

# Kedrion Group - Annual Report 2010





## Letter from the CEO Paolo Marcucci

We, the Kedrion Group, obtained good results in 2010: we maintained our leadership on the Italian market and we increased exports up to 40% of net sales.

We finished the financial year with 247.8 million Euro in net sales (+3.5% with respect to 2009) and with a profit margin of 27.3%.

The adjusted EBITDA was 67.8 million Euro (68.6 in 2009) and the EBIT was 47.2 (50.5 in 2009).

In a highly competitive global scenario, we continued our strategy of growth in international markets, with special attention towards increasing volumes.

At the same time, our successes on the domestic market and with the National Healthcare Service have been confirmed through continuation of the strategic plan for national self-sufficiency of plasma-derived medicines.

Being well aware that we are operating in a sector that is growing on a worldwide level, we have initiated and been working on innovative strategies for products and processes.

With the objective of maximizing synergy between the Group's various sites, we have, for example, been intensely busy in the transfer of technology and know-how to the Gödöllő facility in Hungary, where we have expanded the main production building and installed the new line for expanding production.

Our future objectives are to maintain our leadership on the Italian market, penetrate deeper into foreign markets, strengthen our sources for the procurement of plasma, increase our overall production capacity and to continue with the plans for constant innovation that characterize our Group.

**Paolo Marcucci**  
**President and CEO of Kedrion S.p.A.**



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## VISION

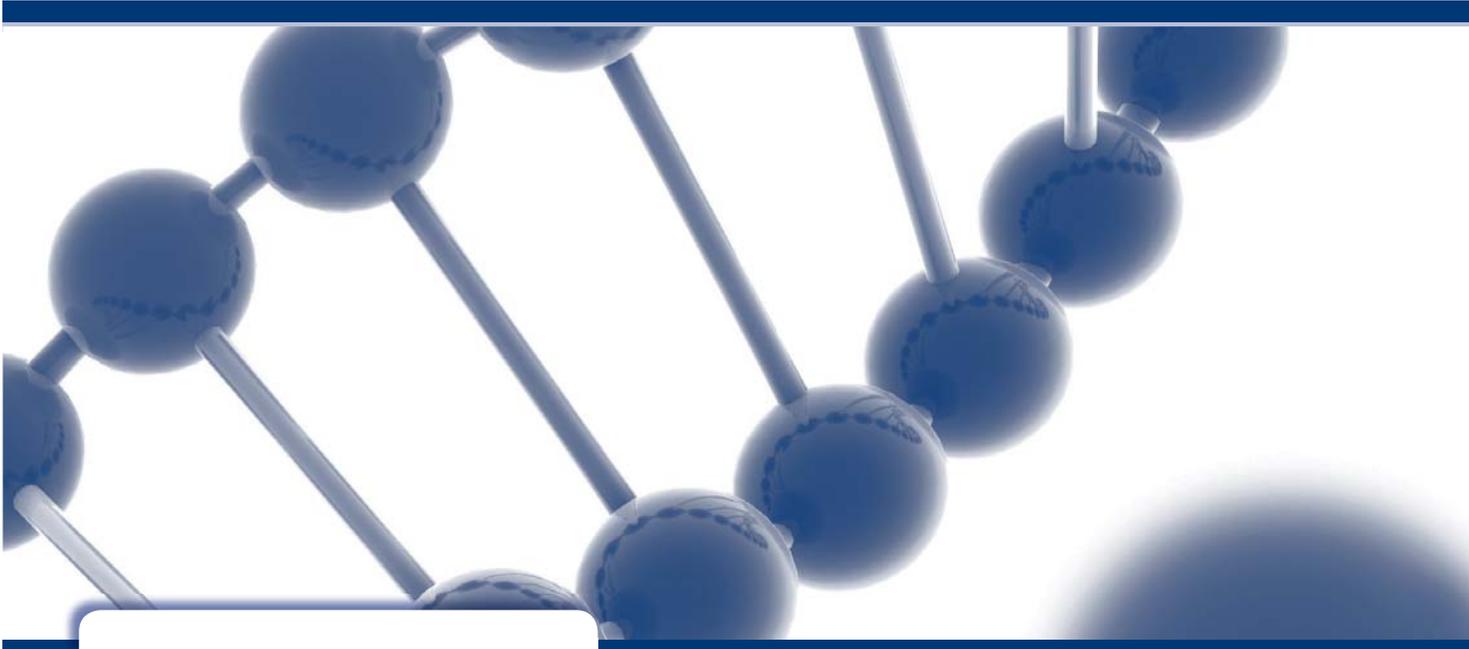
*Everyone has the right to life, liberty and security of person\**

Sometimes, natural, accidental or social causes obstruct the natural right to life, liberty and personal security.

Because of the special nature of its products, Kedrion supports people, communities and institutions in reducing or removing those obstacles that prevent people enjoying such rights.

Kedrion helps turn the natural rights (life, liberty, security) into the social right to live in the best possible conditions. For this reason, it collects and converts, makes active and usable that vital energy that is generated and regenerated, preserved and carried through blood; so that it can be transferred from one human being to the next, and anyone can enjoy one's fundamental rights.

\*Universal Declaration of Human Rights, art. 3.



## MISSION

Kedrion produces and distributes human plasma-derived medicinal products, which can improve people's quality of life.

It works to maintain its excellent industry standards and aspires to ongoing improvement, in order to retain its leading position in Italy and increase its share of the international market.

It works to strengthen its role as the accredited partner of the medical, scientific and institutional communities.

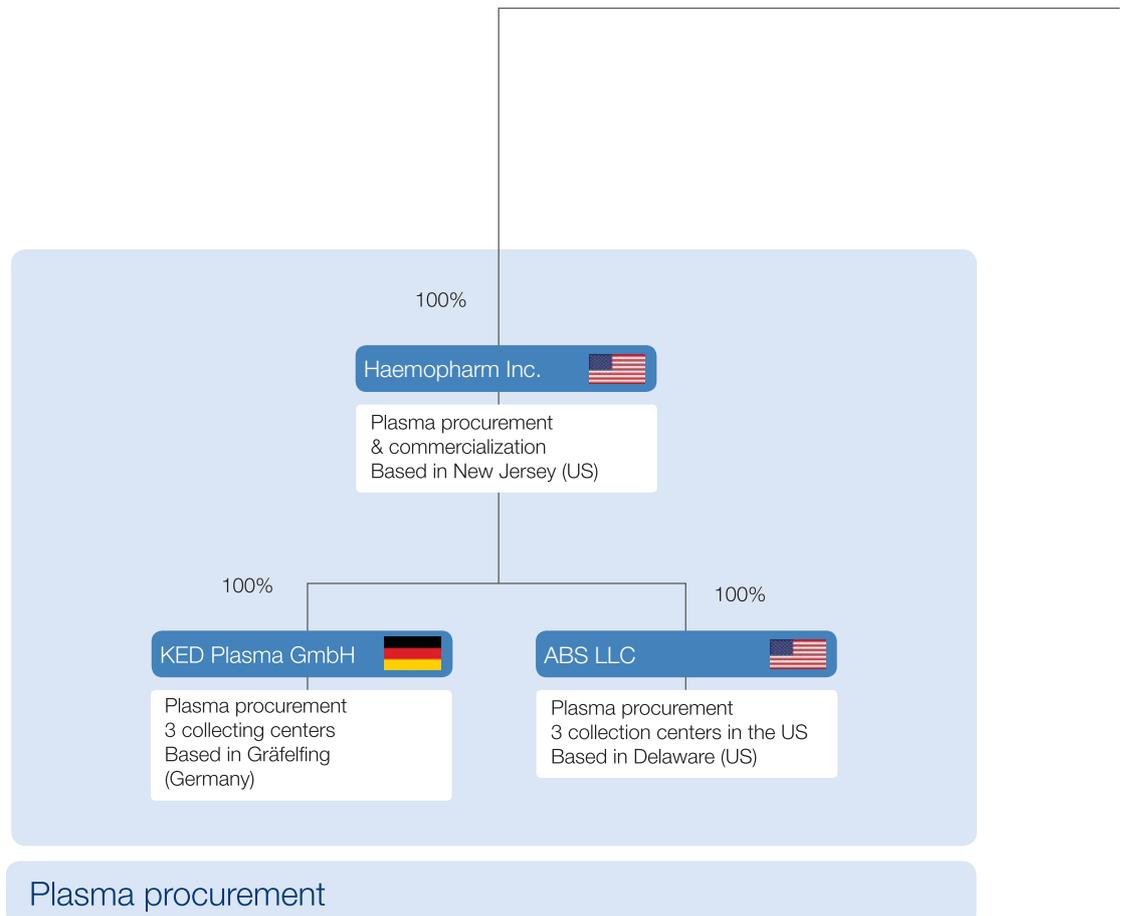
Its ambition is to strengthen its worldwide role as a strategic partner of the national health systems of those countries which aim at becoming self-sufficient in the availability of plasma-derived products.

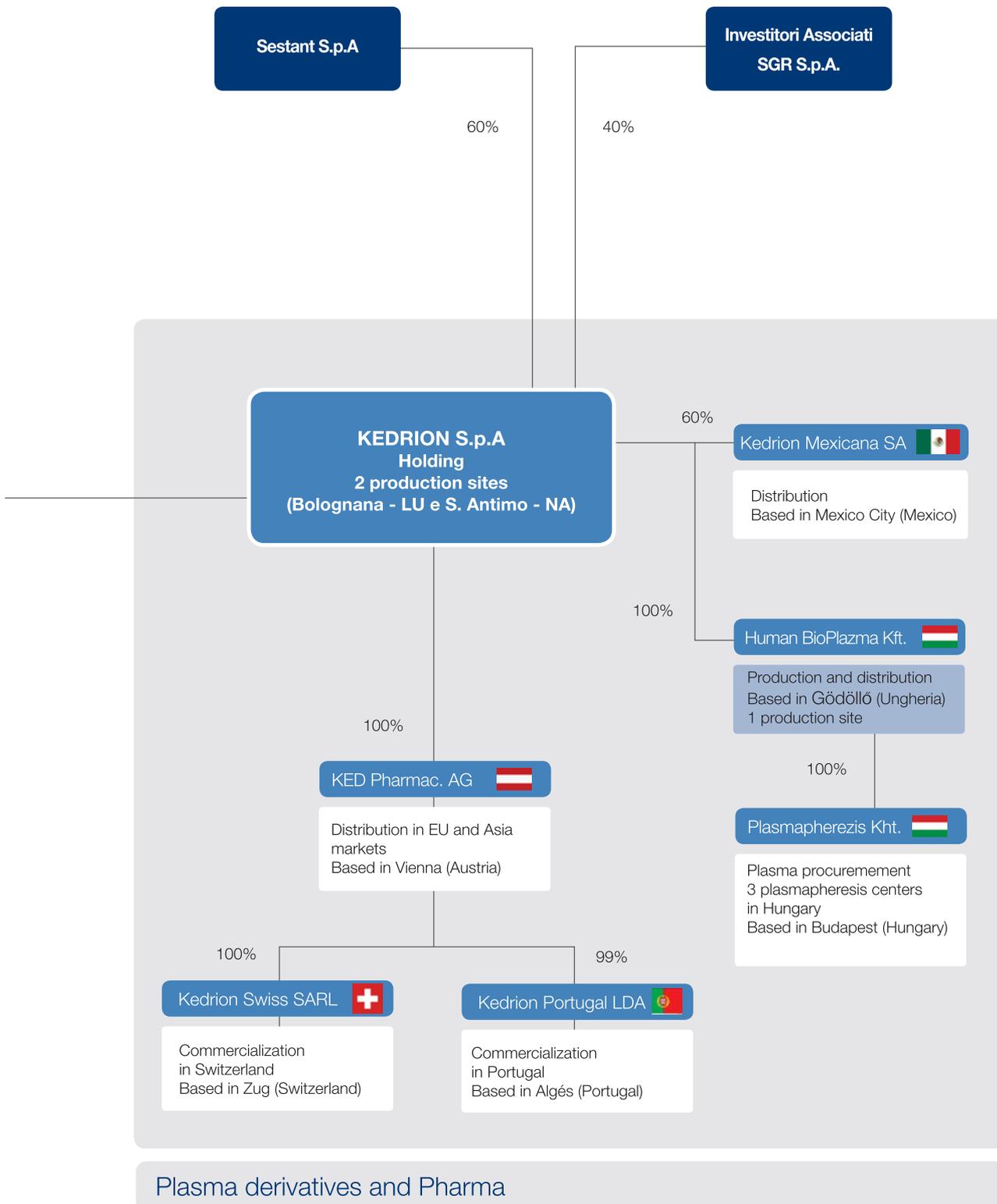
Kedrion produces wealth for its investors, for its employees, for the local community, and does it consistently with its own vision and with its values, which are responsibility, transparency, confidence in and respect for people.

## Structure and Profile of the Group

From a perspective of further strengthening its structure on an international level, the Kedrion Group added a new company in 2010, Kedrion Portugal, with head office in Algés, which will be responsible for distribution.

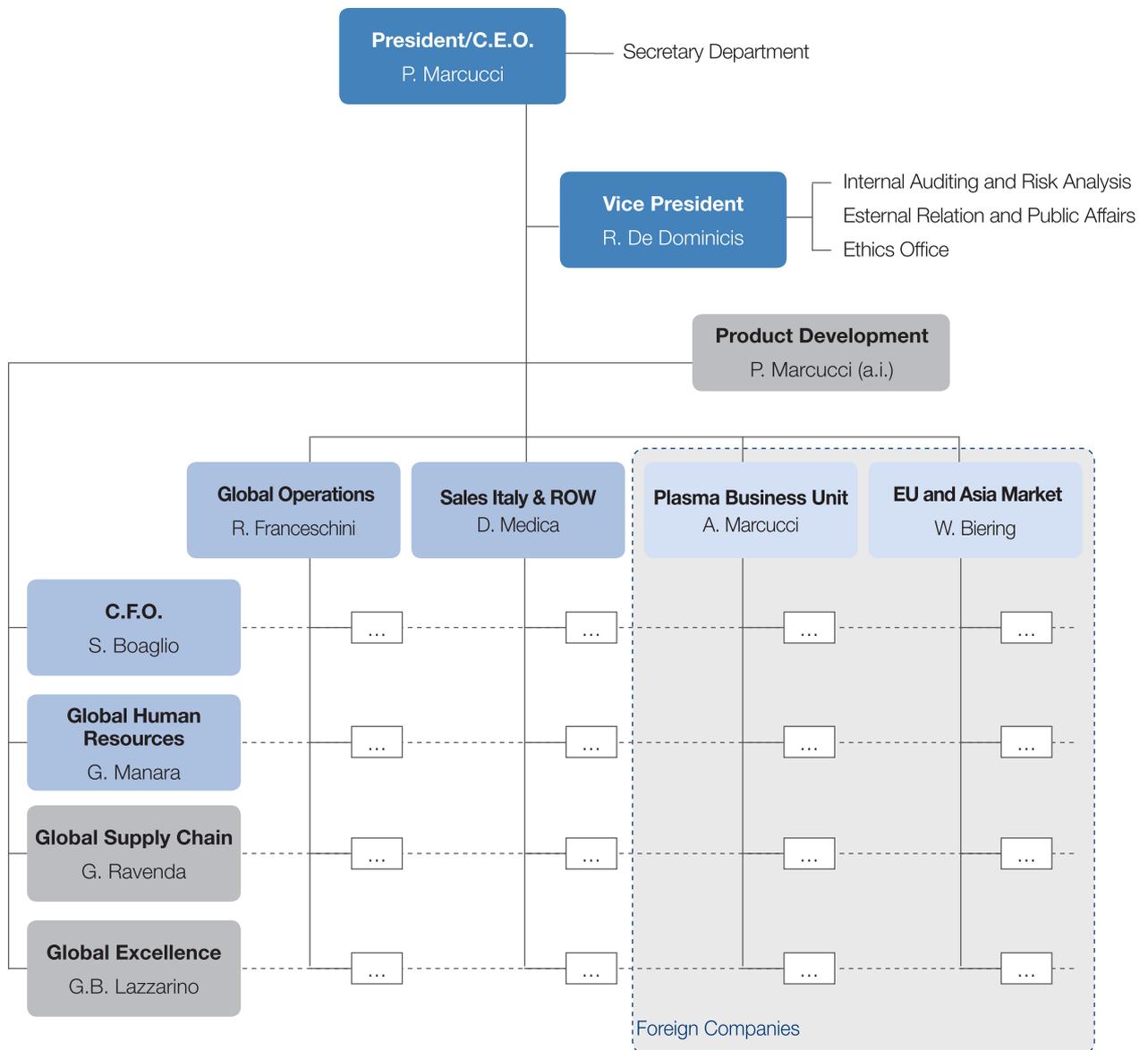
With Kedrion Portugal and the subsidiaries of Haemopharm, Ked Pharmaceuticals and Human Bioplazma, there are now a total of 8 companies that are connected by the Kedrion Group to which we can add the Joint Venture in Mexico (Kedrion Mexicana) in which Kedrion holds 60%.





