





Kedrion Group - Annual Report 2009



Letter from the CEO Paolo Marcucci

2009 was a positive year.

We achieved outstanding results, maintained our leadership position and continued with growth in international markets.

The Kedrion Group finished the year with 239,5 million euros in net sales.

An 8,5% increase over 2008 and with an EBITDA margin of 28,6%.

The net sales from export are now 37,5% of the overall total (29.8% one year ago); we increased sales in the European Union by 43,4% and by 32,6% in the rest of the world.

This is a significant result which, fully following the Group's clear strategic direction, will allow foreign sales to surpass Italian sales within the next three years, while maintaining our commitment to the activities performed for the Italian Healthcare Service.

2009 was also a year of investments for the Gödöllő manufacturing facility (Budapest, Hungary), where we have set up a development and expansion plan of more than 20 million euros over three years, with the objective of increasing the Kedrion Group's production capacity.

The obtaining of the Quality Standards of Excellence, Assurance, and Leadership (QSEAL) certification by the Plasma Protein Therapeutics Association (PPTA) recognises the success of our continuous improvement policy and our constant commitment to the development of our global quality system.



In the future

- we intend to fully implement our vertical integration strategy for the activities
- continue increasing our production capacity for more presence in international markets
- broaden our product portfolio
- continue to invest in clinical research and R&D
- accept the new and demanding challenges in the study of orphan drugs.

Our central point, and key-word, for the prospects of this industry, is:

INNOVATION

I therefore would like to clearly and resolutely say that it is strategic and of utmost importance to maintain and improve our level of performance and to further strengthen our policies of product, process, procedural and service excellence.

Thanks to all those who have directly and indirectly helped us achieve these results, in this manner they have contributed to the Group's growth.

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.



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 plasmaderived 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.

MISSION

About Kedrion

Kedrion is a biopharmaceutical company specialising in the development, production, marketing and distribution of plasma-derived medicinal products.

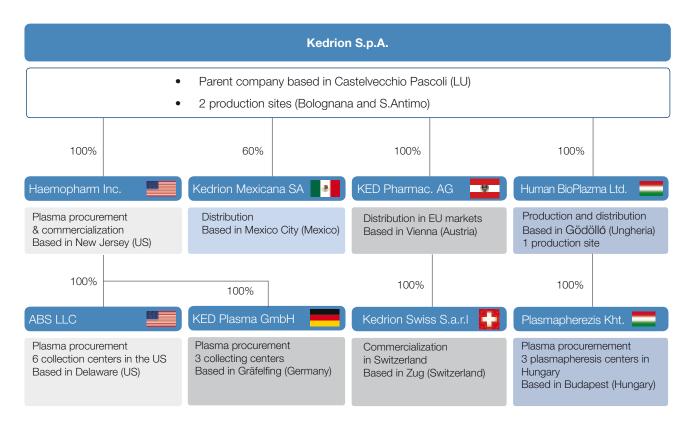
Because of its expertise, the company plays a leading role in Italy, in Europe and worldwide.

The company's competitive edge relies on the quality of its products, its relentless commitment to research and development, its substantial industrial capacity, as well as its established position in the domestic and international markets.

In Italy, Kedrion partners with the National Health Service to achieve self-sufficiency in terms of plasmaderived medicinal products.

Its expertise is also put to use in strategic partnerships with health institutions in other countries.

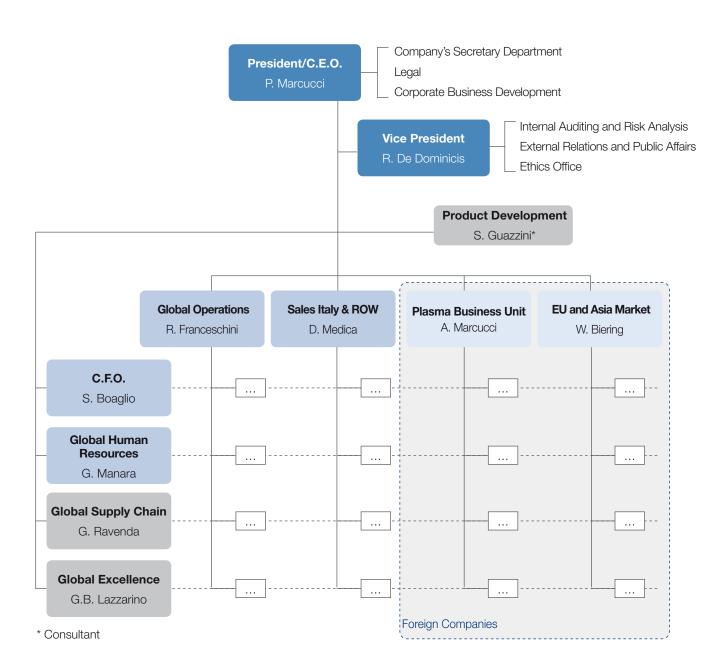
Kedrion Group Today





Organization Chart

- In 2008 Kedrion adopted a new organizational structure designed to protect the entire value chain.
- The completion of the new organization, which was designed to help create strategic company goals, was done in 2009 with the defining of certain Key Functions.



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 Castelvecchio 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.



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..

Stefano Guazzini

Product Development Manager

Degreed in Biological Sciences, he has been the Product Development Manager since October 2008. He was the company's Director of Scientific and Business Development from 2002 to 2008. He began working with the company in 1998 in the production and distribution of plasma-derived products owned by the Marcucci family and held the position of Marketing Director. Since 1973 he has held numerous positions at Immuno S.p.A., among which was Medical Scientific Assistant Manager from 1973 to 1978, Diagnostics Line Manager from 1978 to 1981, Medical Scientific Director from 1981 to 1991 and Co-General Manager from 1991 to 1997.

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. I.. 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.

Annual Report 2009 - Top Management



Gianbattista 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.











