manifestations of cystinosis. Following the positive outcome of the clinical development a Marketing Authorization Application was filed with the European Medicines Agency (EMA) to obtain the indication for the treatment of deposits of cystine crystals in the cornea. Thanks to the support of the authorities which allowed the use of the product under a Named Patient Use (NPU) distribution plan in Europe and through *Autorisations Temporaries d'Utilisation* (ATU) in France, many patients affected by the ocular manifestations of cystinosis have already been able to benefit from treatment with Cystadrops®.



## **REVIEW OF OPERATIONS**

Net consolidated revenue in 2015 is € 1,047.7 million, up 6.1% over the preceding year, with an increase in international sales of 8.8% to € 836.1 million, which represent 79.8% of total sales. Pharmaceutical sales are € 1,011.6 million, up by 6.1%. Pharmaceutical chemicals sales are € 36.1 million, up by 7.1%, and represent 3.4% of total revenues.



## **PHARMACEUTICALS**

The group's pharmaceutical business, which represents 96.6% 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 and in the United States of America 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.

The performance of products sold directly in more than one market (corporate products) during 2015 is shown in the table below.

€ (thousands)	2015	2014	Change 2015/2014	%
Zanidip® (lercanidipine)	115,707	109,245	6,462	5.9
Zanipress® (lercanidipine+enalapril)	65,675	61,272	4,403	7.2
Urorec® (silodosin)	68,275	59,052	9,223	15.6
Livazo® (pitavastatin)	28,418	25,518	2,900	11.4
Other corporate products*	199,290	191,942	7,348	3.8
Drugs for rare diseases	153,130	123,183	29,947	24.3

<sup>\*</sup> Include the OTC corporate products for an amount of  $\leqslant$  55.1 million in 2015 and  $\leqslant$  49.7 million in 2014.



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 the aforementioned ones co-marketing agreements are in place.

€ (thousands)	2015	2014	Change 2015/2014	%
Direct sales	60,570	59,188	1,382	2.3
Sales to licensees	55,137	50,057	5,080	10.1
Total lercanidipine sales	115,707	109,245	6,462	5.9

Direct sales of lercanidipine based products are slightly up. Sales increase in Germany, the U.K., Poland and Turkey and while they are down mainly in France. Sales to licensees, which represent 47.7% of total lercanidipine sales, are up by 10.1% and grow significantly in China and in Australia.

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 new product is already marketed successfully by Recordati or by its licensees in 26 countries.

€ (thousands)	2015	2014	Change 2015/2014	%
Direct sales	47,808	44,649	3,159	7.1
Sales to licensees	17,867	16,623	1,244	7.5
Total lercanidipine+enalapril sales	65,675	61,272	4,403	7.2

Direct sales of Zanipress® in 2015 are up by 7.1% mainly due to the performance of the product in Italy and in Turkey. 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 2015 by Zanipril® and Lercaprel® are € 14.6 million, up by 19.2%. Overall the product has achieved a market share of 34.4%. 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 € 10.3 million, growing slightly despite a price cut in September. Overall the product has achieved a market share of 28.1%. In Germany, Recordati Pharma sells Zanipress®, which recorded sales of € 7.8 million, down by 11.0%. 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 leader in its class with a market share of 45.7%. In Portugal, where sales of Zanipress® are € 4.1 million (-0.9%), and in Spain where sales are € 2.9 million (+4.7%), generic versions of the product are present in the market with the resulting price decline. The lercanidipine/enalapril fixed combination is also sold by our marketing organizations in Turkey with sales of € 5.8 million (+43.8%), in Greece, in Ireland, in the Czech Republic in Russia and other C.I.S. and in North Africa. Sales to licensees, which represent 27.2% of total sales, are up by 7.5%.

Urorec® (silodosin) is a new 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 30 countries and has achieved a share of 18.2% 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™ and generated sales in 2015 of € 68.3 million, up by 15.6%. Urorec® is doing particularly well in Italy achieving sales in 2015 of € 19.3 million (+19.1%). The product is also well accepted by physicians in France and in Spain where sales are € 11.6 million (+15.0%) and € 7.2 million (+11.8%) respectively. Urorec® is also growing significantly in Turkey where it was launched in 2012 and generated sales of € 6.8 million (+40.5%) in 2015.

Livazo® (pitavastatin) is a novel 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, Ukraine and Greece. It is also sold in Switzerland by our licensee Eli Lilly. Sales generated in 2015, including sales to licensees, are € 28.4 million, up by 11.4%, and have achieved a share of 6.9% of the statins market in the four reference 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® 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 2015 are € 22.7 million and are generated mainly in Russia. Sales are down by 15.7% due to the severe devaluation of the rouble. In Russia, in local currency, this product's sales grow by 5.9%.
- 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 2015 sales of Citrafleet® are € 20.2 million and those of PhosphoSoda® are € 5.8 million. Fleet enema and Casenlax®, two other gastrointestinal products, generated sales of € 10.9 million and € 5.0 million respectively.
- Polydexa®, Isofra® and Otofa® are combination products for the treatment of ENT infections sold mainly in Russia. In 2015 sales of Polydexa® are € 17.8 million, those of Isofra® are € 10.7 million while Otofa® generated sales of € 3.8 million. Overall sales are down compared to the preceding year due to the devaluation of the Russian rouble. In local currency sales of these products grow significantly in Russia.
- The Hexa line of products comprises biclotimol based antibacterial treatments of the oral cavity and includes the brands Hexaspray®, Hexalyse®, Hexapneumine® and Hexarhume®. Overall sales of these products in 2015 are € 17.5 million, an increase of 18.3%, and are generated mainly in France and North Africa.
- · 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 2015 are € 17.3 million, up 14.8% over the preceding year.

- 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 2015 are € 14.5 million, up by 13.0%.
- TransAct® LAT, a transdermal patch containing 40 mg of flurbiprofen indicated for the symptomatic relief of localized pain involving the musculoskeletal system, obtained under license from Amdipharm, is sold on the Italian and Portuguese markets. Sales of this product are € 10.5 million (-3.7%) in 2015.
- 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 2015 are € 10.2 million, up by 6.1%.
- 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 2015 total € 10.1 million (+7.6%).
- Kentera® is an oxybutynin transdermal patch indicated for the symptomatic treatment of disorders of the lower urinary tract such as incontinence, increased urinary frequency and urgency, obtained under license from Allergan (previously Actavis and before that Watson Pharmaceuticals) and marketed in 16 countries. Sales of Kentera® are € 7.2 million (+12.7%) in 2015.
- Lopresor® (metoprolol) is a selective beta blocker for the treatment of different cardiovascular disorders, in particular hypertension and angina pectoris, marketed in Greece and in other European markets. Sales of this product in 2015 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 2015 are € 4.9 million and € 2.7 million respectively.

Our specialties indicated for the treatment of rare and orphan diseases are marketed directly all over Europe, in Turkey, in the Middle East and in the U.S.A., and mainly through partners in other parts of the world. Sales of these products in 2015 total € 153.1 million, an increase of 24.3% due to the good performance of the business as well as to the positive foreign exchange effect following the revaluation of the U.S. dollar. 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.

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



€ (thousands)	2015	2014	Change 2015/2014	%
Italy	204,847	212,275	(7,428)	(3.5)
France	110,590	111,036	(446)	(0.4)
Germany	94,753	84,639	10,114	11.9
U.S.A.	82,091	56,767	25,324	44.6
Turkey	74,073	68,003	6,070	8.9
Russia, other C.I.S. countries and Ukraine	72,382	81,339	(8,957)	(11.0)
Spain	71,981	68,153	3,828	5.6
North Africa	43,686	38,280	5,406	14.1
Portugal	39,346	36,241	3,105	8.6
Other C.E.E. countries	30,926	27,521	3,405	12.4
Other Western European countries	28,502	24,608	3,894	15.8
Other international sales	158,443	144,842	13,601	9.4
Total pharmaceutical sales	1,011,620	953,704	57,916	6.1

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

Sales in countries affected by strong currency exchange oscillations in 2015 and in 2014 are shown hereunder in their relative local currencies.

Local currency (thousands)	2015	2014	Change 2015/2014	%
Russia (RUB)	4,038,461	3,459,720	578,741	16.7
Turkey (TRY)	211,079	184,766	26,313	14.2
United States of America (USD)	91,118	75,482	15,636	20.7

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

#### ITALY

€ (thousands)	2015	2014	Change 2015/2014	%
Prescription pharmaceuticals (a)	160,131	168,313	(8,182)	(4.9)
Self-medication pharmaceuticals (b)	44,716	43,962	754	1.7
Pharmaceuticals, Italy	204,847	212,275	(7,428)	(3.5)

<sup>(</sup>a) Prescription pharmaceuticals include both reimbursable and non-reimbursable drugs.

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

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



€ (thousands)	Indication	2015	2014	Change 2015/2014	%
Peptazol®	gastric ulcers	23,651	25,374	(1,723)	(6.8)
Cardicor®	heart failure	20,250	18,205	2,045	11.2
Urorec®	benign prostatic hyperplasia	19,308	16,208	3,100	19.1
Zanedip®/Lercadip®	hypertension	18,407	18,876	(469)	(2.5)
Zanipril®/Lercaprel®	hypertension	14,554	12,205	2,349	19.2
Tora-Dol®	pain	12,202	13,310	(1,108)	(8.3)
Rextat®/Lovinacor®	hypercholesterolemia	11,953	10,726	1,227	11.4
Entact®	depression	-	16,660	(16,660)	(100.0)

Sales of pharmaceuticals in Italy are down by 3.5%, as compared to the preceding year due to the termination of the license for Entact® (escitalopram), an antidepressant, as from the month of June 2014. Urorec® (silodosin) and Zanipril®/Lercaprel® (lercanidipine+enalapril) show strong growth and sales of both Cardicor® (bisoprolol) and the statins Rextat® and Lovinacor® (lovastatin) are developing significantly. Sales of Zanedip®/Lercadip® (lercanidipine), Peptazol® (pantoprazole) and Tora-Dol® (ketorolac) were affected by generic competition. Sales of products for the treatment of rare diseases are up by 31.0% in Italy.