# Organization Chart

The organization structure that Kedrion has had since 2008 has remained essentially unchanged with regard to the Key Functions. In 2010 there was a reinforcement of intermediate level positions.



## Top Management

### **Paolo Marcucci**

#### **President and CEO**

Degreed in Business Economics from the Università degli Studi in Pisa, he obtained his Masters in Business Administration in 2006 from the Grand Ecole Edhec di Lille in Nice, France. He has been the Group's Chief Executive Officer since 2006. He is also a member of the Global Board of Directors for PPTA, a member of the Board of Directors for the Banca del Monte di Lucca and is part of the Confindustria Council of Lucca as well as Farmindustria (National Association of the Pharmaceutical Industry).

### **Rodolfo De Dominicis**

#### **Vice President**

He has a degree in Aeronautical Engineering from the Università di Napoli, and a Masters in A.P.R. from the University of California (Berkeley). He has held numerous academic positions at different universities, both in Italy and abroad, is the author of many publications and collaborates with numerous scientific magazines. He joined the company in 2001 and is currently in charge of Internal Auditing and Risk Analysis, Internal Communication and Foreign Relations, and the Ethics Office.

### **Andrea Marcucci**

#### **Director of the Plasma Business Unit**

Degreed in Political Science from the Università di Bologna, he is currently a senator in the Italian parliament. As CEO of Kedrion in 2001, his primary responsibility was to coordinate the company's expansion abroad as well as the export activities. He was a parliamentarian in the Italian Lower House of Parliament from 1992 to 1994. On May 17, 2006 he gave up his position as C.E.O. of Kedrion because of incompatibility with the job, in the mean time becoming the Undersecretary of Cultural Heritage for the Italian government, a position which he held until February 2008. In October 2008 he became the Director of the Plasma Business Unit and C.E.O. of the Hemopharm Inc. subsidiary with registered office in USA.

### **Rodolfo Franceschini**

#### **Director of Global Operations Business Unit**

Degreed in Chemistry, he joined Kedrion in 2000. He has held the position of Director of the Global Operations BU since October 2008. He had various titles from 2000 to 2007, including Technical Director and Director of the Bolognana Facility, Technical Director of Kedrion's Castelvechio Pascoli Facility, Corporate Technical Director and Industrial Director of Kedrion. He worked as Technical Director and Operations Manager for Nycomed Amersham Sorin S.r.l. from 1999 to 2000. From 1993 to 1998 Franceschini held various positions in the Sorin Group's radiopharmaceuticals sector, including Production Director, Director of Research and Development, Production Director, Technical Director of the radiopharmaceuticals unit, Technical Director and Operations Manager. From 1993 to 1995 he was an Adjunct Professor for the Radiopharmaceuticals Course at the Università di Torino's Nuclear Medicine School of Specialization.

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## **Wolfgang Biering**

### **Direttore Business of the EU and Asia Business Unit**

#### **General Manager Ked Pharmaceuticals and Human BioPlazma**

He has a degree in Chemistry from the University of Saarbruecken, and received a Masters in Business Administration in 1976. He began his professional career with Rhone Poulenc and from 1979 to 1998 occupied various positions with Immuno AG of Vienna, where he was Director of Sales and Marketing, CEO, President and a member of the executive board. From 1998 to 2002 he worked for Octapharma AG where he was General Manager, Production Manager, Regulatory Affairs Manager and Director of International Sales. Since 2002 he has been CEO of EPBS GmbH and Puls and President of Ked Pharmaceuticals. Since January 1, 2008 he has been General Manager of Human BioPlazma and has been the Director of the EU and Asia BU since October 2008.

## **Danilo Medica**

### **Director of Italy and RoW Business Unit**

47 years old from Liguria, degreed in Biological Sciences from the Università degli Studi in Genoa, Danilo Medica is the Director of the Italian and Rest of World markets for Kedrion S.p.A.

Medica has a professional background obtained in the marketing and sales of products and services in the healthcare sector. He began working in 1991 for Medical Systems S.p.A., subsidiary of the American Diagnostic Product Corporation (D.P.C.) leader in immunometric diagnostics, where he eventually held the position of Group Product Manager. In 1999 he started work to develop the Marketing Department for the newly established Fresenius Kabi Italia, division of the German multinational Fresenius AG. Within this new company, Medica assumed the role of Director of the Critical Care Business Unit and then Sales and Marketing Director. In 2006 he guided Fresenius Kabi Italia's modernization process with the goal of focusing their activities on generic medicines. He was also entrusted to direct the Infusion Technology division, previously called Fresenius Vial, in order to reorganize their sales network.

## **Simone Boaglio**

### **Chief Financial Officer**

Degreed in Business Economics from the Università degli Studi in Florence, he began his career with Kedrion in 2001 as Finance and Strategic Control Manager. From 2003 to 2007 he was the Financial Controller and in March 2007 became the company's Chief Financial Officer. He previously worked as a consultant at Deloitte & Touche, Centrosviluppo S.r.l. and at Ceccarelli PIMS & Associati S.r.l.

**Giuseppe Ravenda****Global Supply Chain Director**

With a degree in Business Economics from the “L. Bocconi” University of Milan, he joined Kedrion in 2002. He began his professional career in 1990 as a Logistics Consultant for I.O.A. S. r. l.. From 1992 to 1998 he was employed at Bolton Alimentari Italia S.p.A. and held the position of Senior Buyer. He worked as Purchasing Manager for Sicor S.p.A. from 1998 to 1999. He held this same role at Knoll Ravizza Farmaceutici S.p.A., BASF AG Healthcare division, from 1999 to 2001 and then became Supply Chain Manager for Abbott Laboratories S.p.A. in 2001.

**Giacomo Manara****Global Director of Human Resources**

Degreed in Literature and Philosophy from the Università Cattolica in Milan, with an MBA from the School of Corporate Administration at the Università Bocconi in Milan, he began working in 1981 initially as a Junior then as a Specialist and finally as Manager of various activities within the Human Resources Departments of important multinational companies (Pirelli, Novartis, Edison).

From 1989 to 2005 he works as Director of Human Resources and Organization at certain Italian and multinational companies (RoloBanca, Periodici San Paolo, Bayer, H3G, Monte Paschi Asset Management). He then worked for approximately 5 years as a Consultant for the Management and Development of Human Resources in strategic projects for departmental redesign and development for important companies, and simultaneously taught this same subject at the Università Cattolica di Milano's Business School and for some Masters courses.

He has been the Global Director of Human Resources for the Kedrion Group since February 2010.

**Gian Battista Lazzarino****Global Excellence Director**

Degreed in Business Administration from the Wharton School of Business - Pennsylvania University -, he obtained his professional experience in strategy consulting and in industry in both North American and Europe. He has held various industrial positions: sales manager in the chemical sector, export manager in the widely-consumed foodstuffs sector, quality control advisor in the automotive industry; in the Transport Logistics sector he held the titles of Purchasing Director, Director of Investments, Brand Manager, Project Manager AV, Operations Director. As a consultant he obtained specific experience in the areas of operations, strategic sourcing, business development, strategic alliances and management of large scale change programs in various industrial sectors, such as Oil&Gas, Pharmaceutical, Consumer Goods, Industrial products, Transportation.

# MILESTONES

## ► 2010

### January 2010

The Region of Tuscany offered Kedrion a contribution for the research and development project in the biosurgery field entitled "MBPA - Materiali nanostrutturati a base di fibrina e fattori piastrinici in grado

di promuovere l'angiogenesi" (MBPA - Fibrin and platelet factor based nano-materials able to promote angiogenesis). The Kedrion Group's Italian facilities, Bolognana (LU) and Sant'Antimo (NA),

substantiated the growth trend in terms of production volumes, affirming the success of the continuous improvement policy for the manufacturing sites.

### February 2010

Trackwise became operational, which is the Quality Assurance Process Management system that manages the quality system in a systematic manner,

computerizing its processes and guaranteeing the traceability, consistency and usability of the data.

### March 2010

Double scale production of the medicinal product Antithrombin III began in the Bolognana facility.

With regard to the upgrading and expansion of the Kedrion Group's Hungarian plant, an appropriation agreement was signed with the Hungarian government, through the government

agency ITD, which will provide incentives worth 1.2 million Euro and future tax credits of up to 6.5 million Euro for the period of 2009-2011.

### April 2010

Kedrion obtained two new patents: "New industrial scale purification process of gamma-globulins from human plasma for industrial use" and "Transferrin for the treatment of autoimmune diseases".

### May 2010

Ceremony at the Bolognana facility for the delivery of the QSEAL certificate with the presence of the president of the PPTA, Plasma Protein Therapeutic Association, and a tour of the new BioSC laboratories.

Kedrion's participation in the study conducted by the National Institute for Biological Standards and Control (NIBSC) relating to the defining of the second international standard

for determining von Willebrand factor.



**July 2010**

The FDA (Food and Drug Administration) office for the development of Orphan Drugs recognized Kedrion's Human Plasminogen as an Orphan Drug in the

form of eye drops used for the treatment of ligneous conjunctivitis.

**September 2010**

The "Journal of Pharmaceutical and Biomedical Analysis" published the article entitled "Characterization of factor VIII pharmaceutical preparations by means

of MudPIT proteomic approach" in which Kedrion researchers collaborated.

**October 2010**

The new company Kedrion Portugal – Distribuição de Produtos Farmac uticos Lda, with head office in Alges (Lisbon, Portugal) and responsible for the

distribution of Kedrion products in Portugal, was presented during the EHC Conference (European Hemophilia Consortium).

**December 2010**

The Biological Safety Centre (BioSC) obtained an extension of its previous GLP certification and is therefore also authorised to perform Immunogenicity

Studies using the immunonephelometric method.

The work performed entirely by Kedrion researchers entitled "A simple method

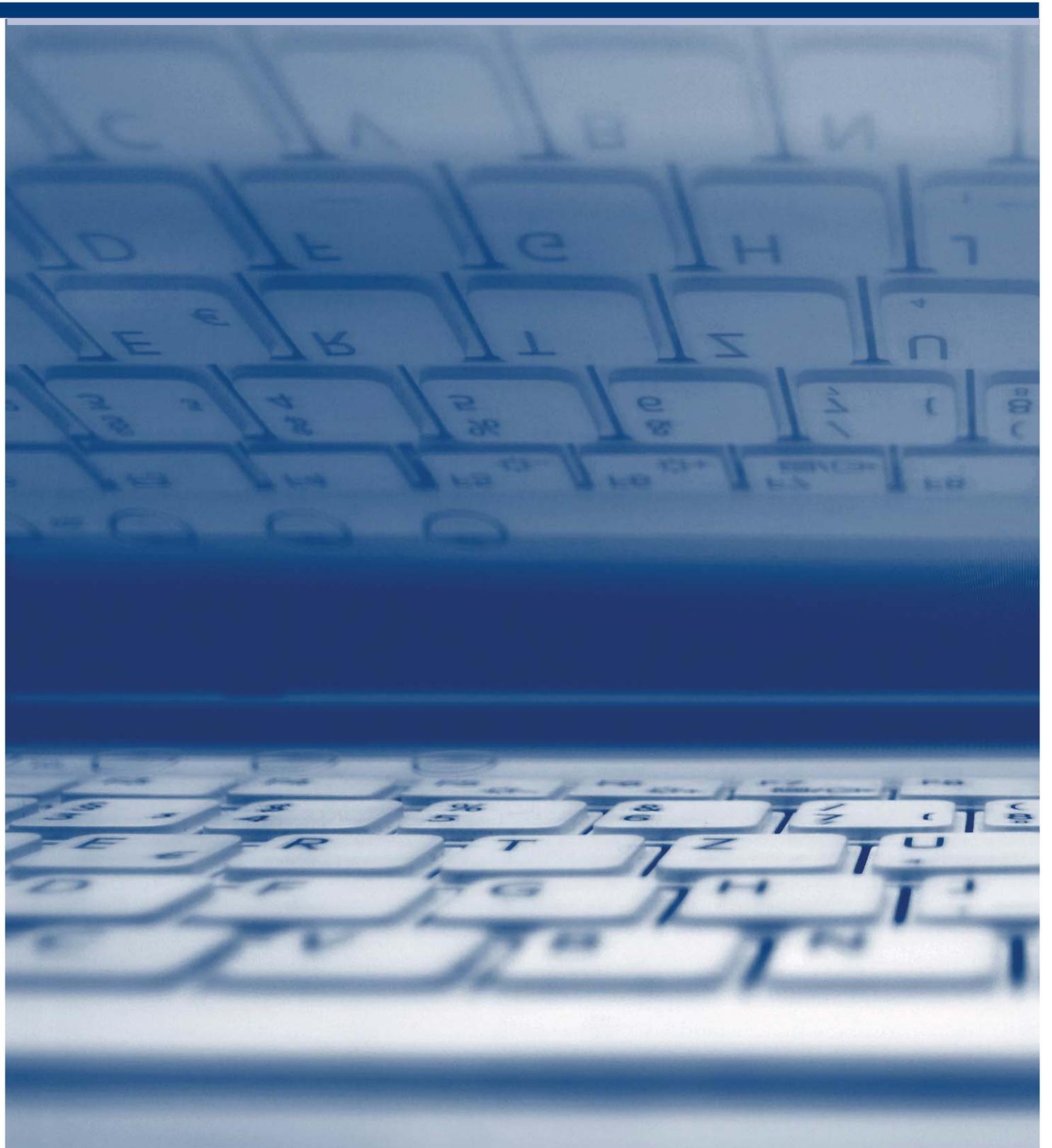
for large-scale purification of plasma-derived apo-transferrin" was published in "Biotechnology and Applied Biochemistry".