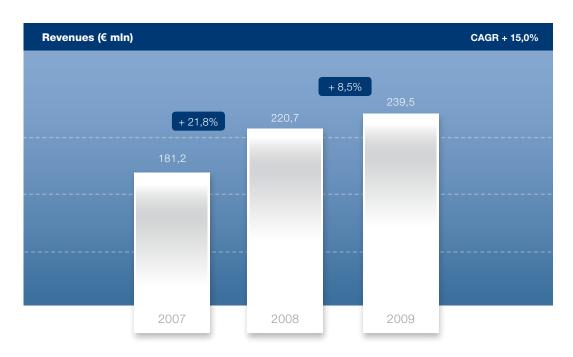


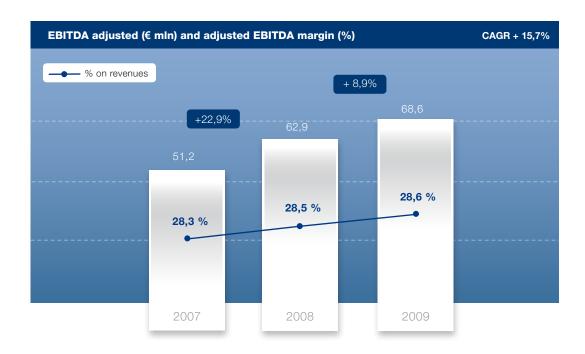
Annual Report 2009 - Key Data* 2007-2009

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



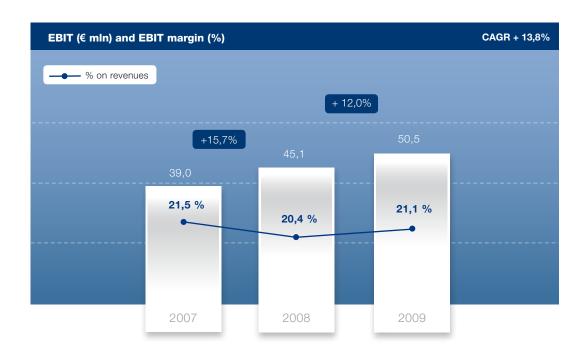
Financial indicators





Annual Report 2009 - Key Data





Even in this very challenging economy, the Kedrion Group achieved significant results during the fiscal year 2009, maintaining its leadership role in the Italian market and continuing with growth in international markets, which now represents 37,4% of overall net sales.

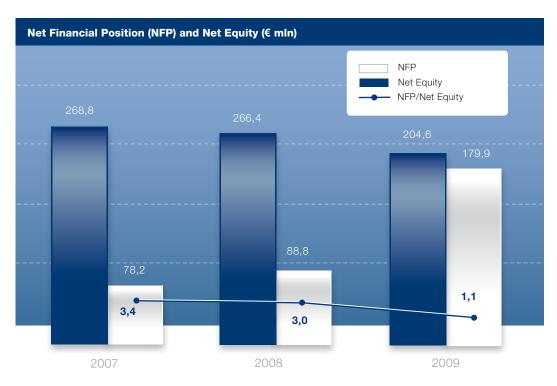
This led to a +8,5% increase in net sales, which reached 239.5 million euros with an adjusted EBITDA margin of 28,6%, equalling 68,6 million euros.

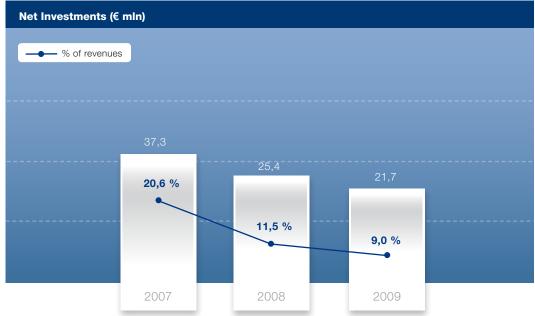
After approximately two years of significant increases in the cost of plasma, the second half of 2009 saw a reduction in the cost of the raw material which anticipated a corresponding stress in the sales price of certain products by a few months. These trends didn't have a substantial impact on the Group's gross profit, which essentially remained the same with regard to total annual sales at 46%.

The Operating Result (EBIT) for 2009 reached 50,5 million euros (21% of net sales) while the Net Income increased to 23,5 million euros, equalling approximately 10% of net sales.

A reverse takeover between the holding of Kedrion Group (Augeo Due) and Kedrion S.p.A. took place in the first quarter of 2009; for consistency of comparison with previous years the balance sheet results from previous fiscal years (2007 and 2008) have been based on the same International Accounting Standards (IAS) in order to give a correct interpretation of the Group's overall equity and financial dynamics.





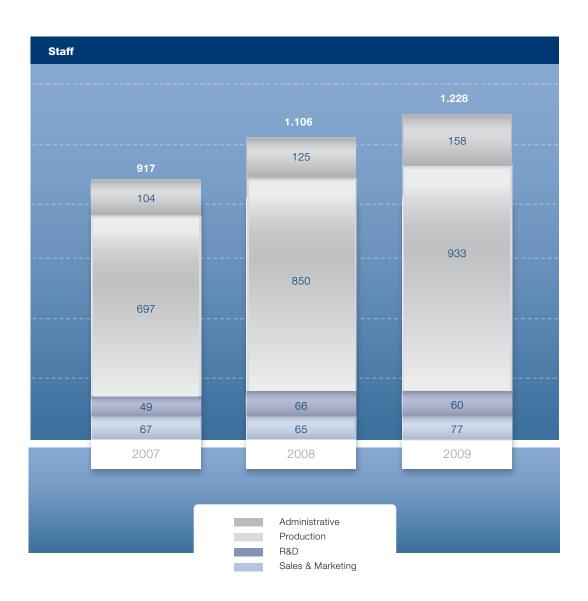


Between 2008 and 2009, Shareholders Equity increased from 89 million euros to nearly 180 million euros, as a result of the shareholders' conversion of subordinated debts into capital and the period-based profit, offset by a decrease in the Net Financial Position, from 266.4 million euros to 204.6 million euros (ratio of 1.1 with Shareholders Equity).

Annual Report 2009 - Key Data



With regards to investments, following the unplanned investments made in 2008 to increase plasma collection from the company-owned centres, overall investments in 2009 amount to nearly 22 million euros (9% of net sales) and primarily refer to investments made to support the Group's production capacity and the start of an investment plan in Hungary to increase fractionation capacity.



