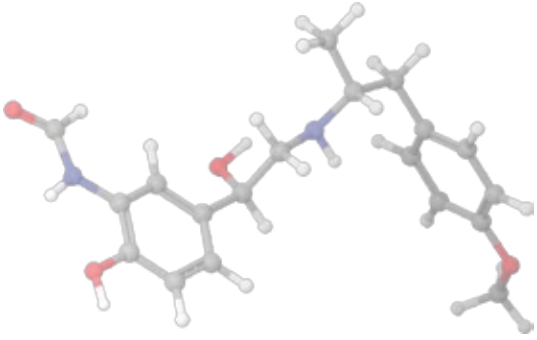
Message from the Chairmen

The financial crisis, which firstly hit the USA in the second half of last year and followed soon after in the European Union and much of the rest of the world, has had a negative impact on the economies of almost all the countries involved. The health sector was also affected, albeit to a lesser extent than that experienced by other sectors.
Restrictions introduced on credit have caused problems for the distribution of drugs in some of the countries in Eastern Europe along with those in some of the emerging markets; on more general note, the growing demand for liquidity from Governments is increasingly responsible for reductions in the resources available for the public health sector, and in particular also for subsidised drugs, in a number of European countries.
These evolutional trends, which were already being felt in the pharmaceutical sector, have begun to accelerate noticeably. The lack of financial backing has made life difficult for many biotech companies; the patent expiries of several products achieving high levels of sales worldwide, together with restrictive policies introduced by institutions on drug prices, have resulted in large multinational groups once again turning to mergers as a solution, whilst acquisitions of generic companies by important research enterprises have also begun.
Despite the current situation, the Chiesi Group has continued to grow internationally at a considerably faster rate than that of the markets in which it operates. This is mainly due to the fact that its drugs for the treatment of respiratory and cardiovascular diseases, the neonatology area and the treatment of several specialist conditions are becoming increasingly well-established in the market.



The number of our direct affiliates has increased (China has been added) as has our market share in the countries in which they operate; the Group's sales in the foreign market have gone up by 18.9%.
Our new drug for the treatment of asthma (Foster, Innovair) was launched in 17 markets in the enlarged EU and the Mediterranean; the positive feedback coming from both doctors and patients is further enhancing the growth in sales, insofar as Foster is to become our top drug in our price list during 2009.
The range of products developed by our internal research centres is constantly being added to in our affiliates' price lists, which is consequently improving the Group's image and the opinion of doctors and patients regarding the activities carried out by the Chiesi Group; since the beginning of this year, all our foreign affiliates are to exclusively bear the Chiesi trademark (excepting some of the countries that have recently joined), as a demonstration of our main objectives as a Group and a range of treatments that is increasingly focussed on "corporate" products.
Our Research and Development activities are simultaneously progressing with the completion of new indications and formulations for Foster, the clinical phase for new generation drugs for the treatment of asthma and COPD, and the control phase on the pharmacological efficacy of new projects taking an innovative approach to respiratory diseases. The key importance of the division for the future of the Company has thus been confirmed.
Construction work to build the new Research Centre in Parma has begun, a project which is to bring together all of the Company's state-of-the-art activities carried out in Italy in a single site equipped with the latest facilities within the next two years.
Technological investments aimed at expanding and modernising production lines in our industrial sites in Italy, France and Brazil have also continued.

2008 Results

Consolidated sales have reached 748.8 million, and are up by 14.1% on the previous year, a growth rate far higher than that seen in the European market. 2008 revenues were due to an overall growth in our products, in particular owing to the continued success of Foster/ Innovair launched in twelve new markets, in addition to the five targeted in 2006 and 2007.
A contribution was also made by the expansion of the Group, with new affiliates operating in Russia, the Netherlands, Turkey and China.
A strongly negative impact continues to be felt because of the drop in sales prices of the drugs in some countries and the currency devaluation in the USA, the UK, the eastern European countries and in some of the emerging markets at the end of last year.
Outstanding results have been achieved in Italy, France, The United Kingdom, Germany, Spain, Greece, Austria, some Central European countries and several export markets. Our new affiliates in Turkey and the Netherlands are consolidating their commercial activities; the new affiliate has also begun operating in China. International sales have reached 461.2 million Euro, with a growth rate of 18.9%, and now represent 61.6% of the Group's total sales.
The turnover generated by "corporate" products, created by our Research and Development Division, has grown by 31.8%, thanks to the remarkable success of the new combination for the treatment of asthma (Foster/Innovair), the

continuing development of manidipine (Iperten) used to treat hypertension and growing sales of Curosurf and other drugs indicated for the treatment of respiratory and rare diseases.
Curosurf has gained a market share of 59.3% at global level and in doing so has once again been reconfirmed as the most common surfactant used in the neonatology field. Spending in Research and Development has increased by 17.1% to a total of 108.5 million Euro, equivalent to a 14.5% share of the sales.
The initiatives set up to improve organisational and technological efficiency in Research activities have clearly been successful, as can be seen from the positive effect they have had on the Group's results.
A new aerosol technology research centre has been opened in Chippenham in the UK. Our gross profit margin (EBITDA) is in excess of 118 million Euro, totalling 15.8% of revenues, with an increase of 14.6% on the previous year; our operating profit margin (EBIT), amounting to 88.7 million, showed an increase of 25%. Our net profit totalled 54.8 million, up by 31.1% on 2007.
Overall, investments totalled 39.1 million Euro (over 60% more than that made in the previous year), and were made both in the production and research areas. Production lines for dosed aerosol were improved in Italy and Brazil as were our warehousing facilities in France; our German affiliate has bought back the licensing rights for the marketing of Curosurf in Germany.
The total workforce at the end of the year numbered 3,243 units (up by 287 on the previous year); areas of growth mainly concerned boosting our sales forces in the new affiliates and our largest production and research activities in Italy.

2009 Objectives

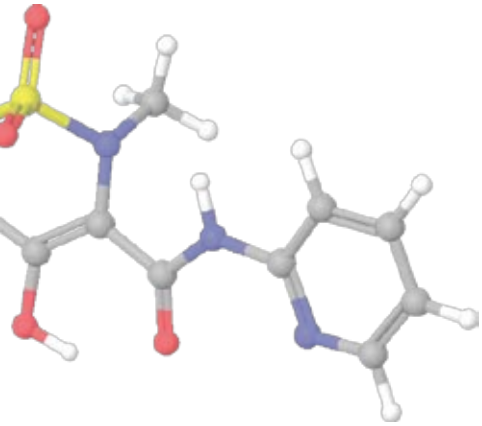
Significant growth is also being targeted for 2009, and this will be driven by the development of Foster/Innovair sales in those countries where recent launches have been made, together with the markets where launches have been planned for this year. Our other "corporate" products, such as Bramitob, Curosurf, Clenil and Iperten are also expected to generate additional revenues.
The impact which the economic crisis has had in our sector is difficult to assess at the present time: we are, however, expecting some further restrictive measures to be introduced regarding prices and refunds, in particular in those countries with weaker economies. The devaluation, which is currently affecting some currencies with regard to the Euro, is also expected to result in some losses due to exchange rates.
Several in-licensing operations concerning specialist products are being studied, and the possibility of buying back the marketing licence for Curosurf in the USA is also being pursued, with the opening of a direct affiliate in that particular market. Our commitment to Research will demonstrate a further push in this direction, with the aim of expanding the pipeline of our projects which are already in place at various stages in the development of new drugs. Collaboration with other companies and academic research centres is to continue, in order to create backup projects that will be used in the event they are needed.
We are grateful to all the Group's managers and collaborators who are dedicating their commitment, proactiveness and great professionalism in order to succeed in reaching the targets we have set ourselves.
We are counting on their full involvement in the future, with the aim of maintaining a satisfactory level of growth.

Alberto Chiesi

President and Chief Executive Officer

Paolo Chiesi

Vice President and R&D Director



Financial highlights

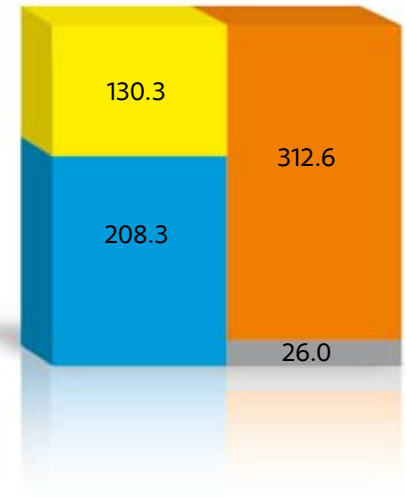
(Value in Eur/000)

Operating results	2008	2007
SALES & REVENUES	748,818	656,013
Growth	14.1%	10.6%
EBITDA	118,413	103,313
% on sales and revenues	15.8%	15.7%
EBIT	88,721	70,986
% on sales and revenues	11.8%	10.8%
NET INCOME	54,782	41,788
% on sales and revenues	7.3%	6.4%

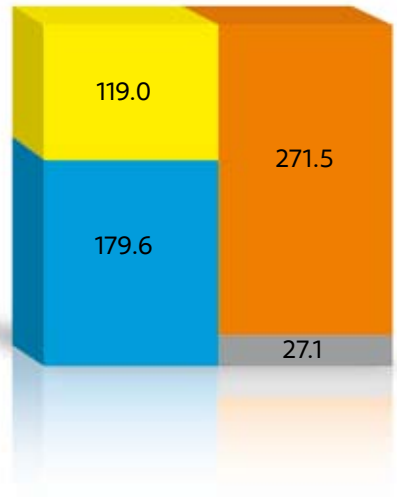
Other informations	2008	2007
R&D	108,455	92,589
% on sales and revenues	14.5%	14.1%
Capital Expenditures	39,093	24,037
of which R&D Investments	9,842	4,637
Number of employees	3,243	2,956

Capital employed

31 December 2008



31 December 2007

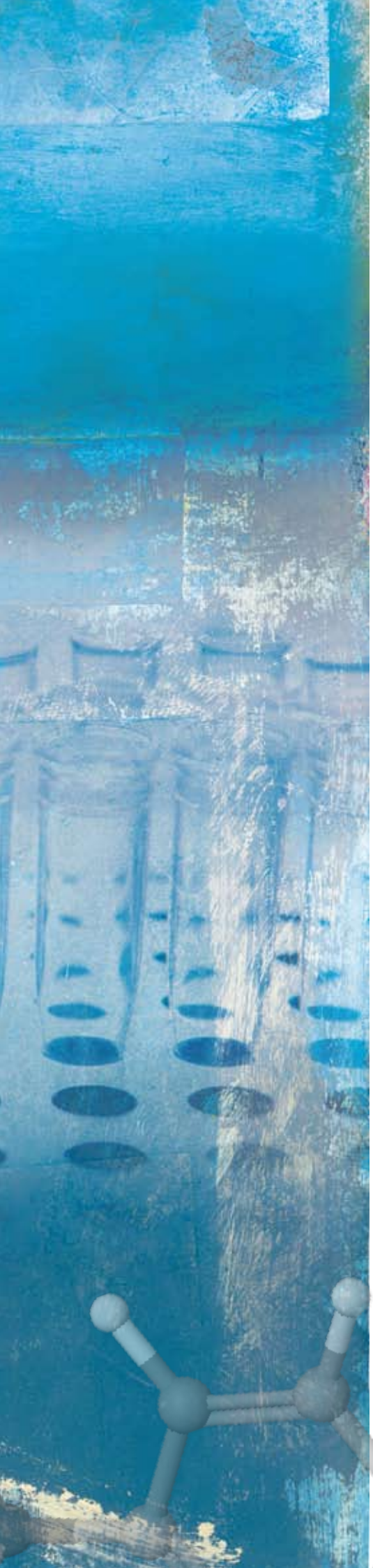


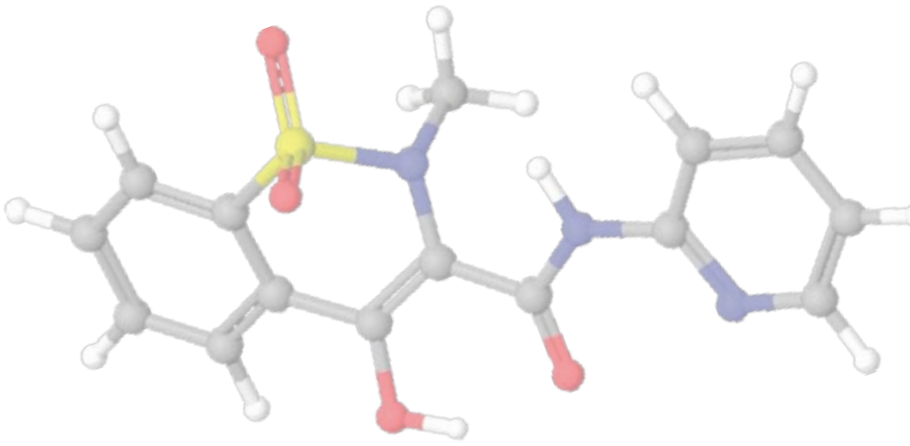
- Net Invested Capital
- Net financial position
- Reserve termination & severance indemnity
- Shareholders' equity (*)