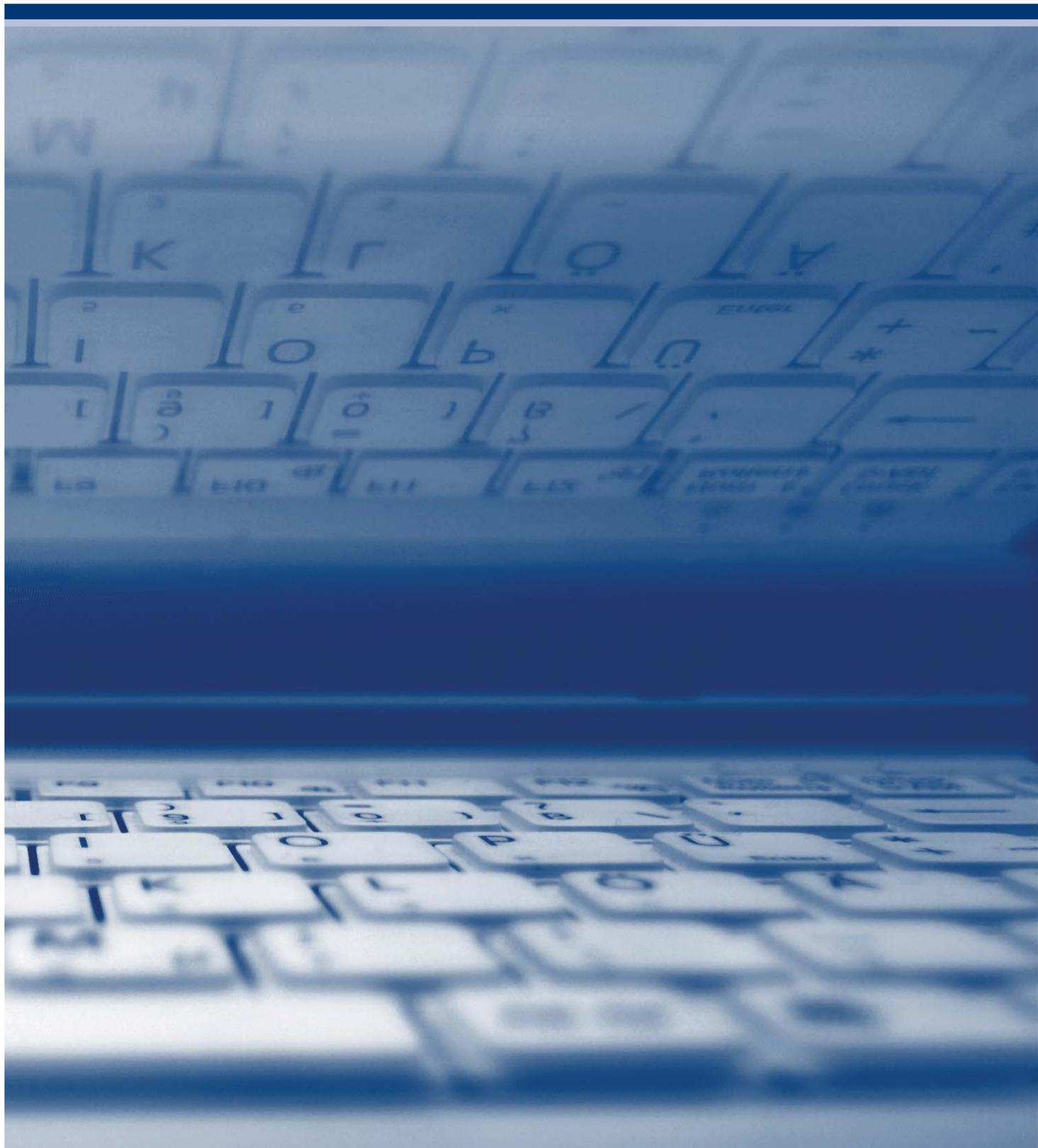
**▶ 2011**

**January 2011**

"Transfusion" accepts the publication of the study "Contribution to safety of immunoglobulin and albumin from virus partitioning and inactivation by cold

ethanol fractionation: a data collection from Plasma Protein Therapeutics Association member companies" in which Kedrion researchers participated.

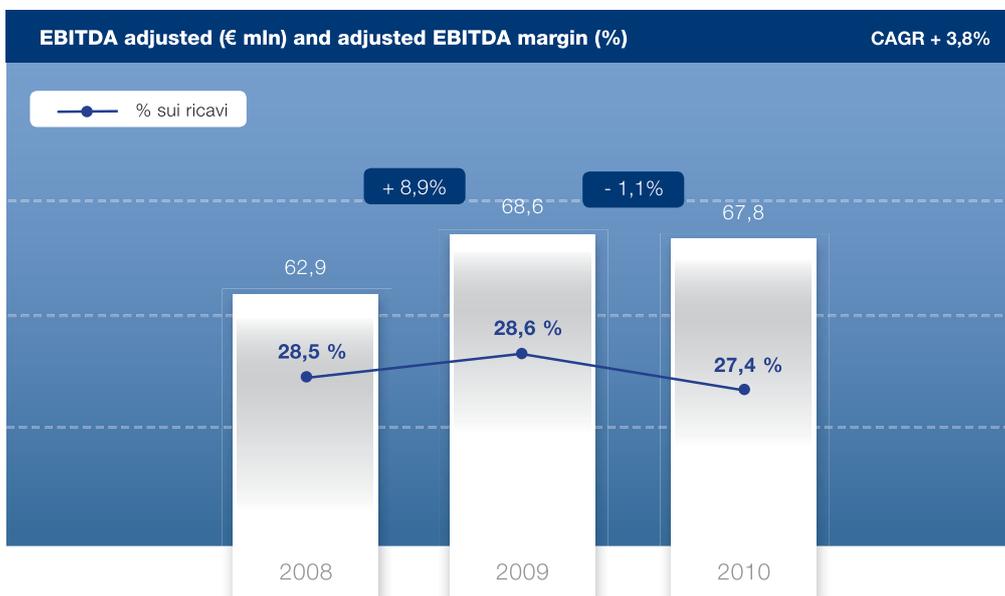
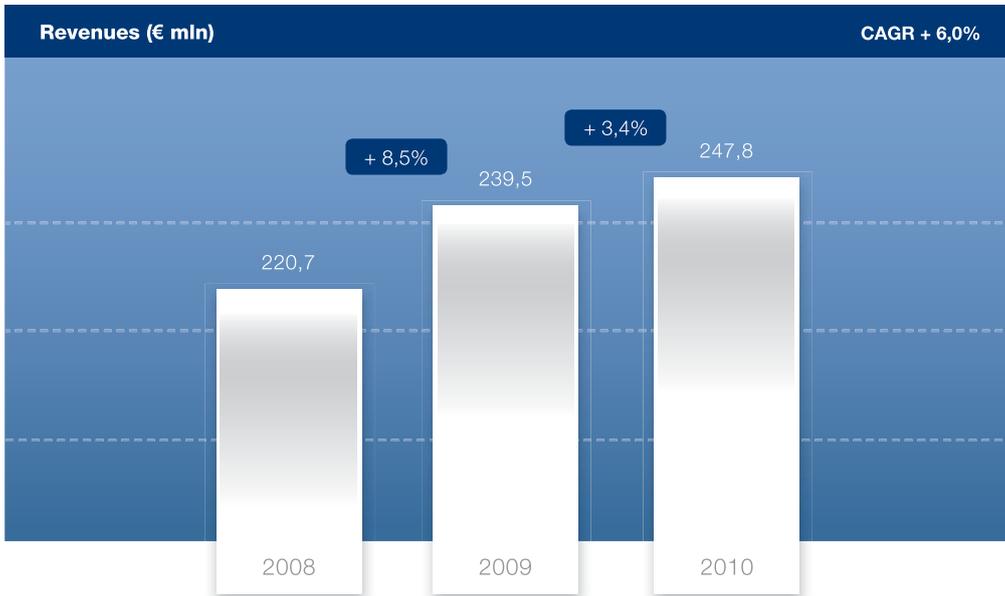




## Annual Report 2010 - Key Data\* 2008-2010

\* Data reported in this section is provided in conformance with the IAS international accounting standards.

## Financial Indicators



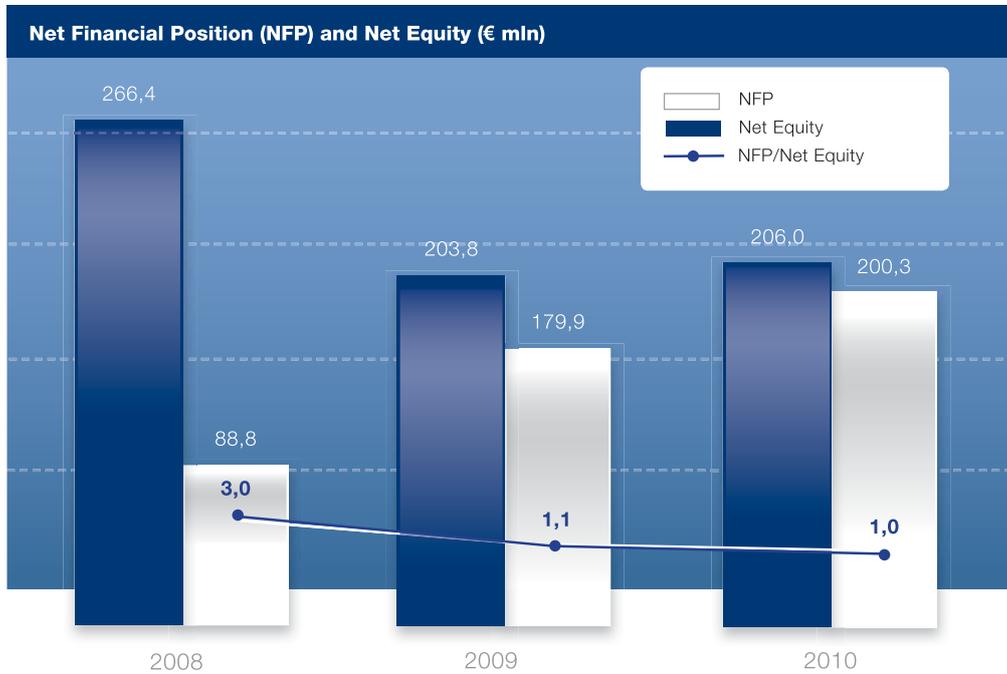


During the fiscal year 2010, the Kedrion Group continued its strategy of growth in international markets, with special attention to the increase in volumes, reaching an export share equal to approximately 40% of overall net sales. This growth, obtained in a highly aggressive competitive scenario, together with maintaining leadership on the Italian market has led to a +3.5% increase in net sales, which reached 247.8 million Euro.

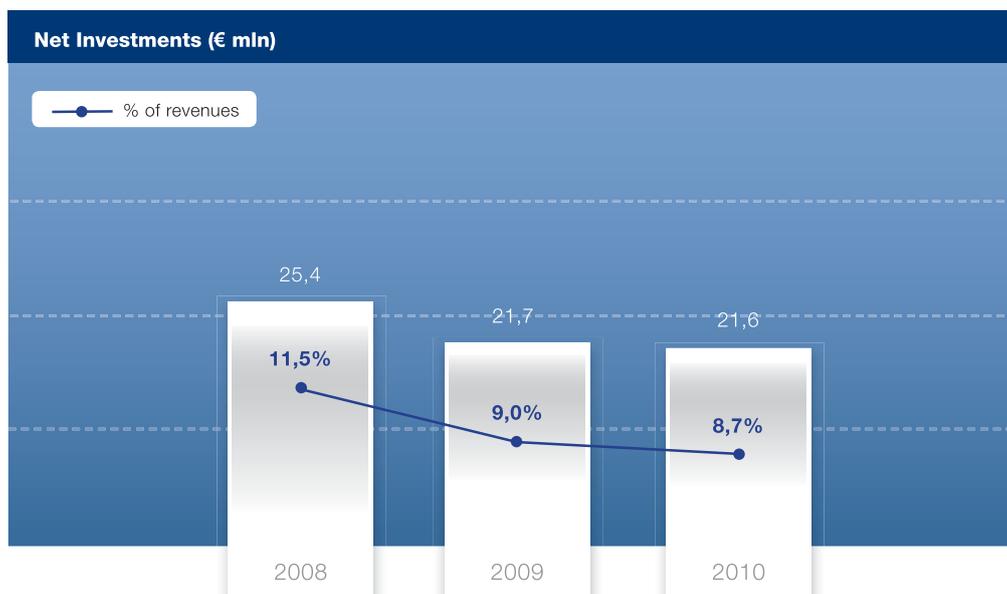
After the second half of 2009, which saw a reduction in the cost of plasma that anticipated a corresponding stress in the sales price by a few months, 2010 was characterized by a substantial stability in price of the raw material and by a decrease in prices in certain markets. These trends generated a slight drop in gross profit (43.7% compared to 45.9% for the previous fiscal year) related to the reduction of the sales prices in some markets where Kedrion faced very aggressive competition and less productivity from the Hungarian plant due to the limited production capacity.

To offset this slight drop in profit margin on a cost of sales level, the Group made constant efforts to improve productivity in all the other operating areas, which allowed an adjusted EBITDA margin of 27.4% to be reached, equalling 67.8 million Euro.

The Operating Result (EBIT) reached 47.2 million Euro (19.1% of net sales) while the net profit decreased to 17.9 million Euro due to higher financial charges and the lesser amount of tax concessions compared to the previous fiscal year.

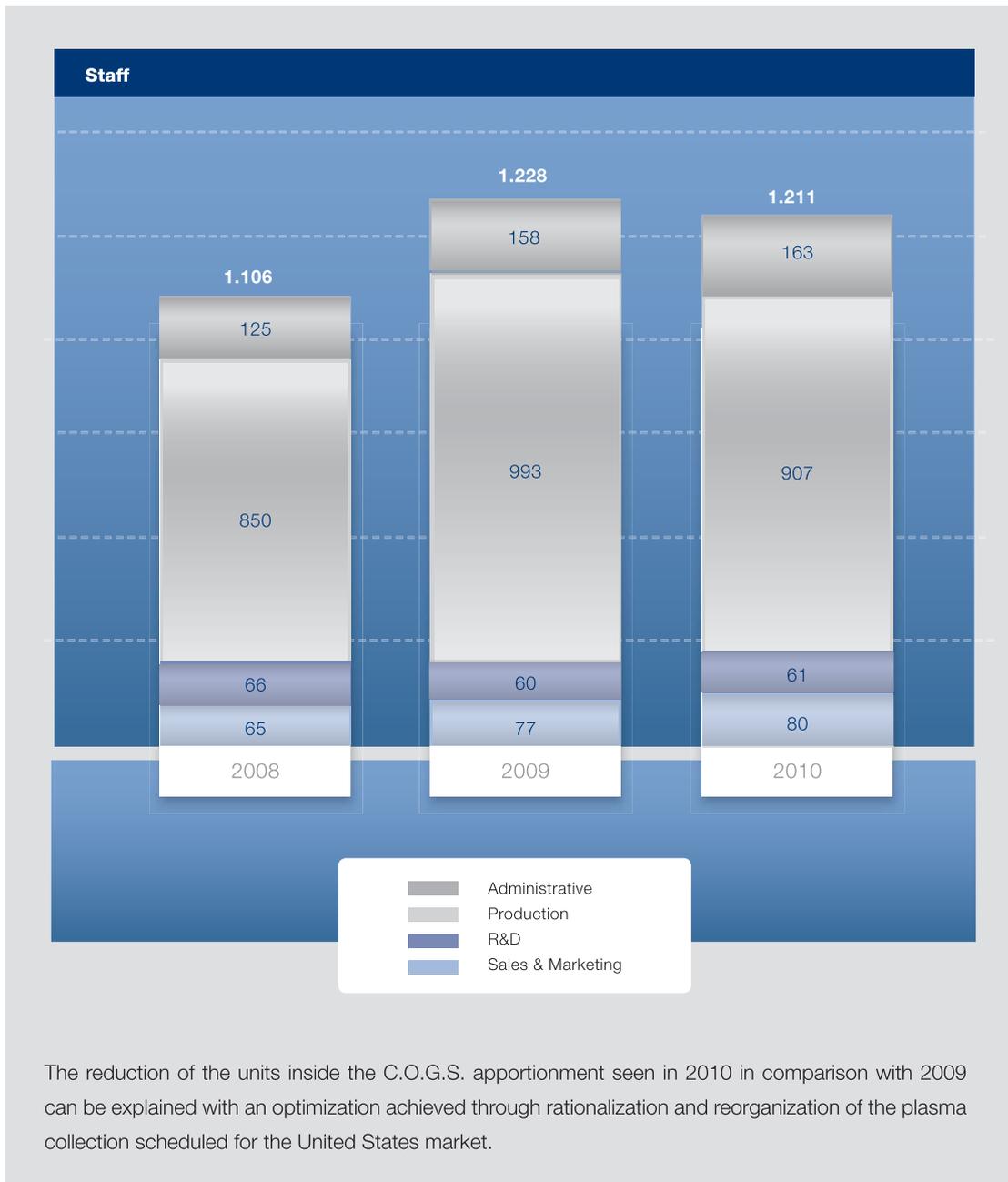


The slight increase in the amount of working net capital and the good operating trend allowed the Net Financial Position to be kept under control, which recorded substantial stability by increasing 2.2 million Euro, reaching 206.0 million Euro with an increase in the current financial debt with respect to the previous fiscal year. The debt-equity ratio of 1.03 has improved compared to the previous fiscal year.