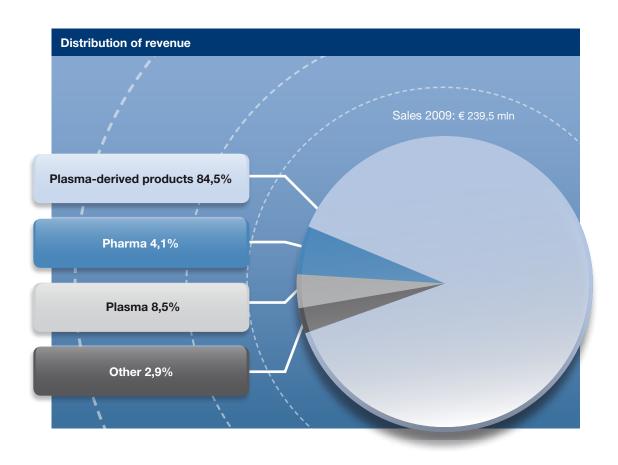






Annual Report 2009 - Business Areas





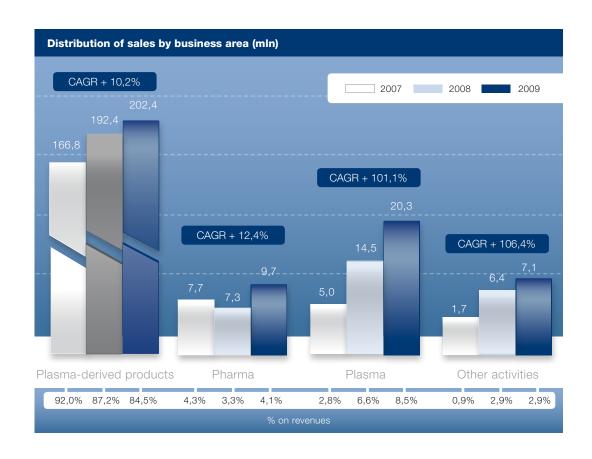
The activities of the Kedrion Group can be divided into four different segments, which relate to:

- 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 foreign plasma (Plasma).
- Other activities, in particular technology transfer.

PLASMA-DERIVED PRODUCTS

The revenues from the production and sale of plasma-derived products as of 31 December 2009 were 202.4 million euros (84.5% of total revenue) and have increased 5.2% with respect to the corresponding period for the year 2008. This growth is mainly the result of the continued focus on penetrating international markets: for standard immunoglobulin and albumin, the improvement relates both to volumes and prices, while for the other products designed for development on international markets, such as factor VIII, the growth mainly relates to volume.





PHARMA

As of 31 December 2009 the revenues from this segment equalled 9.7 million euros (equal to 4.1% of total revenue) and saw an increase of 33.5% with respect to 2008 mainly due to the effects from the H1N1 virus prevention campaign which increased the request for flu vaccine.

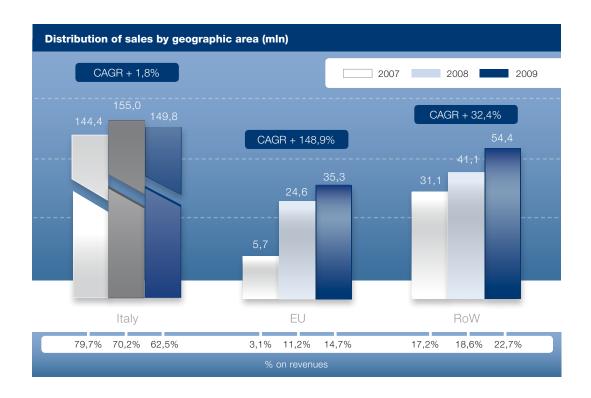
PLASMA

The revenues from the collection and sale of plasma as of 31 December 2009 were 20.3 million euros (representing 8.5% of total revenue) and have increased 40.2% with respect to 2008. This sharp increase is mainly related to the increase in collections at company-owned centres in the United States and Germany, the opening of new centres, and the continued collaboration with an operator in the sector to which Kedrion is currently selling plasma in order to purchase successive intermediates.

OTHER ACTIVITIES

The revenues of this segment, as of 31 December 2009, were equal to 7.1 million euros with an increase of 9.4% with respect to the corresponding period from the previous fiscal year. This is mainly due to contract manufacturing revenues by Human Bioplazma for an operator in the sector and the progression of the technology transfer project stipulated with a European engineering company for the creation of a plant in Russia.





ITALY

As of 31 December 2009, Italy remained the main reference market, with net sales equal to 149.8 million euros, corresponding to 62.5% of the overall revenue. With respect to the previous fiscal year, the revenues in Italy fell by 3.4% mainly due to the higher volumes of products that were made available for export in accordance with the company's internationalization strategy.

EUROPEAN UNION

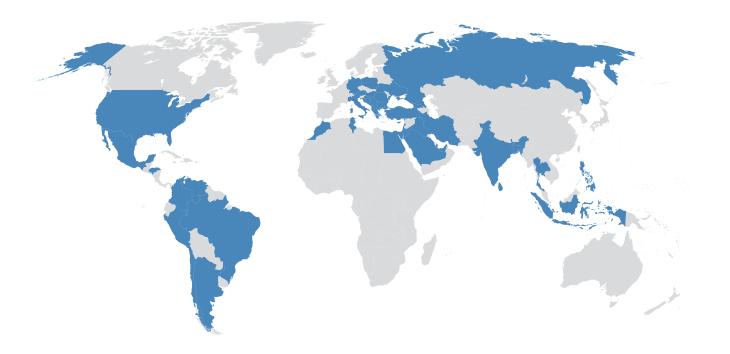
The revenues in the European Union for the year ended 31 December 2009 were 35.3 million euros, representing 14.7% of total revenue with an increase of 43.4% with respect to the previous fiscal year. This increase is mainly related to the start of activities at the Hungarian company Human Bioplazma with revenues in Hungary and Germany and the continued growth of sales by Ked Pharmaceuticals in Greece, Austria, Germany, Poland and Romania in order of net sales, with standard immunoglobulin and albumin being the top selling products.

REST OF THE WORLD

The revenues for this geographic area for the year ended 31 December 2009 were 54.4 million euros and represent 22.7% of total revenue. The increase of 32.6% with respect to 2008 comes mainly from the strong increase in sales of plasma on the American market, resulting from more collections in its centres and, with regard to the plasma-derived products market, the sales of albumin and immunoglobulin thanks to the improved availability of product. The Middle East remains the top market for plasma-derived products in terms of net sales and, along with Turkey, Mexico, Serbia and Russia account for more than 70% of the revenue for plasma-derived products.



Geographic presence



Italy: 62,5% of revenues

European Union: 14,7% of revenues

Countries: Austria, Bulgaria, Germany, Greece, Malta, Poland, Rumania and Hungary.

Rest of the world: 22,7% of revenues

Europe: Bosnia and Herzegovina, Cyprus, Croatia Georgia, Kosovo, Macedonia, Montenegro, Russia, Serbia, Ukraine, Turkey.

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

North Africa: Egypt, Morocco, Tunisia.

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

USA (sales of plasma).

Note: data obtained from 2009 consolidated revenues. Source: corporate information.





