

#01



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The Chairmen's message

Alberto Chiesi
Chairman

Paolo Chiesi
*Vice Chairman
and R&D
Director*

Eighty years are an important milestone that no organisation takes for granted. In 2015 the Chiesi Group celebrated this anniversary, demonstrating year after year its ability to develop innovative solutions that have enabled it to adapt to ever-changing scenarios. The company has such a long story that its current workforce is made up of people with widely diverse ages and experience. This represents a resource in which enthusiasm, innovative vision and high levels of seniority all feature within the working groups. International development has at the same time enhanced collaboration between professionals from very different cultures yet with shared values, such as the centrality of people, striving for excellence and entrepreneurial spirit. This ensures a plentiful supply of ideas, which are needed to find original solutions for the increasingly complex problems arising in the pharmaceutical market.

Changing scenarios

One of the phenomena likely to alter the pharmaceutical scenario is the increasingly significant role played by market forces in the evaluation of a drug. The conditional approval regulation, introduced by the EU in 2006, tends to accelerate access to innovative products and is particularly beneficial in the case of rare diseases. On the other hand, it requires companies to provide additional clinical evidence after marketing has begun, not only to support the efficacy and tolerance of the new product but also its added value compared to competitors already on the market.

In the last decade information technology has also been applied in the management and monitoring of several chronic diseases, for example asthma and COPD. This is achieved using an online device which is able to transmit parameters such as treatment efficacy and patient compliance to doctors. Aside from their particular use, clinical data gathered in this way tend to amass such a large volume of information that specific analytical technologies and methods are often required to obtain its added value. Although this analysis raises completely new issues of an IT and ethical nature, these data sources represent a new resource whose use is destined to characterise the future evolution of the world of healthcare.



2015 results

Three numbers effectively summarise the trend of the Group's activities during 2015: its turnover, which reached €1.467 billion; its source, over 80% of which originates outside the domestic market, and the work-

force, which exceeds 4,500 people. This data indicates that the company is growing (+9.4% on 2014), is increasingly international and has a strong focus on enhancing the value of human resources, which it considers the driving force behind its development.

Markets

Europe, where the Group is well-established, achieved positive results: Italy, aside from the loss of Provisacor, has grown in a stagnant market; the UK has benefitted both from high levels of sales and the favourable sterling exchange rate. The Netherlands, Austria and the CEE countries, and Greece have gone into double figures. Newly-created Chiesi Nordics has also had an extremely encouraging start, whilst sales have increased in a satisfactory way in France and Germany, as well as in Spain, although to a lesser degree due to the general economic situation.

The Russian and Brazilian markets have been strongly influenced by fluctuating exchange rates, and Turkey has also partly been affected. On the Chinese market, demand slowed significantly in the second half of the year because of the domestic situation.

The US market has achieved significant growth partly thanks to the favourable exchange rate and Mexico also ended the year positively. Moreover, exports showed a favourable trend, particularly in the Middle and Far East.

Major investments

2015 was a year in which significant investment was made in registration trials for the triple association and, to a lesser extent in those for velmanase alfa. In addition, three new projects in the respiratory field have made good progress in the pre-clinical phase and the first clinical trials are expected to begin in 2016.

It was likewise an important year for Industrial Operations, with a number of key events including the inauguration of the new Curosurf production plant at the San Leonardo site and the completion of the Dry Powder Inhaler plant, now fully operative, in Blois, France.

Product trends

Foster, the Group's main product, achieved a turnover of €492 million, confirming its continued popularity with doctors and patients. Curosurf has further increased its market leadership for the treatment of respiratory distress syndrome in pre-term neonates, whereas Clenil, the company's very first respiratory drug, has maintained its position in all of its markets.

Among the new products, Envarsus, which is indicated for the prevention of liver and kidney transplant rejection and is already on the market in several European countries, has recently ob-



tained price determination in Italy. Last January, treatment with Holoclar, approved by the EMA for corneal reconstruction following serious burns, was used on its first patient. In 2015 Glybera, indicated for the treatment of pancreatic lipoprotein lipase deficiency (LPLD), was also successfully used to treat the first patient in Germany.