Sales of self-medication products are € 44.7 million, slightly up compared to the preceding year. Alovex<sup>™</sup>, indicated for the treatment of oral cavity aphthas, is our best-selling self-medication product with sales of € 7.5 million and a market share exceeding 30%. TransAct® LAT (a transdermal patch containing 40 mg of flurbiprofen indicated for the symptomatic relief of localized pain involving the musculoskeletal system) generated sales of € 6.5 million. Proctolyn® (treatment of haemorrhoids) with sales of € 6.5 million, up by 4.5%, remains market leader. Dentosan®, a line of oral care products, generated sales of € 5.3 million and sales of Imidazyl® (eye drops) at € 4.8 million are up by 3.4%. Sales of Eumill® (eye drops) grow by 27.5% thanks to the launch of a new multiple dose 10ml bottle marketed alongside the traditional single dose presentation.

## **FRANCE**

The 2015 revenue realized by our subsidiaries in France is € 110.6 million, down by 0.4% compared to the preceding year. The decrease is to be attributed entirely to the residual effect of the termination of the license for Adagen®, one of the rare disease treatments. Excluding the rare diseases business sales in France increase by 2.7% in a market which decreased by 0.2%. Below is the performance of the main products:

€ (thousands)	Indication	2015	2014	Change 2015/2014	%
Methadone	drug addiction	28,139	26,266	1,873	7.1
Urorec®	benign prostatic hyperplasia	11,560	10,049	1,511	15.0
Zanextra <sup>®</sup>	hypertension	10,300	10,088	212	2.1
Hexa line	antibacterial	8,231	6,958	1,273	18.3
Neocodion®	cough	6,620	6,478	142	2.2
Zanidip®/lercanidipine	hypertension	5,623	7,419	(1,796)	(24.2)

Sales of Urorec® (silodosin) and of methadone are growing significantly. Sales of the OTC line of products indicated for the treatment of ENT disorders, in particular the Hexa line and Neocodion®, are performing well. Overall the line of self-medication products in France generates sales of € 24.0 million, up by 8.5% as compared



to the preceding year. The performance of drugs for the treatment of rare diseases is negatively affected by the termination of the Adagen® license.

#### **GERMANY**

Sales generated by our subsidiaries in Germany are € 94.8 million, an increase of 11.9% compared to the preceding year. The following table shows sales of the main products.

€ (thousands)	Indication	2015	2014	Change 2015/2014	%
Ortoton®	muscle relaxant	27,776	19,207	8,569	44.6
Claversal®	ulcerative colitis	12,588	12,848	(260)	(2.0)
Zanipress®	hypertension	7,777	8,735	(958)	(11.0)
Corifeo®/lercanidipine	hypertension	7,137	4,648	2,489	53.5
Recosyn®	muscolo-skeletal	6,271	6,005	266	4.4
Mirfulan®	healing ointment	5,992	6,061	(69)	(1.1)
Lipotalon®	anti-inflammatory	4,968	5,437	(469)	(8.6)

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 which favourably competed against other generics in the assignment of tenders. Sales of Zanipress® (lercanidipine+enalapril) are down due to the presence in the market of lower priced imports from countries where Zanipress® has reduced its price following the entry of generics. The overall sales of self-medication products in Germany are € 16.9 million, substantially unchanged compared to the preceding year. Sales of the treatments for rare diseases in this country are up by 13.6%.

## 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. Sales in 2015 are € 82.1 million, up by 44.6%, and include an estimated positive currency exchange effect following the strengthening of the U.S. dollar of € 13.5 million. Sales in local currency grow by 20.7%. 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.

#### **TURKEY**

Sales in Turkey are € 74.1 million, up by 8.9%, and were impacted by the devaluation of the Turkish Lira during the year which generated a negative currency exchange effect estimated at € 2.8 million. In local currency, sales in Turkey increase by 14.2%. Recordati Ilaç, one of the top 30 pharmaceutical companies in Turkey, records higher growth than that of the market.

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



TRY (thousands)	Indication	2015	2014	Change 2015/2014	%
Cabral®	muscle relaxant	38,122	34,797	3,325	9.6
Lercadip®	hypertension	37,824	35,419	2,405	6.8
Mictonorm®	urinary incontinence	35,057	28,191	6,866	24.4
Kreval®	cough	20,819	17,922	2,897	16.2
Urorec <sup>®</sup>	benign prostatic hyperplasia	20,698	14,149	6,549	46.3
Zanipress <sup>®</sup>	hypertension	17,586	11,747	5,839	49.7
Procto-Glyvenol®	hemorrhoids	12,962	11,857	1,105	9.3

Worth mentioning is the good performance of the corporate products, mainly Urorec® (silodosin), Zanipress® (lercanidipine+enalapril) and Procto-Glyvenol® (tribenoside).

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

Revenue generated in Russia, Ukraine and in the countries within the Commonwealth of Independent States (C.I.S.) is € 72.4 million, down by 11.0% compared to the preceding year mainly due to an estimated negative currency exchange effect of € 20.9 million. Sales in Russia, in local currency, are RUB 4,038.5 million, up by 16.7% over the same period of the preceding year thanks to the growth of all products including the corporate products Procto-Glyvenol® and Urorec® and taking into account the low level of sales generated in 2014 following the reorganization of the distribution channel in the first quarter.

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

RUB (thousands)	Indication	2015	2014	Change 2015/2014	%
Tergynan®	gynaecological infections	992,558	937,259	55,299	5.9
Polydexa®	ear infections	850,968	782,060	68,908	8.8
Isofra®	nasal infections	640,558	465,700	174,858	37.5
Alfavit®	food supplement	560,664	452,031	108,633	24.0
Qudesan®	food supplement	317,488	314,475	3,013	1.0

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® and Qudesan®, the two main brands of the five lines of self-medication products, recovered in 2015 despite the economic situation in the country. In addition to the main products outlined above, sales in Russia comprise other corporate products, mainly Procto-Glyvenol® (tribenoside), Urorec® (silodosin) and Lomexin® (fenticonazole) which record significant growth.

Sales generated in the other C.I.S. countries, mainly Belarus, and in Ukraine are € 11.8 million, down by 9.2%. Sales in the C.I.S. countries decreased by 21.5% while those in Ukraine increased by 13.3%.

#### **SPAIN**

Revenues in Spain are € 72.0 million, up by 5.6% compared to the preceding year. The following table shows sales of the main products.



€ (thousands)	Indication	2015	2014	Change 2015/2014	%
CitraFleet®	bowel cleansing	12,292	12,177	115	0.9
Livazo®	hypercholesterolemia	10,168	9,263	905	9.8
Enema Casen	bowel cleansing	7,881	8,055	(174)	(2.2)
Urorec®	benign prostatic hyperplasia	7,233	6,471	762	11.8
Cidine®	gastroprokinetic	5,077	5,750	(673)	(11.7)
Bi-OralSuero	rehydrating solution	4,798	4,478	320	7.1
Zanipress®	hypertension	2,906	2,775	131	4.7

The main product in the portfolio is CitraFleet®, a preparation for colonoscopy. Livazo® (pitavastatin) and Urorec® (silodosin) are performing well and the treatments for rare diseases record a 9.6% growth. Sales of Zanipress® (lercanidipine+enalapril) grow despite competition from generic versions of the product helped by the promotion of the new higher dose formulation (lercanidipine 20mg+enalapril 20mg), while sales of Cidine® (cinitapride) are impacted negatively by generic competition. In May Virirec® (alprostadil), a new topical treatment for erectile dysfunction, was successfully launched on the Spanish market.

#### **NORTH AFRICA**

Overall sales in North Africa are € 43.7 million and comprise both the export sales from Bouchara Recordati into these territories, in particular Algeria, and the sales generated by Opalia Pharma mainly in Tunisia. Opalia Pharma, a Tunisian pharmaceutical company acquired in 2013, markets branded generic drugs with leading products in dermatology and in the gastrointestinal and respiratory therapeutic areas, generated sales of € 19.2 million in 2015, up 21.1% compared to the preceding year.

#### **PORTUGAL**

Revenue generated by our subsidiaries in Portugal is € 39.3 million, up by 8.6%.

€ (thousands)	Indication	2015	2014	Change 2015/2014	%
Livazo®	hypercholesterolemia	7,227	6,331	896	14.2
Zanipress®	hypertension	4,124	4,161	(37)	(0.9)
TransAct® LAT	anti-inflammatory	3,924	4,029	(105)	(2.6)
Microlax <sup>®</sup>	laxative	2,839	2,943	(104)	(3.5)
Urorec®	benign prostatic hyperplasia	2,355	2,065	290	14.0

The corporate products Livazo® (pitavastatin), second brand in the Portuguese statin market, and Urorec® (silodosin), alpha-blocker market leader, are performing very well. Sales of the self-medication products grow by 10.4%. The weakness of Zanipress® (lercanidipine+enalapril) sales is due mainly to a reduction in price. Generic versions of the product are present in the Portuguese market as from 2014.