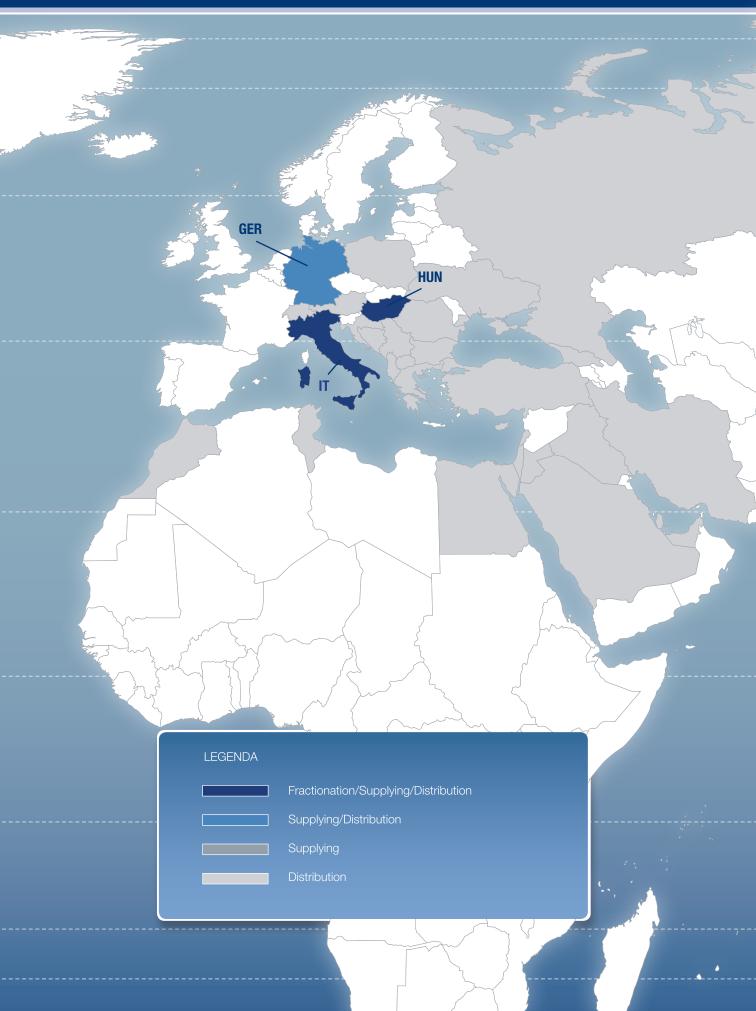


Annual Report 2009 - Kedrion Group











Supplying

PLASMA BU

In order to fully implement its vertical integration strategy, the Plasma Business Unit, directed by Dr. Andrea Marcucci, was created within the Kedrion Group in October 2008.

The Plasma BU works through the reference company (Haemopharm, with headquarters in the United States), which directly controls the two companies operating in plasma collection:

- ABS, company with 6 collection centres operating in the United States
- KEDPlasma, owner of 3 collection centres in Germany (Bavaria).

The procurement activity performed by the BU is done not only through company owned collection centres but also through dedicated centres, such as third party centres that work exclusively for the Kedrion Group, or through long term supply contracts with other qualified suppliers, mainly plasma collection centres located in Germany and Austria.

The plasma that cannot be used within the Group, or plasma relating to pharmaceutical products not on the price list or bound by long term agreements being concluded with third party customers stipulated by recently acquired centres and which are gradually expiring, is sold on the market and helps create revenue for the Plasma business area.

After the first "full" year in operation, the results are satisfying: overall the BU went from a total of approximately 240 thousand litres collected at the end of 2008 to more than 350 thousand litres for 2009 (+46%).

This result was achieved through strong growth in the Group's American centres, which surpassed 300 thousand litres, and especially with the Reseda (California) centre, the Group's main centre and one of the largest in the United States, which collects almost 80 thousand litres a year by itself.

This centre, known for its excellence due to the extremely high quality standards adopted and the innovative technologies used for donor and donation management, will undergo a significant expansion in the coming year along with rationalization of the existing spaces in order to provide an ever better service for its donors. This project, which will cause a drop in the plasma collection capacity during 2010, falls within a complete rationalization and cost control plan started by the BU at the beginning of 2010.

With regard to the German centres, the strong growth is mainly due to both the start-up of the Bayreuth centre, purchased from the Bavarian Red Cross along with the centre already in operation in Ingolstadt, as well as the positive start-up of the new Furth centre.

At the end of 2009 the BU employed more than 300 people, 80% of which were in the United States with the remaining 20% in Germany.

The company-owned and dedicated centres have highly specialized staff in order to ensure that the most innovative quality and safety procedures are followed. Significant investments and actions have been made to ensure that the centres are managed efficiently and professionally.

Annual Report 2009 - Kedrion Group



KED PLASMA

KEDPlasma was founded in June 2008 through Kedrion's vertical integration strategy in order to ensure a continuous supply of high quality plasma. KEDPlasma has three plasma collection centres in Bavaria (Germany): one centre was opened on October 13, 2008 in Fürth, while the Bayreuth and Ingolstadt centres were purchased in December 2008 from the Bavarian Red Cross' Transfusion Service.

Dr. Stephan Walsemann joined KEDPlasma as the Managing Director in January 2009 and the entire KEDPlasma administration moved into new offices in Gräfelfing near Munich. 2009 was a year dedicated to increasing the collection of plasma in its centres. The objectives of aligning the quality system to the Kedrion Quality Program (KQP) as well as integrating the internal administrative process with those of the Kedrion holding company were also reached during this period.

KEDPlasma MILESTONES 2009	
January:	The first shipment of plasma from Bayreuth and Ingolstadt is delivered to Kedrion.
February	The Bavarian government performs a GMP audit of the Bayreuth centre.
March April	The Fürth centre is included in the Kedrion PMF (Plasma Master File); the first shipment of plasma is made from Fürth; Bayreuth reaches 106 donations/day, surpassing the 100 mark for the first time.
Aprii	The Bavarian government issues the complete production licenses for all the Bayreuth, Fürth and Ingolstadt centres; Ingolstadt reaches 214 donations/day, surpassing the 200 mark for the first time; Fürth reaches 108 donations/day, surpassing the 100 mark for the first time.
July	KEDPlasma becomes a member of ARGE (Arbeitsgemeinschaft Plasmapherese, German association of plasmapheresis centres).
October	KEDPlasma becomes a member of the European Plasma Collection Committee, EPCC
December	The Plasma Business Unit holds its Meeting in Miami.

Human BioPlazma procures from three company owned centres (plasmapheresis) located in Budapest (two) and Debrecen (one), as well as from the national healthcare service.



