

KEDRION
BIOPHARMA

Keep Life *Flowing*

ANNUAL
REPORT

2012

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"EVERYONE HAS
THE RIGHT TO LIFE,
LIBERTY AND SECURITY
OF PERSON"

Universal Declaration of Human Rights, art. 3

KEDRION
B I O P H A R M A

VISION

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 tran-

sferred from one human being to the next, and anyone can enjoy one's fundamental rights.

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.



CEO LETTER TO STAKEHOLDERS

FOR KEDRION, 2012 WAS A YEAR THAT COULD, WITHOUT EXAGGERATION, BE DESCRIBED AS EXTRAORDINARY, IN THE COURSE OF WHICH THE COMPANY MAINTAINED AND CONSOLIDATED ITS NATIONAL MARKET LEADERSHIP; MOREOVER, IT GAVE FURTHER DRIVE TO ITS ACTIVITIES ABROAD, WHICH AT YEAR-END ACCOUNTED FOR 65.7% OF TOTAL SALES.

Export growth was driven also by subsidiary Kedrion Biopharma Inc.'s acquisition on the US market of RhoGAM™, a medical specialty that has allowed the Company to target the US hyperimmunes market. This acquisition was made possible by a new shareholder, Fondo Strategico Italiano, which in addition to acquiring an 18.6% share in the Company, made a € 75 million line of credit available to it. It is a source of great satisfaction for all of us that Fondo Strategico Italiano identified Kedrion as one of the first companies in which to invest. It is a well know fact that the fund's mission is to identify Italian companies of major national interest that are economically and financially sound, and whose

profitability prospects are adequate, and whose opportunities for development are considered significant: Kedrion, very clearly, matched these characteristics.

In Italy, Kedrion continued to work in close cooperation with the National Health Service, inasmuch as the Company shares its strategy of pursuing plasma derivatives self-sufficiency. In this spirit, we are preparing to meet the new challenges that, in the near future, will arise from the regulations, decided on recently by legislators, concerning the allocation of the batches of plasma collected in Italy for the contract manufacturing of plasma-derived drugs. This new regulatory framework will open up the market to new companies, encouraging us to further improve our competitiveness.

We will continue to focus, with increased determination, on our objectives: consolidating our national market leadership, developing our business presence abroad, increasing our production capacity and our research activities, into orphan drugs too, continuing to invest in product and process innovation, which has always characterised the way we operate.