## OTHER CENTRAL AND EASTERN EUROPEAN COUNTRIES

Sales in Poland in 2015 are € 12.6 million, up by 35.3% thanks to the good performance of the main products in the portfolio and a favourable comparison base following the change during 2014 in the distribution model



which resulted in de-stocking of the distribution channel. The Polish subsidiary's main product Procto-Glyvenol® (tribenoside) generated sales of € 3.5 million, up by 64.7%.

Sales generated by Herbacos Recordati in the Czech and Slovak Republics are € 12.4 million, down by 2.4% compared to the preceding year. Sales of Urorec® (silodosin) are up by 29.7%.

Sales in Romania reported by our subsidiary Recordati Romania are € 3.5 million, down by 3.2%. Worth mentioning is the good performance of Procto-Glyvenol® (tribenoside) which grows by 9.6%.

Sales in these markets of the specialty products indicated for the treatment of rare and orphan diseases amount to  $\le 2.4$  million, up by 29.7%.

#### OTHER WESTERN EUROPEAN COUNTRIES

Sales in the United Kingdom are € 9.0 million and relate mainly to products for the treatment of rare diseases which account for 64.4% of our revenues in this country. The other sales are generated mainly by lercanidipine based products.

Sales in other countries in Western Europe comprise sales of products for the treatment of rare diseases in a number of countries for a total of € 7.7 million, sales in Ireland recorded by Recordati Ireland of € 1.3 million, mainly generated by Urorec® (silodosin), Kentera® (oxybutynin TP) and Zanidip® (lercanidipine), and sales in Greece reported by Recordati Hellas Pharmaceuticals of € 10.5 million up by 18.0% thanks to the good performance of Livazo® (pitavastatin), launched during 2014, Lopresor® (metoprolol), Urorec® (silodosin) and Lomexin® (fenticonazole).

#### OTHER INTERNATIONAL SALES

Other international sales comprise revenues generated by the Group's international business through licensing agreements and exports. Included are the sales to and other revenues from our licensees for our corporate products, Bouchara Recordati's export sales, except those generated in the C.I.S. and in North Africa which are stated separately, Casen Recordati's export sales and export sales realized by Orphan Europe worldwide excluding the U.S.A..

€ (thousands)	2015	2014	Change 2015/2014	%
Sales to international licensees	109,484	99,622	9,862	9.9
Bouchara Recordati (export sales excluding C.I.S. and North Africa)	14,908	14,699	209	1.4
Casen Recordati (export sales)	6,558	7,571	(1,013)	(13.4)
Orphan Europe (sales to licensees and exports)	20,297	16,408	3,889	23.7
Other income	7,196	6,542	654	10.0
Total	158,443	144,842	13,601	9.4

Sales to international licensees grow by 9.9% thanks to the sales performance of lercanidipine (+10.1%), mainly to licensees in China and Australia, fenticonazole (+35.9%), lercanidipine+enalapril (+3.9%), oxybutynin (+35.6%), silodosin (+4.0%) and flavoxate (+9.4%).



Sales outside France by our French subsidiary Bouchara Recordati are up by 1.4% while sales outside Spain by our Spanish subsidiary Casen Recordati are down by 13.4% as exported brands, mainly Citrafleet® and Phosphosoda®, 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 € 20.8 million, up by 16.8%, and include other income of € 0.5 million deriving mainly from the Carbaglu® license in Japan.

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

#### PHARMACEUTICAL CHEMICALS

€ (thousands)	2015	%	2014	%	Change 2015/2014	%
Italy	2,870	8.0	2,866	8.5	4	0.1
Europe (Italy excluded)	13,976	38.8	12,649	37.5	1,327	10.5
United States of America	8,812	24.4	2,339	7.0	6,473	276.7
America (U.S. excluded)	2,435	6.7	7,701	22.9	(5,266)	(68.4)
Australasia	6,104	16.9	6,327	18.8	(223)	(3.5)
Africa	1,859	5.2	1,770	5.3	89	5.0
Total	36,056	100.0	33,652	100.0	2,404	7.1

Sales of pharmaceutical chemicals, which comprise active substances produced in the Campoverde d'Aprilia (Latina, Italy) plant, increase by 7.1% as compared to 2014, mainly due to a positive foreign exchange effect following the revaluation of the U.S. dollar. In particular, the products verapamil, mebeverine and dimenhydrinate performed well.



## 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. 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 within 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 2015 the Campoverde (Latina, Italy) plant passed an on-site inspection performed by the certifying body DNV (Det Norske Veritas), which renewed its certification of the environmental management system recognizing it as compliant with the UNI EN ISO 14001/04 standard.



## FINANCIAL REVIEW

## **INCOME STATEMENT**

The following table shows the profit and loss accounts, including their expression as a percent of sales and change versus 2014:

€ (thousands)	2015	% of revenue	2014	% of revenue	Change 2015/2014	%
Revenue	1,047,676	100.0	987,356	100.0	60,320	6.1
Cost of sales	(335,210)	(32.0)	(327,054)	(33.1)	(8,156)	2.5
Gross profit	712,466	68.0	660,302	66.9	52,164	7.9
Selling expenses	(293,204)	(28.0)	(282,946)	(28.7)	(10,258)	3.6
R&D expenses	(76,736)	(7.3)	(85,267)	(8.6)	8,531	(10.0)
G&A expenses	(58,980)	(5.6)	(57,173)	(5.8)	(1,807)	3.2
Other income (expense), net	(5,029)	(0.5)	(3,886)	(0.4)	(1,143)	29.4
Operating income	278,517	26.6	231,030	23.4	47,487	20.6
Financial income (expense), net	(13,080)	(1.2)	(16,255)	(1.6)	3,175	(19.5)
Pre-tax income	265,437	25.3	214,775	21.8	50,662	23.6
Provision for income taxes	(66,634)	(6.4)	(53,582)	(5.4)	(13,052)	24.4
Net income	198,803	19.0	161,193	16.3	37,610	23.3
Attributable to:						
Equity holders of the parent	198,792	19.0	161,187	16.3	37,605	23.3
Minority interests	11	0.0	6	0.0	5	83.3

In 2015 international revenues went from € 768.5 million to € 836.1 million, an increase of 8.8%, and represent 79.8% of total revenue. Their breakdown by geographic area is shown in the table below:

€ (thousands)	2015		2014	
		%		%
Europe (Italy excluded)	616,464	73.7	589,470	76.7
United States of America	91,467	10.9	59,525	7.7
America (United States excluded)	18,904	2.3	21,377	2.8
Australasia	53,731	6.4	49,687	6.5
Africa	55,540	6.6	48,468	6.3
Total	836,106	100.0	768,527	100.0

Gross profit is € 712.5 million with a margin of 68.0% on sales, an increase over that of the preceding year due to the higher proportion of higher margin product sales to total product sales.

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 € 76.7 million, down by 10.0% compared to those recorded in 2014 due to the interruption of expenses related to the phase III clinical trial ERNEST involving the product NX-1207 for benign prostatic hyperplasia under license from Nymox.

G&A expenses are up by 3.2% but decrease as percent of sales.

Overall, labor cost in 2015 is € 241.2 million, an increase of 3.3% over 2014, with the cost per employee up by 3.0%.

Personnel and other human resources data at 31 December 2015 and 2014 are shown in the following table:

	2015	2014
Employees at year-end	3,929	3,923
Average age	42	41
Average service (years)	7.3	6.8
Labor productivity:		
Labor cost on net sales	23.0%	23.6%
Sales per employee (€ thousands) <sup>(a)</sup>	274.7	259.7
Value added per employee (€ thousands) <sup>(a)</sup>	146.4	133.4

Labor cost includes wages, related charges and additional costs.

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 2015. During the year a new project aimed at identifying and evaluating personnel competencies within the group with the objective of improving staff development and career planning was initiated.

Other expenses net of other income are € 5.0 million and include an accrual of € 2.6 million for re-organization costs and € 0.8 million pay-back due to AIFA (the Italian medicines agency) in substitution of the 5% price reduction on selected products.

Net financial charges are € 13.1 million, a decrease of € 3.2 million compared to the preceding year due mainly to the reduction of interest charges related to medium/long-term loans and to the lower net foreign exchange losses.

The effective tax rate during the period is 25.1%, substantially in line with that of the preceding year.

Net income at 19.0% of sales is € 198.8 million, an increase of 23.3% over the preceding year.

#### **FINANCIAL POSITION**

The net financial position at 31 December 2015 records net debt of € 88.7 million compared to net debt of € 186.0 million at 31 December 2014.

<sup>(</sup>a) Data per employee for both years are computed on the average number of personnel, 3,813 in 2015 and 3,803 in 2014.



€ (thousands)	31.12.2015	31.12.2014	Change 2015/2014	%
Cash and short-term financial investments	225,525	136,990	88,535	64.6
Bank overdrafts and short-term loans	(9,849)	(8,552)	(1,297)	15.2
Loans – due within one year	(34,469)	(28,281)	(6,188)	21.9
Net liquid assets	181,207	100,157	81,050	80.9
Loans – due after one year <sup>(1)</sup>	(269,944)	(286,202)	16,258	(5.7)
Net financial position	(88,737)	(186,045)	97,308	(52.3)

<sup>(1)</sup> 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 € 110.8 million, of which € 49.2 million for the balance of the financial year 2014 dividend and € 61.6 for the interim financial year 2015 dividend.

An amount of € 31.3 million was invested in property, plant and equipment, mainly involving the Parent company's Milan headquarters and production sites (€ 7.3 million) and in Turkey by Recordati Ilaç for the advancement of the activities related to the construction of a new production plant (€ 21.0 million).