With regard to investments, the increased level of investment over these past few years has allowed the production plants to constantly undergo technological evolution in order to achieve excellence and to regularly make them more efficient. This guarantees safety standards that are higher than those required by the current regulations at all levels of production as well as optimum use. The expansion of the production capacity in the Hungarian plant continued in 2010, where its fractionation capacity will be more than doubled. All this has led to a significant overall investment level equalling 21.6 million Euro.



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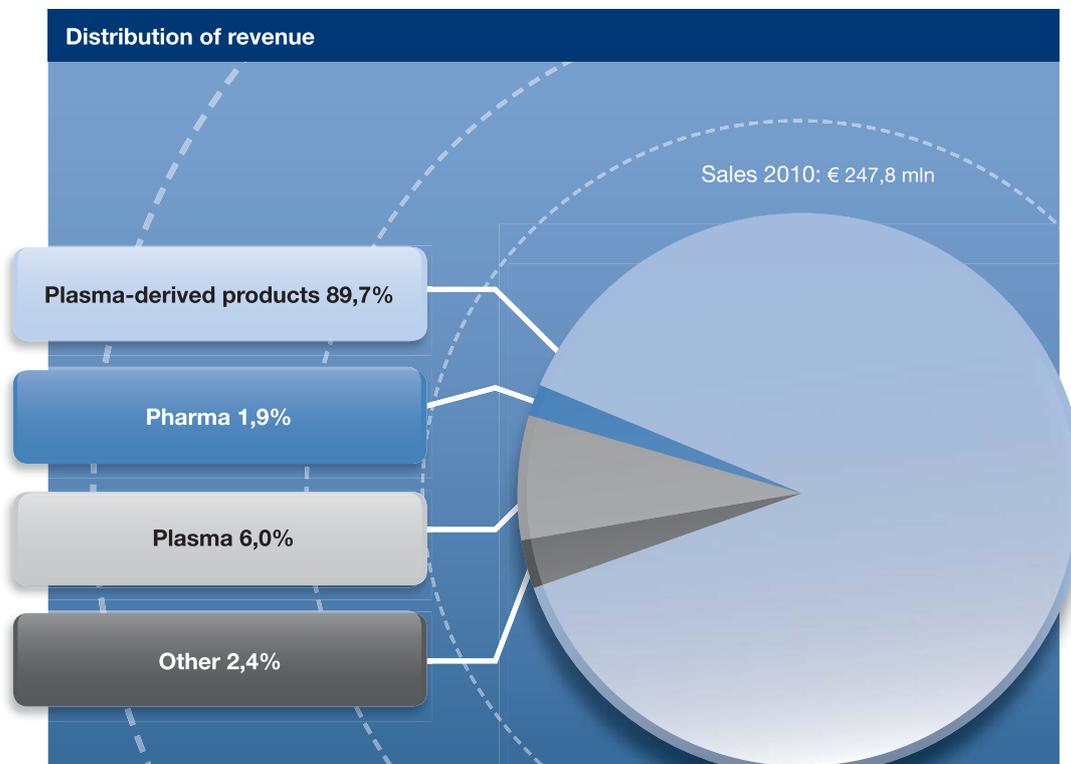
scheduling  
immunodeficiencies  
standardization  
removal  
rare diseases  
safety  
Biophar  
plasma  
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resourcefulness  
commitment  
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team work  
attention  
inactivation  
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ership  
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liability  
planning  
efficacy  
cross-disciplinary  
synergy  
constructiveness  
growth

# pharmaceutical

critical care  
quality  
transparency  
service  
change  
quality of life  
donation  
haemophilia  
design  
innovation

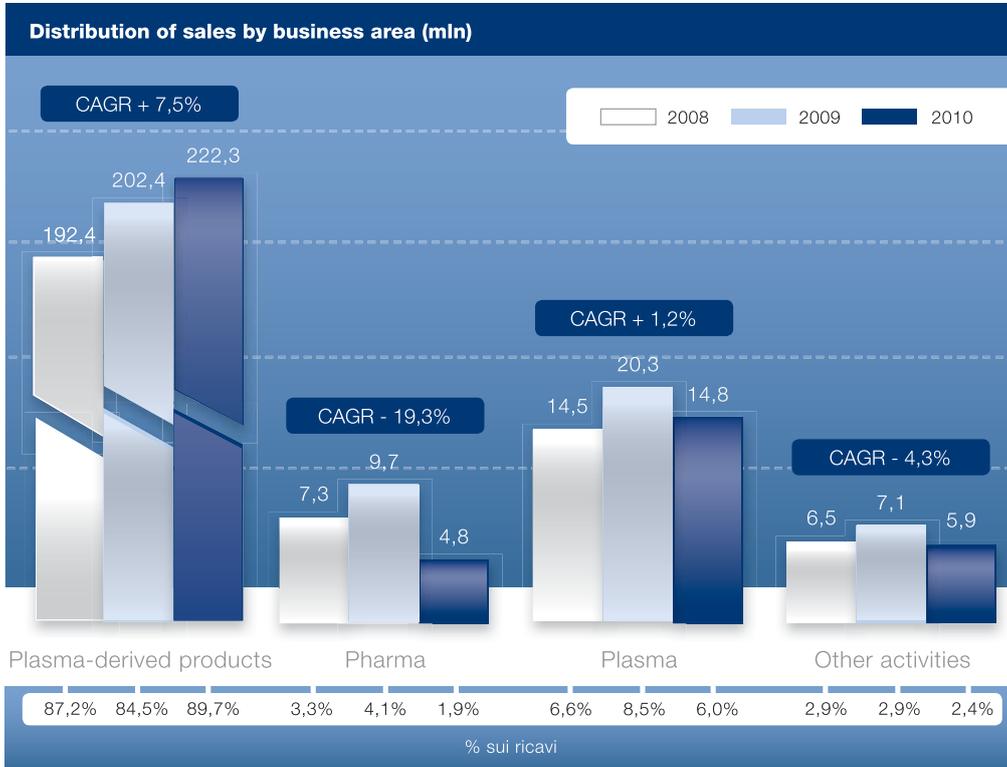


The activities of the Kedrion Group can be divided into four different segments, which pertain to:

- Production and marketing of plasma-derived products obtained from the plasma-fractionation process
- The commercialisation of flu vaccines and synthetic pharmaceutical products (Pharma)
- Collection and sale of plasma (Plasma)
- Other activities, especially technology transfer

### **PLASMA-DERIVED PRODUCTS**

The revenues from the production and sale of plasma-derived products as of 31 December 2010 were 222,264 thousand Euro (89.7% of total revenue) and have increased 9.8% with respect to the corresponding period for the year 2009. This increase is the result of the continued positive trend of the national and international plasma-derived products market: for standard immunoglobulin, albumin and factor VIII the growth came from an increase in volumes sold against slight price dilutions caused by a very aggressive competitive scenario.



**PHARMA**

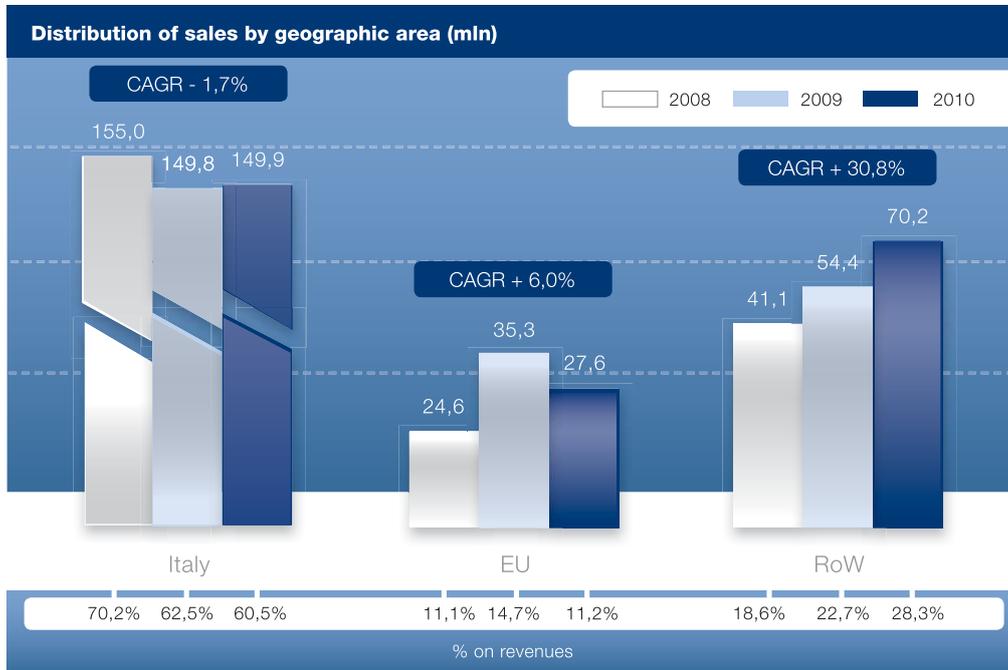
As of 31 December 2010 the revenues from this segment equalled 4,760 thousand Euro (equal to 1.9% of total revenue) and saw a decrease of 51% with respect to 2009, which was a year that saw a peak in sales due to the massive H1N1 virus prevention campaign which increased the request for flu vaccine.

**PLASMA**

The revenues from the collection and sale of plasma as of 31 December 2010 were 14,849 thousand Euro compared to 20,327 thousand Euro for 2009, a year in which a collaboration relationship ended with an operator in the sector to which Kedrion sold plasma in order to purchase successive intermediates. Apart from this non-recurring relationship, this segment, managed mainly by the Plasma Business Unit to which Haemopharm, Advanced Bioservices and Ked Plasma belong, has therefore maintained steady sales with third party operators predominantly in the United States. Most of the plasma collected is kept within the group, the most profitable segment of the plasma-derived products.

**OTHER ACTIVITIES**

The revenues of this segment, as of 31 December 2010, were equal to 5,907 thousand Euro with a decrease of 16.3% with respect to the corresponding period from the previous fiscal year. This is mainly due to the reduction of the production capacity in the Godollo facility (Hungary) caused by the expansion works for the production plant, which also affected the contract manufacturing by Human Bioplazma for an operator in the sector.



### ITALY

As of 31 December 2010, Italy remained the main reference market, with net sales equal to 149,911 thousand Euro, corresponding to 60.5% of the overall revenue. With respect to the previous fiscal year, the revenues in Italy remained stable mainly due to the higher volumes of products that were made available for export in accordance with the company's internationalization strategy.

### EUROPEAN UNION

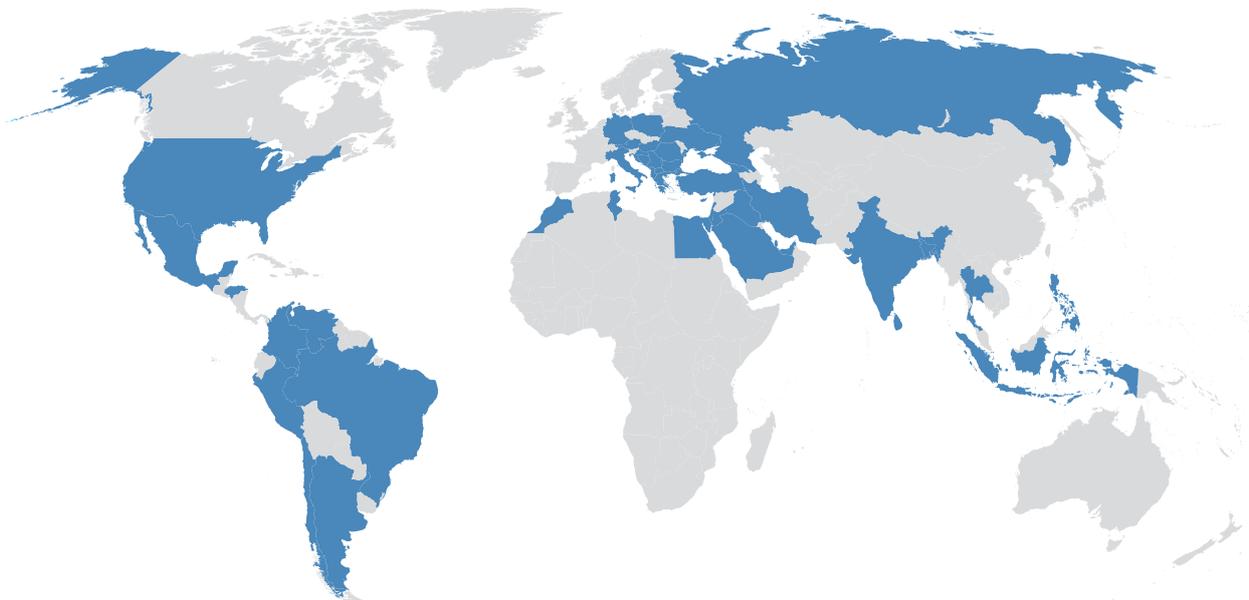
The revenues in the European Union for the year ended 31 December 2010 were 27,650 thousand Euro, representing 11.2% of total revenue with a decrease of approximately 21.7% with respect to the previous fiscal year. This was mainly due to the reduction in sales by Ked Pharmaceuticals generally motivated by the reduction in supplies (immunoglobulin and albumin) to Greece caused by the difficult financial situation there and to delays in payments as well as the reallocation of some of the products on the ROW markets where the prices remained more stable during the year.

### REST OF THE WORLD

The revenues for this geographic area for the year ended 31 December 2010 were 70,219 thousand Euro and represent 28.3% of total revenue. The increase of 29% with respect to 2009 comes from the increased availability of product, especially albumin, immunoglobulin and factor VIII thanks to better production efficiency. Turkey remains the top market for plasma-derived products in terms of net sales and, together with the Middle East, Mexico, Venezuela and Tunisia, account for more than 75% of the revenue for plasma-derived products. The United States however remains the target market of the plasma and the third overall after Turkey and the Middle East.



Geographic presence



**Italy: 60,5% of revenues**

**European Union: 11,2% of revenues**  
**Countries:** Austria, Bulgaria, Germany, Greece, Malta, Poland, Rumania and Hungary.