(*) *net of owned shares*

Rations	31 December 2008	31 December 2007
ROE (Net Income / Shareholders' equity)	17,5%	15,4%
ROCE (EBIT / Capital employed)	42,6%	39,5%

Chiesi
2008





8 Research and Development

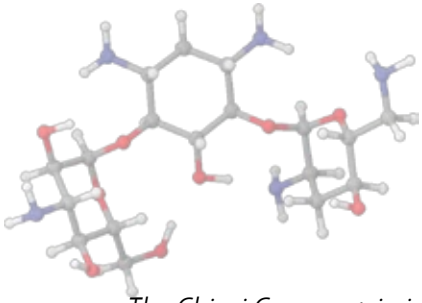
12 Industrial Operations

14 Therapeutic Areas

15 Main Products

18 Human Resources

20 Information and Communication Technology



Research & Development

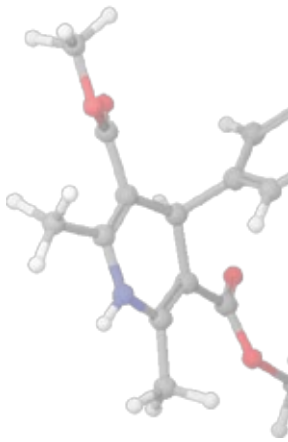
The Chiesi Group again invested more than 14% of its turnover in research in 2008, increasing its investment by 17.1% from 92.6 million (2007) to 108.5 million Euro (2008), which is in line with what was achieved in the previous year.
In 2008 Foster, corticosteroid - beta agonist for inhalation, continued to represent a significant commitment for R&D in the form of a carefully planned development for new indications and formulations. The pipeline of new products remained focussed on respiratory diseases, neonatology and cystic fibrosis. A fourth laboratory located in Chippenham (UK) has been added to the three existing research centres in Parma, Paris and Rockville (USA). The new lab, which was set up in record time, is designed to bring innovative solutions to the field of pressurised aerosols using studies centred on the phenomenon of atomisation. The considerable increase in clinical trials, the fourteen patents obtained and the nineteen new patent applications submitted in 2008 represent a record for the Group and are evidence of the unstinting efforts of our research centres. R&D has also begun implementing the OPERA project, which is aimed at making its development procedures simpler, better integrated and supported by technology and characterised by an improved cost-efficacy relationship.

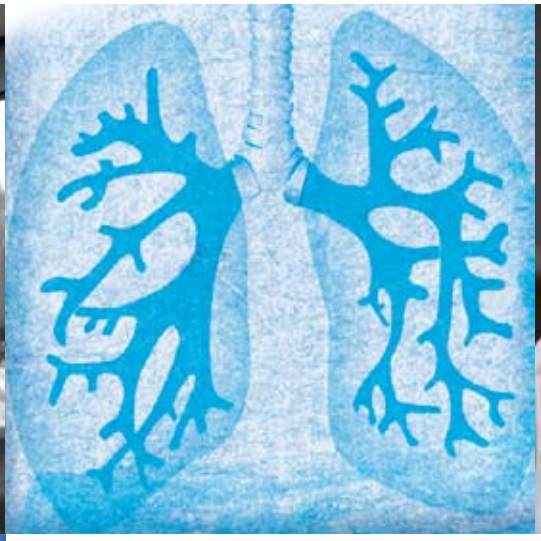
Pre-clinical research

Our alliances with the academic world and external partners, coordinated by pre-clinical research and development scientists, have facilitated the completion of the pre-clinical optimisation for the compounds of four new classes:

- phosphodiesterase 4 inhibitors
- three new classes of long-acting muscarinic antagonists
- a new synthetic surfactant
- a γ-secretase inhibitor.

Phosphodiesterase 4 (PDE4) is a molecular target for the treatment of inflammation. A considerable amount of data indicates that the inhibition of this enzyme induces a powerful anti-inflammatory effect and as such it is also considered an extremely interesting target for the treatment of chronic inflammation of the airways. A PDE4 inhibitor could offer an effective alternative to the use of corticosteroids in the treatment of COPD. Chiesi researchers have patented four chemical classes of PDE4 inhibitors, following the careful investigation of numerous chemical entities, and are planning to start pre-clinical development for the first candidate at the beginning of 2009.
Muscarinic antagonists act on bronchial smooth muscle, thereby inhibiting bronchoconstriction and are indicated to maintain bronchodilation in patients with COPD. Three classes of these compounds are currently undergoing research studies, two of which take an entirely new approach.
Following the success of the natural surfactant Curosurf, the Group's researchers are working on the identification of a **new and completely synthetic surfactant**. Although the first compound was abandoned, as it did not possess the necessary characteristics required for the formulation, our researchers have now identified a new, more promising version which completed the optimisation procedure in 2008.
Finally, CHF 5074, a **γ-secretase** inhibitor which has demonstrated potential action on the development of β-amyloid plaques in animal models, has completed the pre-clinical optimisation phase along with initial toxicological trials.





Clinical research

The combined use of inhalant drugs has already become standard practice in the treatment of patients affected by asthma and COPD. Foster (LABA + ICS) has introduced an innovative formulation for the treatment of asthma in adults. The Foster clinical group has further developed the product's profile, which has resulted in significant clinical activities and has also completed:

- a study on the use of *spacers* in adolescent patients
- a study of a one-year treatment plan for COPD patients.

Significant progress has been made in the enrolment of patients for a trial to evaluate the use of Foster for the treatment of severe asthma. The following clinical projects have also begun:

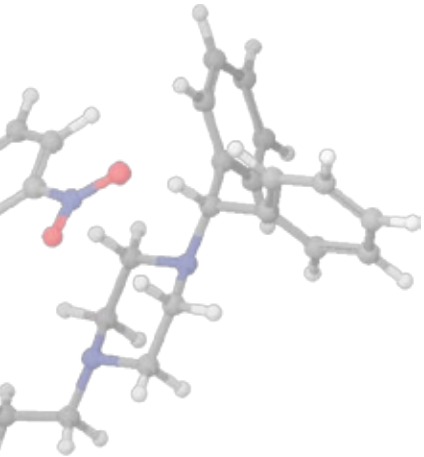
- a programme of trials for the treatment of asthma according to a protocol based on variable dosing;
- a registration programme for a new powder formulation of Foster which is to be administered using an innovative inhaler designed and created by Chiesi partnered by Bespack and CCL (NEXT-DPI). The inhaler is easy to use, activated when the patient breathes in and also features a dose counter.

The clinical development phase is also still underway for carmoterol (long-acting β2-agonist) both alone for the treatment of COPD and in combination with a steroid for the treatment of asthma.

After the initial progress made with CHF 5407, the development of M3 Long-Acting Muscarinic Antagonists (LAMA) is now being focussed on a project to develop two new drug candidates in the same class within the short term.

An important step forward has been made in the regulatory procedures concerning the development of Nymusa (caffeine citrate), which is indicated for the treatment of primary apnoea in premature neonates. The EMEA registration procedure was commenced using e-CTD, representing the first time a centralised electronic procedure was used by the Chiesi Group. Nymusa has been recently approved by EMEA.

Throughout 2008 several important clinical trials were completed for the natural surfactant Curosurf (poractant alfa) – word leader in the treatment of respiratory distress syndrome in premature neonates.



- Balcapulco: a pilot trial designed to investigate the efficacy of broncho-alveolar lavage combined with the administration of Curosurf in adults affected by thoracic trauma and a high risk of RDS.
- CURPAP (Prophylactic Use of Curosurf with Early Continuous Positive Airway Pressure). The trial is considered a milestone by neonatologists insofar as it has demonstrated the equal value of two respiratory stabilisation strategies for extremely premature neonates, both of which are based on the administration of Curosurf in the first five days following birth.
- NIPPV vs SIMV. The trials compared two assisted ventilation strategies in premature neonates treated with Curosurf within 60 minutes of birth. The trial has demonstrated that extubation in patients treated with Curosurf and the transfer to a non-invasive ventilation system (NIPPV) has minimised the need for mechanical ventilation by means of endotracheal tube and reduced clinical and physiological pulmonary bronchopathy in high-risk neonates.

The registration process for Bramitob (nebulized tobramycin), used to treat patients affected by cystic fibrosis with an infection caused by *Pseudomonas aeruginosa*, has been successfully completed in most European countries. The registration programme for the USA is however still underway.

Scientific Partnerships

2006: Consortium with Italian Universities for the PNR research programme for COPD

2007: Presentation to the General Management of Inserm (France)

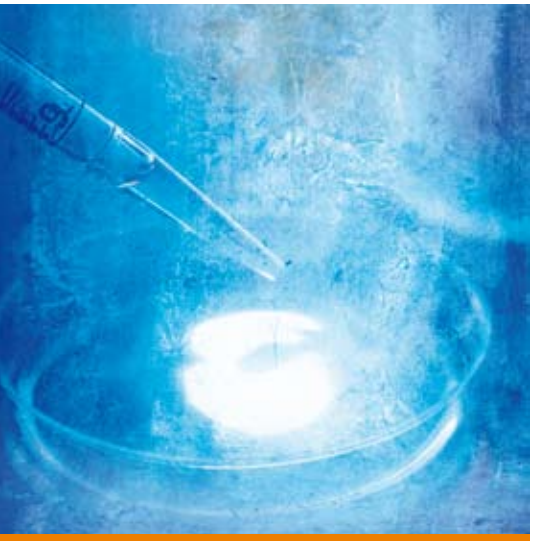
2008: Synthetic Surfactant for aerosolisation funded by FUI / Direction Générale des Entreprises (France)

2008: Start-up of a "Spin-off" project with the University Modena and Reggio Emilia (Holostem Advanced Therapies)

2008: Leading role in the IMI - Innovative Medicine Initiative calls (EFPIA and European Commission) on severe asthma and COPD

2008: Participation in European consorta on proteomics, stem cells and gene therapy within the FP7 project (7° European consortium, EU support programme for research)

2009: Strategic partnership with Florence University on COPD.