Net working capital for operations at 31 December 2015 is € 130.6 million and is thus comprised:

€ (thousands)	31.12.2015	% of revenue	31.12.2014	% of revenue	Change 2015/2014	%
Trade receivables, net	177,219	16.9	179,029	18.1	(1,810)	(1.0)
Inventories	143,093	13.7	141,223	14.3	1,870	1.3
Other current assets	34,163	3.3	37,243	3.8	(3,080)	(8.3)
Current assets	354,475	33.8	357,495	36.2	(3,020)	(0.8)
Trade payables	106,597	10.2	112,536	11.4	(5,939)	(5.3)
Tax payable	14,592	1.4	12,541	1.3	2,051	16.4
Other current liabilities	102,710	9.8	91,573	9.2	11,137	12.2
<b>Current liabilities</b>	223,899	21.4	216,650	21.9	7,249	3.4
Net working capital for operations	130,576	12.5	140,845	14.3	(10,269)	(7.3)
Days of sales outstanding	59		62			
Inventories as % of cost of sales	42.7%		43.2%			

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 € 4.4 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 2015 the provisions of art. 36 of the Financial Markets Regulation apply to the subsidiaries Recordati İlaç, Recordati Rare Diseases Inc. and Rusfic LLC and that the conditions indicated in the abovementioned art. 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 2015**

€ (thousands)	IV quarter 2015	%	IV quarter 2014	%	Change 2015/2014	%
Revenue	263,244	100.0	245,268	100.0	17,976	7.3
Cost of sales	(83,562)	(31.7)	(82,269)	(33.5)	(1,293)	1.6
Gross profit	179,682	68.3	162,999	66.5	16,683	10.2
Selling expenses	(73,685)	(28.0)	(71,667)	(29.2)	(2,018)	2.8
R&D expenses	(21,513)	(8.2)	(23,307)	(9.5)	1,794	(7.7)
G&A expenses	(16,027)	(6.1)	(15,124)	(6.2)	(903)	6.0
Other income (expense), net	(2,987)	(1.1)	(2,241)	(0.9)	(746)	33.3
Operating income	65,470	24.9	50,660	20.7	14,810	29.2
Financial income (expense), net	(2,913)	(1.1)	(3,129)	(1.3)	216	(6.9)
Pretax income	62,557	23.8	47,531	19.4	15,026	31.6
Provision for income taxes	(16,259)	(6.2)	(10,360)	(4.2)	(5,899)	56.9
Net income	46,298	17.6	37,171	15.2	9,127	24.6
Attributable to:						
Equity holders of the parent	46,297	17.6	37,170	15.2	9,127	24.6
Minority interests	1	0.0	1	0.0	0	0.0

Revenues during the fourth quarter 2015 are € 263.2 million, an increase of 7.3% compared to the same period of the preceding year. Pharmaceutical sales are € 253.4 million, up by 7.5% compared to the fourth quarter 2014. Pharmaceutical chemicals revenue, at € 9.9 million, up by 3.9% compared to the same period of the preceding year.

Operating income, at 24.9% of sales, is  $\le$  65.5 million up by 29.2%. Other expenses net of other income include an accrual of  $\le$  2.6 million for re-organization costs and  $\le$  0.2 million pay-back due to AIFA (the Italian medicines agency) in substitution of the 5% price reduction on selected products.

Financial charges decrease due mainly to the lower net foreign exchange losses and to the reduction of interest charges related to medium/long-term loans.

Net income increases by 24.6%, less than the increase in operating income due to the increase in the tax rate for the period as compared to a particularly favourable tax rate in the fourth quarter of 2014.



## 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 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 launch of new products to reinforce 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 36 to the financial statements.



# SUBSEQUENT EVENTS AND BUSINESS OUTLOOK

On 11 February 2016 the company announced its financial targets for 2016. The objective is to to achieve sales ranging from € 1,070 million to € 1,100 million, EBIT of between € 290 and 300 million and net income of between € 205 and 215 million.

Group consolidated sales during the first two months of 2016 are particularly positive growing more than expected thanks also to favourable seasonality factors in some countries.

Milan, 8 March 2016

Giovanni Recordati 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 2015

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 2014.



# RECORDATI S.p.A. AND SUBSIDIARIES

CONSOLIDATED INCOME STATEMENT FOR THE YEAR ENDED 31 DECEMBER 2015

## **INCOME STATEMENT**

€ (thousands)	Note	2015	2014
Revenue	3	1,047,676	987,356
Cost of sales	4	(335,210)	(327,054)
Gross profit		712,466	660,302
Selling expenses	4	(293,204)	(282,946)
R&D expenses	4	(76,736)	(85,267)
G&A expenses	4	(58,980)	(57,173)
Other income (expense), net	4	(5,029)	(3,886)
Operating income		278,517	231,030
Financial income (expense), net	5	(13,080)	(16,255)
Pretax income		265,437	214,775
Provision for income taxes	6	(66,634)	(53,582)
Net income		198,803	161,193
Attributable to:			
Equity holders of the parent		198,792	161,187
Minority interests		11	6
Earnings per share			
Basic		€ 0.968	€ 0.792
Diluted		€ 0.951	€ 0.771

Earnings per share (EPS) are based on average shares outstanding during each year, 205,270,094 in 2015 and 203,573,320 in 2014, net of average treasury stock which amounted to 3,855,062 shares in 2015 and 5,551,836 shares in 2014.

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 2015

# **ASSETS**

cash and cash equivalents  Total current assets	18	225,525 <b>592,671</b>	4,132 136,990 <b>498,61</b> 7
·	10		136,990
	10		
Short-term financial investments,	4.0		4,132
Fair value of hedging derivatives (cash flow hedge)	17	12,671	4 4 2 2
Other current assets	16	5,280	4,927
Other receivables	15	28,883	32,316
Trade receivables	14	177,219	179,029
Current assets Inventories	13	143,093	141,223
Total non-current assets  Current assets	12	876,215	876,6
Deferred tax assets	12	30,500	33,02
Other non-current assets	11	4,549	4,74
Goodwill Other investments	9	453,285 32,444	463,47 17,07
Intangible assets	8	246,450	266,01
Property, plant and equipment	7	108,987	92,27
Non-current assets			
e (mousanus)	Note	31 December 2015	31 Decembe 201
€ (thousands)	NI-t-	24 Danasahan	24 Danasalaa



CONSOLIDATED BALANCE SHEET AT 31 DECEMBER 2015

## **EQUITY AND LIABILITIES**

€ (thousands)	Note	31 December 2015	31 December 2014
Shareholders' equity			
Share capital		26,141	26,141
Additional paid-in capital		83,719	83,719
Treasury stock		(35,061)	(30,727)
Hedging reserve (cash flow hedge)		(3,290)	(683)
Translation reserve		(66,918)	(56,314)
Other reserves		42,543	29,865
Retained earnings		685,587	627,240
Net income for the year		198,792	161,187
Interim dividend		(61,606)	(53,080)
Group shareholders' equity	19	869,907	787,348
Minority interest		85	74
Shareholders' equity	20	869,992	787,422
Loans – due after one year  Staff leaving indemnities  Deferred tax liabilities	21 22 23	282,615 18,895 22,360	286,202 18,388 21,553
Other non-current liabilities	24	2,517	3,102
Total non-current liabilities		326,387	329,245
Current liabilities			
Trade payables	25	106,597	112,536
Other payables	26	72,351	64,886
Tax liabilities	27	14,592	12,541
Other current liabilities		959	903
Provisions	28	29,400	25,784
Fair value of hedging derivatives (cash flow hedge)	29	4,290	5,075
Loans – due within one year	21	34,469	28,281
Bank overdrafts and short-term loans	30	9,849	8,552
Total current liabilities		272,507	258,558
Total equity and liabilities		1,468,886	1,375,225



STATEMENT OF COMPREHENSIVE INCOME FOR THE YEAR ENDED 31 DECEMBER 2015

€ (thousands)	2015	2014
Net income for the year	198,803	161,193
Gains/(losses) on cash flow hedges	(2,607)	1,587
Gains/(losses) on translation of foreign financial statements	(10,604)	(13,461)
Other gains/(losses)	11,137	3,783
Income and expense for the year recognized directly in equity	(2,074)	(8,091)
Comprehensive income for the year	196,729	153,102
Attributable to:		
Equity holders of the parent	196,718	153,096
Minority interests	11	6

## 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	Mino- rity in- terest	Total
Balance at 31.12.2013	26,141	83,719	(37,791)	(2,270)	(42,853)	25,776	559,878	133,678	(44,526)	68	701,820
Allocation of 2013 net income:											
- Dividends								(66,841)	44,526		(22,315)
- Retained earnings							66,837	(66,837)			
Change in the reserve for share based payments						306	1,803				2,109
Purchase of own shares			(7,127)								(7,127)
Sale of own shares			14,191				(1,051)				13,140
Interim dividend									(53,080)		(53,080)
Other changes							(227)				(227)
Comprehensive income for the year				1,587	' (13,461)	3,783		161,187		6	153,102
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