Main activities in 2015

The forecasts made in the 2011 – 2018 strategic plan have mostly been reached, thus confirming the reliability of the development method adopted. The new plan, which will take the company to 2025, is designed to gradually update the Group as a whole.

Particular focus was made on staff exchanges organised between the Italian head office and the affiliates: this has ensured that Chiesi's key values are spread throughout the entire Group and promoted international training for new managers.

The implementation of the SAP system has continued with roll-outs in Austria, including the CEE countries and Brazil. The significant changes made to the management of the processes, supported by adequate training and communications programmes, are proving to be an effective tool for the application of common working standard at all of the affiliates.

Prospects for 2016

Key events within research and development activities will be EMA submission for the triple association and velmanase alfa.

Aside from the internal research and development of its drugs, the Group is also interested in opportunities for the potential acquisition of organic products indicated for the respiratory field.

For the special care area, and neonatology in particular, Chiesi aims to become a reference supplier for hospitals, offering a range of combined products and services.

Glybera, the first gene therapy drug registered by the EMA, will be made available to some European patients currently eligible for its use. Launches for Holoclar and Foster 200 µg, indicated for cases of severe asthma, are also imminent.

In order to meet the numerous challenging objectives for 2016, the company will once again rely on both its management and all the people within Chiesi, in the awareness that their commitment and skills form the basis for its innovative results and growth achieved in the past eight decades.



The CEO's comment

2015 was characterised by outstanding sales: turnover reached €1.467 million (+9.4%), almost into double digit growth. The Group also achieved a positive result from a financial perspective, in particular taking into account further investment in Research and Development, with the EBITDA standing at €407 million (+ 9.4% on 2014).

Investment in Research and Development went up by nearly 30%, exceeding 20% of total sales. This additional investment in innovation was made possible thanks to an overall increase in efficiency, based on constant monitoring of selling, general and administrative expenses (SG&A) and a significant improvement in the cost of goods sold (COGS).

Ugo Di Francesco
CEO or Chief
Executive Officer

The Group's products

Foster generated sales of €492 million, with an increase of 19.7% on the previous year. Sales of Curosurf were in excess of €200 million, up by 14.4% on 2014, confirming world leadership among surfactants. Clenil has also grown, increasing sales by value by 2.9% and generating turnover in excess of €176 million.

In line with the Group's strategic objectives, products dedicated to special care, including Cardene in the USA, have increased their share of the Group's turnover to an impressive 26.8% on total sales.

Seen from a geographical perspective, the turnover generated outside the domestic market is in excess of 80%, further highlighting the international dimension of the Group. In spite of unfavourable conditions and several price cuts for key products, the European markets were on average up by 5.2% in terms of turnover, equivalent to 3.2% in local currency.

Currency fluctuation clearly had a significant impact on results in some of the most important emerging markets: for example in Russia, the devaluation of the Rouble partially eroded turnover growth, which was up by 13.5% in local currency. The situation was similar in Brazil, Turkey and, for different reasons, China, Pakistan and Mexico. Nevertheless, the emerging markets overall were up by 11.7% in local currency on 2014.

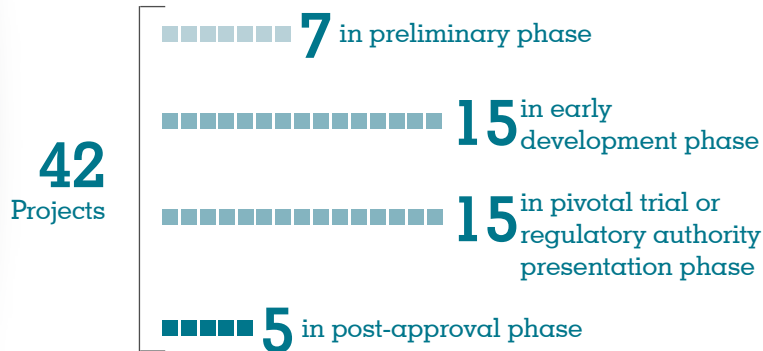
Research and Development

R&D activities follow the Group's strategy and therefore focus on respiratory diseases, neonatology and special care.

In addition to the Foster lifecycle management programme, 2015 was characterised by considerable investment in the development of the triple association, both for the pMDI and DPI formulations. The respiratory pipeline was also further consolidated following new clinical trials for three novel anti-inflammatories and bronchodilators, which have joined the more mature inhalable phosphodiesterase inhibitor.