Production

HUMAN BIOPLAZMA

In 2009 the Kedrion Group made a significant investment plan for the development of the Gödöllő (Budapest) facility, with the objective of adapting the plants to the Group's highest standards. The project, scheduled for completion in 2011, is called HuGE, Hungary Gödöllő Expansion, and involves a total investment of more than 20 million euros over three years and focuses on the industrial development of the production site in order to increase its fractionation capacity to 550.000 litres of plasma from the current 200.000 litres per year. At the end of 2009, this plan also received support from the Hungarian government through special financial incentives and tax credits.

As scheduled, the activities for the new viability of the area in front of the site began midway through the year and the detailed engineering phase for the facility was completed. The work relating to the production for the Gödöllő plant then began, which involves the engineering, procurement, construction management/commissioning and project management for the facility's upgrading and expansion. These works, including the installation of a new production line, were carried out according to Good Manufacturing Practices (GMP) are expected to be completed in 2011.

Also, in the first part of the year, the computer systems were completely integrated between the Kedrion holding company and Human BioPlazma, the company managing the Hungarian plant, in order to harmonize all the operating and managerial processes.

These investments were accompanied by positive financial results in 2009 for Human BioPlazma both in terms of net sales and production volumes.







BOLOGNANA AND S.ANTIMO

In 2009 the Kedrion Group's Italian production plants confirmed their high level of performance by reported records in terms of batches produced at both the Bolognana and S.Antimo production facilities, thus confirming the success of the continuous improvement policy in place at the production sites for the past few years. The Bolognana plant recorded a growth in volume of almost 12% over the previous year, while S.Antimo saw a 20% increase with respect to 2008.

The optimal use of all the production areas, the perfecting of the organizational model as well as some improvement steps for the processing and testing equipment all contributed in achieving these significant results in 2009. An example is the routine use of the new thawing technique introduced in Bolognana; the use of this technology provides a significant improvement in the yields of Factor VIII.

All the preparatory activities for the Group's entrance into the American market continued in 2009 at the Bolognana facility. Albumin will be the first product to be introduced into this new and important market.



Distribution

KED PHARMACEUTICALS

In 2009, in order to strengthen its presence in Europe, KED opened an affiliate for the Swiss market, called Kedrion Swiss, beginning sales activities this same year.

After strengthening its position on the European market, KED Pharmaceuticals has expanded its activities in the Middle East and Asia. As in Europe, KED is responsible for the sale, distribution and marketing of Kedrion products in these territories.

KED Pharmaceuticals reached its goal of 20 million euros in net sales for 2009, an increase of almost 100% over the previous year. This positive result was obtained through the increase in sales in Austria, Germany, Greece, Poland, Romania, Indonesia and India.

The company is forecasting further growth in 2010 thanks to the consolidated presence and effective support of the marketing activities in the new countries.

The expansion of KED Pharmaceuticals into new European markets as well as the Middle and Far East will contribute to the Group's growth and its diversification strategy.



First row: Wolfgang Aigner, Simone Biering, Wolfgang Biering. Second row: Klaus Dieter Wolf, Claudia Sieber, Annette Klinger,Birgit Kammerer, Brigitte Klingesberger, Estela Rey González.

Third row: Wolfgang Geifes, Oliver Michel, Elisabeth Clodi, Siawash Abasinejad, Dorthe Planck.





KEDRION MEXICANA

Mexico is the top pharmaceutical market in Latin America with regard to the total value of pharmaceutical products sold in this Central American country, which also has an enormous potential for plasma-derived products.

In 2008, Kedrion decided to create a joint venture company in this country with an important local pharmaceutical group (Somar Group). In 2009, Kedrion Mexicana worked mainly to develop the sales of human albumin, reaching approx. 2 million euros in net sales.

In the meantime, the first batches of Factor VIII and IVIG were also imported.

The push to expand the product portfolio also continued with the beginning of two new product registrations: Factor IX and anti-D immunoglobulin. Besides marketing development, Kedrion Mexicana's top priority is to become the reference partner of the main public healthcare institutions for the processing of plasma collected in Mexico, offering a complete fractionation service.

In 2009, the company maintained and developed contacts with the major opinion leaders of the sector and particularly with the main agencies that provide healthcare services in Mexico. The structure is currently composed of three people:

- Jose Luis Hernandez: Director of Sales and Marketing
- Sonia Torres: Institutional Sales Manager
- Adriana Juarez: Logistics and Customer Care Manager.







Annual Report 2009 - Product Portfolio



Kedrion Group's Product Portfolio

The Kedrion Group's products are the fruit of many years of experience in the plasma fractionation sector and in the purification of intermediate protein fractions. In 2009 Kedrion's constant commitment and investments for innovation and quality led to an overall improvement in the range of products in its portfolio, with regard to improved ease of use and better compliance for the patients.

HAEMOPHILIA AND OTHER BLEEDING CONDITIONS

EMOCLOT/PLASMACLOT

Factor VIII/von Willebrand factor concentrate

HUMAFACTOR-8**

Factor VIII concentrate

AIMAFIX / HUMAFACTOR-9**

Factor IX concentrate

UMAN COMPLEX

Prothrombin complex concentrate

EMOSINT

DDAVP Desmopressin

PLASMASAFE*

Virus-inactivated plasma



New device for coagulation factors: 2009 saw a small revolution in the packaging of AlMAFIX, UMAN COMPLEX and EMOCLOT. With the objective of reducing the size, improving environmental sustainability (all packaging is made of cardboard), but most importantly improving the ease of use of the product, Kedrion began using a simplified device for its lyophilized products that allows it to be reconstituted and then infused with minimal work by the operator. The safety has also been improved:

^{*} products only available for the Italian market

^{**} products only available for the Hungarian market

Annual Report 2009 - Product Portfolio



the system no longer involves direct contact with the needles and eliminates certain steps before the administration of the product.

The change will have a gradual impact on the three products and will be permanently implemented in the first quarter of 2010.

Like for **EMOCLOT,** authorisation was given to extend the shelf life of UMAN COMPLEX from 2 to 3 years. The same is expected in 2010 for AIMAFIX, for which the stability data has already been presented to the appropriate healthcare authorities.

Distribution of Wilfactin in Italy

In collaboration with the French company LFB, Kedrion's Marketing Corporate & Products organised the symposium entitled "Current treatment of von Willebrand disease: from Desmopressin to pure von Willebrand factor concentrate". The event was held in Milan in the middle of October and analyzed the treatment of von Willebrand disease with a focus not only on the use of Desmopressin, the first choice for treating this illness, but also on the pure human von Willebrand factor concentrate, distributed in Italy by Kedrion and indicated for those patients who do not respond to Desmopressin treatment. Wilfactin has some particular characteristics which differentiate it from all the other products currently on the market:

1) a safety with regard to the risk of virus and prions that is greater than the European requirements (EMEA Recommendations) guaranteed through 3 specific viral inactivation/removal methods; 2) the maintaining of all the functional properties of the von Willebrand factor in the plasma of healthy subjects; 3) safer with regard to thrombotic risk compared to other concentrates used for treating von Willebrand disease, ensured by the almost total absence of FVIII.