Paolo Marcucci
Kedrion President and CEO





2012
REVIEW

2012 AT A GLANCE

FACTS

ITALIAN BASED COMPANY WITH
A WORLDWIDE PRESENCE

1ST LARGEST SUPPLIER OF PLASMA
DERIVED PRODUCTS IN ITALY

DISTRIBUTION IN MORE THAN 80
COUNTRIES

SUBSIDIARIES IN EU, US AND LATIN
AMERICA

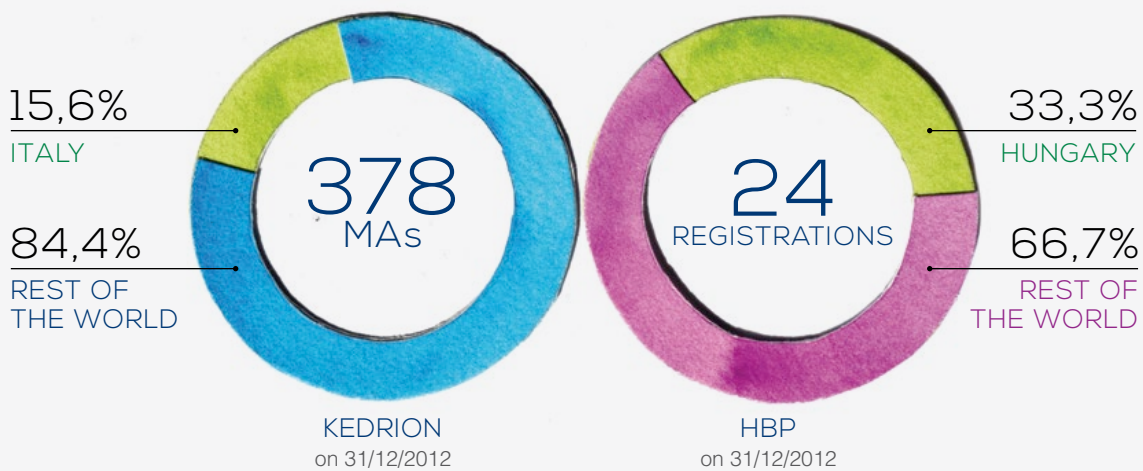
4 MANUFACTURING PLANTS
IN 3 COUNTRIES

CAGR OF 10,7% FROM 2001

COMPANY CERTIFIED FOR SA8000
AND OTHERS

FIGURES

MARKETING AUTHORISATION (MA) NUMBER



TURNOVER 2012: 378.000.029 €

TOTAL NUMBER OF EMPLOYEES



REVENUES GENERATED OUTSIDE ITALY:
234.300.000 €

15 COLLECTION CENTERS

WORLDWIDE PRESENCE



KEDRION
MEXICO

KEDRION
UNITED STATES

KEDPLASMA
UNITED STATES
KEDRION GROUP

KEDPLASMA
DEUTSCHLAND
KEDRION GROUP

KEDRION
SWITZERLAND

KEDRION
PORTUGAL

KEDRION
INTERNATIONAL

KEDPLASMA
PLAZMAFEREZIS
KEDRION GROUP



KEDRION
BIOPHARMA

KEDRION
BIOPHARMA

GROUP STRUCTURE



KEDRION GROUP
S.p.A.



KEDRION
S.p.A.

Parent company based in
Castelvecchio Pascoli (Lucca)
2 production sites in Italy



KEDRION BIOPHARMA
INC.

Commercialization in the USA



HAEMOPHARM
INC.