Pipeline 2015



In neonatology, the development of new and more efficient Curosurf administration techniques continues, alongside that of the synthetic surfactant, for which two new clinical trials began in 2015. The neonatology pipeline is also developing new programmes concerning bronchopulmonary dysplasia and neonatal brain damage.

Key research and development projects in special care concern Holoclar, a cutting-edge product for corneal regeneration in patients affected by severe burns to the eye, a

gene therapy project for haemophilia B and velmanase alfa for the treatment of alpha mannosidosis, a rare disease involving lysosomal accumulation.

Industrial operations

The inauguration of the new Curosurf plant in Parma, located within the San Leonardo area, has created the industrial base from which to continue the development of its world-leading product for the treatment of respiratory distress syndrome in preterm neonates, making effective technological improvements to the production cycle. The Blois plant for the production of Foster DPI is now fully operative, and can therefore guarantee the volumes demanded by the market and consolidate the Group's strategy for the development of production centres of excellence.

The value of teamwork

At organisational level, 2015 brought with it a number of innovations: the creation of the Region Europe, which merges South and North Europe, the complete integration of the IT function across the Group, the setting up of the Global Manufacturing Division, responsible for the global coordination of production activities at the Group's plants and the integration of the procurement activities in Italy. A Centre of Excellence has also been created by the Group Finance, aimed at achieving the uniform development and management of areas relating to Accounting & Reporting. This Centre will be constituted by people from various countries who, whilst continuing to fulfil their responsibilities at their affiliates, will also work together to successfully harmonise the management of these areas for the company as a whole.

People development

Over the past few years, international development has substantially altered the face of the Group, acknowledging it as a successful global entity among medium-sized pharmaceutical businesses. This is based on a firm belief in the values which have characterised the company since it was created and continue to represent an essential point of reference for its future development. The concept of the centrality of people is one of its

cornerstones and this is why the Group continues to focus its attention on the development of human resources. The People Development and talent database projects are designed to further the growth of Chiesi professionals who are increasingly taking part in international programmes to gain new experiences and opportunities for improvement.

Priorities for 2016

Commitment to R&D for the development of new products will continue and grow in light of the submission for the Triple association, which is scheduled sometime between October and November. In addition, investment will continue to be made in rare diseases, in particular with the submission of velmanase alfa, which is expected between July and September 2016.

The process of innovation will also involve Business Development, with the aim of finding new opportunities in particular in special care products and maintaining a key focus on the continued international expansion of the Group.

Information technology offers new business development opportunities and the Group has already begun to see its benefits, both for their use within the scope of clinical trials and their potential application in gathering and transmitting data concerning the drug and its use by the patient to the doctor.

On the commercial side, 2016 will continue to be a turbulent year particularly in the emerging countries. Within this panorama, the Group will be required to manage the evolving Turkish market, monitor the complex currency issue in Russia, consolidate its presence in neonatology and the development in the respiratory area in China, support and develop business in Brazil, in order to consolidate its longstanding presence in the largest Latin American market. With regard to the USA, opportunities for growth by means of local business and/or product acquisition will be evaluated.

The main objective is to ensure a sufficient increase in turnover, which will in turn support the growing investment in research and development, required to guarantee the continued innovation at the basis of future growth.

This task will once again be entrusted to the company's people, who through motivation and ideas will contribute to creating a shared future, giving the entire Group a new lease of life and continuing to pursue the ultimate aim of a company whose focus is innovation: the research and development of new drugs which provide patients with therapeutic options able to treat the diseases they are affected by.