CONSOLIDATED CASH FLOW STATEMENT FOR THE YEAR ENDED 31 DECEMBER 2015

€ (thousands)	2015	2014
Operating activities		
Cash flow		
Net Income	198,803	161,193
Depreciation of property, plant and equipment	11,948	11,205
Amortization of intangible assets	26,535	31.583
Write-down of assets	0	814
Revaluation of assets	0	(3,752)
Total cash flow	237,286	201,043
(Increase)/decrease in deferred tax assets	3,510	(7,816)
Increase/(decrease) in staff leaving indemnities	507	1,690
Increase/(decrease) in other non-current liabilities	(4,200)	(1,240)
	237,103	193,677
Changes in working capital		-
Trade receivables	1,810	746
Inventories	(1,870)	(793)
Other receivables and other current assets	3,080	(6,901)
Trade payables	(5,939)	5,380
Tax liabilities	2,051	(3,410)
Other payables and other current liabilities	7,521	(5,874)
Provisions	3,616	(3,670)
Changes in working capital	10,269	(14,522)
Net cash from operating activities	247,372	179,155
nvesting activities		
Net (investments)/disposals in property, plant and equipment	(31,239)	(22,231)
Net (investments)/disposals in intangible assets	(2,451)	(2,876)
Net (increase)/decrease in other non-current receivables	194	(487)
Net cash used in investing activities	(33,496)	(25,594)
Financing activities		
Medium/long term loans	52,043	110,571
Re-payment of loans	(66,234)	(82,222)
Purchase of Treasury stock	(17,730)	(7,127)
Sale of Treasury stock	11,751	13,140
Effect of application of IAS/IFRS	2,846	(1,236)
Other changes in equity	(62)	(227)
Dividends paid	(110,770)	(75,395)
Change in translation reserve	1,518	(874)
Net cash from/(used in) financing activities	(126,638)	(43,370)
Changes in short-term financial position	87,238	110,191
Short-term financial position at beginning of year *	128,438	18,247
Short-term financial position at end of period *	215,676	128,438

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



NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2015

#### 1. GENERAL

The consolidated financial statements at 31 December 2015 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 as a result of the following operations: the merger by incorporation of SGAM AI Kantara Co II s.a.r.l. into Recordati S.A. Chemical and Pharmaceutical Company, the incorporation of Recofarma S.r.l. into Innova Pharma S.p.A., the establishment of the new company Recordati Rare Diseases Colombia S.A.S. and the liquidation of Recordati Services Sp z o.o..

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

#### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The financial statements have been prepared in accordance with International 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 2014.

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 2014.

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.
- b. Intercompany payables and receivables and transactions, as well as intra-group profits and losses not yet realized, are eliminated.
- c. Any excess of the cost of acquisition over the value of equity at the date of acquisition is recognized as goodwill.
- d. Minority interests in the equity of consolidated subsidiaries are shown separately under equity, while minority interests in the net income of such companies are shown separately in the consolidated income statement.

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

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

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

### **Balance sheet**

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



paragraph on *Impairment*). Depreciation is computed on a straight-line basis using rates which are 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 2015 and 2014 is € 1,047.7 million and € 987.4 million respectively and can be broken down as follows:

€ (thousands)	2015	2014	Change 2015/2014
Net sales	1,032,447	971,415	61,032
Royalties	5,424	5,981	(557)
Up-front payments	5,748	5,225	523
Other revenue	4,057	4,735	(678)
Total revenue	1,047,676	987,356	60,320

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 2015 are mainly relative to agreements for the licensing of the lercanidipine+enalapril fixed combination ( $\in$  3.2 million), of pitavastatin ( $\in$  1.2 million), of lercanidipine ( $\in$  0.7 million) and of silodosin ( $\in$  0.3 million).



Other revenue includes commissions of € 1.7 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 2015 and 2014 are € 769.2 million and € 756.3 million respectively and are analyzed by function as follows:

Total operating expenses	769,159	756,326	12,833
Other (income) expense, net	5,029	3,886	1,143
General and administrative expenses	58,980	57,173	1,807
Research and development expenses	76,736	85,267	(8,531)
Selling expenses	293,204	282,946	10,258
Cost of sales	335,210	327,054	8,156
€ (thousands)	2015	2014	Change 2015/2014

Labor cost in 2015 is € 241.2 million, an increase of 3.3% compared to 2014, and includes charges of € 2.7 million related to stock option plans determined in accordance with IFRS 2.

Depreciation and amortization charges are € 38.5 million. Depreciation of property, plant and equipment is € 11.9 million, up by € 0.7 million as compared to the preceding year. Amortization of intangibles is € 26.5 million, a decrease of € 5.0 million compared to 2014 which had included the revision of the useful life of some products.

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)	2015	2014	Change 2015/2014
Amounts due to the Italian healthcare system	(755)	(606)	(149)
Organizational restructuring charges	(2,637)	(3,007)	370
Write-downs	(1,074)	(814)	(260)
Others	(563)	541	(1,104)
Total other income (expense), net	(5,029)	(3,886)	(1,143)

The amounts due to the public healthcare system in Italy refer to the pay back to be paid to the Italian medicines agency (AIFA) in substitution for the 5% price reduction on selected products. This mechanism which was already applied during preceding years, was extended to 2015. The amount due is calculated on the sales of the products in 2014 and is spread equally over the period.

Organizational restructuring charges include those incurred by the Turkish subsidiary in view of the transfer of the production activities to the new plant ( $\in$  1.2 million).



#### FINANCIAL INCOME AND EXPENSE

In 2015 and 2014 financial items recorded a net expense of € 13.1 million and € 16.3 million respectively which are comprised as follows:

Interest expense on loans  Net interest income (expense) on s/t financial position	(8,700) (3,536)	(11,919) (4,713)	3,219 1,177
Interest cost in respect of defined benefit plans	(272)	(407)	135
Net income (expense) from other investments	0	3,752	(3,752)
Total financial income (expense), net	(13,080)	(16,255)	3,175

The net exchange losses are significantly reduced compared to 2014 when operations with the Russian subsidiary were affected by the significant devaluation of the rouble during the last quarter of that year.

The decrease in interest expense on loans is to be attributed mainly to the reimbursement of the notes due in December 2014 and to the renegotiation at the beginning of the year of the conditions of some of the existing loans (see Note 21).

The change in the short-term net financial position is mainly due to the increase in the average amount of funds invested and to the decreased use of short-term lines of credit in local currency by the subsidiaries in Russia, Poland and Turkey.

The net income from other investments in 2014 refers entirely to the revaluation of the holding in the U.S. company PureTech Ventures LLC up to the original amount invested.

#### 6. PROVISION FOR INCOME TAXES

The provision for income taxes amounts to € 66.6 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:



Effective tax rate, including IRAP	25.1	25.0
IRAP reimbursement request	-	(0.3)
IRAP	1.0	2.0
Effective tax rate on income	24.1	23.3
Other differences, net	0.4	0.3
Consolidation effect	(4.3)	(5.0)
Dividends from foreign subsidiaries	0.5	0.5
Standard income tax rate on pre-tax income of the parent company	27.5	27.5
	2015 %	2014 %

IRAP is levied only on the Italian companies and is computed applying a 4.10% 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 € 109.0 million and € 92.3 million at 31 December 2015 and 2014 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 31.12.14	58,021	197,023	58,944	27,075	341,063
Additions	320	3,480	1,356	26,165	31,321
Disposals	0	(1,931)	(1,443)	0	(3,374)
Other changes	1,485	9,015	1,159	(14,726)	(3,067)
Balance at 31.12.15	59,826	207,587	60,016	38,514	365,943
Accumulated depreciation					
Balance at 31.12.14	35,068	168,150	45,572	0	248,790
Depreciation for the year	2,213	6,435	3,300	0	11,948
Disposals	0	(1,931)	(1,361)	0	(3,292)
Other changes	51	(453)	(88)	0	(490)
Balance at 31.12.15	37,332	172,201	47,423	0	256,956
Carrying amount at					
31 December 2015	22,494	35,386	12,593	38,514	108,987
31 December 2014	22,953	28,873	13,372	27,075	92,273

Additions during the year of € 31.3 million refer mainly to investments made by the Parent in the Milan production plant and headquarters for an amount of € 7.3 million and by the Turkish subsidiary Recordati llaç for an amount of € 21.0 million for the advancement of activities connected with the construction of a new production plant.

At 31 December 2014 land and/or buildings held under financial leases amount to € 0.3 million and are held by the company in Tunisia Opalia Pharma.



#### 8. INTANGIBLE ASSETS

Intangible assets, net of accumulated amortization, at 31 December 2015 and 2014 amount to € 246.5 million and € 266.0 million respectively. Their composition and variation are shown in the following table:

	403 738
Additions 162 413 197 1,966 2,	
	738
Disposals (3,390) (819) (86) (183) (4,4	
	178)
Other changes 5,392 679 (82) (449) 5,	540
Balance at 31.12.15 318,997 147,558 16,981 7,667 491,	203
Accumulated amortization	
Balance at 31.12.14 110,053 95,446 15,886 0 221,	385
Amortization for the year 15,292 10,909 334 0 26,	535
Disposals (3,285) (819) (87) 0 (4,3	.91)
Other changes 708 369 (53) 0 1,	024
Balance at 31.12.15 122,768 105,905 16,080 0 244,	753
Carrying amount at	
31 December 2015 196,229 41,653 901 7,667 246,	450
31 December 2014 206,780 51,839 1,066 6,333 266,	

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

The overall reduction in net book value of  $\le$  19.6 million compared to that at 31 December 2014 is due mainly to amortization for the period ( $\le$  26.5 million) partly offset by an increase in the equivalent value of intangible assets held in the U.S.A. following the revaluation of the local currency against the euro ( $\le$  7.9 million).

### 9. GOODWILL

Goodwill at 31 December 2015 and 2014 amounted to € 453.3 million and € 463.5 million respectively and changed as follows:



€ (thousands)	Goodwill
Cost	
Balance at 31.12.14	501,138
Exchange rate adjustments	(10,189)
Balance at 31.12.15	490,949
Accumulated amortization	
Balance at 31.12.14	37,664
Changes during the year	0
Balance at 31.12.15	37,664
Carrying amount at	
31 December 2015	453,285
31 December 2014	463,474

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  $\le$  10.2 million as compared to 31 December 2014 resulted. In particular, the goodwill associated with the acquisitions in Turkey and Russia decreased respectively by  $\le$  9.5 million and  $\le$  1.5 million, while the goodwill associated with the acquisitions in Tunisia and in the Czech Republic increased respectively by  $\le$  0.5 million and  $\le$  0.3 million.