The R&D pipeline

The respiratory pipeline – phases of research and development

Research	Learn	Confirm, Launch & Grow
Development of a Lead Candidate (active substance with proven mechanism of action)	Production of a Clinical Proof of Concept (evidence of clinical efficacy and safety up to a maximum of two therapeutic doses)	Production of documentation to obtain approval from regulatory authorities and allow biggest sales possible in all geographical areas

0 Start of research

1 Start of preliminary development

2 Initiation of complete development

3 Initiation of registration

4 Initiation of the launch

LAMA back up
PDE4 back up
IKK2
LA ICS
New targets

Synthetic Surfactant

LAMA Combos

iPDE4 CD1

4226 pMDI

5188 pMDI

Foster pMDI COPD

Foster pMDI Paediatric

Foster pMDI Flex dosing

Foster pMDI High Strength

Foster DPI

The Chiesi Pipeline – Other projects

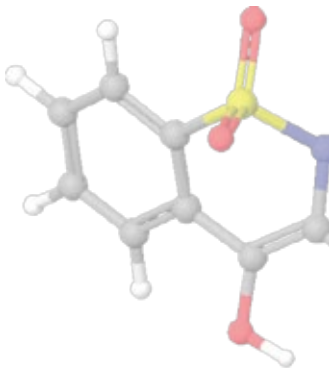
Project	Trademark	Active ingredient/Action	Indication	Regulatory Status	Partnership
CHF 1521	Vivace	Manidipine + delapril	Hypertension	MRP completed (selected EU countries)	In-licensed from Takeda
CHF 4227		SERM Breast Cancer	Osteoporosis, completed Postmenop. Syndrome	Phase I per licenza	Available for license
CHF 5074		γ-secretasi modulators	Alzheimer's Disease	Pre-clinical	Available for license
CHF 3381		LDME + carbidope	Dolore neuropatico	Phase II	Vernalis
CHF 1512		LDME + carbidopa	Malattia di Parkinson	Phase III	Vernalis (except Italia)
CHF 1514	Clipper	Beclomethasone dipropionate	Ulcerative colitis	Registered in selected EU countries. Launched in Italy and Spain	

Industrial Operations

The Chiesi Group's production plants are located in three different sites: the Officine Farmaceutiche di Parma (Italy), with over 420 staff members, split into the San Leonardo and the via Palermo sites; the Blois-La Chaussée plant in Saint Victor (France), with 65 employees, and the Santana de Parnaiba plant (Brazil) with more than 100 workers.

Parma

Our most important plant, which is in Parma, is an international supply centre and exports products to over 60 countries. The plant operates in accordance with the ISO 9001:2000 Certified Quality Management System and has successfully passed a number of inspections carried out by regulatory authorities from many countries, including the US Food and Drug Administration, the Canadian Therapeutic Products Program and the Agenzia Italiana del Farmaco (Italian drug Agency).
Recently a Management System for Occupational Health and Safety was implemented in accordance with the British Standard OHSAS 18001.
The correct application of the international Good Manufacturing Practice standards, successfully adopted by Chiesi using the very latest technologies involving a high degree of automation and product segregation, also represents the best guarantee of safety for employees and respect for the environment.
The careful management of our partnerships with suppliers, who are required to ensure a high standard of service, safety and quality in their Organization, contributes significantly to the achievement of an excellent level of service in the supply of products to our affiliates and clients and ensures business continuity.
Annual production at the Parma plant totals around 45 million finished packages.
The San Leonardo production plant site manufactures solid formulations: tablets and powders for DPI (Dry Powder Inhalers), solutions and suspensions for pressurised MDIs (Metered Dose Inhalers) with eco-friendly propellants (Hydrofluoroalkanes), or alternatively packaged in sterile unit-dose vials using "Blow Fill Seal" technology for nebulized inhalant therapy (UDV).
The production laboratories in Via Palermo prepare vials of sterile suspensions designed for endotracheal administration (Curosurf), liquid formulations, such as drops and syrups, and nasal sprays.
The current capacity for three-shift production of unit-dose vials (UDV) stands at over 210 million units per year. MDI production capacity is 24 million aerosol containers using two shifts and can be further increased working on three shifts, as has already been successfully trialled.
The new production department for the Curosurf sterile suspension has been approved by both European health authorities and the FDA. As a result of investments made to expand the output of plants supplying this active ingredient, production capacity has now reached over 350,000 vials.
An automated DPI filling and assembly line for the new DPI has been installed alongside the extensions made to the office and laboratory premises.
Production and back-up processes (Cleaning in Place, Sterilizing in Place) are managed and monitored by means of fully-validated computerised systems.
In addition, the Manufacturing Execution System (MES) IT Framework, recently implemented is now managing the dispensing operations and the ***electronic batch record system*** on the first production line selected as a pilot (Sterile UDV).



Blois

Manufacturing capacity at the Blois plant stands at around 6 million finished packages a year, mainly supplying other Group's Affiliates. The French production laboratories specialise in blister packaging for capsules and tablets, in the final stages of the MDI assembly and production processes; ample refrigerated storage space is available for these products.
The Blois site is also equipped to distribute directly to clients in the French and export markets.

Santana de Parnaiba

Annual Production at the Santana de Parnaiba plant totals around 6 million finished packages. The production lines at the plant manufacture solid formulations (tablets) and pressurised solutions and suspensions for inhalant therapy (MDI), including the formulations with the environmental friendly propellant HFA. Besides the domestic market, Santana also supplies the Group's other Affiliates including Italy and the export to licensees and distributors.

Technological support

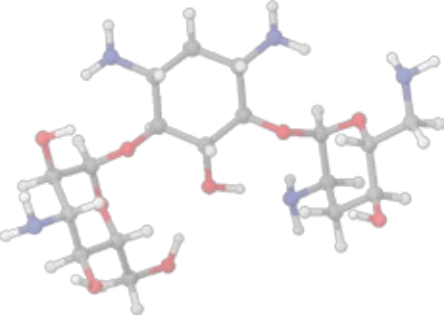
The Corporate Manufacturing Technology and the Corporate Engineering departments support Research & Development as the scale of production of developed products increases, and in the transfer of production between plants either within or outside the Group, or when a partner decides to manufacture by itself, using technology which has been patented by the Chiesi Group.

Lean Manufacturing

In 2008 an initiative was set up at the San Leonardo plant with the aim of increasing the efficiency and flexibility of production lines, based on the use of management tools and systems inspired by the well-known principles of Lean Manufacturing. The 2008 project was designed with three main features:

- the introduction of a system to measure and monitor the efficiency of the lines based on the OEE model (Overall Equipment Effectiveness)
- the setting-up of several Improvement Groups, responsible for analysing and correcting certain causes of loss of efficiency with the collaboration of line operators.
- the creation of a training programme to pass on maintenance skills to these operators.

In addition to its quantitative objectives, this initiative was aimed at ensuring that operators became increasingly involved in the improvement process, with the further benefits in terms of professional growth, motivation and the working environment.
As a result of the initial success achieved in 2008, the project is to be further developed over the next few years by extending it to a wider range of systems that have already been tested and by the gradual introduction of other continuous improvement tools. A similar project, albeit using different methods, has been set up in the Quality Control facility. By mapping out the key processes and effecting an analysis in the laboratories of the main causes which negatively affect the efficiency and efficacy of release processes, to which variations and changes of a technical or organisational nature may be made, it is hoped that progress in respect of a more efficient use of resources will result in this area.



Therapeutic areas

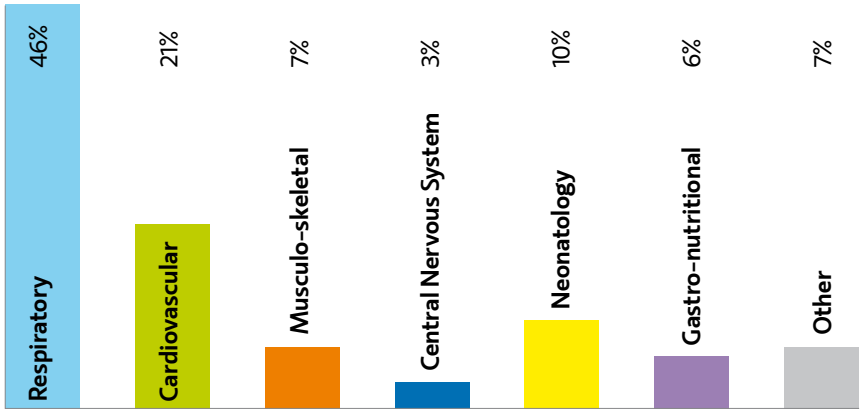
Respiratory pathologies

Chiesi is committed to the treatment of pulmonary diseases. To this end, we have created technological platforms designed to release active ingredients into the lungs. Today asthma is a reasonably well-controlled condition and one where there has been a significant reduction in unmet medical needs. Nevertheless, levels of patient adherence to treatment regimes are still low and this limits treatment efficacy. Our main achievement in 2008 was the pan-European launch of Foster, a new combination of a long-acting bronchodilator and a steroid, in an extra-fine formulation based on Modulite technology. Thanks to the innovative technological platform Modulite, Foster is easy to use and guarantees efficient delivery. The Modulite spray, which is able to release extra-fine particles of active ingredient, ensures that the drug is evenly distributed throughout the bronchial tree, allowing optimal coverage for both central and peripheral airways. Besides improving the treatment of asthma, the company is committed to finding new efficacious treatments for chronic obstructive pulmonary disease (COPD), a pathology characterised by a series of therapeutic needs that have yet to be met. The Chiesi pipeline mainly consist of projects aimed at offering an important step forward in the treatment of this disease, which according to the World Health Organisation will become the third main cause of death by the end of 2020.

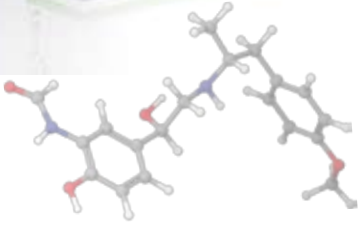
Rare diseases

The Group also has a strong focus on the treatment and support of patients affected by rare diseases whose life is at risk as a result. We are currently concentrating our efforts on this objective, which is considered to be of strategic importance for the future but also of great social impact. In particular, significant skills have been developed in intensive therapy for premature neonates. Besides its traditional commitment to the treatment of respiratory stress syndrome (RDS), an area in which the surfactant Curosurf has become the ***standard*** of care at global level, Chiesi is also turning its attention to other neonate respiratory pathologies, such as apnoea of the premature and bronchopulmonary dysplasia. By combining its knowledge in the physiopathological field with its technological skills in inhalant formulations, the Group aims to offer the medical-scientific community new therapeutic alternatives for the treatment of serious diseases including cystic fibrosis. The first few steps taken towards this goal involved the launch of Bramitob for the treatment of infections caused by *Pseudomonas aeruginosa* in patients affected by cystic fibrosis and the start of a collaboration between Chiesi, doctors and associations to improve the management of these patients.