**Rest of the world: 28,3% of revenues**

**Europe:** Bosnia and Herzegovina, Georgia, Kosovo, Macedonia, Montenegro, Serbia, Switzerland, Ukraine, Turkey.

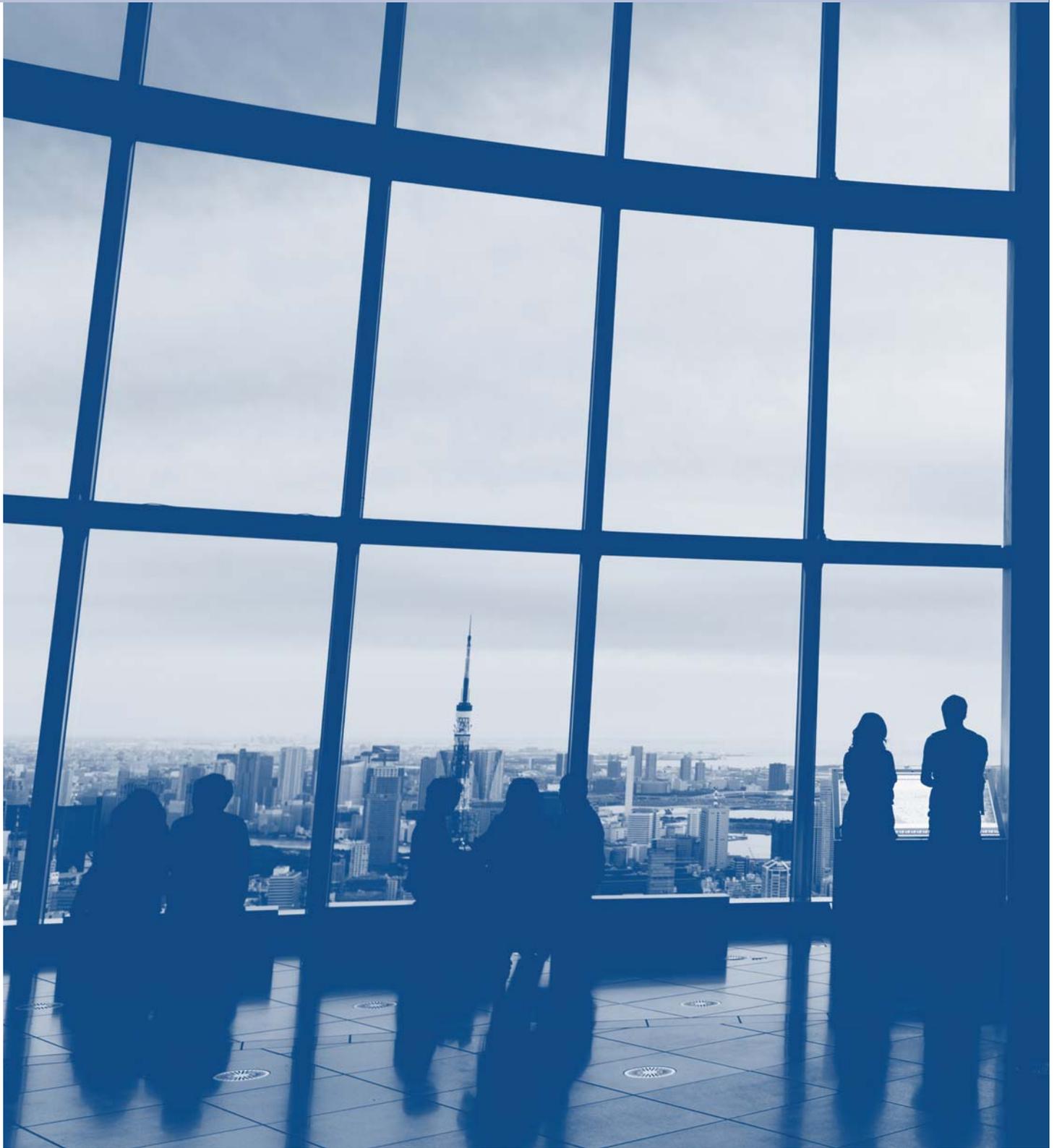
**Centre and South America:** Argentina, Brazil, Chile, Honduras, Mexico, Peru, Dominican Rep. and Venezuela.

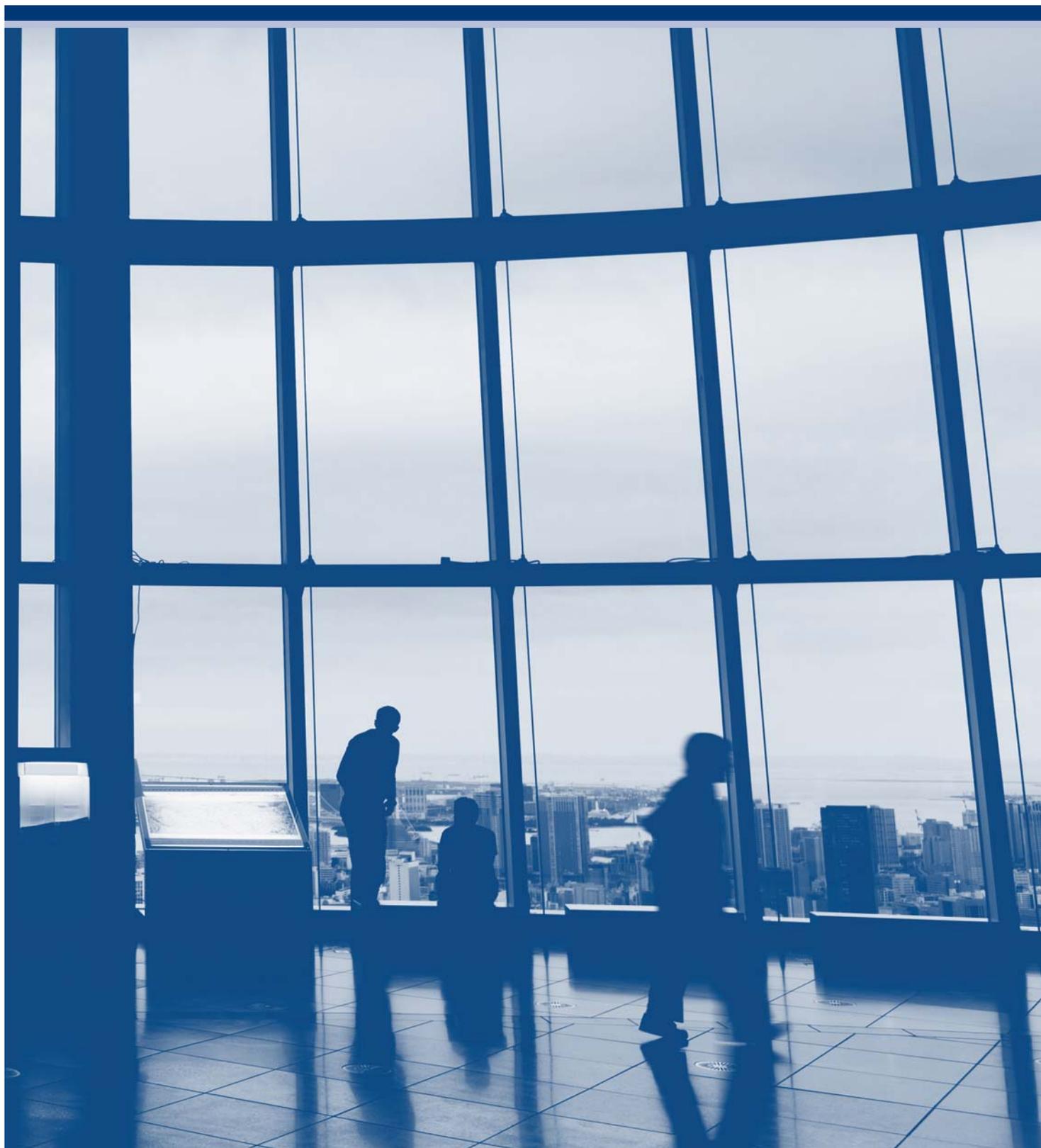
**North Africa:** Morocco and Tunisia.

**Asia:** Saudi Arabia, Bahrain, Bangladesh, United Arab Emirates, Philippines, Jordan, Hong Kong & Macau, Indonesia, Israel, Iraq, Lebanon, Singapore, Middle East, Sri Lanka, Thailand.

**USA** (sales of plasma).

Note: data obtained from 2010 consolidated revenues. Source: corporate information.





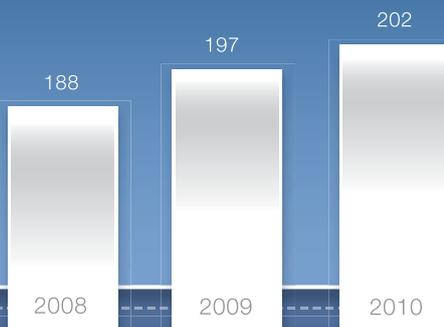
**Annual Report 2010 - Kedrion Group**

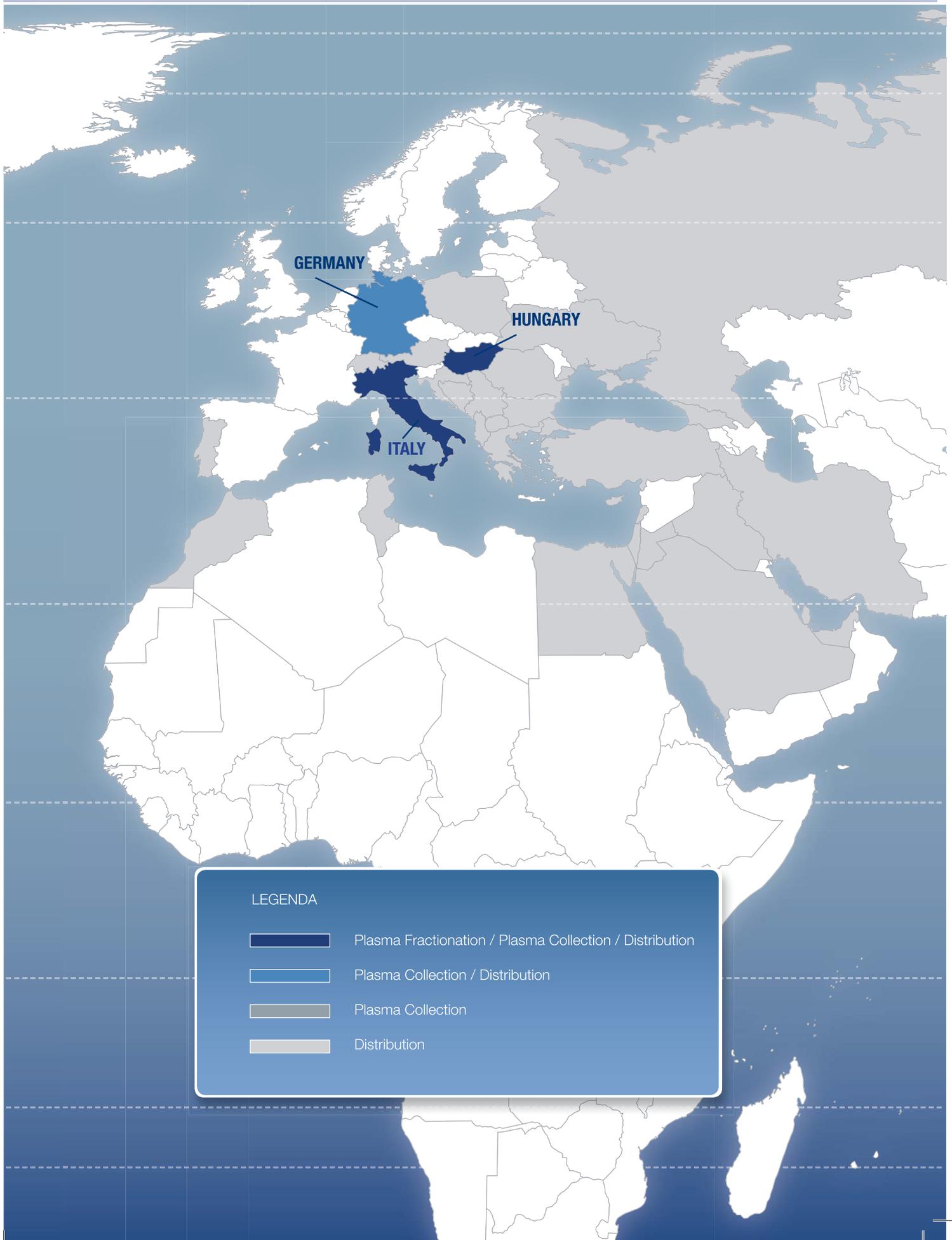
USA

# KEDRION GROUP

WORDWILDE

Grafico delle registrazioni Gruppo Kedrion





## Plasma Procurement

### **BU PLASMA**

Over the past few years the Kedrion Group has developed an effective and diversified plasma procurement model based on access to Italian plasma in collaboration with the Italian Healthcare System and on the collection of foreign plasma. Procurement occurs through company-owned centres which collect both standard and hyperimmune plasma, as well as through long-term agreements with third party operators.

This activity is coordinated by the Plasma Business Unit, which has been operational since the end of 2008, and whose objective is to continuously protect the upstream supply chain to ensure a steady and increasing supply of raw material.

The Plasma BU works to ensure that plasma needs are completely covered and to bolster the current and future activities through the consolidation and strengthening of its network of company-owned collection centres, but also through long-term agreements with operators in the sector designed to provide an exclusive supply of plasma collected in their centres and with highly qualified third party suppliers for both supplying and the exclusive opening of dedicated centres.

The Group currently has 6 company-owned centres operating in the United States managed by ABS, and 3 company-owned centres operating in Germany (Bavaria) managed by KedPlasma. Both companies are directly controlled by Haemopharm, with head office in the United States.

The results obtained over the past few years, especially through the start-up and operation of new plasma collection centres, confirm the success of the vertically integrated business model, based on the direct protection of all the strategic phases of the supply chain. After the strong growth in plasma collection in 2009, 2010 saw a consolidation of the levels obtained in the previous year, with a reduction in the American centres, already forecasted in a substantial expansion and rationalization plan for the collection centres.

The Plasma BU guarantees and promotes the highest quality and safety standards in its centres. A significant result in 2010 was the completion of IQPP certification for all its company-owned centres managed by Haemopharm. Besides the IQPP certified centres in the United States, the three German centres in Fürth, Bayreuth and Ingolstadt were also certified at the end of 2010. IQPP is an international program of the PPTA, the Plasma Protein Therapeutic Association, based on the independent and third party assessments that recognize strict adherence to the highest quality and safety standards in plasma collection.



## Production

### **BOLOGNANA (LU) FACILITY**

The Bolognana production facility confirmed its excellent level of performance in 2010 with an increase in volume of 12% over the previous year.

The numbers obtained in 2010 are even more significant if one considers that this trend is associated with an increase in the yields of certain finished products, particularly the coagulation factors. For example, Factor VIII + 10% compared to the previous year and Factor IX was even + 13%.

Some improvement projects, which were completed in 2010 in the Bolognana facility, also contributed to these results.

Among these, for example, was the double scale production of the medicinal product Antithrombin III, which began at the beginning of the year after receiving Ministerial authorization. Thanks to the implementation of this method, the facility now produces double the amount of product with a similar use of resources, thus helping to meet the potential market requests.

The preparatory activities for the Kedrion Group's entrance into the United States market continued in 2010. The first product that will be introduced in this market will be albumin, where the first validation batches were created in 2010 in accordance with that required by the FDA regulation.

And finally, from a plant development and qualification point of view, 2010 saw the completion of the construction, commissioning and qualification activities relating to the creation of a new sterile area for the aseptic dosing and successive lyophilization operations for coagulation factors/inhibitors. The objective is to further increase the production capacity of the coagulation factors. Start-up is expected to take place in 2011.



### **SANT'ANTIMO FACILITY (NA)**

The Sant'Antimo facility also had good production performance in 2010 compared to the previous year with production volumes in line with the budget forecasts.

Excellent results were obtained in particular in the production of S/D inactivated plasma, a characteristic medicinal product for the facility, thanks to the introduction of a new advanced technology filling machine.

The new equipment now allows the filling capacity to meet the plant's production capacity and will also be able to handle future prospective increases in volume for this product. Since the second half of 2010, the excellent overall performance of this new system has allowed the production times to be substantially reduced, accelerating the department operations while at the same time providing a considerable increase in the processing yields of the filled product.

### **GÖDÖLLŐ FACILITY**

The production of the Gödöllő plant in Hungary was essentially in line with that forecasted in the budget, with a slight decrease with respect to the previous year. This drop had however already been inserted into the production plan as a result of the creation of the new fractionation line foreseen for the Hungary Gödöllő Expansion (HuGE). HuGE is the expansion project for the site that will increase the facility's



fractionation capacity from 200,000 litres of plasma to 550,000 litres per year by the end of 2011. In line with Kedrion's international growth objectives, the expansion plant will allow the Group to reach an overall fractionation capacity of approximately 1.6 million litres per year by 2012.

All the HuGE works have fully respected the time schedules set for 2010, which included the expansion of the main production building, the installation of the new line and the expansion of the utilities. In fact 99% of the engineering phase has been completed, as well as 91% of the construction works, 95% detachment of the services bid out to the previous owner and 100% on-site delivery of the technical equipment.

The expansion plan will be finalized with the process validation activities and the review of the procedures and technical documentation. The design of the new production line was based on Kedrion's process technology to meet the goal of maximum integration and synergy between the Group's production facilities.



## Distribution

### EU AND ASIA MARKET

During the year 2010 Kedrion's subsidiary based in Vienna, KED Pharmaceuticals, has assured its position in the European Countries, and built up its market presence in Middle East and numerous countries in Asia.

Due to the price deterioration in all countries and the declining product demand in the key market Greece the division "EU and Asian Market" was faced with sales stagnation in 2010. Other targets were met as activities in marketing and sales were mainly focused on strengthening the market presence and on the development of additional markets. Major achievements were made in the Asian markets where the commercial presence has been substantially expanded.