Key events in 2015



- Chiesi Farmaceutici S.p.A. celebrates 80 years



- The Chiesi Foundation celebrates 10 years



- Foster approaches a turnover of 500 million Euro



- Chiesi Nordics is born. It aggregates Denmark, Finland, Norway, and Sweden

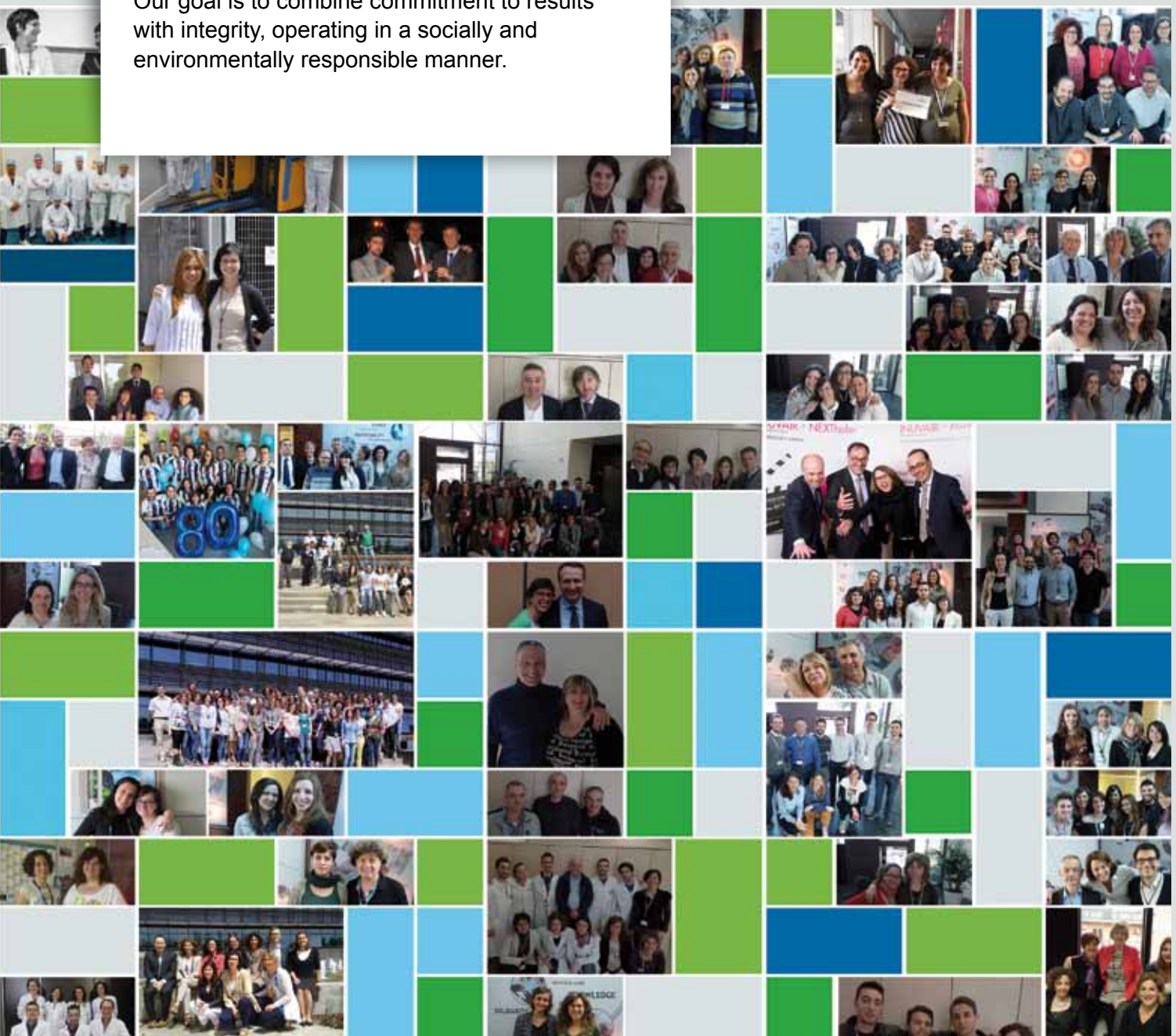


- New organisational model of the Regions, now divided into Europe, Emerging Countries & IMDD, and USA



Mission

Our aim is to be recognised as a research-focused international Group, able to develop and commercialise innovative pharmaceutical solutions to improve the quality of human life. We want to maintain a high quality entrepreneurial team characterised by self-confidence and a collaborative spirit. Our goal is to combine commitment to results with integrity, operating in a socially and environmentally responsible manner.