Sales by therapeutic area



Main products

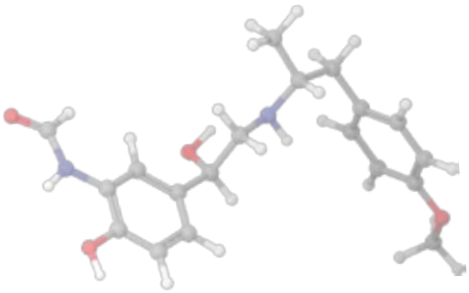


FOSTER
Beclometasone+Formoterol

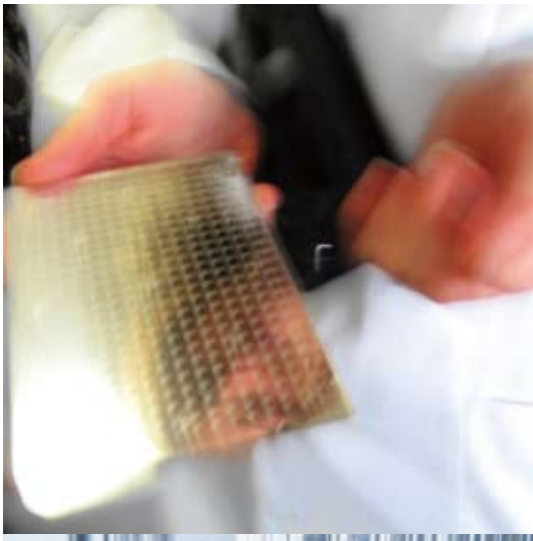
Foster is a fixed combination of inhaled beclomethasone dipropionate (corticosteroid) and formoterol fumarate (a rapid and *long-acting* β2-agonist). The drug is available as pMDI in "extra-fine" solution. This formulation, which is based on Modulite technology, ensures a simple and flexible dose regime: one or two **inhalations** twice a day. Foster's unique feature is its extra-fine formulation, which guarantees even distribution and a high deposition of the drug throughout the entire bronchial tree. The thinking behind the development of a formulation where both active ingredients are delivered in microscopic particles is based on evidence that the inflammation caused in asthma affects the whole bronchial area. Optimal deposition of the drug must therefore be delivered to both the central and peripheral airways. Clinical trials have demonstrated that Foster is effective in improving lung function, clinical symptoms and asthma exacerbations in patients affected by moderate to severe asthma. In all trials, the drug showed a favourable safety profile in terms of adverse events and effects on cortisol plasma levels. Foster was launched in Germany in October 2006 and has since been approved in seventeen European countries by means of a mutual recognition procedure (MRP). Foster is currently being marketed in Italy, Austria, France, Germany, Greece, the United Kingdom, Spain, The Netherlands, Belgium, Denmark, Norway, Sweden, Slovenia, Slovakia, Hungary, Turkey and Tunisia. Further launches are scheduled for 2009 and the development of additional indications, such as the treatment of chronic obstructive pulmonary disease (COPD) and the therapeutic use of Foster for paediatric and adolescent patient populations, is currently also underway.

Clenil

Clenil (beclomethasone dipropionate) is one of Chiesi's historic brands, and has become a well-established product since its launch in Italy in 1979. Indicated for the treatment of asthma as well as other inflammatory and allergic condi-



tions, this is the most versatile drug in our portfolio, in that it is available in various formulations (pMDI, DPI and solution for nebulization in UDV). The pMDI formulation adopts the Chiesi patented Modulite technology, and has achieved significant results for the drug in European countries such as the United Kingdom, where it has gained consistently increasing sales and market share over the past year. In 2008 Clenil's outstanding performance exceeded all budget expectations. To date, this drug still represents one of Chiesi's most important assets thanks to its remarkable therapeutic properties.

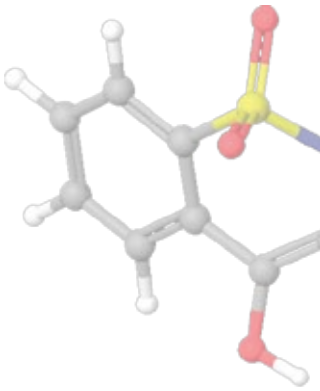


ATIMOS

Atimos is a pressurised inhaled solution for inhalation (pMDI) of formoterol fumarate, based on Modulite technology, and is indicated for the long-term symptomatic treatment of asthma and chronic obstructive pulmonary disease (COPD). Formoterol is currently considered to be one of the ***best long acting*** β2-agonists (LABA) available on the market thanks to its rapid and long-lasting therapeutic action (up to 12 hours). By virtue of its extra-fine particles, Atimos guarantees optimal distribution of formoterol throughout the entire bronchial tree, including the peripheral airways. It therefore possesses a notable bronchodilatory effect and is as effective as the other inhaled formoterol formulations (DPI). The drug has also demonstrated that it is well tolerated when compared with the other DPI and pMDI formulations. Licensing our Modulite technology to Novartis is further confirmation of its efficacy. The drug is currently being marketed in all of the major European countries.

BRAMITOB

Bramitob is the new formulation of tobramycin in sterile solution for inhalation, which was developed by Chiesi for the long-term management of chronic pulmonary infections caused by *Pseudomonas aeruginosa* in patients affected by cystic fibrosis (CF). The drug comes in single-dose vials, to be taken twice a day on an alternate 28-day on/off treatment cycle. Tobramycin nebulized solution has been tested in multi-centre, double-blind placebo-controlled clinical trials. Bramitob has been demonstrated to be efficacious in improving lung function and reducing both the length of hospital stays and the need for intravenous antibiotics in CF patients. This is Chiesi's first product indicated for Cystic Fibrosis. It has been registered and marketed in Italy since 2006 and is now also available in Germany, Spain, the Netherlands, Greece, Austria, the Czech Republic, Slovakia, Hungary, Poland, Portugal, the United Kingdom, Russia, Croatia, Serbia, Bosnia and Montenegro.



clipper

Clipper is an oral corticosteroid indicated for the treatment of mild to moderate ulcerative colitis flares. The drug is available in gastro-resistant slow release tablets containing 5 mg of beclomethasone dipropionate, to be taken once daily. Its unique drug release system ensures targeted delivery of the active ingredient to the mucosa of the distal ileum and proximal colon where inflammation occurs, thus exerting a local anti-inflammatory action whilst minimising the systemic side effects normally associated with this corticosteroid. Clipper represents the first oral modified-release corticosteroid indicated

for the treatment of ulcerative colitis. It is currently registered and marketed in Italy, Belgium, Spain and the United Kingdom.

Curosurf is a natural surfactant for intratracheal administration indicated for the prevention and treatment of respiratory stress syndrome in premature neonates. This condition is among the most common causes of neonatal mortality and is due to underdeveloped lungs in pre-term neonates. Curosurf is an extract of natural porcine lung surfactant consisting in polar lipids and surfactant associated proteins. Since its introduction in 1992, Curosurf has been used to treat over 800,000 neonates. Today it is world leader with a market share of 59% and is available in more than 65 countries across the world. The use of Curosurf in combination with different non-invasive ventilation techniques has been investigated in two recent clinical trials, the CURPAP and NIPPV studies that have provided neonatologists with landmark evidence for the management of RDS in the preterm infants.

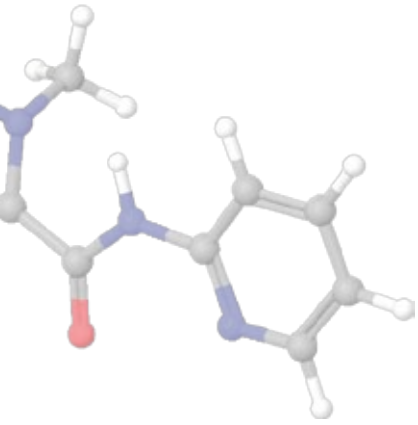
Brexin

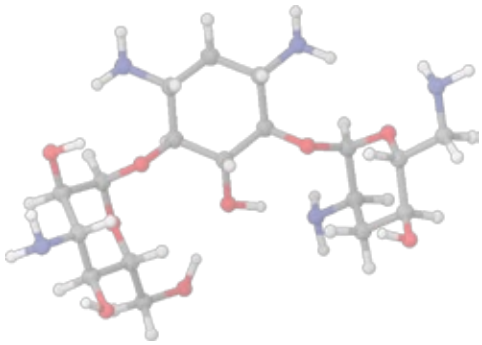
Pyroxicam β-cyclodextrin (PBC) is a successful example of the clinical application of the Nobel prize-winning "host-guest" technology, whereby the host, a starch derivative such as β-cyclodextrin, solubilises the guest pyroxicam, a non-steroidal anti-inflammatory, to enhance its pharmacological properties. Pyroxicam β-cyclodextrin is mainly indicated for the treatment of painful and inflammatory conditions in patients affected by rheumatic diseases such as rheumatoid arthritis, osteoarthritis and ankylosing spondylitis. The product was launched 18 years ago and is still marketed in Europe, South America, Asia and Africa.

Manidipine, a third generation dihydropyridine calcium-channel blocker, is indicated for the treatment of patients affected by mild to moderate arterial hypertension. Thanks to its vasodilatory effect, this drug induces a significant reduction both in arterial systolic and diastolic pressure. In addition to its antihypertensive effect, Manidipine also exerts specific effects aimed at reducing the overall cardiovascular risk and improving the quality of life of hypertensive patients, unlike other traditional calcium blockers. The drug differs from the other molecules in the same class by virtue of its:

1. improved nephroprotective profile, because of a more balanced dilatation of the afferent and efferent glomerular arterioles and thus, as a result, a marked reduction in the microalbuminuria and proteinuria;
2. its metabolic profile, which improves insulin sensitivity and adiponectin secretion;
3. absence of sympathetic activation which helps to improve drug tolerance, as a result of a lower incidence of ankle oedema.

Today Manidipine is available in numerous countries under various brand names: Italy, France, Tunisia and Morocco (Iperten); Brazil - (Manivasc); Greece and Germany (Manyper); Spain (Artedil).





Human Resources

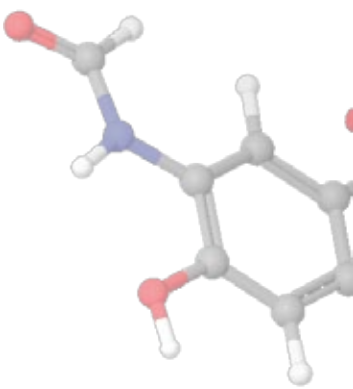
Human Resource Management activities throughout 2008 have provided concrete solutions for the levels of expansion and cultural development currently being experienced by the Group.
Last year's growth, which was mainly achieved at international level, has created an even greater need for talented human resources, characterised both by professional and organisational skills in line with the objectives of innovation and development that the Group has set itself.

Our values: our key to success

Our company values – a reliable company, focus on people, team spirit, "Every one of us is Chiesi", generating value, client focus – are an integrative part of Chiesi's cultural worth. These values, which were widely broadcast via a specific information programme from 2006 to 2007, formed one of the cornerstones on which to base the Organisation, Management and Control model adopted in accordance with Decree Law 231/2001 of the Italian Republic in 2008.
The brochure dedicated to our values, which has been distributed to all our major affiliates, has further encouraged the adoption of these principles that today make up part of the assessment criteria of the Group.

Training and professional development

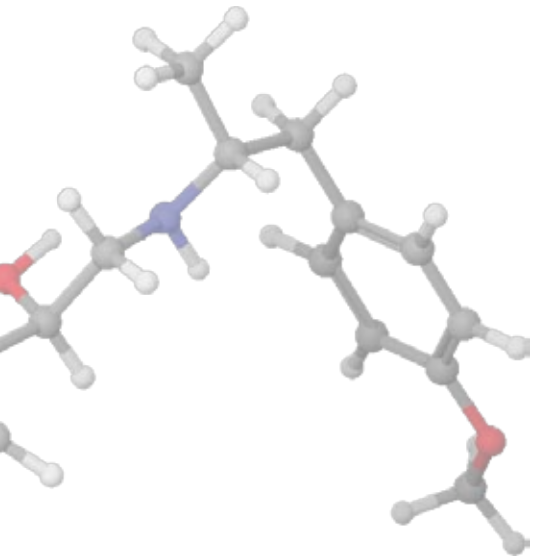
Our training policy stems from our belief that human resources make a decisive contribution to business results. Motivated and competent staff are able to respond with greater flexibility to the changes called for by the pharmaceutical market and today's growing internationalisation.
Consistent investment in training made in 2008 (see table on pg. 38) was once again aimed at ensuring that new recruits were integrated more smoothly, consolidating and updating technical and scientific skills and developing the managerial skills needed to handle changes relating to staff, technology and the market.
In 2008 the Human Resources Management founded the **Chiesi Academy**, a programme which identifies the Chiesi Group's Corporate initiatives. The Chiesi Academy is intended to provide an ideal context in which to improve



managerial skills and conduct. The essential criteria of projects coming under this programme require high levels of internationalisation and also of excellence.
The first Chiesi Academy project is the **Chiesi Corporate Master**, a two-year course managed with our partners at SDA Bocconi which aims to promote an in-depth knowledge of the company with training sessions dedicated to the Pharma world, direct contact with the Group's management and the development of an effective and well-established network for the thirty participants. As far as Chiesi Farmaceutici S.p.A. is concerned, the **Competence Lab** must also be mentioned, which has brought about a significant improvement in the training and development of young graduates, and the **training courses for newly-appointed heads**, who are required to take on new management responsibilities.
Besides carrying on with existing courses, more effective training and development courses are to become more widely available at our major affiliates in 2009, along with a particular focus on coaching programmes and training sessions dedicated to business issues which are also to be set up.