Another milestone was the successful start up of an affiliate for the Portuguese market. The entry into Portugal as a strategically important country, has boosted the divisions growth's and contributes to a stable supply of plasma derivatives in the market. Thanks to the commitment of the professional and experienced team, lead by the Country Director Abel Vizeu Fernandes, sales were generated from the very first beginning and performed excellent during 2010.

In KED Pharmaceutical's distribution region the leading plasma derivatives in terms of turnover are Human Albumin and intravenous Immunoglobulins.

KED and its affiliates are working to ensure the company's sustained growth and to intensify its position as a reliable and professional provider of Kedrion's plasma derivatives.



*From left to right: Luis Filipe de Sá; Susana Alfonso; Ana Sofia Mercedes dos Santos; Abel Vizeu Fernandes; João Marta (not on the pict.)*

### **Contract Manufacturing, Italy and Rest of World Sales BU**

The Kedrion Group currently operates in more than 40 countries and is the leader in Italy in the production and sale of plasma-derived products.

This business model includes the collection of plasma in Italy (approximately 360 transfusion centres throughout the country) and abroad (in the United States, Germany, Austria and Hungary and through company-owned collection centres). It also includes the production of a wide range of biological products derived from the fractionation and purification of plasma and the selling of products to end customers (mainly hospitals) in Italy, Europe and the rest of the world through affiliates of the Kedrion Group and a network of more than 40 distributors.

In Italy, Kedrion partners with the National Healthcare Service to achieve self-sufficiency in plasma-derived medicinal products with plasma coming from Italian donors.

In this regard, Kedrion receives the plasma, which remains public property, transforms it into finished products and distributes it throughout Italy to meet the population's therapeutic needs.

In 2010 the revenues from the production and sale of plasma-derived products increased by 9.8% with respect to the corresponding period for the year 2009. This increase is the effect of the continued positive trend of the national and international plasma-derived products market. For standard immunoglobulin, albumin and factor VIII the growth came from an increase in sales volumes against slight price dilutions caused by a very aggressive competitive scenario.

### **Rest of the world**

The revenues for this geographic area represent 19% of total revenue. An increase of 47% was recorded with respect to 2009. This is supported by the increased availability of product, especially albumin, immunoglobulin and factor VIII obtained through improved production efficiency.

Over the past few years, in response to a clear strategic direction, the Group has been pursuing an important internationalization process designed to strengthen its presence on the main international markets. Although the time requirements of this objective are considered medium term due to the regulatory obstructions that characterize the sector, further growth is forecasted in the upcoming years at rates sustained by the foreign component of total sales.



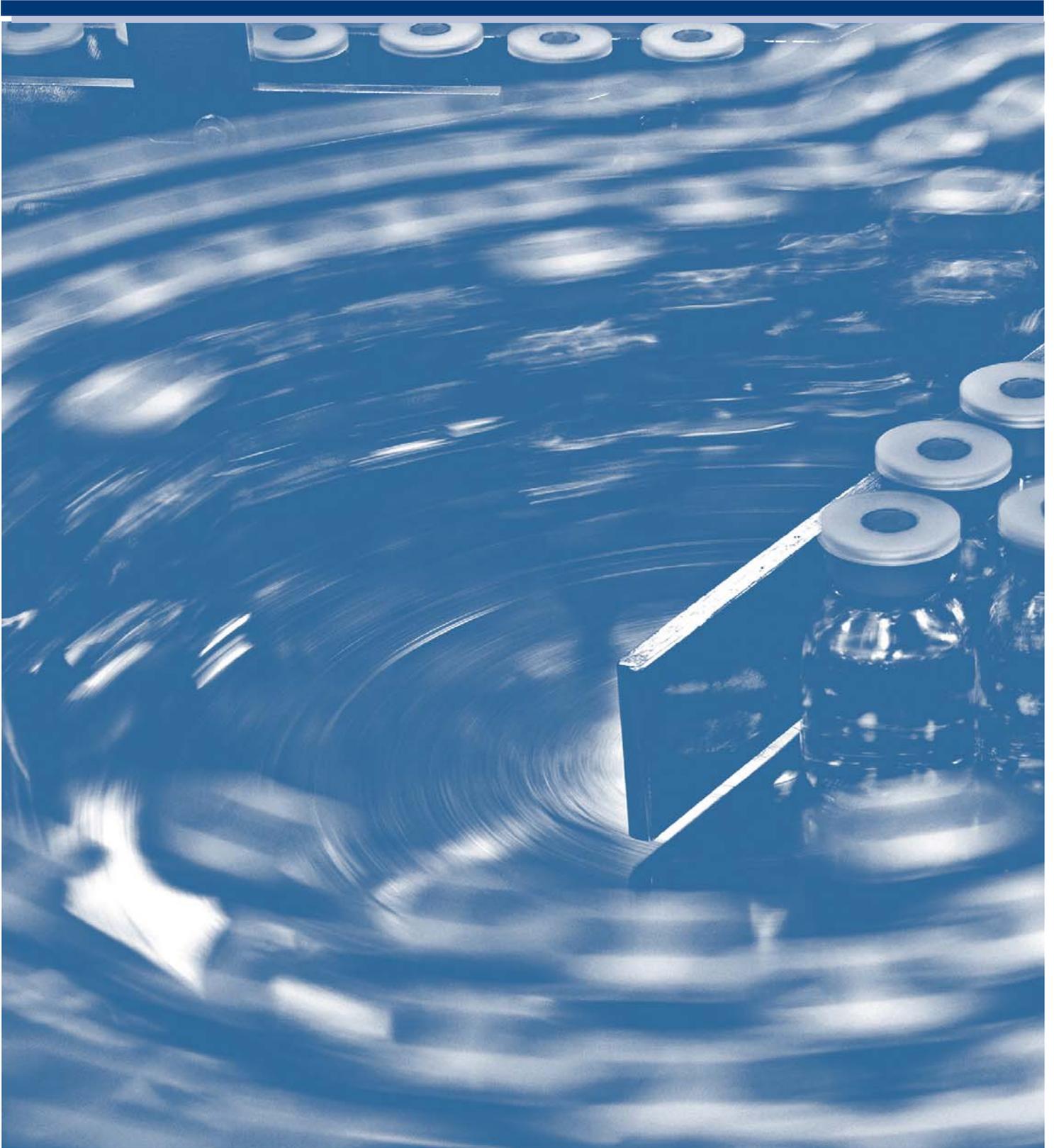
### **The Italian market**

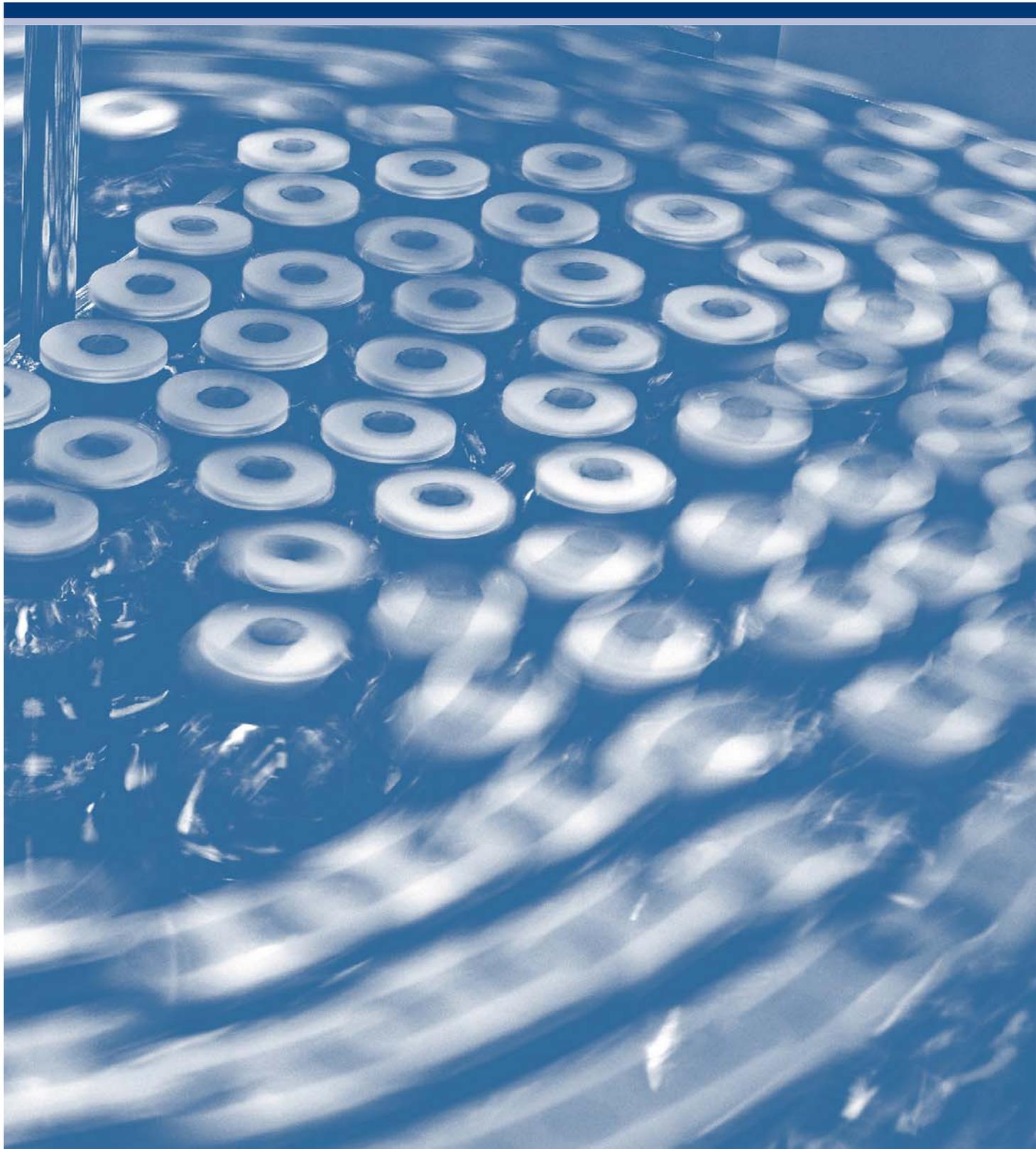
The Italian market for plasma-derived products is divided into the commercial market, and the processing of plasma from Italian donors on behalf of the Regions.

In 2010, Italy again remained the main reference market for Kedrion, with net sales corresponding to 60.5% of overall revenue. With respect to the previous fiscal year, the revenues in Italy remained stable mainly due to the higher volumes of products that were made available for export in accordance with the company's internationalization strategy. In this context, the contract manufacturing agreements with the Italian Regions saw an increase of approximately 7% in 2010 compared to 2009.

The Italian market provides further resources for total sales through the "Commercialisation of flu vaccines and synthetic pharmaceutical products".

The revenues from this segment equalled 1.9% of total revenue and saw a decrease of 51% with respect to 2009, which was a year that saw a peak in sales due to the massive H1N1 virus prevention campaign which increased the request for flu vaccine.





Annual Report 2010 - Product Portfolio

## Portafoglio Prodotti Gruppo Kedrion

### HAEMOPHILIA AND OTHER BLEEDING CONDITIONS

#### **EMOCLOT / PLASMACLOT**

Factor VIII/von Willebrand factor concentrate

#### **HUMAFACTOR-8\*\***

Factor VIII concentrate

#### **WILFACTIN\***

Von Willebrand factor concentrate

#### **AIMAFIX / HUMAFACTOR-9\*\***

Factor IX concentrate

#### **EMOSINT**

DDAVP Desmopressin

#### **UMAN COMPLEX**

Prothrombin complex concentrate

#### **PLASMASAFE\***

Virus-inactivated plasma

### CRITICAL CARE

#### **UMAN ALBUMIN / ALBITAL / HUMAN ALBUMIN / KEDRIALB / PLASBUMIN\***

Human albumin solution

#### **AT III KEDRION**

Antithrombin concentrate

#### **K FLEBO\***

Potassium aspartate

\* products only available for the Italian market

\*\* products only available for the Hungarian market



## PRIMARY IMMUNE DEFICIENCIES AND IMMUNE-MEDIATED CONDITIONS

### **Ig VENA / HUMAGLOBIN / KEDRIGAMMA**

Standard i.v. immunoglobulin

### **16% GAMMAGLOBULIN**

Standard i.m. immunoglobulin

### **VENBIG**

Anti-hepatitis B i.v. immunoglobulin

### **IMMUNOHBs / UMAN BIG**

Anti-hepatitis B i.m. immunoglobulin

### **TETANUS GAMMA / TETIG**

Anti-tetanus i.m. immunoglobulin

### **IMMUNORHO**

Anti-D i.m. immunoglobulin

## OTHER PRODUCTS

### **INFLUVIRUS F\* / ISIGRIP ZONALE SPLIT\***

Flu vaccine - split

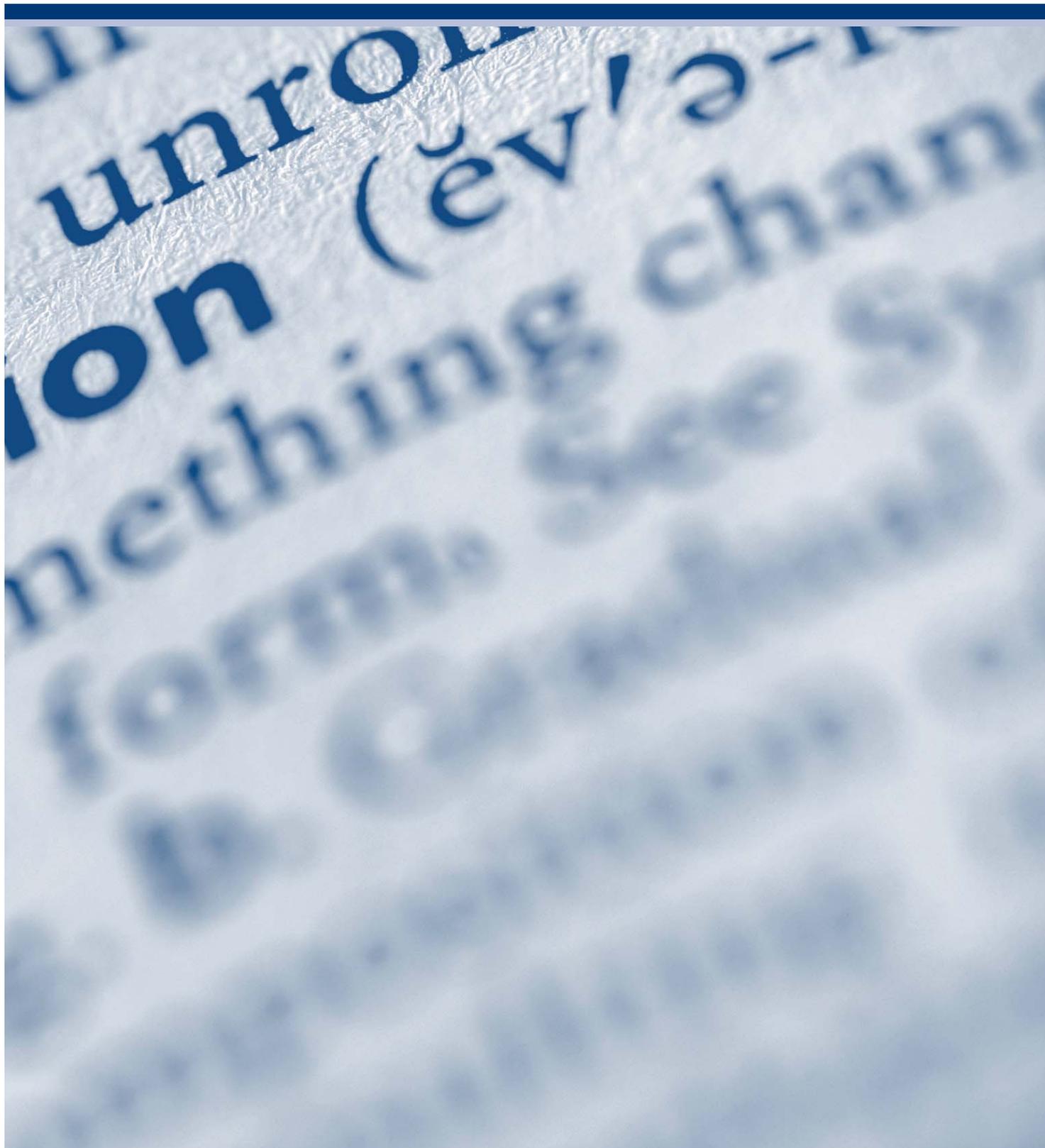
### **ISIFLU\***

Flu vaccine - virosomal

### **PROLASTIN\***

Alpha-1 antitrypsin concentrate

evolution  
centers of  
evolve, to  
**evolution**  
which  
better



**Annual Report 2010 - Research & Development**

## Industrial Research and Development Activities

For the Kedrion Group, innovation is a distinguishing element in its industrial model and one of the main strategic components. Thanks to continued innovation, the company has been able to obtain excellent results, identifying the most advanced and efficient production and technological solutions currently available and creating a virtuous circle of continuous improvement for its products and processes.