Net goodwill at 31 December 2015, amounting to € 453.3 million, relates to the following operational areas, which represent the same number of cash generating units:

France: € 45.8 million;

Russia: € 25.6 million;

Germany: € 48.8 million;

Portugal: € 32.8 million;

Treatments for rare diseases business: € 110.6 million;

Turkey: € 78.3 million;

Czech Republic: € 13.1 million;

Romania: € 0.2 million;

Poland: € 15.4 million;

Spain: € 58.1 million;

Tunisia: € 24.6 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 (2016-2018) were taken from the 2016 Budget approved by the Board of Directors of the Parent and were developed using reasonable hypotheses in line with the Budget itself and the 2015-2017 plan approved by the Board of Directors of the Parent on 12 February 2015.

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	4.88%
Russia	14.15%
Germany	4.24%
Portugal	8.15%
Business dedicated to treatments for rare diseases	4.88%
Turkey	12.02%
Czech Republic	4.77%
Poland	7.41%
Spain	6.51%
Tunisia	12.75%

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 2015 and therefore no loss in the value of goodwill was recognised.

#### **10. OTHER INVESTMENTS**

Investments in equity instruments of non-consolidated companies are as follows:



€ (thousands)	Balance sheet value		Percentage of equity owned	
	31.12.15	31.12.14	31.12.15	31.12.14
PureTech Health p.l.c., United Kingdom	21,218	5,224	4.0%	6.0%
Erytech Pharma S.A., France	11,043	11,672	5.4%	6.3%
Tecnofarmaci S.p.A., Italy	87	87	4.2%	4.2%
Consorzio C4T, Italy	77	77	n.s.	n.s.
Fluidigm Corp., U.S.A.	10	10	n.s.	n.s.
Codexis Inc., U.S.A.	5	5	n.s.	n.s.
Others	4	4	n.s.	n.s.
Total equity investments	32,444	17,079		

During 2015 the shares of the U.S. company PureTech Ventures LLC were exchanged with those of the new U.K. company PureTech Health p.l.c., specialized in investment in start-up companies dedicated to new therapies, medical devices and new research technologies. Starting 19 June 2015 the shares of the new company were admitted to trading on the London Stock Exchange. At 31 December 2015 the overall fair value of the 9.554.140 shares held is of € 21.2 million. The € 16.0 million increase in value compared to that at 31 December 2014 is booked as income 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 € 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 € 0.6 million as compared to that at 31 December 2014 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 2015 are € 4.5 million and refer mainly to guarantee deposits on rental and service contracts.

#### 12. DEFERRED TAX ASSETS

Deferred tax assets at 31 December 2015 and 2014 amount to € 30.5 million and € 33.0 million respectively. The main deferred tax assets and their change are analyzed below.

Balance at 31 December	30,500	33,021
Utilizations	(8,938)	(5,172)
Additions	6,417	12,988
Balance at 1 January	33,021	25,205
€ (thousands)	2015	2014



€ (thousands)	Previous years' losses	Profit and loss temporary differences	Other	Total
Balance at 31.12.2014	3,215	14,750	15,056	33,021
Additions	2,145	3,900	372	6,417
Utilization	(983)	(4,851)	(3,104)	(8,938)
Balance at 31.12.2015	4,377	13,799	12,324	30,500

<sup>&</sup>quot;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 2015 and 2014 amount to € 143.1 million and € 141.2 million respectively, net of their respective obsolescence provisions of € 4.9 million and € 5.6 million. Composition of inventories is as follows:

€ (thousands)	31.12.2015	31.12.2014	Change 2015/2014
Raw materials and supplies	41,242	40,677	565
Intermediates and work-in-process	28,231	28,433	(202)
Finished goods	73,620	72,113	1,507
Total inventories	143,093	141,223	1,870

## 14. TRADE RECEIVABLES

Trade accounts receivable at 31 December 2015 and 2014 amount to € 177.2 million and € 179.0 million respectively. These are shown net of the allowance for doubtful accounts which at 31 December 2015 is € 13.3 million (€ 11.8 million at 31 December 2014) 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 59, an improvement over those at 31 December 2014.

#### 15. OTHER RECEIVABLES

Other receivables amount to € 28.9 million, a decrease of € 3.4 million compared to those at 31 December 2014, and their breakdown is as follows:

Total other receivables	28,883	32,316	(3,433)
Other	4,105	3,512	593
Balances due from employees and agents	2,500	2,544	(44)
Tax receivable	22,278	26,260	(3,982)
€ (thousands)	31.12.2015	31.12.2014	Change 2015/2014

Tax receivable comprises value added tax (VAT) receivable (€ 9.5 million) and advance payments of income tax. Receivables from employees and agents comprise advances on expense accounts and other



credits. Under "Other" are included advances paid to suppliers and other parties and to computed credits under licensing-in agreements.

#### **16. OTHER CURRENT ASSETS**

At 31 December 2015 other current assets amount to € 5.3 million (€ 4.9 million at 31 December 2014) and relate mainly to prepaid expenses.

#### 17. FAIR VALUE OF HEDGING DERIVATIVES

The currency rate 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 2015 give rise to a 12.7 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 8.4 million, and that covering the \$ 25 million tranche of the loan, provided by UniCredit, yielded a 4.3 million positive value change.

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

A break down is shown in the following table.

€ (thousands)	31.12.2015	31.12.2014	Change 2015/2014
Short term time deposits	52,520	56,794	(4,274)
Deposits in bank current accounts	172,965	80,162	92,803
Cash on hand	40	34	6
Total short term financial investments, cash and cash equivalents	225,525	136,990	88,535

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

At 31 December 2015 cash and cash equivalents are denominated in euro (142.5 million), in U.S. dollars (56.6 million, mainly in the U.S. subsidiary Recordati Rare Diseases) and in pounds sterling (17.9 million, mainly in the U.K. subsidiaries).

#### 19. SHAREHOLDERS' EQUITY

Share capital — At 31 December 2015 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 2015 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. 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. The 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 2015 are analyzed in the following table.

	Strike price (€)	Options outstanding at 1.1.2015	Options granted during 2015	Options exercised during 2015	Options cancelled or expired	Options outstanding at 31.12.2015
Date of grant						
27 October 2009	4.8700	35,000	-	(35,000)	-	-
9 February 2011	6.7505	2,192,500	-	(750,000)	(70,000)	1,372,500
8 May 2012	5.3070	3,412,500	-	(1,012,500)	(140,000)	2,260,000
17 April 2013	7.1600	190,000	-	(47,500)	-	142,500
30 October 2013	8.9300	360,000	-	(90,000)	-	270,000
29 July 2014	12.2900	6,075,000	-	-	(340,000)	5,735,000
Total		12,265,000	-	(1,935,000)	(550,000)	9,780,000

Additional paid-in capital — At 31 December 2015 additional paid-in capital is € 83.7 million, unchanged compared to the preceding year.

Treasury stock — At 31 December 2015, 3,685,358 shares are held as treasury stock, a decrease of 1,022,312 shares compared to those held at 31 December 2014. The change is due to the sale of 1,935,000 shares, for an amount of € 11.8 million, to service the exercise of options granted to company employees under the stock option plans, and to the purchase of 912,688 shares for an amount of € 17.7 million. The total cost incurred for the purchase of current treasury stock is € 35.1 million and the average purchase price per share is € 9.51.

Hedging reserve — In accordance with IAS 39, the assets resulting from the measurement at market value of the currency rate 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 2015 this fair value measurement gives rise to a net liability, after-tax, of € 3.3 million.

Other reserves — These amount to € 42.5 million at 31 December 2015, an increase of € 12.7 million compared to those at 31 December 2014. 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 € 5.9 million and € 0.7 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 € 15.3 million (of which € 11.3 million attributable to Puretech Health and € 4.0 million to Erytech Pharma).

Retained earnings and net income for the year — These amount to € 685.6 million at 31 December 2015 and increase by € 58.3 million as compared to 31 December 2014. Net income for the year is € 198.8 million, an increase of 23.3% compared to the € 161.2 million 2014 net income.

The shareholders' equity of the Italian companies includes untaxed reserves of € 101.1 million, net of € 16.6 million withholding tax already paid, and their distribution is subject to taxation under fiscal law. In



accordance with IAS 12 deferred taxes are not recognized on these reserves until their distribution is resolved.

*Interim dividend* — During the year the Board of Directors of Recordati S.p.A. resolved to distribute an interim dividend for 2015 of € 0.30 per share, for a total amount of € 61.6 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% ( $\epsilon$  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 2015 medium and long-term loans total € 317.1 million. The net increase of € 2.6 million compared to 31 December 2014 was determined by the granting of new loans for an amount of € 52.0 million, reimbursements during the year of € 66.2 million and the effect of the conversion of loans in foreign currency which generated an increase of € 16.8 million.