CRITICAL CARE

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

Human albumin solution

AT III KEDRION

Antithrombin concentrate

K FLEBO*

Potassium aspartate



^{*} products only available for the Italian market



New Device: The new device for the simplified reconstitution and administration of lyophilized products, already authorised for the coagulation factors, will also be used for Kedrion AT III in 2010, thus completing the project designed to improve the conditions for using Kedrion products.

PRIMARY IMMUNE DEFICIENCIES AND IMMUNE-MEDIATED CONDITIONS

Ig VENA / HUMAGLOBIN / KEDRIGAMMA

Standard i.v. 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

16% GAMMAGLOBULIN I.M.

Standard i.m. immunoglobulin



New 1000 IU/3ml packaging of IMMUNOHBs in prefilled syringes, for intramuscular use

The Kedrion initiatives are continuing for product innovation and for improvement in the quality of life of patients. The new 1000 IU/3ml packaging became available in 2009 for IMMUNOHBs for intramuscular use, which is the hepatitis B immunoglobulin destined mainly for patients who have had liver transplants. This innovative formulation contains a concentration of active ingredient that is almost double that of the previous version, with a subsequent reduction in the volume of product to be administered. The product is also supplied in a prefilled syringe, thus allowing the patient to slightly reduce the administration times. IMMUNOHBs 1000 IU/3ml in prefilled syringes is therefore the only product on the Italian market that can offer the advantage of a reduced administration volume (only 3 ml compared to 5 ml for the other

Annual Report 2009 - Product Portfolio



products on the market) and a ready-for-use format.

IMMUNOHBs 1000 IU/3ml was completely developed by Kedrion in the S.Antimo plant (Naples) and is the result of the teamwork and the combining of expertise from different Kedrion departments: R&D, Medical Affairs and Pharmacovigilance, Technical Department and RAO.

IMMUNORHO in solution

The procedure for the preparation of the registration request for the new product IMMUNORHO 300 mcg liquid and prefilled syringes was completed in 2009. The product will be marketed in 2010 in Italy and will later be sold in countries of interest to Kedrion.

The new formulation therefore offers the advantage of eliminating the time need to reconstitute the lyophilized product, providing simple and immediate use.

OTHER PRODUCTS

INFLUVIRUS F* / ISIGRIP ZONALE SPLIT*

Flu vaccine - split

ISIFLU*

Flu vaccine - virosomal

PROLASTIN*

Alpha-1 antitrypsin concentrate

PROLASTIN, the start of distribution in Italy

The distribution of Prolastin in Italy began in November. Prolastin is the Alpha-1 antitrypsin human concentrate produced by Talecris, which until now has been known and sold around the world by Kedrion under the name Prolastina. Prolastin, which has the same characteristics as Prolastina, became mutually recognized in many European countries in 2009 and is now being launched in Italy following the signing of a new contract with the American company. There have been numerous initiatives and activities to increase the awareness of Prolastin, the most important of which was a symposium on Alpha-1 antitrypsin deficiency, organised in November in Catania by Kedrion in collaboration with the Università di Catania and was the first symposium on this subject ever to take place in Italy.

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^{*} products only available for the Italian market





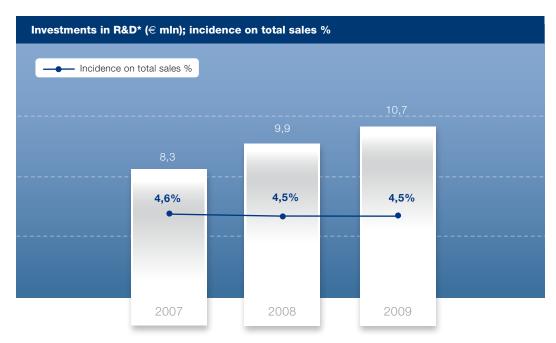


Annual Report 2009 - Research & Development



Research & Development (R&D)

The activity of the Kedrion Group is characterised by a constant attention towards technological innovation, with regard to both the production process and the product, and is the reason why investments are consistently destined for the R&D sector, which in 2009 surpassed 10.7 million euros, equalling 4.5% of total revenue with a total of 60 employees.



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

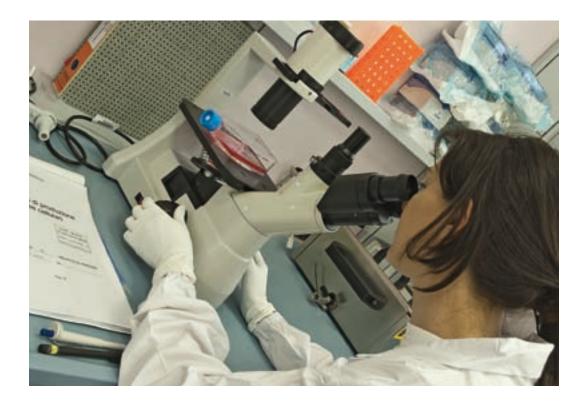
All of the R&D activities, from basic research to the preparation of the registration dossiers until they are obtained, is coordinated by a specific committee (Research and Development Committee), made up of different functions from **Product Development** (which includes Strategic Marketing, Medical Affairs & Pharmacovigilance, Regulatory Affairs) as well as from **Global Operations, Industrial Research and Development, Marketing and Sales Departments, Corporate & Business Development and Global Excellence.**

Every project that is examined is carried out in two macro phases:

- the first phase involves basic research, laboratory development and pre-industrial development and
 is the responsibility of the "Industrial Research and Development" department (which is within
 the Global Operations Business Unit), headed by Dr. Claudia Nardini;
- the second phase involves the pre-clinical development, clinical development, regulatory aspects, obtaining of the marketing authorisations, and is the responsibility of the "Product Development" department (part of the Administrative Department), headed by Dr. Stefano Guazzini.



BioSC, Kedrion's new Biological Safety Centre dedicated to viral validation studies



BioSC, the new Biological Safety Centre, is now operational. Its 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.

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, which were recently opened 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). Some services developed for viral validations are available for single use (PCR analysis - OGM search, contaminants search in cell cultures used for the biopharmaceutical production processes, development and consulting of PCR methods, consulting for





statistical analysis methods, characterisation of the cell cultures).

The building, which recently obtained GLP (Good Laboratory Practice) certification from the Ministry of Health, 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 Kedrion personnel who are able to follow the most innovative procedures for quality and safety.