\* Management data, including expenses incurred in the regulatory field and from investments (capex).

Over the past few years Kedrion's research and development has been oriented in two directions:

- industrial development focusing on both achieving maximum efficiency in the production process and guaranteeing the highest standards in terms of quality and safety
- industrial research looking to identify new products and new production processes



Over the course of 2010, the industrial development activities concentrated on three main areas:

**Optimization of products and existing cross-disciplinary productions at the three Kedrion facilities (Bolognana- S.Antimo Italy, HBP Hungary),** such as

- increase in the yield for immunoglobulins,
- formulation change for hyperimmune gamma-globulins from lyophilized product to liquid
- transfer of production methods between sites.

**Development of new products,** such as

- development of a new generation of 10% chromatographic gamma-globulins
- purification of plasma proteins for use in rare bleeding disorders.

Since the end of 2010, Kedrion has been using a plant for small scale GMP productions. This system will allow Kedrion to autonomously develop new products from the research phase to the pre-clinical and clinical phase in relation to production lines dedicated to manufacturing registered products. This plant will help reduce the times needed for the preparatory stages for the market launch of a new product and to control the costs.

**Financed research projects**

In 2010, the industrial research activities paid close attention to some projects approved by Italian organizations regarding the maturation of contributions.

Of particular interest are the participation and entrance into AIFA (Italian Drug Agency) program agreements and two tenders in the Region of Tuscany. The most important project for both scientific content and the contribution amount from the region is that on "Research and development of orphan drugs of a plasmatic origin". In September 2010, Kedrion was admitted to the negotiation phase with the region of Tuscany.

## The Biological Safety Centre dedicated to viral validation studies - BioSC obtains GLP certification (Good Laboratory Practice)



BioSC, the new Biological Safety Centre, whose core business is to perform viral validation studies, more specifically, “studies on the inactivation/removal of viral and non viral (prions) pathogens for biological and biotechnological production processes”, for in-house and external services has obtained GLP certification with approval by the Ministry of Health.

The Centre has performed safety studies as a Test Facility and in a multi-site configuration; with these initial studies, BioSC has already positioned itself as a centre of excellence in carrying out investigations on prionic pathogens.

Kedrion is the only company in Italy and one of only three in Europe able to offer this service and is particularly distinguished as being a safety centre supporting the regulatory agencies for the consolidated knowledge of the current scenario and the outlook of future scenarios. BioSC's mission is to use its expertise to meet current and future needs regarding safety against biological contaminations by working from a perspective of constant innovation and continuous improvement of its services.

The new laboratories, located in the Kedrion Group's Bolognana (Lucca) facility, achieve the dual objective of making Kedrion autonomous with respect to safety studies, which up to this point were performed by outside laboratories, and becoming a national and international reference point for safety for those who



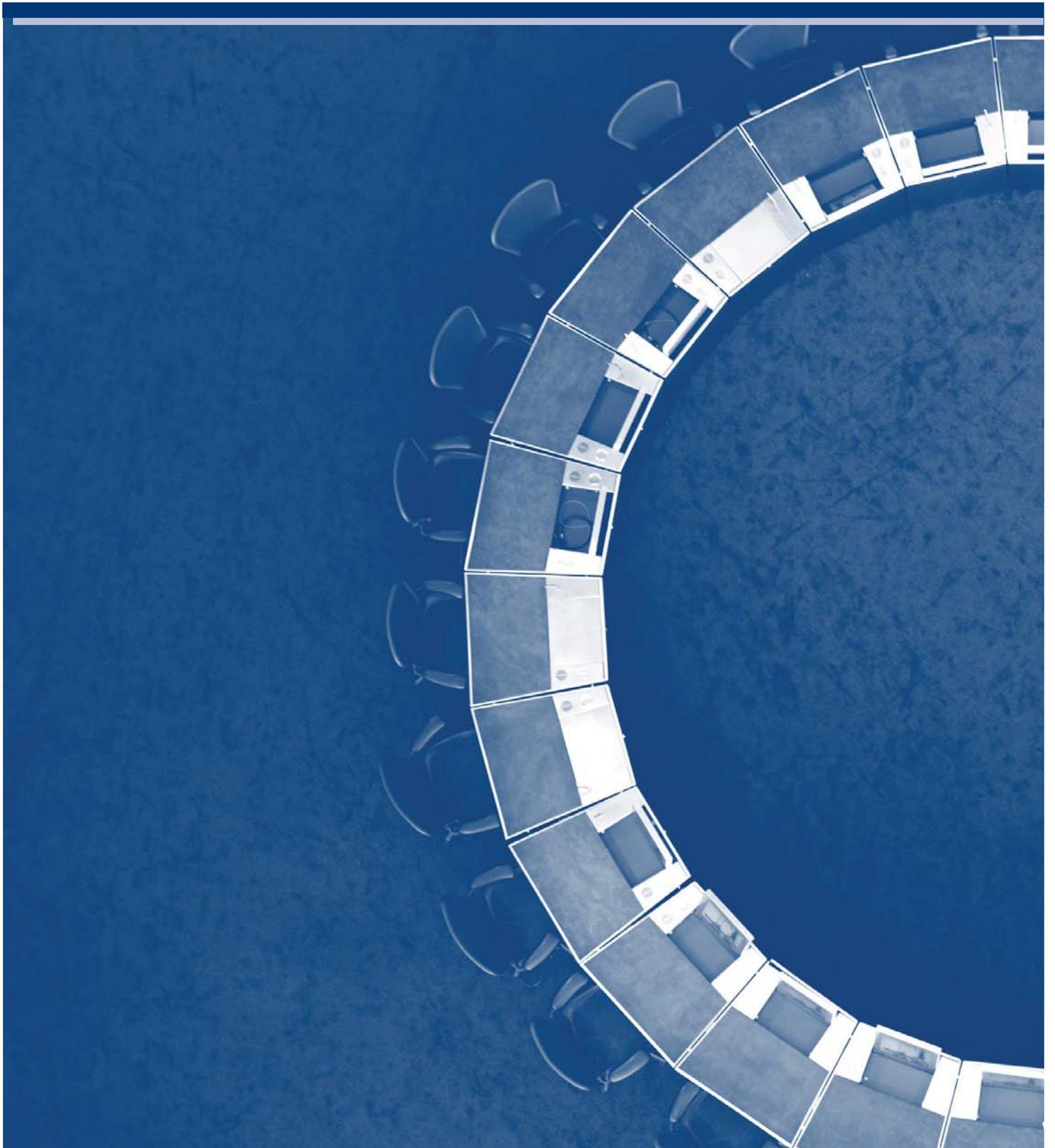
need to perform viral validation studies on their processes and products (manufacturers and suppliers of biological and biotechnological products as well as devices and additional equipment inserted into biological and biotechnological production processes).

The viral validation studies are the centre's main activity (selection and testing of raw materials, product testing at appropriate phases in the production process, checking the ability of a given method to inactivate and/or remove contaminating pathogens) while some services are developed for single use viral validations (PCR analysis - OGM search, contaminants search in cell cultures used for the biopharmaceutical production processes, development and consulting of PCR methods, consulting on statistical analysis methods, characterization of cell cultures).

The building is the result of solid experience gained by Kedrion in the plasma-derived products safety sector, the knowledge obtained through the cooperation with important partners in the sector and with international regulatory bodies like the EMA and FDA and, above all, the expertise from highly specialised personnel.

The studies give priority to the investigation of processing stages in order to show their effectiveness in removing prions, now recognised as being pathogens of unknown contaminating agents, or rather those agents that, according to the European and American guidelines, are to be attributed to the more complex scenarios since they are mutagenic pathogens that are difficult to diagnose.

For more information on BioSC contact [BioSC@kedrion.com](mailto:BioSC@kedrion.com)





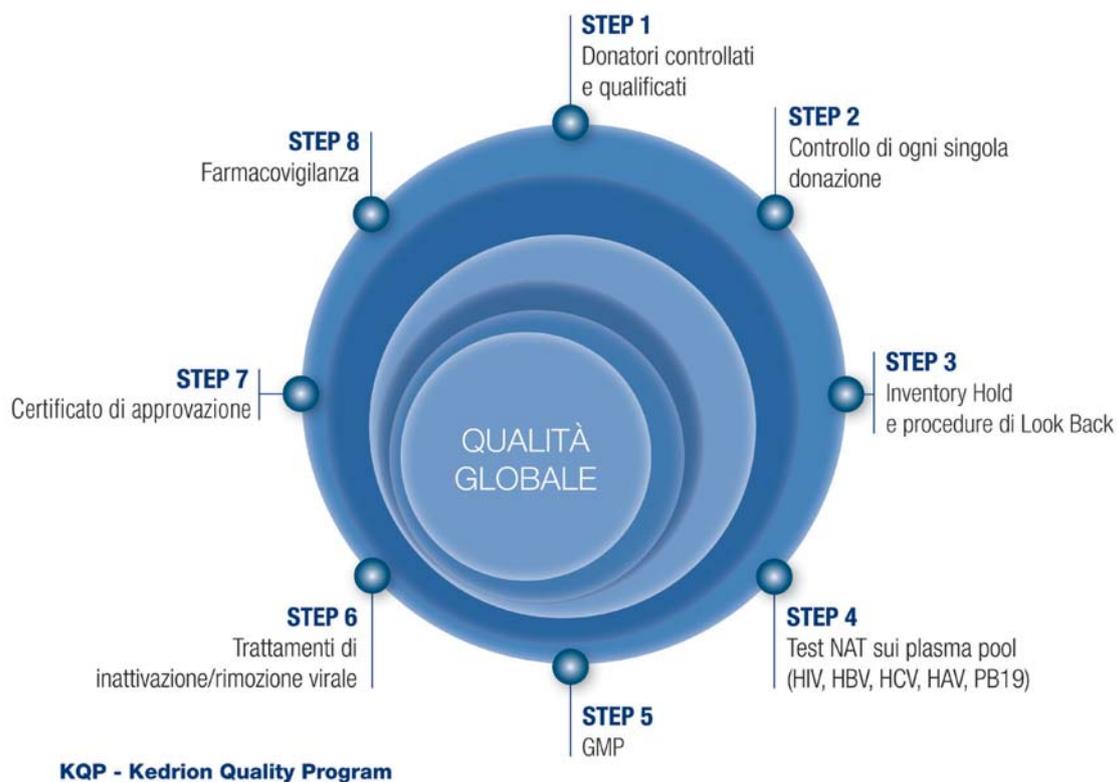
## Annual Report 2010 - Global Quality

## Global Quality

The Kedrion Quality System is a fundamental competitive advantage for the company.

In regard to this multi-step programme – Kedrion Quality Program (KQP) – which constantly monitors every step of the production process and the life cycle of every single product, from development to marketing, through close analysis of the specific safety profile, Pharmacovigilance now plays an increasingly important role and represents STEP 8 of the KQP.

2009 saw further confirmation of this concept and especially that concerning STEP 1, where Kedrion worked to obtain the prestigious QSEAL qualification given by the PPTA to the most qualified manufacturers.





## The Pharmacovigilance System

The concept of Pharmacovigilance as a necessary and indispensable means to ensure continuous monitoring of the safety profile, tolerability as well as the therapeutic validity of the medicinal products has been extensively covered over the past few years through recent European Legislation that confirm the importance that the Marketing Authorization Holder has an “appropriate” Pharmacovigilance and Risk Management System in place. This is to ensure responsibility with respect to the medicinal products put onto the market, but also to guarantee that the proper preventive and/or corrective actions are taken (if necessary) for patient protection.

This System, subject to specific requirements, involves the collection, analysis and management (from registration to reporting to the proper Regulatory Authorities) by the MA Holder of all Adverse Drug Reactions (ADR) attributed to its medicines, coming from any source (doctors/other healthcare operators, patients/consumers, literature, clinical studies, etc.) and which occurred in either the European Community or third country nations.

The data on adverse reactions are the “heart” of Pharmacovigilance: they can be analyzed statistically or descriptively and provide valuable information for the companies, Regulatory Authorities, doctors and anyone else interested in the use of the drug (pharmacists, nurses, patients).

The Pharmacovigilance activities begin during the initial study phases of a medicinal product, when it is not yet available on the market and which continue for the entire duration of the MA and beyond.

In the 2nd half of 2005, Kedrion began a project that focused on developing a Pharmacovigilance System according to the requirement requested by national and European regulations.

In this context, Kedrion has been regularly registered with the Italian Drug Agency's National Pharmacovigilance Network and with numerous other European Drug Agency sites, as well as with EudraVigilance (European Union Drug Regulatory Activities Vigilance). The latter is the system foreseen by the EMA (European Medicines Agency) that is dedicated to the exchange of information on ADRs relative to authorized medicines in the European Economic Area, between the EMA, Regulatory Authorities and the pharmaceutical companies. With regard to this, 5 units of Kedrion's Pharmacovigilance System have obtained certification and are authorized for use of this system.

Besides that, Kedrion's Pharmacovigilance System began performing electronic transmission tests of ADRs in 2008 with all the countries in the European Union where our products are registered. All the tests were successful.

Many departments within Kedrion collaborate diligently in the development of the Pharmacovigilance System, which is increasingly becoming a “cross” function within the company.

From 2009-2010 the Pharmacovigilance System, aided by the Pharmacovigilance, Preclinical & Clinical Trials QA which is the head of Global Excellence, worked to increase and/or start new collaboration relationships with other departments within Kedrion. This has been done through an informational process sensitive to the aspects of this discipline and the creation of procedures for shared activities.