The composition of medium and long-term loans at 31 December 2015 and 2014 is shown in the following table:



€ (thousands)	31.12.2015	31.12.2014
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 currency rate 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 currency rate swap into a € 18.7 million loan at a fixed interest rate of 3.15%.	*68,571	55,614
Loan granted by Centrobanca, at variable interest rate covered by an interest rate swap, repayable in semi-annual installments starting 2012 through 2022	*47,574	54,370
Loan granted by UniCredit, at variable interest rate partly covered by an interest rate swap, repayable in semi-annual installments starting 2015 through 2020	*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	*37,156	49,531
Loan granted by ING Bank, at variable interest rate covered by an interest rate swap, repayable in semi-annual installments starting 2016 through 2020	*29,880	29,850
Loan granted by UniCredit, at variable interest rate covered by an interest rate swap, prematurely extinguished in 2015	-	41,155
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)	*63,744	57,108
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  Loan granted by ING Bank to Recordati Ilaç for an amount of TRY 5.9 million, at a fixed interest rate of 13.25%, repayable in a single installment in 2018	*22,197 1,851	24,890
Various loans granted to Opalia Pharma S.A. due within 2019	1,167	1,516
Various interest-free loans granted to Casen Recordati due within 2021	387	449
Total amortized cost of loans	317,084	314,483
Portion due within one year	34,469	28,281
Change in the fair value of the portion due within one year	-	-
Total loans in current liabilities	34,469	28,281
Portion due after one year	282,615	286,202
Change in the fair value of the portion due after one year	-	-
Total loans in non-current liabilities  * Net of direct issue costs for a total of € 2.3 million amortized using the effective interest met	282,615	286,202

<sup>\*</sup> Net of direct issue costs for a total of € 2.3 million amortized using the effective interest method (private placement by Recordati S.p.A. € 0.3 million, Centrobanca € 0.2 million, Banca Nazionale del Lavoro € 0.3 million, UniCredit € 0.4 million, ING Bank € 0.1 million, private placement by Recordati Rare Diseases € 0.6 million, IFC-World Bank € 0.4 million).

At 31 December 2015, the repayment schedule of long-term debt due after 31 December 2016 is as follows:



2021 and subsequent years  Total	152,026 <b>282,615</b>
2020	18,963
2019	27,901
2018	42,785
2017	40,940
€ (thousands)	

The average effective interest rate at 31 December 2015, applying the rates resulting from the interest rate swaps, is 3.50%.

On 30 November 2015 the subsidiary Recordati Ilaç was granted a loan by ING Bank for an amount of 5.9 million Turkish lira to be repaid on 22 March 2018. Funds were received for an equivalent of € 1.9 million. Main terms are: fixed interest rate of 13.25%, quarterly payment of interest accrued and reimbursement of the entire principal at expiry date.

In May 2015 a loan agreement with UniCredit was undersigned by the Parent company for an amount of € 50.0 million and the residual amount of € 41.7 million from the loan obtained from the same institution on 26 November 2013 was prematurely reimbursed. The main terms and conditions provide for variable interest rate fixed at the six months Euribor plus a spread of 80 basis points (as opposed to the 190 basis points in the previous agreement) and a duration of 5 years with semi-annual repayments of capital from November 2015 through May 2020. 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 2015 of the swap covering € 33.3 million generated a liability of € 0.7 million which is recognized directly as a decrease in equity and stated as an increase of the 'Fair value of hedging derivatives (cash flow hedge)' under current liabilities (see Note 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 main long-term loans outstanding are:

a) 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 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 2015 generated a liability of € 0.8 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.

- b) 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 conversion of the loan into euros at 31 December 2015 resulted in a reduction of the liability by € 2.7 million as compared to that at 31 December 2014 due to the devaluation of the Turkish lira. 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.

c) 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 2015 resulted in an increase of the liability by € 12.9 million as compared to that at 31 December 2014 due to the revaluation of the U.S. dollar. The loan was simultaneously covered with two currency rate swaps transforming the overall debt to € 56.0 million, of which € 37.3 million at a fixed interest rate of 2.895% on the 12 year tranche and € 18.7 million at a fixed interest rate of 3.15% on the 15 year tranche. At 31 December 2015 the measurement at fair value of the hedging instruments generated an overall positive amount of € 12.7 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.

d) 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 € 37.1 million at 31 December 2015. 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 2015 generated a liability of € 0.7 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.

- e) 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 2015 resulted in an increase of the liability by € 6.6 million as compared to that at 31 December 2014 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.

- f) 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 € 47.6 million at 31 December 2015. 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 2015 generated a liability of € 2.1 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 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 2015 and 2014 is € 18.9 million and € 18.4 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:

Change in fair value	(269)	1,266
Utilization	(1,138)	(634)
Additions	1,914	1,058
Balance at 1 January	18,388	16,698
€ (thousands)	2015	2014

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  $\in$  12.8 million. The remaining part of this provision comprises employee benefit plans in the French subsidiary Laboratoires Bouchara Recordati ( $\in$  3.1 million), in the German subsidiary Recordati Pharma ( $\in$  0.4 million) and in Orphan Europe ( $\in$  0.6 million). The fair value calculation made using actuarial parameters updated at 31 December 2015 determined an adjustment of  $\in$  0.3 million compared to the value of the funds at 31 December 2014 which is recognized in the statement of comprehensive income net of the tax effect.

#### 23. DEFERRED TAX LIABILITIES

Deferred tax liabilities at 31 December 2015 are € 22.4 million, a net increase of € 0.8 million over the balance at 31 December 2014. The roll forward of this account is as follows::

Balance at 31 December	22,360	21,553
Utilization	(4,249)	(5,928)
Additions	5,056	6,409
Balance at 1 January	21,553	21,072
€ (thousands)	2015	2014

Additions during the year include the deferred tax liability of € 4.6 million arising from the increase in value of the holding in Puretech Health as compared to the original amount invested.

At 31 December 2015 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 2015 are € 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 2017.

The reduction of € 0.6 million compared to the balance at 31 December 2014 is to be attributed to the classification under 'Other current liabilities' of the deferred payments to be made in 2016 for the Farma-Projekt acquisition.

#### 25. TRADE PAYABLES

Trade accounts payable, which are entirely of a commercial nature and include allocations for invoices to be received, at 31 December 2015 and 2014 amount to € 106.6 million and € 112.5 million respectively.

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

Other accounts payable at 31 December 2015 and 2014 amount to € 72.4 million and € 64.9 million respectively. Their composition is as follows:,

€ (thousands)	31.12.2015	31.12.2014	Change 2015/2014
Personnel	25,982	23,990	1,992
Social security	13,530	13,278	252
Agents	846	738	108
Balance due for the acquisition of equity	586	2,017	(1,431)
Other	31,407	24,863	6,544
Total other payables	72,351	64,886	7,465

The balance due in 2016 for the acquisition of equity is relative to the € 0.6 million due for the acquisition of the Polish company Farma-Projekt.

The line "Other" includes:

- € 8.7 million due by Recordati Rare diseases to the U.S. healthcare insurance schemes;
- € 3.2 million to be paid to the "Krankenkassen" (German healthcare schemes) by Recordati Pharma GmbH;
- € 1.4 million which results from a mandatory discount of 1.83% on the retail selling price of reimbursed medicines to be paid by Recordati S.p.A. and Innova Pharma S.p.A. to the Italian regional healthcare systems:
- € 0.8 million to be paid back to the Italian public healthcare system (see Note 4).

## 27. TAX LIABILITIES

Tax liabilities at 31 December 2015 and 2014 amount to € 14.6 million and € 12.5 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 2015 amount to € 29.4 million and include tax provisions and other provisions for future contingencies which are uncertain as to timing and value. The following tables contain their composition and changes.



€ (thousands)	31.12.2015	31.12.2014	Change 2015/2014
Tax	4,362	4,500	(138)
Other	25,038	21,284	3,754
Total provisions	29,400	25,784	3,616

## Changes in provisions are as follows:

€ (thousands)	2015	2014
Balance at 1 January	25,784	29,454
Additions	10,237	3,586
Utilization	(6,621)	(7,256)
Balance at 31 December	29,400	25,784

The additions during the year are related mainly to accruals for organizational restructuring and claw-backs by national healthcare schemes as a result of expenditure exceeding the budget for pharmaceutical spending.

#### 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 2015 give rise to a € 4.3 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 (€ 2.1 million), Banca Nazionale del Lavoro (€ 0.7 million), ING Bank (€ 0.8 million) and by UniCredit (€ 0.7 million).

#### 30. BANK OVERDRAFTS AND SHORT-TERM LOANS

Bank overdrafts and short-term loans at 31 December 2015 are € 9.8 million and comprise mainly overdrafts and temporary use of lines of credit. During July Recordati Ilaç, the subsidiary in Turkey, obtained a revolving line of credit for a period of 24 months for a maximum amount of 40 million Turkish Lira from which, at 31 December 2015, 20 million Turkish Lira were drawn down. This short-term financing instrument 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. FAIR VALUE OF FINANCIAL INSTRUMENTS

As prescribed by IFRS 7 hereunder are stated the balance sheet values and fair values at 31 December 2015 of financial assets and liabilities:



€ (thousands)	Book value	Fair value
C (thousands)	DOOK VAIGE	Tall Value
Financial assets		
Short-term financial investments, cash and cash equivalents	225,525	225,525
Trade receivables	177,219	177,219
Equity investments	32,444	32,444
Other receivables	28,883	28,883
Fair value of hedging derivatives (cash flow hedge)	12,671	12,671
Financial liabilities		
Borrowings		
- loans at variable interest rates	22,197	22,197
- loans at variable interest rates covered with interest rate swaps	159,167	159,167
- loans at fixed interest rates	67,149	66,402
- loans at fixed interest rates covered with currency rate swaps	68,571	67,770
Trade payables	106,597	106,597
Other payables	86,943	86,943
Fair value of hedging derivatives (cash flow hedge)	4,290	4,290
Bank overdrafts and short-term loans	9,849	9,849

#### 32. 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 2015 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 2015, total trade receivables of € 190.5 million include € 20.8 million of receivables overdue by more than 90 days. Of these, € 1.3 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 € 13.3 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.