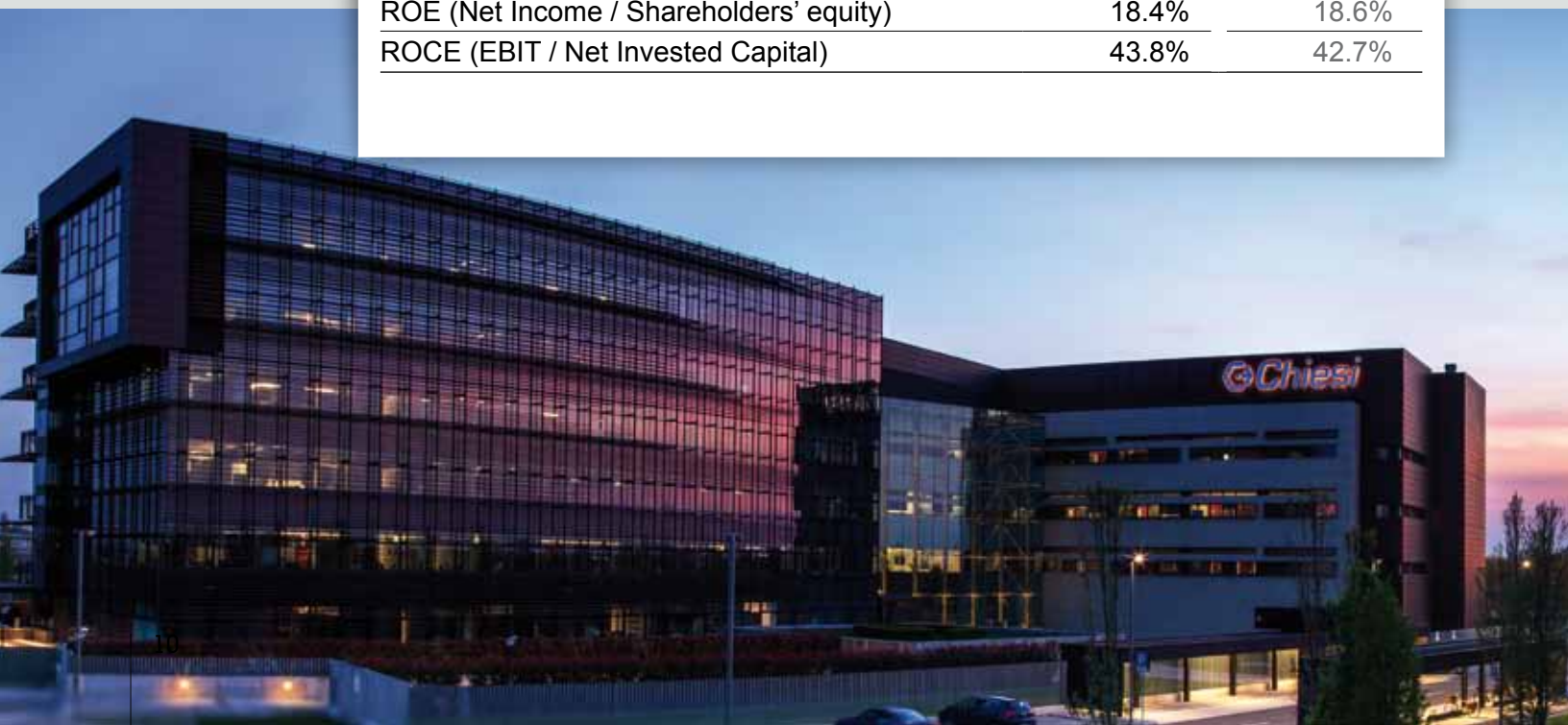


Key financial results

2015 Group Financial Highlights

(Value in Euro/000)

Operating Results	2015	2014
Sales & Revenues	1,467,172	1,341,651
<i>Growth</i>	9.4%	8.4%
EBITDA	407,379	372,385
<i>% on sales and revenues</i>	27.8%	27.8%
Net income	227,668	192,748
<i>% on sales and revenues</i>	15.5%	14.4%
Other Information	2015	2014
R&D costs	301,919	235,540
<i>% on sales and revenues</i>	20.6%	17.6%
Capital Expenditure	68,744	176,350
- Mergers and Acquisitions	1,763	89,428
- Tangible and Intangible assets	67,981	86,922
<i>of which R&D investments</i>	11,517	10,328
Permanent staff	4,252	4,077
Temporary staff	287	325
Ratios	2015	2014
ROE (Net Income / Shareholders' equity)	18.4%	18.6%
ROCE (EBIT / Net Invested Capital)	43.8%	42.7%