**Annual Report 2010 - Kedrion in the World**

## Europe

### EUROPEAN UNION

**KED PHARMACEUTICALS AG** Kärntnerring 5-7, Top 501 A-1010 Wein, Austria

Tel.: +43 1 513 29 44 12 | Fax: +43 1 513 29 44 22

office@kedag.at | [www.kedag.at](http://www.kedag.at)

### BOSNIA AND HERCEGOVINA

**PHARMA MAAC D.O.O.** Bačići b.b., 71000 Sarajevo, Bosnia and Hercegovina

Tel.: +387 33 770 480 | Fax: +387 33 770 499

office@pharmamaac.com | [www.pharmamaac.com](http://www.pharmamaac.com)

### GEORGIA

**NUGESHI** Shartava street 35/37, Tbilisi 0160, Georgia

Tel.: +995 32 304934 | Fax: +995 32 305454 | [nugeshi@wanex.net](mailto:nugeshi@wanex.net)

### KOSOVE

**AGANI Ltd** pharmaceutical division

Shelgjet e Prronit, 10000 Pristina, Kosove

Tel.: + 381 38 543485 | Fax: +381 38 544534

info@agani.net | [www.agani.net](http://www.agani.net)

### MACEDONIA

**FARMATREJD D.O.O.** Ognjan Prica 1/1 - 3, 1000 Skopje, Macedonia

Tel.: +389 2 3298 782 | Fax: +389 2 3298 782 | [farmatrejd@mt.net.mk](mailto:farmatrejd@mt.net.mk)

### MONTENEGRO

**BAYPHARM D.O.O.** Mitra Bakica br. 50, 81000 Podgorica, Montenegro

Tel.: +382 (0) 20 601210/623123 | Fax: +382 (0) 20 602490 | [baypharm@baypharm.co.me](mailto:baypharm@baypharm.co.me)

### PORTUGAL

**KEDRION PORTUGAL DISTRIBUIÇÃO DE PRODUTOS FARMACÊUTICOS LDA**

Av. José Gomes Ferreira, 15 Edifício Atlas IV Piso 5 Fracção Q, Miraflores 1495-139 Algés, Portugal

Tel: +351 214 107 246 | Fax: +351 214 100 645 | [info@kedrionportugal.com](mailto:info@kedrionportugal.com) | [www.kedrionportugal.com](http://www.kedrionportugal.com)

### SERBIA

**MAKLER D.O.O.** Partizanske avijacije 3b., 11000 Belgrado, Serbia

Tel.: + 381 11 3183670 | Fax: +381 (11) 3187703 | [office@makler.rs](mailto:office@makler.rs) | [www.makler.rs](http://www.makler.rs)



## SWITZERLAND

### KEDRION SWISS SARL

Obmoos 4, 6301 Zug, Switzerland  
office@kedrion-swiss.ch | [www.kedrion-swiss.ch](http://www.kedrion-swiss.ch)

## TURKEY

### ONKO/KOCSEL Kosuyolu Cad. 34, 34718 Kadiköy, Istanbul, Turkey

Tel.: +90 216 544 90 00 | Fax: +90 216 545 59 99 | [info@onkokocsel.com](mailto:info@onkokocsel.com)

## UCRAINE

### LLC KIEV REGIONAL PHARMAENTERPRISE Ushinskogo st. 405, 03151 Kiev, Ukraine

Tel.: +38 044 4993620 | Fax: +38 044 4993621

## Central and Southern America

## ARGENTINA

### SCOTT CASSARÀ Av. Gaona 4302 - 1407 Buenos Aires, Cap. Federal, Argentina

Tel.: +54 11 46729300/9118 | Fax: +54 11 46725999 | [aucello@scottcassara.com.ar](mailto:aucello@scottcassara.com.ar)

## BRAZIL

### MACROFARMA Av. Sete de Setembro, 1210 – Centro CEP: 09912-010- Diadema – San Paolo, Brazil

Tel./Fax.: +55 11 4053 2222 | [gui@macromed.com.br](mailto:gui@macromed.com.br)

## CHILE

### LABORATORIO BIOSANO S.A. Aeropuerto n. 9941, Cerrillos, Santiago, Chile

Tel.: +56 2 3901300 1 | Fax: +56 2 3901305

[mreginato@biosano.cl](mailto:mreginato@biosano.cl) | [www.biosano.cl](http://www.biosano.cl)

## DOMINICAN REPUBLIC

### BIO-NUCLEAR S.A. Av.Tiradentes 74 Ens.la Fè, Santo Domingo, Dominican Republic

Tel.: +1 809 5678172 | Fax: +1 809 5416352 | [jlrodriguez@bionuclear.com.do](mailto:jlrodriguez@bionuclear.com.do)

## HONDURAS

### DROGUERIA, LABORATORIO Y DISTRIBUCIONES AMERICANA S. de R.L. de C.V.

Via Bustamante y Rivero 3002, Tegucigalpa, MDC, Honduras

Tel.: +504 2 804444 | Fax: +504 2 804445 | [rgiron@damericana.com](mailto:rgiron@damericana.com)

## **MEXICO**

### **KEDRION MÉXICANA S.A. DE C.V.**

Adolfo Prieto 1427-C Col del Valle Deleg. Benito Juárez C.P. 03100 Messico D.F., Mexico  
j.hernandez@kedrion.com.mx | [www.kedrionmexicana.com.mx](http://www.kedrionmexicana.com.mx)

## **PERU**

### **PHARMA HOSTING PERÙ** Av Mariscal Oscar Benavides (Ex Av. Diagonal) N° 380 – Of. 504 Miraflores,

Lima, Peru

Tel +511 6281086 | Fax +511 6281087

gerencia@phpsac.com | [www.phpsac.com](http://www.phpsac.com)

## **VENEZUELA**

### **MEDIFARM** Ave.Caurimare C.C.Caroní Módulo B Ufficio 11-B Colinas de Bello Monte Caracas, Venezuela

Tel.: +58 212 7511419 / 7516691

medifarm@medifarm.com.ve | [www.medifarm.com.ve](http://www.medifarm.com.ve)

## North Africa

### **MOROCCO**

#### **LABORATOIRES PHARMA 5**, 21 Rue des Asphodèles – Casablanca, Morocco

Tel.: +212 022 33 44 73 | Fax: +212 022 59 04 14 | [akioud@pharma5.ma](mailto:akioud@pharma5.ma)

### **TUNISIA**

#### **BIOMAGHREB** 24, Avenue Ibn Khaldoun – BP 543 2080 Ariana, Tunisi, Tunisia

Tel.: +216 1 71821257 | Fax: +216 1 71821253 | [biomaghreb@planet.tn](mailto:biomaghreb@planet.tn)

## Asia

### **HONG KONG AND MACAU**

#### **T-BOMA**, 06-07, 32<sup>nd</sup> Floor, Clifford Centre, 782 Cheung Sha Wan Road, Kowloon, Hong Kong, Cina

Mr. Joseph Lau | [joseph-lau@t-boma.com](mailto:joseph-lau@t-boma.com)

### **LEBANON**

#### **MACROMED S.A.R.L.** Zarif Quarter, Midhat Pacha St. P.O. Box 11-1299 Riad El-Solh 1107 2080

Beirut, Lebanon

Tel: +961 1 735 463 / 735 197-8-9 | Fax: +961 1 735201 | [macromed@cyberia.net.lb](mailto:macromed@cyberia.net.lb)



**SINGAPORE**

**NOVEM HEALTHCARE PTE**, 12 New Industrial Road #02-01, Morningstare Centre, Singapore 536202

Mr. Albert Ng (Amministratore Delegato) | [albert@novemhealthcare.com](mailto:albert@novemhealthcare.com)

**THAILAND**

**BIOGENETECH CO. LTD.** 18 Soi Udomsuk 37, Sukhumvit 103 Rd. Bangjak, Prakanong, Bangkok 10260, Thailand

Tel.: +66 2 7489333 | Fax: +66 2 7489393 | [luechaw@inet.co.th](mailto:luechaw@inet.co.th)

**UNITED ARAB EMIRATES**

**PHARMALINK DRUG STORE** P.O. Box 41412 Khalifa Street Bainunah Pharmacy Bldg. 2nd Floor Suite # 202, Abu Dhabi, U.A.E.

Tel.: +971 2 6262665 | Fax: +971 2 6261608 | [pharmlnk@emirates.net.ae](mailto:pharmlnk@emirates.net.ae)

**SAUDI ARABIA**

**JORDAN**

**SRI LANKA**

**BAHRAIN**

**INDONESIA**

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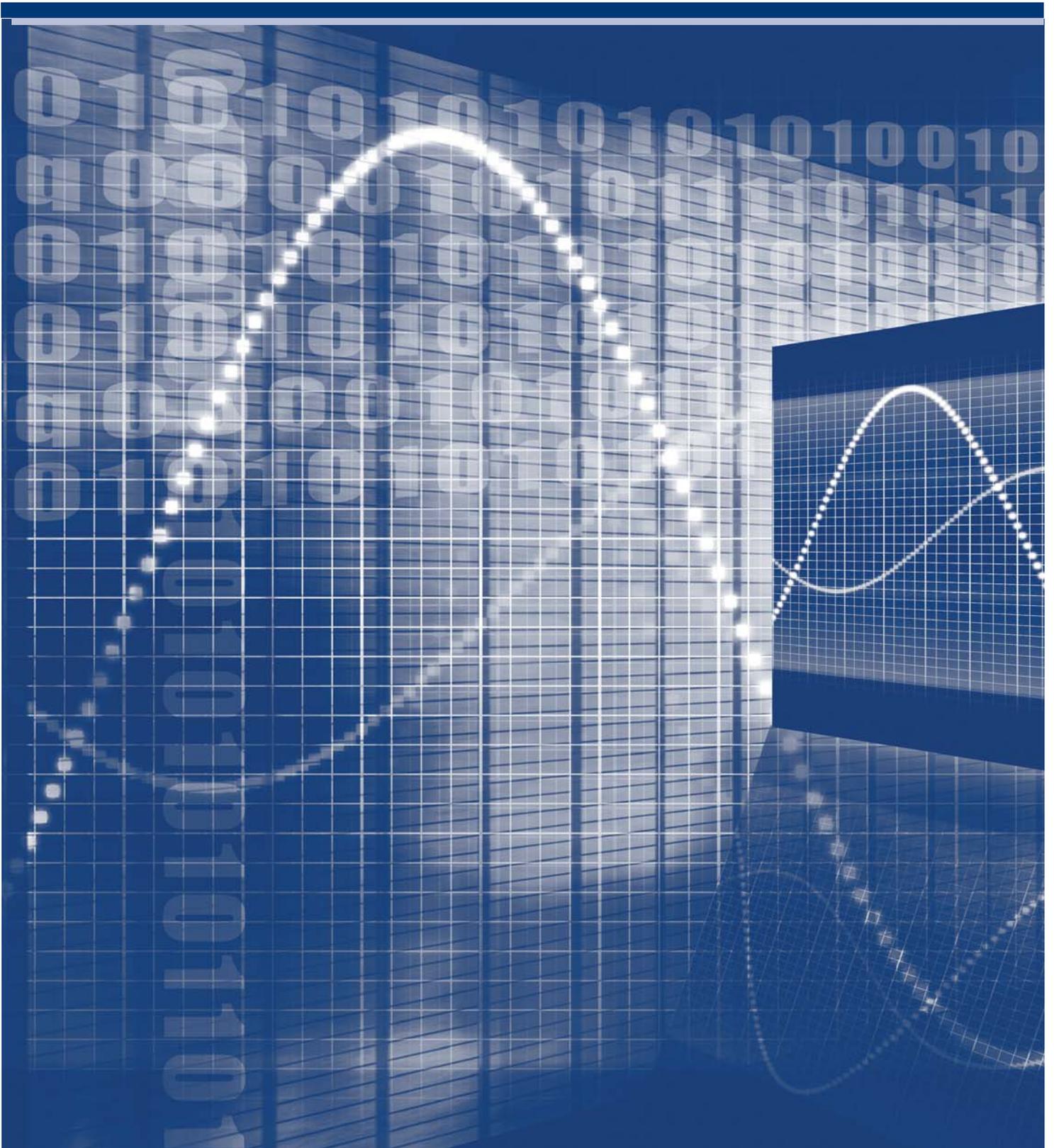
**KED PHARMACEUTICALS AG**

Kärntnerring 5-7, Top 501 A-1010 Wien, Austria

Tel.: +43 1 513 29 44 12

Fax: +43 1 513 29 44 22

[office@kedag.at](mailto:office@kedag.at)





## Annual Report 2010 - Financial Data

## Consolidated financial\* statements at december 2010 and 2009

<b>Consolidated balance sheet</b>		
	<b>year ended at 31/12/10</b>	
<b>(in thousands of Euro)</b>	<b>2010</b>	<b>2009</b>
<b>Non current assets</b>		
Property, plant and equipment	98.008	93.537
Property investment	1.774	1.793
Goodwill	165.354	164.739
Fixed duration intangible assets	9.857	12.429
Equity investment in other companies	1	1
Other non current financial assets	401	608
Other non current assets	653	742
<b>Total non current assets</b>	<b>276.048</b>	<b>273.850</b>
<b>Current assets</b>		
Inventories	116.445	102.958
Trade receivables	93.748	87.894
Current tax credits	881	1.360
Other current assets	6.740	10.808
Other current financial assets	544	116
Cash and cash equivalents	13.192	8.715
<b>Total current assets</b>	<b>231.550</b>	<b>211.851</b>
<b>Total assets</b>	<b>507.597</b>	<b>485.701</b>

\* Consolidated financial statements prepared in compliance with the IAS principles.



<b>Consolidated balance sheet</b>		
	<b>year ended at 31/12/10</b>	
<b>(in thousands of Euro)</b>	<b>2010</b>	<b>2009</b>
<b>Shareholders' equity</b>		
<b>Group shareholders' equity</b>		
Share capital	52.116	52.116
Reserves	127.713	105.529
Total Group net profit	20.112	22.108
<b>Total Group shareholders' equity</b>	<b>199.941</b>	<b>179.752</b>
<b>Shareholders' equity pertaining to minority shareholders</b>		
Minority interests in capital and reserves	103	66
Net profit pertaining to minority shareholders	287	37
<b>Total shareholders' equity pertaining to minority shareholders</b>	<b>390</b>	<b>103</b>
<b>Total shareholders' equity</b>	<b>200.331</b>	<b>179.856</b>
<b>Non current liabilities</b>		
Medium/long-term	174.587	182.250
Provisions for risks and charges	400	420
Liabilities for employee benefits	5.573	5.295
Deferred tax liabilities	884	3.629
Other non current liabilities	3.919	6.131
<b>Total non current liabilities</b>	<b>185.363</b>	<b>197.724</b>
<b>Current liabilities</b>		
Amounts due to banks and other lenders	20.796	12.442
Current portion of medium/long-term loans	24.744	18.585
Provisions for risks and charges	36	469
Trade payables	49.832	53.234
Current tax payables	4.739	1.195
Other current liabilities	21.756	22.198
<b>Total current liabilities</b>	<b>121.904</b>	<b>108.122</b>
<b>Total liabilities</b>	<b>307.267</b>	<b>305.846</b>
<b>Total shareholders' equity and liabilities</b>	<b>507.597</b>	<b>485.701</b>

<b>Consolidated balance sheet</b>		
	<b>year ended at 31/12/10</b>	
<b>(in thousands of Euro)</b>	<b>2010</b>	<b>2009</b>
Revenues from sales and services	247.780	239.525
Cost of sales	139.524	129.489
<b>Gross margin</b>	<b>108.256</b>	<b>110.036</b>
Other income	4.291	6.300
General and administrative expenses	38.654	40.343
Sales and marketing expenses	16.650	14.700
Research and development expenses	7.720	7.975
Other operating costs	2.289	2.834
<b>Operating result</b>	<b>47.235</b>	<b>50.484</b>
Financial charges	18.577	18.284
Financial income	4.141	2.640
<b>Pre-tax result</b>	<b>32.799</b>	<b>34.839</b>
Income taxes	12.747	11.356
<b>Net profit for the year</b>	<b>20.052</b>	<b>23.483</b>
of wich:		
Net profit attributable to the Group	19.766	23.446
Net profit attributable to minority shareholders	287	37

<b>Aggregate consolidated income statement</b>		
	<b>year ended at 31/12/10</b>	
<b>(in thousands of Euro)</b>	<b>2010</b>	<b>2009</b>
<b>Net profit for the year</b>	<b>20.052</b>	<b>23.483</b>
<b>OTHER NET AGGREGATE PROFITS / (LOSSES)</b>		
Translation differences on foreign company financial statements	46	(542)
Net loss on cash flow hedging instruments (cash flow hedges)	301	(796)
<b>Aggregate net profit for the year</b>	<b>20.399</b>	<b>22.145</b>
of wich:		
Aggregate net profit attributable to the Group	20.112	22.108
Aggregate net profit attributable to minority shareholders	287	37



<b>Consolidated cash flow statement</b>		
	<b>year ended at 31/12/10</b>	
<b>(in thousands of Euro)</b>	<b>2010</b>	<b>2009</b>
Net cash flow generated from operating activities	35.369	31.208
Net cash flow absorbed by investment activities	(14.872)	(15.318)
Net cash flow generated/(absorbed) by financing activities	(16.199)	(21.772)
<b>Total net cash flow</b>	<b>4.298</b>	<b>(5.882)</b>
Cash and cash equivalents opening balance	8.711	14.594
Net effect of conversion of foreign currencies on cash and cash equivalents	145	(2)
<b>Cash and cash equivalents closing balance</b>	<b>13.154</b>	<b>8.710</b>