The selection process

Throughout 2008 the Chiesi Group paid particular attention to the development of partnerships with recruitment companies specialised in the pharmaceutical sector for the recruitment of resources with specific skills, above all in the field of research and development.
Our website www.chiesigroup.com, which now features additional new functions, has enabled us to access numerous applications, some of which were unsolicited whilst others were responses made to public adverts.
Our participation in national and international events, such as the International Placement Exchange, Top Employers and so on, has also helped increase the Group's visibility internationally and has made it more attractive particularly within scientific areas.
Assessment, tests, group and individual interviews were the main features of selection programmes set up last year, and were increasingly focussed on finding people who matched the culture and values of the company.
Company tutors and induction programmes are provided to help newly-recruited employees integrate better.

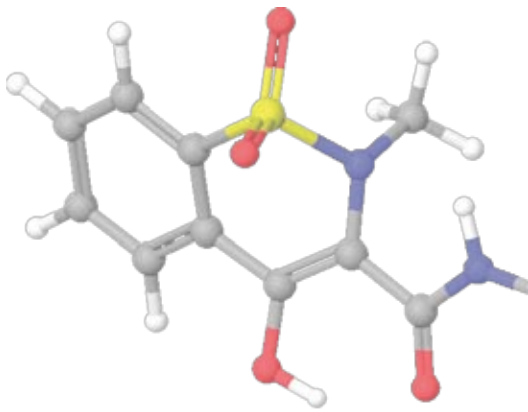


Information & Communication Technology

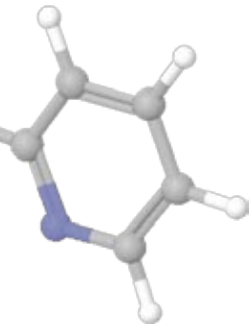
In accordance with what is set out in its mission, the main point of reference for Corporate Information & Communication Technology (CICT) remains to constantly strive for alignment with the business. Numerous changes are taking place to modify the operative scenario of the Chiesi Group: in particular, some of these have had a significant impact on the activities carried out by CICT. Among these, we must not forget the increasing level of globalisation, the constant need for standardised processes and information, the higher level of complexity of the company system and the increasing availability of information. In order to deal with these changes, CICT has introduced a strategy and methodological support to strengthen the information governance system (IS), in which the Global Enterprise Architecture design (see table 1) constitutes a fundamentally important component as it ensures the overall consistency its Systems.

Business Architecture		Security Architecture
Application Architecture	Information Architecture	
Technical Architecture		

Table 1: The Business architecture adopted by the Chiesi Group is an overall picture of our visions, principles, standards and processes and its objective is to guide the purchase, planning and implementation of information services for the support of the business.



Increasing complexity also means that there is a greater need to further reinforce and structure internal processes towards the management, in particular the processes of demand management and the management of the project portfolio, described in terms of their underlying functional principles, which are in line with the criteria defined in the IS Governance document (see flowchart illustrated in table 2).



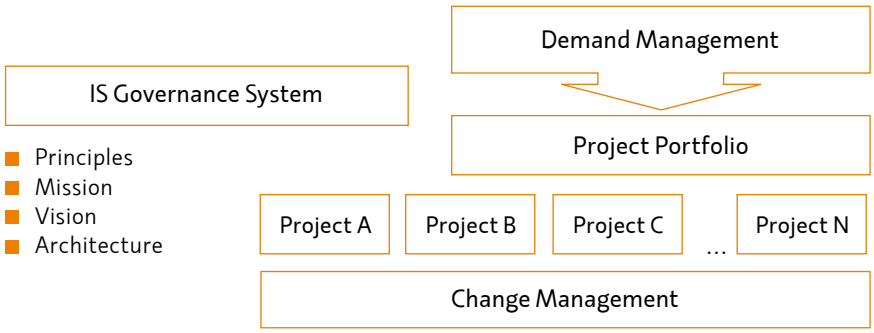


Table 2: The demand for information & communication technology projects generated within the company supplies the portfolio and contributes to the creation of an area of innovation and change management relating to business processes in line with the principles defined by the governance system.

Technology

Research into homogeneous and harmonising solutions at Group level is characterising the technological choices made in recent years. This has been done taking into account the criteria of simplification and strength which lie at the heart of the technological architecture design.
CICT is committed to meeting the challenge that is the annual growth of the company's technological infrastructure, whilst working to control costs. This represents a constant incentive to reduce complexity and optimise management costs. At the same time, we are continuing to look for flexible and adaptable technological solutions and to overhaul redundant infrastructures.

International dimension

Each new application introduced within the company is evaluated in terms of compatibility and applicability on an international scale. This involves the need to gather requirements for new projects not only at head office level but also from our affiliates. Furthermore it represents a stimulus to achieve greater standardisation and efficiency from a technological point of view.

Main achievements in 2008

Implementation of a system to support Discovery

Implementation of a system for the collection of data relating to Clinical Trials

Availability of a support platform for Quality processes

The Electronic Batch Record implemented on the sterile Monodose production line

Significant implementations have been made in the infrastructural area (MPLS network, VOIP Telephone)

Main projects for 2009

One of our most important objectives is to define a strategy for the Group in the ERP area

Further steps have been taken towards the completion of the architecture of laboratory systems (LIMS, Long Term Archiving, eNotebook)

Implementation of the new Treasury system

New implementation phases for long-term projects already underway (Manufacturing Execution System, Human Resource Platform, Documentation Management).

Chiesi
worldwide

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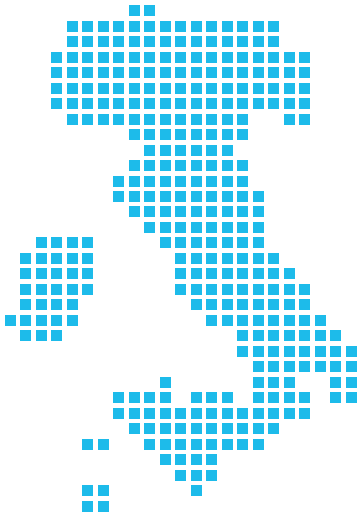
34 International Commercial Operations

35 Strategic Alliances

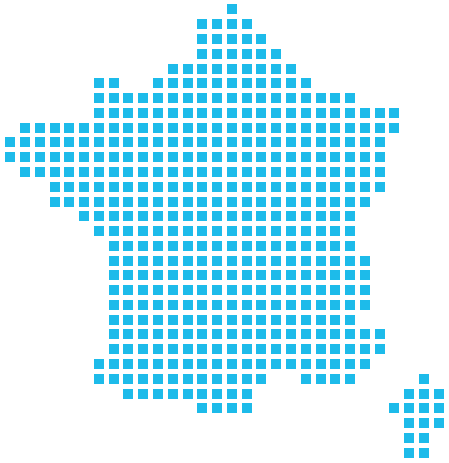


Italy

Pharmaceutical Division Italy

The Italian pharmaceutical market, like western markets, is faced with a new and painful reality; that of stagnation. This is mainly due to cost-cutting measures and the impact of competition from generics.
Against this backdrop, Chiesi has maintained an excellent performance, closing the year in 11th place in the retail market, and achieving one of the best growth rates among the top 15 Companies and a 2 % market share of the retail market.
This year, the driving forces behind Chiesi's growth have once again been the respiratory and cardiovascular portfolios. Our top five products, accounting for 50% of the total Company turnover, are all doing well, and some have shown significant growth on the previous year; our best performers were Provisacor, Iperten and Foster: the latter, which achieved a turnover of €16 m in its first full year of marketing, currently ranks fifth in the company portfolio.
Sales of Foster are well above forecasts, with over 500,000 units distributed. Overall, Foster revenues and those of its co-marketers Formodual and Inuver have exceeded 20 million Euro.
In the special care area, our best performers are Xenazine (launched November 2007), Bramitob and Sirio.
Of particular note among our numerous development projects is the strategic approach to new channels (Direct sales to Pharmacies were in excess of 16 % of total domestic sales in 2008) and the establishment of a Regional perspective through Local Business Teams that identify opportunities and tackle problems at local level. A new sales force specialising in the muscle-skeletal sector has recently been introduced.
For 2009 the focus in primary care will remain on Foster and on careful portfolio management, to maintain results in all our competitive arenas.

Italy	
Direct sales (K€)	260,302
Variation versus 2007	6.5%
Human resources	1,434
Commercial network	497



France

France	
Direct sales (K€)	105,363
Variation versus 2007	15.4%
Human resources	381
Commercial network (direct + interim)	242

France SA

In 2008, CHIESI SA achieved a good rate of growth of around 16%, with sales of more than 105.5 million Euro at a time when the French market was depressed. If the Intercompany and Export activities are included, sales reached 130.5 million Euro.

These results are linked to the growth of several products both in the hospital and retail markets, and have largely compensated for the drop in mature product sales.

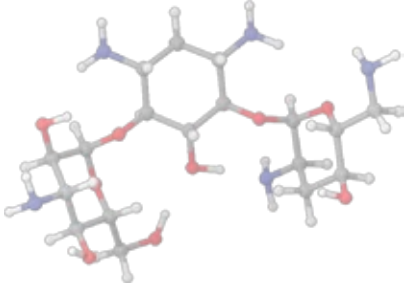
With the support of a co-promotion agreement with Abbot at the end of January 2008, the Group's key product was launched under the Inovair trademark. In the first twelve months following the launch, 470,000 units were distributed, generating a turnover of around 15 million Euro and more than 24,000 prescriptions from general medicine doctors. With the launch of Inovair, the respiratory area, which also includes Formoair (Formoterol), Beclojet, Beclospin and Curosurf, represents more than half of the affiliate's sales.

The excellent performance of Chiesi France in 2008 is the demonstration of the high level of specialisation and know-how of the company. The successful achievement of this objective means that the company has been recognized as a key player in the French pharmaceutical industry, and particularly in the respiratory area.

From an industrial point of view, the plant has invested Euro 1.7 million in the last 2 years. The Blois head office has successfully managed the internationalisation of distribution to wholesalers for all the products sold by the affiliate, resulting in 46,000 orders for a total of 950 tons of shipped goods. The plant has now an adequate storage capacity both at room temperature at 4°C.

With the advent of canister packaging for pressurised sprays produced for the Parma plant, the plant's production volume increased to 5.6 million units including 1.5 million canisters.

The plant, which employs 65 people, is now fully integrated in the strategic industrial plan for the production of blister packs and canisters for the French, UK and export markets.



Chiesi Spain

In 2008, Chiesi Spain's turnover was up by 21% on 2007 thanks to the Foster launch and Pfizer's licensing-in of its second brand Formodual.
The successful launch of Foster was accompanied by that of Bramitob, which is consolidating sales month after month. With these launches in 2008, the portfolio of the affiliates is changing significantly as expected: corporate products have reached 50% of the turnover and these products will increase this share over the next few years.
The affiliate is looking to the future optimistically, on the basis that sales are expected to grow and new products to be developed. For this reason, it has begun this year to introduce the organizational changes needed to be able to face the challenging projects that are hoped will ensure the company achieves a higher ranking among Spanish pharma companies in ethical market than 47° place.