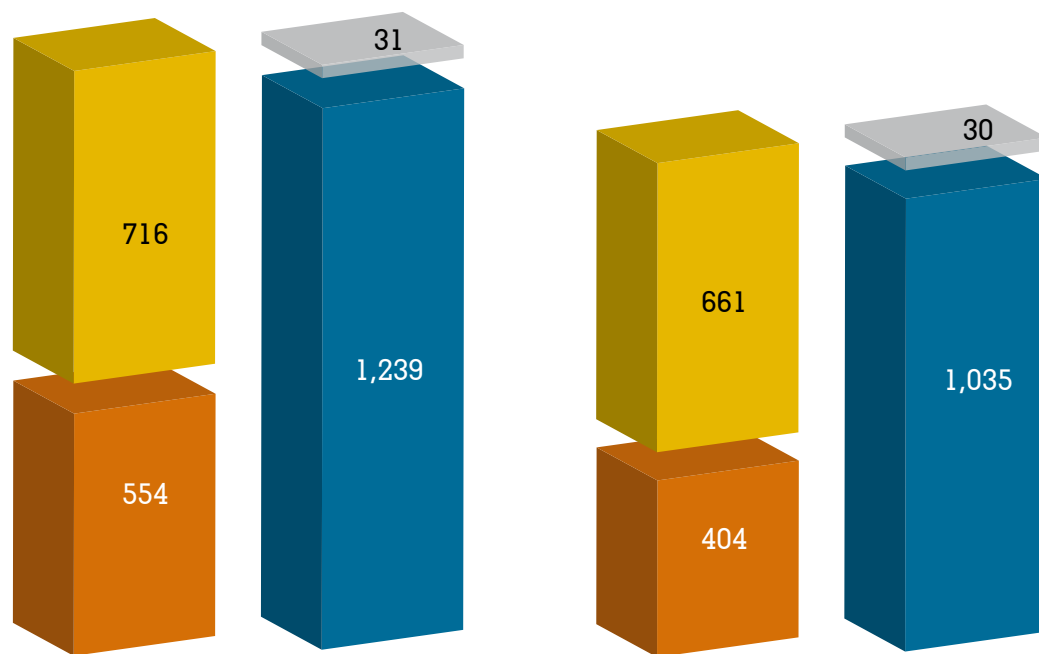


Group Financial Highlights

(Value in M/Eur)

31st December 2015

31st December 2014



■ Net Invested Capital
■ Net Financial Position

■ Reserve Termination & Severance Indemnity
■ Shareholders' Equity (*)

(*) net of owned shares

Board of Directors

Alberto Chiesi
 Paolo Chiesi
 Alessandro Chiesi
 Andrea Chiesi
 Maria Paola Chiesi
 Giacomo Chiesi
 Ugo Di Francesco
 Carlo Salvatori

Board of auditors

Giuseppe Piroli
 Paolo Alinovi
 Vincenzo Simonazzi

Executive Committee

Chairman
 Alberto Chiesi

*Vice-Chairman and
 R&D Director*
 Paolo Chiesi

Chief Executive Officer
 Ugo Di Francesco

*R&D Planning and Control
 Director*
 Andrea Chiesi

Strategic Planning Director
 Maria Paola Chiesi

*Group Human Resources &
 Organisation Director*
 Ugo Bettini

*Corporate Drug Development
 Director*
 Mark Parry-Billings

*Global Business Development
 & Licensing Director*
 Anton Giorgio Failla

Strategic Planning Director
 Thomas Gauch

*Global Manufacturing Division
 Director*
 Giovanni La Grasta

Corporate Finance Director
 Danilo Piroli

*Legal & Corporate Affairs
 Director*
 Marco Vecchia

Corporate Marketing Director
 Andrea Bizzi

Head of Region Europe
 Alessandro Chiesi

*Head of Region Emerging
 Countries & IMDD*
 Cosimo Pulli

Head of Region USA
 Ken McBean

*Business Development
 Executive Region US*
 Giacomo Chiesi