The studies give priority to the investigation of processing stages in order to show their effectiveness in removing prions, now recognised as pathogens from 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.

Kedrion is the only company in Italy and one of only three in Europe able to offer this service and is also distinguished as being a safety centre supporting the regulatory agencies for the consolidated knowledge of the current scenario and the outlook of future scenarios.



Product Development

The Product Development activities relate to the finalizing of development projects for new products, as well as to the clinical development of products in the portfolio. Among the main projects that have just been completed or are still ongoing, we can mention:

Immunology

- IVIG efficacy and safety study for the treatment of CIDP (Chronic Inflammatory Demyelinating Polyneuropathy) with Kedrion's IG Vena i.v. immunoglobulin, which will allow the product's specific indication to be obtained.
- New generation immunoglobulin G. This project will develop a standard immunoglobulin concentrate at 10%, with improvement in the production yields, purity, tolerability and safety of the product, as well as increasing Kedrion's competitiveness in this market. The project is currently in the pre-clinical testing phase.

Coagulation

- SIPPET study (Survey of Inhibitors in Plasma-Product Exposed Toddlers). The study, in
 which Kedrion participates with its product, is designed to evaluate the incidence of inhibitor
 development in haemophiliacs treated with plasma-derived or recombinant Factor VIII. This
 survey will last approximately 6 years and will involve about 300 "virgin" patients, who have never
 before undergone replacement therapy with Factor VIII.
- Standardization of the von Willebrand (vW) factor in Emoclot, Factor VIII Kedrion. The objective here is to obtain a higher concentration of vW Factor, a protein that is involved in the stabilising and prolonging of the half-life of Factor VIII by trying to increase the Factor VIII:vW ratio.

Rare diseases

 Plasminogen concentrate for ophthalmic use for the treatment of ligneous conjunctivitis in patients with plasminogen deficiency. The project is currently in the pre-clinical testing phase.

Biosurgery

- Fibrin Glue, where the clinical testing phase has finished for pulmonary surgery and is in the concluding stages for hepatic surgery.
- Platelet Glue is a standardised human platelet-based industrial preparation that has been shown
 to be effective in treating cutaneous ulcers when mixed with certain coagulation factors, and has
 received positive indications to continue by healthcare authorities.

Critical care

Plasma S/D. This project is designed to develop a Plasma in powder form that will undergo two
viral inactivation steps (solvent/detergent and prion removal). It is currently still in the process
development phase.







Annual Report 2009 - Global Quality



Global Quality

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

Kedrion is constantly investing in quality, both in terms of company processes and the expertise of its personnel.

The ongoing training of the staff and the monitored integration of the company processes are integral parts of Kedrion's Quality System. There are four staff departments that report to the CEO: **Product Development, Supply Chain, Human Resources and Global Excellence.** The latter is responsible for ensuring that the Group's activities conform with the provisions of the law and the voluntary non GMP regulations (standard compliance and HSE), preventing non-conformity risks and implementing solutions for the continuous improvement of the entire company.

In order to guarantee the safety of its products and processes, Kedrion has developed a multi-step programme - **Kedrion Quality Program (KQP)** - which constantly monitors every step of the production process.



2009 saw further reinforcement of this concept and particularly concerning STEP 1, KEDRION has worked to obtain the prestigious QSEAL qualification given by the PPTA to the most qualified manufacturers.



QSEAL

In 2009 Kedrion took another step forward in its policy of excellence and the implementation of the Global Quality System. At the end of the year, Kedrion obtained a positive result from the audit by the PPTA (Plasma Protein Therapeutic Association) to obtain the QSEAL certification (Quality Standards of Excellence, Assurance, and Leadership).

QSEAL certifies the quality system for the procurement and testing of the company's plasma obtained by aphaeresis and is issued by the PPTA, the global reference association for the fractionation industry.

The purpose of this international Program is to provide independent, third-party evaluation and recognition of a fractionator's adherence to a series of voluntary standards, underscoring the industry's commitment to the safety of patients who rely on therapeutic plasma protein. To obtain the QSEAL certification, a manufacturer of plasma derivatives must show that all of its facilities have passed inspection by an independent auditor in order to check adherence to the QSEAL standards. To maintain QSEAL certification, audits are required every two years. The primary objective of the QSEAL audits is to assess adherence to multiple standards: the selection of rigorously qualified plasma donors, which excludes plasma from first time donors; the implementation of a 60 day inventory hold which ensures that only the highest quality plasma is used for the manufacturing of drugs; the use of the advanced nucleic acid amplification technology (NAT test); the test for Parvovirus B19, a common infection that is often asymptomatic; and finally, an intermediates standard that checks the suitability, quality and traceability of the intermediate products used to make the finished products.





Certifications

Because of the special nature of its products, Kedrion has long been committed to quality, safety and environmental protection as well as to the respect of the community as a whole. In this regard, Kedrion adheres to the 10 principles of Global Compact, the UN organisation which promotes ethical corporate management, in terms of human rights, working conditions and environmental protection.

Therefore, Kedrion's management recognizes the importance of implementing, maintaining and documenting:

- an Environmental Management System in accordance with EN ISO 14001 standards and EMAS
 regulations; the environmental performance data are reported annually in the environmental
 declaration;
- a Quality Management System in accordance with EN ISO 9001:2000 standards;
- an Ethical Management System in accordance with **SA 8000:2001** standards;
- an Occupational Health and Safety Management System in accordance with BS OHSAS
 18001:2007 standards.

In Italy, Kedrion has been recognised as conforming to the requirements expressed in the guidelines for the certification of the procedures relating to scientific information and to the Ethical Code for the Pharmaceutical industry.

The implementation of these systems is part of Kedrion's policy for a global quality system and the ongoing improvement of its quality, environmental and safety performance from a sustainable development perspective.

















Social Responsibility

Kedrion sees itself as a proactive member of society. It operates with a synergy between its business activities, patients' requirements and expectations, health institutions and international partners.

This is why Kedrion has started a global process for applying ethical principles to all areas of its company management.

To accomplish this ambition, Kedrion:

- has developed a Code of Ethical Conduct, a guide to ethical behaviour for the company's staff;
- has appointed an Ethics Officer, in charge of coordinating and supervising all areas of the ethical management of the company's business;
- has established an Ethics Committee, mostly composed of independent members, who express
 their opinions on the ethical consistency of the company's strategic choices;
- has adhered to the 10 principles of Global Compact, the UN organisation which promotes ethical corporate management (human rights, working conditions, the environment).
- has been awarded the SA 8000 certification, an international standard taking inspiration from ILO principles (International Labour Organization) which acknowledges the ethical and social management of a company's human resources;
- maintains a Communication System for the management of notices regarding the application
 of the SA 8000 standard, to promote communication between the parties concerned. In addition,
 the Company has implemented further ethical business schemes, such as the Organisation,
 Management and Control Model pursuant to LD 231/2001.