Chiesi United Kingdom

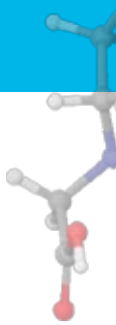
During a difficult and challenging year for the UK pharmaceutical industry, Trinity-Chiesi 'bucked' the trend and experienced its best ever year in terms of sales results.
Total sales for the year were 63.4 million Euro representing a 33% year on year increase, which saw the UK affiliate break into the top 30 companies in the sector for the first time.
This resulted in one of the biggest growth rates (compared to the previous year) ever recorded by a UK company
During the year, the respiratory drug portfolio grew rapidly to stand in excess of 55% of total company sales. This result confirms Trinity-Chiesi's growing presence within the UK respiratory market.
CLENIL attained a market share in excess of 40% and is now firmly established as the UK's leading Beclomethasone drug
FOSTAIR, the company's new innovative combination inhaler was launched and has firmly established itself as the year has progressed.
The company's strategy has been to strengthen the respiratory portfolio whilst maintaining the level of sales of the modified release product range – this goal has been successfully achieved.
At the same time, the special care product range, dominated by Curosurf, has also experienced a very successful year with a continuous growth.
Plans for 2009 include a full restructuring of the respiratory sales division which strategically guides the team toward a perfect fit for the latest NHS requirements and will ensure the correct level of contact and coverage is directed toward both secondary and primary care customers.
The aim for 2009 is to further consolidate sales of CLENIL and achieve rapid levels of growth with Fostair – and in doing so, further establishing Chiesi Ltd as a key UK respiratory player.

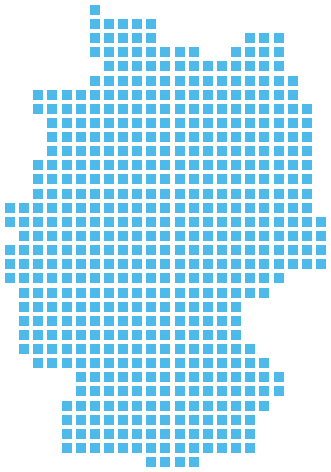
Spain

United Kingdom

Spain	
Direct sales (K€)	53,486
Variation versus 2007	13.0%
Human resources	250
Commercial Network (direct + interim)	241

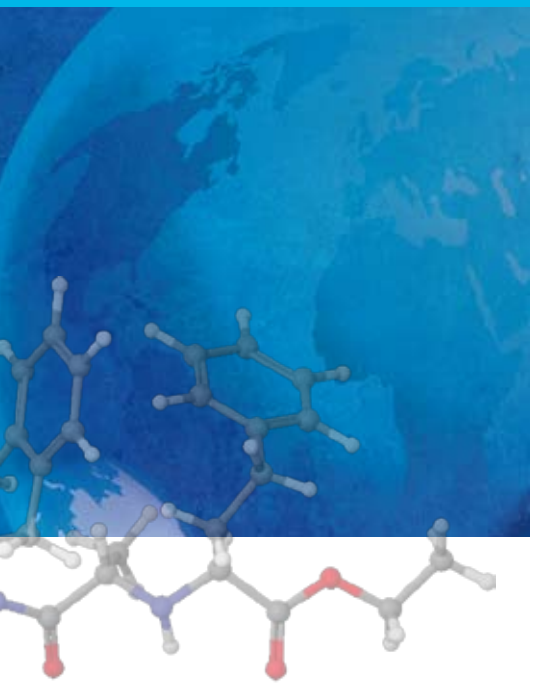
United Kingdom	
Direct sales (K€)	63,395
Variation versus 2007	33.0%
Human resources	141
Commercial Network (direct + interim)	132





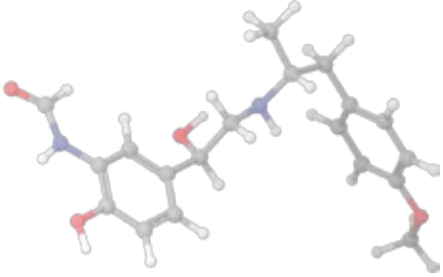
Germany

Germany	
Direct sales (K€)	48,075
Variation versus 2007	41.8%
Human resources	115
Commercial Network (direct + interim)	168



Chiesi Germany

2008 was a very successful year for the German affiliate. Total revenues grew compared to the previous year by 41.8% to 48.1 million Euro.
As in the previous year, this result was achieved thanks to our main product Foster. The drug, which is being promoted by numerous medical reps, gained a record market share of 5.1% in December 2008. The double-size package was launched in October thus extending the range of formulations available for the product. Besides Foster, Forair and Sanasthmax also made a significant contribution to this remarkable performance. As a result, Chiesi Germany was able to speed up the integration process and establish itself as an important player in the German respiratory market. In order to achieve this objective, the affiliate focussed on enlarging its sales force capacities, hiring new highly skilled reps throughout 2008.
In total Chiesi Germany relies on front line of medical reps targeting general medicine doctors and a second line focussing on paediatricians and GPs. Our third line, the special care hospital field force, has successfully promoted Curosurf and launched Bramitob for the treatment of cystic fibrosis since it was set up.
Two key projects in 2008 concerned the implementation of leadership principles, involving forty members of staff from all of the organisation's hierarchical levels, along with our employee attitude survey. The results of the survey as well as the leadership principles were announced during our annual convention in January 2009.
Lastly, the affiliate continued to focus on business enlargement and sales increase. The first step towards achieving this was the change of the company name from Asche Chiesi GmbH to Chiesi GmbH as of January 1st, 2009. Under the Chiesi name, we can show that we are an integrative part of the Group and demonstrate our expertise in the respiratory sector.



The Torrex Chiesi Group – Austria and Central Eastern European Countries (CEEC)

The Torrex Chiesi Group with its headquarters in Austria is a regional structure representing the Chiesi corporation in the Central Eastern European Countries including Russia and the Countries within the Commonwealth of Independent States (CIS). Besides Chiesi's corporate products in respiratory, rheumatology and neonatology the Torrex Group portfolio includes products indicated for anaesthesiology, intensive care, systemic antifungal therapy and for addiction treatment. The Torrex Chiesi Group is actively looking for further in-licensing products in selected business areas and using its effective coverage in the CEEC countries.

Torrex Chiesi Pharma GmbH, Austria

Torrex Chiesi Pharma GmbH, located in the centre of Vienna, provides the whole Torrex Group with logistic, regulatory, medical and financial services. In May 2008, after obtaining the reimbursement, the asthma combination product Foster was launched. Together with Budiair (budesonide) and Prolastin (1-proteinase inhibitor) Foster forms the respiratory portfolio. At the beginning of 2009 Curosurf was bought back from Nycomed.

Torrex Chiesi Kft, Hungary

Despite the difficult pharma-economic situation in Hungary the business was successfully developed in 2008, mainly on the basis of sales of Flamexin (pyroxicam betacyclodextrin) and also through the launch of Foster (October 2007).

Torrex Chiesi CZ s.r.o., Czech Republic

The anaesthesiology portfolio represents an important basis in the local affiliate. Bramitob was launched in 2008 and was added to the special care products, such as Curosurf and Amphocil.

Torrex Chiesi Slovakia s.r.o., Slovakia

The subsidiary started operations in 2004 and has now become one of the most dynamic business units. In 2008 the sales of Foster (launched in October 2007) were further developed and reached one of the highest local market shares worldwide (approximately 10%).

Torrex Chiesi s.r.l., Romania

Sales are mainly generated by Flamexin which gained one of the highest local market shares in the NSAID-market range in 2008. In addition, anaesthesiology and special care products are contributing to a balanced portfolio.

Torrex Chiesi Slovenija d.o.o., Slovenia

This well established affiliate generates most of its revenues in respiratory area with Foster, Budiair and Atimos. ReVia (an anti-addiction drug) and "Midazolam Torrex" are also among the main contributors to sales.

Torrex Chiesi Bulgaria Ltd., Bulgaria

The company was recently established at the beginning of 2008. In addition to Curosurf, Naltrexone (anti-addiction drug) and the anaesthetics portfolio, its biggest sales are primarily generated by Flamexin.

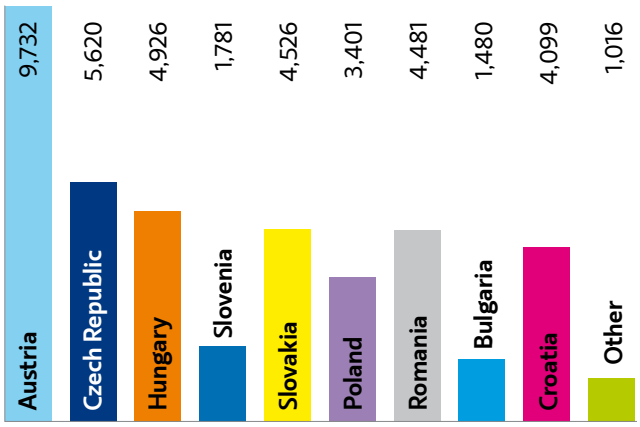
Torrex Chiesi Polska z.o.o., Poland

The Polish affiliate was established beginning of 2005. The local team is mainly focused on hospital products such as Amphocil, Curosurf, Pamitor (pamidronic acid) and the anaesthetics portfolio. Bramitob has been part of the special care product range since 2008. The launch of the respiratory products is expected in 2009.

Torrex Chiesi

Austria & EEC	
Direct sales (K€)	41,064
Variation versus 2007	23.2%
Human resources	200
Commercial network	132

Direct sales by country



Greece

The Netherlands

Greece	
Direct sales (K€)	7,380
Variation versus 2007	34.6%
Human resources	50
Commercial network	36

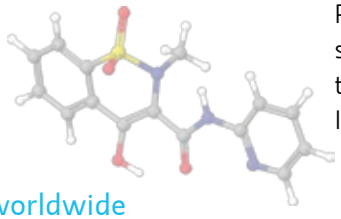
The Netherlands	
Direct sales (K€)	1,819
Variation versus 2007	n.a.
Human resources	37
Commercial network	22

Chiesi Greece

2008, the eleventh year in the short life of Chiesi Hellas, was undoubtedly the most important and challenging year for this affiliate, which successfully launched Becloneb, Bramitob and above all Foster.
The three new products brought a significant change to the size and the operations of the affiliate, highlighting the fact that the company is experiencing rapid growth, as it aspires to become a leader in the respiratory field.
To meet this challenge, the Sales Force was reinforced with the addition of new medical reps.
The 36-strong team of well-trained and motivated people is aiming for highly ambitious targets.
This new sales force seized the golden opportunity represented by the new launches to achieve remarkable results with its enthusiasm and dedication, in particular generating a growth of over 35% on the previous year.
Our affiliate is now recognized by the medical community as a significant player in the market, especially in the respiratory field.

Chiesi Pharmaceuticals B.V. – The Netherlands

The affiliate's key objective is to establish a well-recognized pharmaceutical company in the Dutch market, creating a strong position in the medical environment with a reputation as a respected patient-focused, innovative and research-driven company.
The organization is directing its efforts towards being established as a high achiever based on social and ethical responsibility and fully embedded within the Chiesi Group.
At the beginning of 2008 Chiesi Netherlands successfully launched Foster and Bramitob in the Dutch market. Both products were well received and have since generated substantial market shares. In November the affiliate also launched Atimos, broadening its respiratory portfolio.
Particular attention was paid to setting up the new sales force which was specifically created for Foster and Special Care. There are now 20 reps on the Foster team, and 3 on the Special Care team.
In January 2009, the sales rights for Curosurf were bought back.