Companies in countries belonging to the European Monetary Union with trade and financial balances in currencies different from the euro are exposed to currency exchange risk. As at 31 December 2015 Group positions in these currencies are the following:

net receivables of 1,302.4 million in Russian roubles; net receivables of 11.3 million in Romanian ron; net receivables of 1.0 million in Polish zloty; net receivables of 1.6 million in U.S. dollars; net receivables of 8.2 million in Tunisian dinars; net receivables of 1.2 million in pounds Sterling;

net payables of 601.5 million in Japanese yen.

Among the companies in countries outside the European Monetary Union, at 31 December 2015 the main net exposure in currencies different from their own is in Euros and is referred to the companies in Turkey (net debt of 3.1 million), in Russia (net debt of 2.1 million), in the United States of America (net debt of 0.9 million) and in Romania (net debt of 0.6 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 2015 the net equity values of these companies are denominated mainly in U.S. dollars (74.9 million), in pounds sterling (17.8 million), in Swiss francs (2.5 million), in Turkish lira (128.7 million), in Czech crowns (305.3 million), in Romanian ron (3.6 million), in Russian roubles (1,968.1 million), in Polish zloty (4.3 million) and in Tunisian dinars (21.2 million). The effect of exchange rate variations on the conversion of these values is recognized in the consolidated statement of comprehensive income and booked to the translation reserve in shareholders' equity which, at 31 December 2015, is negative by € 66.9 million.

Liquidity Risk — The liquidity risk to which the Group may be exposed is the inability to raise sufficient financial resources for the its ongoing business and for the development of its industrial and commercial activities. The two main factors which determine the Group's liquidity are, on the one hand, the cash generated or absorbed by operations and by investments, and on the other, the expiry and renewal terms of debt or the degree of liquidity of financial investments and market conditions. At 31 December 2015 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.

#### 33. 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 2015 and includes comparative data.

€ (thousands)	Pharmaceutical segment*	Rare diseases segment	Non-allocated	Consolidated accounts
2015				
Revenues	894,546	153,130	-	1,047,676
Expenses	(678,899)	(90,260)	-	(769,159)
Operating income	215,647	62,870	-	278,517
2014				
Revenues	864,173	123,183	-	987,356
Expenses	(679,636)	(76,690)	-	(756,326)
Operating income	184,537	46,493	-	231,030

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

€ (thousands)	Pharmaceutical segment*	Rare diseases segment	Non-allocated **	Consolidated accounts
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		
31 December 2014				
Non-current assets	669,910	189,619	17,079	876,608
Inventories	126,284	14,939	-	141,223
Trade receivables	155,924	23,105	-	179,029
Other current assets	28,364	8,879	4,132	41,375
Short-term investments, cash and				
cash equivalents	-	-	136,990	136,990
Total assets	980,482	236,542	158,201	1,375,225
Non-current liabilities	39,906	840	288,499	329,245
Current liabilities	184,837	31,813	41,908	258,558
Total liabilities	224,743	32,653	330,407	587,803
Net capital employed	755,739	203,889		
* Includes the pharmacoutical chemicals open	ations ** Non allocat		other equity investm	ants short tarm

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



The pharmaceutical chemicals operations are considered part of the 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:

Europe of which Italy	828,034 211,570	808,299 <i>218,829</i>	2015/2014 19,735 (7,259)
Australasia	53,731	49,687	4,044
America	110,371	80,902	29,469
Africa	55,540	48,468	7,072
Total revenue	1,047,676	987,356	60,320

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.

#### 34. NET FINANCIAL POSITION

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

€ (thousands)	31.12.2015	31.12.2014	Change 2015/2014
Deposits in bank current accounts and cash on hand	173,005	80,196	92,809
Short-term time deposits	52,520	56,794	(4,274)
Liquid assets	225,525	136,990	88,535
Bank overdrafts and short-term loans	(9,849)	(8,552)	(1,297)
Loans - due within one year	(34,469)	(28,281)	(6,188)
Short term borrowings	(44,318)	(36,833)	(7,485)
Net current financial position	181,207	100,157	81,050
Loans - due after one year	(150,301)	(173,480)	23,179
Loan notes issued (1)	(119,643)	(112,722)	(6,921)
Non-current loans	(269,944)	(286,202)	16,258
Net financial position	(88,737)	(186,045)	97,308

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

# 35. 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:



Translation adjustments  Consolidated financial statements	(66,918) <b>869,907</b>	(56,314) <b>787,348</b>	198,792	161,187
Revaluation of holdings in controlled companies	-	-	(6,872)	-
Dividends received from consolidated subsidiaries	-	-	(90,018)	(70,011)
Net income for the year of consolidated subsidiaries, net of amounts already booked by Recordati S.p.A.	167,179	139,907	167,179	139,907
Retained earnings of consolidated subsidiaries at beginning of the year, net of amounts already booked by Recordati S.p.A.	400,781	346,706	-	-
Other adjustments	1,815	1,802	(971)	(773)
Related deferred tax	8,142	9,874	(1,732)	(1,621)
Margin in inventories	(25,662)	(31,282)	5,620	5,039
Consolidation adjustments:	304,370	370,033	123,360	00,040
Recordati S.p.A.	384,570	376,655	125,586	88,646
€ (thousands)	Sharehold 31.12.2015	ers' equity 31.12.2014	Net income for 2015	r the year 2014

#### 36. 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.

In December 2015 the same Italian Tax Police (Guardia di Finanza) notified the Company of the initiation of 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. 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 inspections which are being carried out at Recordati Ireland Ltd and Recordati S.A. Chemical and Pharmaceutical Company, also in consideration of available information at this initial stage of the activity.



## SUBSIDIARIES INCLUDED IN THE CONSOLIDATED ACCOUNTS AT 31 DECEMBER 2015

## 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	y 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.  Provision of services, holds pharmaceutical marketing rights	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	13,900,000.00	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



Consolidated Companies	Head Office	Share Capital	Currency	Consolidation Method
ORPHAN EUROPE S.A.R.L.  Development, production, marketing and sales of pharmaceuticals	France	320,000.00	Euro	Line-by-line
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 ILAÇ 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. <sup>(1)</sup> Marketing of pharmaceuticals	Tunisia	20,000.00	TND	Line-by-line
RECORDATI RARE DISEASES S.A. DE C.V. <sup>(1)</sup> Marketing of pharmaceuticals	Mexico	50,000.00	MXN	Line-by-line
RECORDATI RARE DISEASES COLOMBIA S.A.S. (2)  Marketing of pharmaceuticals	Colombia	150,000,000.00	СОР	Line-by-line
(1) Established in 2014				

<sup>(1)</sup> Established in 2014 (2) Established in 2015



						AGE OF OW				
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.	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						100.0
RECORDATI PHARMA GmbH		55.00			45.00					100.0
RECORDATI PHARMACEUTICALS LTD	3.33	96.67								100.00
RECORDATI HELLAS PHARMACEUTICALS S.A.	0.95	99.05								100.0
JABA RECORDATI S.A.					100.00					100.0
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				100.0
ORPHAN EUROPE UNITED KINGDOM LTD							100.00			100.0
ORPHAN EUROPE GERMANY GmbH							100.00			100.0



	PERCENTAGE 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.	Total
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 İLAÇ Sanayi Ve Ticaret A.Ş.					100.00						100.00
RECORDATI POLSKA Sp. z o.o	100.00										100.00
ACCENT LLC		100.00									100.00
RECORDATI UKRAINE LLC		0.01		99.99							100.00
CASEN RECORDATI PORTUGAL Unipessoal Lda					100.00						100.00
OPALIA PHARMA S.A.		90.00									90.00
OPALIA RECORDATI S.A.R.L. <sup>(1)</sup>				1.00						99.00	100.00
RECORDATI RARE DISEASES S.A. DE C.V. $^{(1)}$		99.998					0.002				100.00
RECORDATI RARE DISEASES COLOMBIA S.A.S. (2)					100.00						100.00

<sup>(1)</sup> Established in 2014 (1) Established in 2015



DISCLOSURE OF AUDITORS' FEES FOR ACCOUNTING AUDITS AND OTHER SERVICES

## ATTACHMENT 2.

Other services	Network of auditor of Parent Company	Subsidiaries	15,172
Other services	Auditor of Parent Company	Parent Company	34,800
Signature on returns and attestations	Network of auditor of Parent Company	Subsidiaries	68,937
Signature on returns and attestations	Auditor of Parent Company	Parent Company	30,100
Tax compliance	Network of auditor of Parent Company	Subsidiaries	106,421
Due diligence	Auditor of Parent Company	Parent Company	20,000
Accounting audit	Network of auditor of Parent Company	Subsidiaries	522,989
Accounting audit	Auditor of Parent Company	Subsidiaries	8,100
Accounting audit	Auditor of Parent Company	Parent Company	104,800
Type of service	Provider of the service	Recipient	Fees Amounts in €



# ATTESTATION IN RESPECT OF THE CONSOLIDATED FINANCIAL STATEMENTS UNDER ARTICLE 154-BIS OF LEGISLATIVE DECREE 58/98

- 1. The undersigned, Giovanni Recordati, in his capacity as the Chief Executive Officer of the Company, and Fritz Squindo, as the Manager responsible for the preparation of the Company's financial statements, pursuant to the provisions 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 2015.

- 2. The undersigned moreover attest that:
- 2.1. the consolidated financial statements at 31 December 2015:
- 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, 8 March 2016

Signed by Giovanni Recordati Chief Executive Officer Signed by
Fritz Squindo
Manager responsible for preparing
the company's financial reports