Annual Report 2009 - Strategy for the Future





- Leadership position in the Italian market, to be maintained through the continued improvement of
 the contract manufacturing activities of national plasma for the Regions, an increased presence
 in the commercial market and the expanding of the range of products made available (new 1000
 IU/3ml intramuscular anti-hepatitis B immunoglobulin, exclusive distribution rights in Italy of a
 von Willebrand concentrate and alpha 1-antitrypsin, ongoing clinical trials for the registration of
 fibrin glue, etc.).
- International growth, by continuing on the same path taken over the past years and with the objective of net foreign sales surpassing Italian net sales within the next 3 years. This strategy is articulated through an ever increasing presence in the Group's main markets, playing on the construction of commercial buildings outside of Italy (KED Pharmaceutical, Human BioPlazma, Kedrion Mexicana), on the close relationship with local distributors in certain areas of the Middle East, South America and in the Balkans, on Technology Transfer projects currently taking place in emerging markets and on the future entrance in the United States market.

Annual Report 2009 - Strategy for the Future





- Vertical integration, the objective on which the Group has invested greatly over the past years and which today allows the Group to rely on a total of 9 company-owned centres in the United States and Germany which can cover more than 80% of its current plasma needs.
- Increase in production capacity, targeted towards growth in international markets and the optimisation
 of the installed purification and filling capacity through agreements with third party intermediate
 suppliers but mostly through the ongoing project of increasing the fractionation capacity at the
 Gödöllő plant from 200.000 litres to 550.000 litres per year.
- Maintaining of a high level of product and process innovation, by continuing to invest in the
 purification of new proteins, by ourselves or in partnership with other operators, in clinical research
 for expanding the therapeutic uses of existing and new products, in the continued technological
 improvement of current products and production processes, designed to ensure an increasingly
 better production efficiency.







Annual Report 2009 - Kedrion in the World



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Annual Report 2009 - Kedrion in the world



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Annual Report 2009 - Kedrion in the world



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Annual Report 2009 - Financial Data



Consolidated financial* statements at december 2009 and 2008

CONSOLIDATED BALANCE SHEET			
	year en	year ended at 31/12/10	
(in thousands of Euro)	2009	2008	
Non current assets			
Property, plant and equipment	93.537	88.750	
Property investment	1.793	1.813	
Goodwill	164.739	165.036	
Fixed duration intangible assets	12.429	14.787	
Equity investment in other companies	1	1	
Other non current assets	858	1.179	
Total non current assets	273.358	271.565	
Current assets			
Inventories	102.958	70.430	
Trade receivables	87.894	89.650	
Current tax credits	1.360	410	
Other current assets	11.416	5.406	
Cash and cash equivalents	8.715	14.674	
Total current assets	212.343	180.569	
Total assets	485.701	452.135	

^{*} Consolidated financial statements prepared in compliance with the IAS principles.

Annual Report 2009 - Financial Data



CONSOLIDATED BALANCE SHEET		
	year ended at 31/12/10	
(in thousands of Euro)	2009	2008
Shareholders' equity		
Group shareholders' equity		
Share capital	52.116	30.000
Reserves	105.529	49.339
Total Group net profit	22.108	9.381
Total Group shareholders' equity	179.752	88.720
Shareholdes' equity pertaining to minority shareholders		
Minority interests in capital and reserves	66	45
Net profit pertaining to minority shareholders	37	21
Total shareholders' equity pertaining to minority shareholders	103	66
Total shareholders' equity	179.856	88.785
Non current liabilities		
Medium/long-term	182.250	253.190
Provisions for risks and charges	420	992
Liabilities for employee benefits	5.295	5.579
Deferred tax liabilities	3.629	5.543
Other non current liabilities	6.131	5.035
Total non current liabilities	197.724	270.339
Current liabilities		
Amounts due to banks and other lenders	12.442	18.256
Current portion of medium/long-term loans	18.585	9.583
Provisions for risks and charges	469	492
Trade payables	53.234	43.460
Current tax payables	1.195	1.872
Other current liabilities	22.198	19.347
Total current liabilities	108.122	93.010
Total liabilities	305.846	363.349
Total shareholders' equity and liabilities	485.701	452.135



CONSOLIDATED INCOME STATEMENT			
	year ended at 31/1		
(in thousands of Euro)	2009	2008	
Revenues from sales and services	239.525	220.685	
Cost of sales	129.489	119.514	
Gross margin	110.036	101.171	
Other income	6.300	4.882	
General and administrative expenses	40.343	37.889	
Sales and marketing expenses	14.700	14.306	
Research and development expenses	7.975	5.706	
Other operating costs	2.834	3.062	
Operating result	50.484	45.090	
Financial charges	18.284	26.488	
Financial income	2.640	4.289	
Pre-tax result	34.839	22.892	
Income taxes	11.356	10.497	
Net profit for the year	23.483	12.394	
of wich:			
Net profit attributable to the Group	23.446	12.374	
Net profit attributable to minority shareholders	37	21	

AGGREGATE CONSOLIDATED INCOME STATEMENT		
	ye	ear ended at 31/12/10
(in thousands of Euro)	2009	2008
Net profit for the year	23.483	12.394
OTHER NET AGGREGATE PROFITS / (LOSSES)		
Translation differences on foreign company financial statements	(542)	(970)
Net loss on cash flow hedging instruments (cash flow hedges)	(796)	(2.023)
Aggregate net profit for the year	22.145	9.401
of wich:		
Aggregate net profit attributable to the Group	22.108	9.381
Aggregate net profit attributable to minority shareholders	37	21

Annual Report 2009 - Financial Data

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CONSOLIDATED CASH FLOW STATEMENT		
	year ended at 31/12/10	
	2009	2008
Net cash flow generated from operating activities (a)	31.092	52.007
Net cash flow absorbed by investment activities (b)	(15.317)	(20.353)
Net cash flow generated/(absorbed) by financing activities (c)	(21.658)	(25.435)
Total net cash flow d=(a+b+c)	(5.883)	6.219
Cash and cash equivalents opening balance (e)	14.595	8.381
Net effect of conversion of foreign currencies on cash and cash equivalents (f)	(2)	(7)
Cash and cash equivalents closing balance g=(d+e+f)	8.711	14.593