Chiesi worldwide

Chiesi Pharmaceuticals LLC Russia

The affiliate in Russia was established in 2006 as a subsidiary of Chiesi Farmaceutici S.p.A., Italy, and was integrated mid 2007 into the management of the Torrex Chiesi Group, who is responsible for CEE and CIS area.
By tradition, sales are mainly based on Vasobral and Clenil, and will be further developed by new products. In 2008 Atimos, Bramitob and Rinoclenil entered the market. The main event planned for 2009 will be the launch of Foster, which foresees the participation in various symposia in a number of Russian cities. Furthermore, Budiair and Amphocil are planned for launch in 2009. Curosurf is marketed by Nycomed under a Chiesi license.
The affiliate is actively looking for cooperation and acquisition opportunities in Russia, and sees the current financial crisis as a chance to further establish its presence in an important future market. A successful and flexible cooperation with the Russian distribution system and a scientifically-based communication with medical areas are its cornerstones for solid development.

Chiesi USA

The US affiliate, Chiesi Pharmaceuticals Inc., provides both local and global Research & Development as well as Business Development and licensing support to Chiesi Group. The company headquarters are in Rockville, MD.
The affiliate has a primary focus on compiling and submitting a US New Drug Application (NDA) for Tobramycin solution for inhalation, for the treatment of Pseudomonas aeruginosa infections associated with Cystic Fibrosis.
Over the past year, clinical trials on new projects being developed in the respiratory area were successfully completed.

Russia

USA

Russia	
Direct sales (K€)	4,249
Variation versus 2007	7.8%
Human resources	53
Commercial network	46

Brazil

Pakistan

Brazil	
Direct sales (K€)	40,980
Variation versus 2007	6.6%
Human resources	303
Commercial network	144

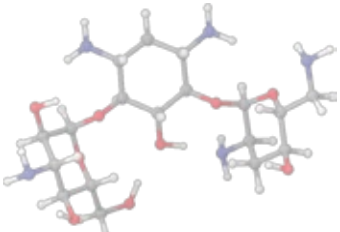
Pakistan	
Direct sales (K€)	6,841
Variation versus 2007	-6.9%
Human resources	103
Commercial network	78

Chiesi Brazil

During 2008 Chiesi Brazil consolidated some important strategies outlined in previous years. Export activities with Pakistan, Egypt and Iran increased as a result of the spray formulations being made available.
The main objective for 2009 is to begin exporting to Italy. New technologies and procedures were implemented in the sales and marketing area: this has contributed to the significant market share growth achieved for important products such as Curosurf, Manivasc and the Clenil Family.
Although no new product launches were made, the Brazilian affiliate recorded a growth rate in line with that of the Brazilian pharmaceutical market.
Since the beginning of this year, the affiliate has became one of the major suppliers of inhalant formulations for regional Governments, and has also adopted the new Chiesi Farmacêutica Ltda name. Thanks to these actions, the Brazilian subsidiary is now fully prepared and committed to enlarging the presence of Chiesi in the Brazilian market.

Chiesi Pakistan

In 2008, Chiesi Pakistan again demonstrated excellent performance standards in the Pharmaceutical Market in Pakistan. With a sizable product portfolio (mostly corporate products) the Affiliate has been able to grow (16%) more than the market (11%) in spite of the global economic recession which has hit Pakistan hard and negatively influenced the exchange rate of the local currency towards the euro. In the market, the affiliate has remained a leader in most of the strategic therapeutic areas, i.e. the respiratory line with Clenil 250 and UDVs. Likewise, its leadership in women's health (Prolifen) was consolidated during 2008. During the year, Chiesi Pakistan launched two corporate products: Curosurf and Atimos. Atimos has become an immediate success and favourable unit sales are expected in the future.



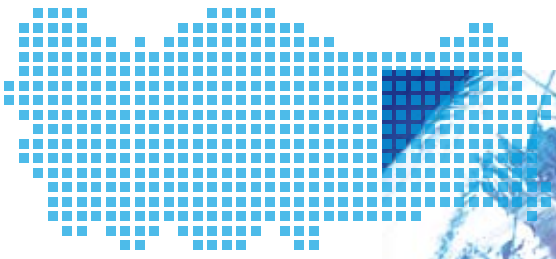
Registration applications for Foster, Clipper, Bramitob and Budiair were successfully submitted to the Regulatory Authorities.
Today Chiesi Pakistan has become an integral and vital part of the Pakistan Pharmaceutical Industry serving the medical community and providing the best therapeutic options for the management of pathologies that are difficult to treat.
The change in the general management was inspired by the philosophy of continuity and participative management. Mr. Ahmed Nadeem Gondal, Marketing Operations Manager, was appointed CEO & General Manager; simultaneously, the former General Manager & CEO Mr. Saeed Aslam Khokhar was appointed Member of the Board of Directors.
The affiliate is confident it will achieve its 2009 objectives on all operational fronts. Its most important objective is to finalize the marketing authorization of Foster and to launch it early in 2010.

Chiesi Ilac Ticaret A.S. - Turkey

Our operations in Turkey have strongly increased in 2008. Rinoclenil has gained a very satisfactory market share in a few months and Curosurf has begun to be recognised as the surfactant of Choice for RDS in neonates.
The affiliate obtained the registration of Foster and Manyper. In June 2008 as a first step towards becoming a key player in the respiratory area, Chiesi Turkey supported the launch of the WHO Global Alliance against Chronic Respiratory Diseases (GARD) in Turkey.
The launch of Foster, pending reimbursement, is planned for early 2009 and the sales force has been expanded to ensure an effective launch of our flagship product.

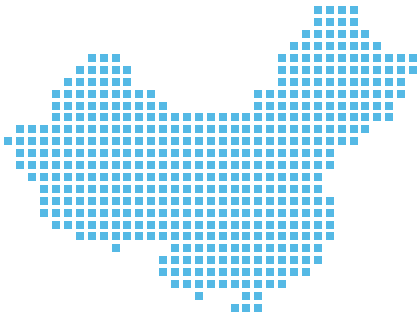
Turkey

Turkey	
Direct sales (K€)	2,813
Variation versus 2007	160.3%
Human resources	119
Commercial network	107



China

China	
Direct sales (K€)	5,562
Variation versus 2007	n.a.
Human resources	48
Commercial network	34



Chiesi China

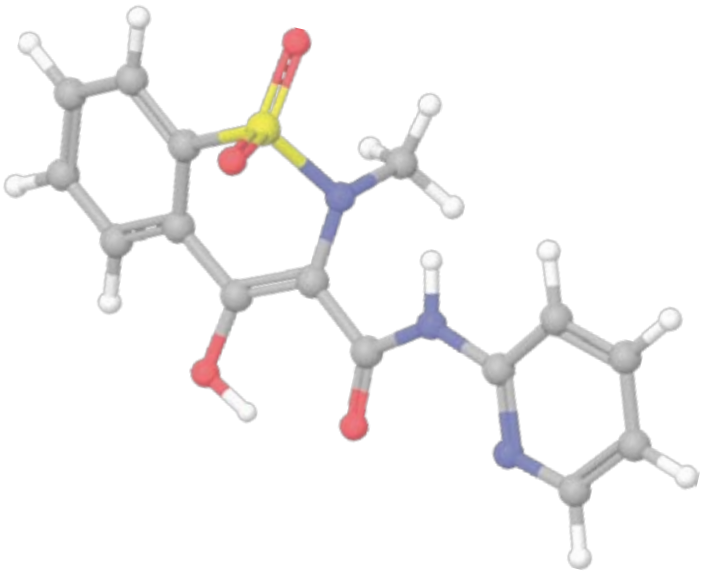
In 2008, the Chiesi Group achieved another milestone in its internationalization with a direct presence in China. Chiesi China operations started in May 2008 with its buyback of Curosurf from its former partner. On 1 Nov 2008, Chiesi China became fully operational through the newly established Chiesi Pharmaceutical (Shanghai) Co., Ltd. The new company is aiming to promote sales of Chiesi products in China's growing pharmaceutical market. Currently Chiesi China is focusing on promoting sales of Curosurf and maintaining its leading market position, while the Regulatory Function deals with the Drug Registration Process for Chiesi respiratory products. The organization includes a Field Force of medical reps, who are geographically scattered across the major regions in China.

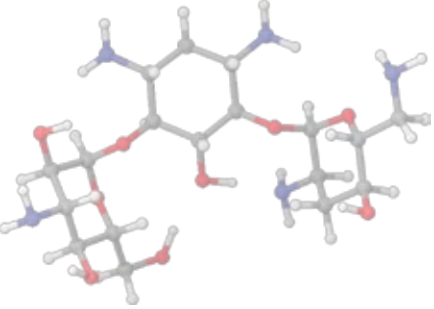
Curosurf's Sales and Marketing achievements exceeded our forecasts by 27% by the end of 2008.

Chiesi China also carried out a number of marketing activities to establish a favourable Corporate Identity. Following the Sichuan earthquake in May 2008, the Company set up a Donation Project to help several disaster-stricken hospitals recover. Chiesi China made concrete contributions to those hospitals including the donation of incubators to paediatric/neonatal departments, funding and sponsoring doctors to update their clinical knowledge. These efforts are evidence of our Group's sense of social responsibility.

Apart from the successful marketing of Curosurf, significant commitment was also made to the registration of Respiratory Products, including Foster, that are due for launch in 2011.

The objectives for 2009 are the continued strong growth of Curosurf sales, keeping our market share at 85%, as well as the progressive development of Chiesi's products in the Chinese clinical practice.





International Commercial Operations

2008 has been highly successful for our International Commercial Operations.
Export has grown by 4% despite a reduction in European sales of Pyroxicam ß Cyclodextrin due to some restrictive measures on NSAIDs.
We have experienced consistent growth of our sales of Curosurf especially in the USA (where the product has generated 31.5 million dollars) and in Russia.
In non-EU countries Brexin is continuing its growth reaching 3 million units/year in Egypt and 500 thousand units in Morocco.
Foster has taken its first steps with its launch in Tunisia and product registration in South Korea. 2009 will see further registrations of Foster and additional launches in South Korea, Portugal and Morocco.

Belgium

Clipper's competitive ranking has remained unchanged, whereas that of Curosurf has improved slightly to stand at around 74%. For the current year our targets are to consolidate Curosurf and Clipper.

Egypt

A dedicated Chiesi sales force was created five years ago for the marketing and promotion of the Group's respiratory and musculoskeletal products. Local sales amounted to about 5.2 million Euro in 2008 thanks to the local team's hard work. Substantial contribution to this achievement was made by the record sales of almost 3 million packs of Clenil Compositum MDI and 1 million packs of Brexin tablets with an extraordinary growth of 30% on 2007.

Maghreb

Our results in **Morocco** were excellent: local sales through our partner Promopharm reached 73 million Dirham with 6% growth thanks to the launch of the antidepressant Divarius in particular. In **Tunisia** our Scientific Office improved its position with 670 million Dinars and a growth rate of +10%. Chiesi ranks 11th among international pharmaceutical companies in the country. Foster had an outstanding launch performance gaining a 15% market share in just 3 months following the launch. In **Algeria**, Chiesi has been able maintain its position at 1.5 MM DZ despite a sharp market shrinkage. Brexin sales were particularly positive in helping to increase the company market share to 1.2%.

Mexico

In 2008 the commercial organisation indicated further growth. Curosurf maintains a market share of around 30% and is included in the Mexican Institute for Social Security handbook. For the current year our objective is to become leader in the treatment of neonatal respiratory distress syndrome. Bramitob and caffeine citrate are currently being registered and it will be possible to market them at the beginning of 2011.

Strategic Alliances

Partnerships in the pharmaceutical industry are becoming increasingly important due to the complex nature of development of new drugs and the need for innovative commercial strategies in particular in an expanding global market, where reimbursement and cost containment are high profile issues. As a matter of fact, partnerships allow pharmaceutical companies to diversify their business strategies, both in geographical terms and in the therapeutic areas scope.

An increasing interest towards special care and rare diseases is certainly one of the areas which the Group intends to expand, in addition to those (Respiratory, Cardiovascular, Musculoskeletal, CNS and Neonatology) where Chiesi has been present for many years. This business strategy is consistent with the Chiesi Group approach, in light of the success it has had with the treatment of rare diseases such as RDS.

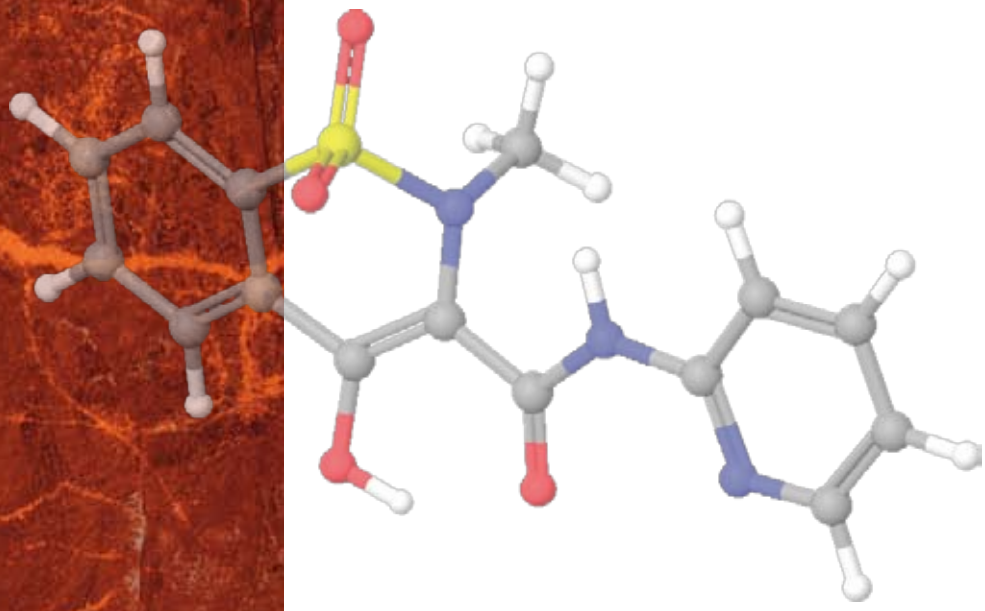
The Chiesi Group has therefore made a series of contacts with companies actively carrying out research and marketing of special care products, which it hopes will lead to commercial agreements in 2009. The Group also plans to extend its activities to countries where it has not had a direct presence, by means of targeted acquisitions of products and/or companies. Furthermore, it is to continue out-licensing its own products so as to make them available to patients living in countries where the Group has no commercial presence, and/or in countries where co-marketing is common practice.

New agreements are also expected for out-licensing opportunities in 2009.

2008 initiatives

The Group's commercial agreements are mainly aimed at promoting and supporting all opportunities for growth both in terms of geographical and therapeutic areas. Throughout 2008 this strategy produced concrete results with the various new in and out-licensing agreements with existing and new partners.

Social responsibility



38 Added Value Determination and Distribution

39 Environmental indicators

Added Value Determination

Added value analysis

An analysis of the added value generated in 2008 indicates a global growth of 23%, mainly constituted by the increase in sales (+14%) in addition to an increase in other activities, and research and development in particular (pgs. 8-11).

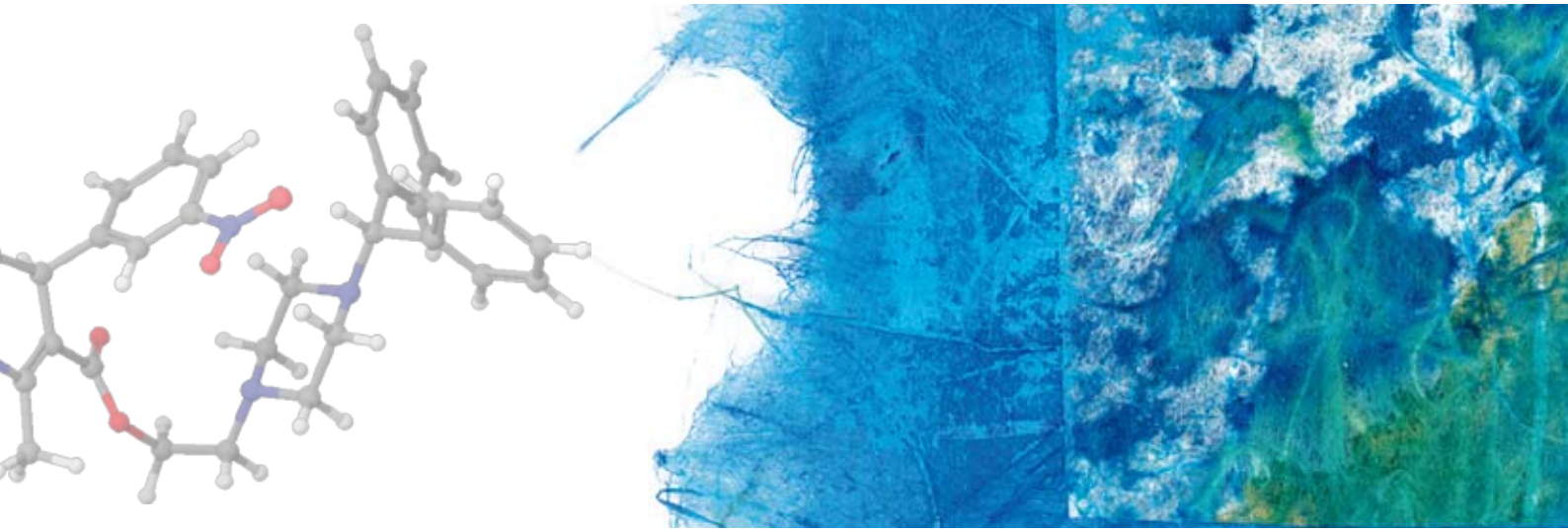
Added value distribution

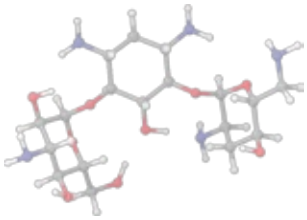
In 2008 the Group has benefited from tax credits and contributions for research activities carried out in France and in Italy, in addition to which there have also been a number of tax breaks.
Staff costs have gone up in line with the increase in employees and have benefited from a reduction in contributions in some countries (France and Italy in particular). Investment in training has also increased significantly because of meetings and refresher courses for the commercial networks.
Investment made in Research and Development has also benefited from an increase of 17.1% compared to the previous year, which has contributed to greater knowledge and the development of future products.
The increased company profit will help support new initiatives and further investment.

Added Value Distribution (Values in K Eur/000)	2008	2007
HUMAN RESOURCES RETURN	213,899	174,809
› Wages & salaries, leaving and severance indemnities, other personnel costs	169,480	137,489
› Social Security Contribution	36,475	34,351
› Training	7,944	2,969
PUBLIC ADMINISTRATI ON RETURN	40,796	34,667
› Income taxes	34,046	29,415
› Other taxes	7,681	5,604
› Public grants for operating expenses	(931)	(352)
COMPANY RETURN (net income)	54,782	41,788
GROUP ADDED VALUE	309,477	251,264

Environmental indicators

In light of an increasing awareness of environmental issues, we have been committed to developing and implementing projects aimed at reducing the impact of our activities on the environment for some time now.
In 2008 the process of completely replacing CFC inhalers with more innovative HFA equivalents has continued.
Despite greater production compared to 2007, a tendency to contain consumption of primary energy sources has also continued in 2008.
A plant is to be created as part of new energy-saving initiatives to produce hot water by means of recovering heat from flue gases along with an internal communication programme to circulate information on simple ways to respect the environment at work.
The French plant has also made progress in this area by replacing a once-through cooling plant with one based on recirculation, introducing a system for recycling printer cartridges, installing a heat pump and modifying the electric lighting system in order to save energy.





Glossary

Beclomethasone dipropionate (BDP): synthesis glucocorticoid steroid, with a potent anti-inflammatory action. When taken as an inhalant, this drug reaches the lungs directly where it exerts its effect. Its low level of absorption in the rest of the body ensures negligible systemic side effects.

Chronic Obstructive Pulmonary Disease (COPD): term used to indicate two related lung diseases – chronic bronchitis and emphysema. Both diseases are characterised by a chronic and progressive obstruction of the airways making it difficult to breathe in and out.

Cystic fibrosis (CF): chronic hereditary disease targeting the lungs and the digestive system, which currently affects roughly 70,000 people worldwide. A mutated gene and the protein deriving from this cause a thick viscous mucus to be produced that accumulates and renders breathing difficult, making it easier for secretions to build up and consequently promotes the development of dangerous infections. In the digestive system the mucus tends to block ducts in the pancreas and prevents digestive enzymes working in the intestine resulting in malabsorption of food and stunted growth.

Dry Powder Inhaler (DPI): a device to deliver drugs for the treatment or control of respiratory diseases and conditions.

Hydrofluoroalkanes (HFA): innovative propellants used in some inhalers for the management of asthma. They do not damage the ozone layer. A propellant is a gas which facilitates the diffusion of an inhalant drug in the lungs.

Long-acting Beta-agonists (LABA): drugs which act to open up and keep both peripheral and central airways unobstructed by relaxing bronchial smooth muscle. They are often administered with steroids in inhalant form as a long-term bronchodilatory treatment for patients with moderate to severe asthma or other chronic lung diseases.

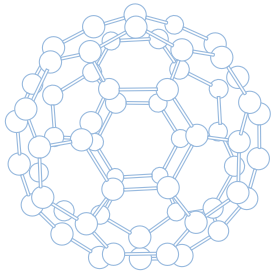
Piroxicam-beta-cyclodextrin (PBC): a successful example of "host-guest" technology, whereby the host, a starch derivative known as beta-cyclodextrin, solubilises the guest, an anti-inflammatory drug known as piroxicam, thus enhancing the pharmacological properties of its active ingredient.

Pressurised metered-dose inhalers (pMDI): A device which ensures that a specific quantity of drug is delivered to the lungs. Widely used by the Chiesi Group for its products, it is commonly used for the treatment of asthma, chronic obstructive Pulmonary Disease (COPD) and other respiratory conditions.

Respiratory distress syndrome (RDS): Disease typically affecting premature neonates caused by insufficient production of endogenous surfactant and immature lungs. The condition may also be due to a genetic problem linked to the production of the proteins associated with the surfactant. RDS affects 1% of neonates and is the main cause of mortality in premature infants.

Unit-dose vials (UDV): non-reusable sterile containers containing a single dose of drug. Pharmaceutical products packaged in vial or mono-dose bottles are easily recognisable and simple to use.

Ulcerative colitis (UC): inflammatory bowel disease (IBD) which causes lesions known as ulcers to develop in the lining of the colon and rectum. Ulcers form where the inflammatory process destroys the cells which normally line the colon, causing in bleeding and pus. The inflammation may also result in frequent bowel movements, and therefore diarrhoea.

Spacer: is a type of add-on device used by asthmatics to increase the effectiveness of a metered-dose inhaler.

Manufacturing Execution Systems (MES): IT solutions that support the primary production processes in a production plant. These applications close the gap between ERP systems and production equipment control or SCADA (Supervisory Control And Data Acquisition) applications. Nowadays, MES applications have become essential to support both real-time production control as well as data collection and reporting ("manufacturing intelligence"), required to improve production performance.