Holding



KEDRION MEXICANA
SA

Commercialization



HUMAN BIOPLAZMA
KFT

Production & Commercialization
1 production site in Hungary



KED PLASMA LLC
MEMBER A

Procurement
8 collection sites in USA



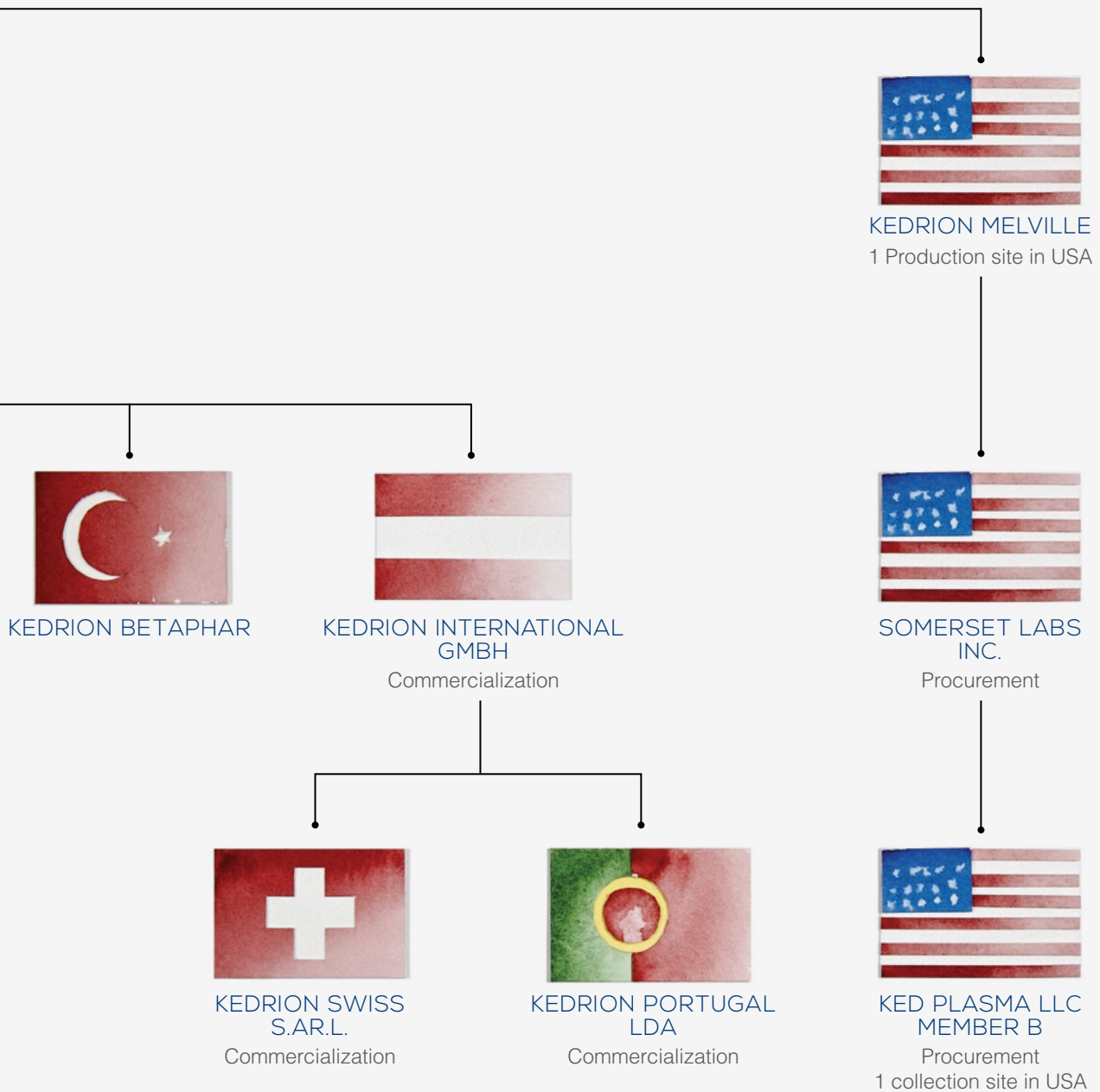
KED PLASMA
GMBH

Procurement
3 collection sites in Germany



PLAZMAFEREZIS
KFT

Procurement
3 collection sites in Hungary



KEDRION IN THE WORLD

SUBSIDIARIES

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Distribution in the following countries:

Austria

Bahrain

Bangladesh

Belgium

Bulgaria

Cyprus

Denmark

Egypt

Germany

Greece

Hong Kong

India

Indonesia

Iraq

Jordan

Kuwait

Lebanon

Malta

Macao

Pakistan

Philippines

Portugal (through Kedrion Portugal Ltda.)

Poland

Qatar

Russia and ex-CIS countries
(through JV based in Moscow)

Romania

Saudi Arabia

Singapore

Sri Lanka

Sweden

Spain

Switzerland (through Kedrion Swiss SarL)

Taiwan

Thailand

United Arab Emirates (U.A.E.)

Vietnam

Yemen

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Col del Valle Deleg. Benito Juárez

C.P. 03100 Mexico D.F., Mexico

info@kedrion.com

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Distribution in Mexico

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www.kedrion-swiss.ch

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Fax: +1 201 242 8913

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Táncsics Mihály út 82.

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hungaryinfo@humanked.com

www.humanked.com

Manufacturing in Hungary and distribution
in the following countries:

Bangladesh

Cyprus

Hungary

India

Kenya

Romania

Saudi Arabia

United Kingdom

Vietnam

Yemen

REPRESENTATIVE OFFICES

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11000 Beograd, Serbia

Tel: +381 11 262 1155

CONTACT FOR THE REST OF THE WORLD

For distribution in all other non EU states,
Latin America and Africa, please contact:

export@kedrion.com

+39 0583 1969.1

PRODUCT PORTFOLIO

HAEMOPHILIA AND OTHER BLEEDING CONDITIONS

EMOCLOT / PLASMACLOT /
Koāte-DVI*

Factor VIII / von Willebrand Factor concentrate

HUMACLOT**

Factor VIII/von Willebrand Factor concentrate

WILFACTIN***

von Willebrand Factor concentrate

AIMAFIX / HUMAFACOR -9**

Factor IX concentrate

EMOSINT

DDAVP Desmopressin

UMAN COMPLEX

Prothrombin Complex concentrate

CRITICAL CARE

UMAN ALBUMIN / UMAN SERUM /
ALBITAL / HUMAN ALBUMIN /
KEDRIALB / PLASBUMIN /
KEDBUMIN* / Albuked*

Human Albumin solution

AT III KEDRION

Antithrombin concentrate

K FLEBO***

Potassium aspartate

PLASMASAFE***

Pharmaceutical grade plasma

PRIMARY IMMUNE DEFICIENCIES AND IMMUNE-MEDIATED CONDITIONS

Ig VENA / HUMAGLOBIN /
KEDRIGAMMA / VENITAL*** /
Gammaked*

Standard i.v. Immunoglobulin

16% GAMMAGLOBULIN

Standard i.m. Immunoglobulin

VENBIG / KEYVENB

Anti-hepatitis B i.v. Immunoglobulin

IMMUNOHBs / UMAN BIG

Anti-hepatitis B i.m. Immunoglobulin

TETANUS GAMMA / TETIG

Anti-tetanus i.m. Immunoglobulin

IMMUNORHO / RhoGAM™ /
MICRhoGAM

Anti-D i.m. Immunoglobulin

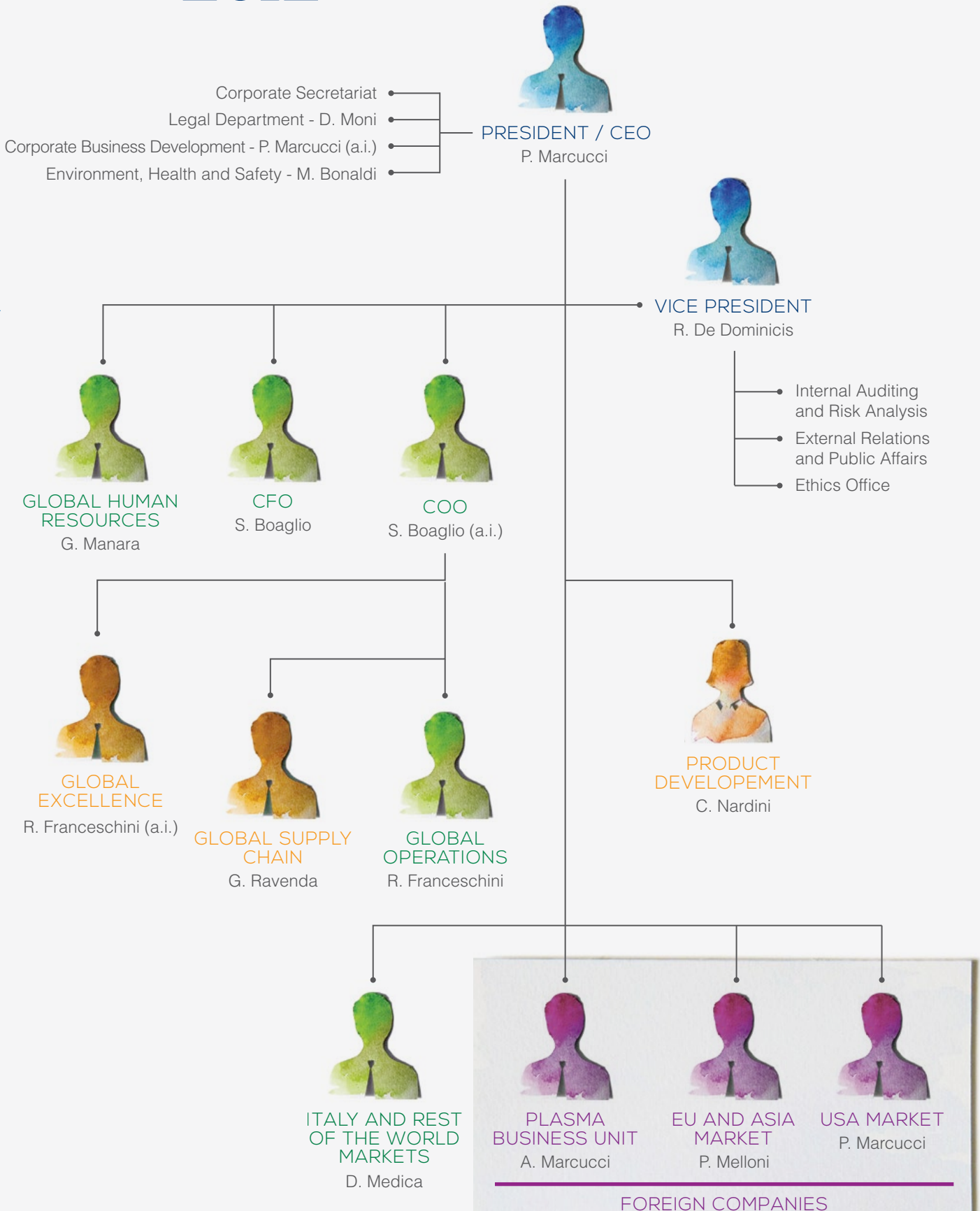
* products only available for the US market

** products only available for the Hungarian market

*** products only available for the Italian market

ORGANIZATION CHART

2012

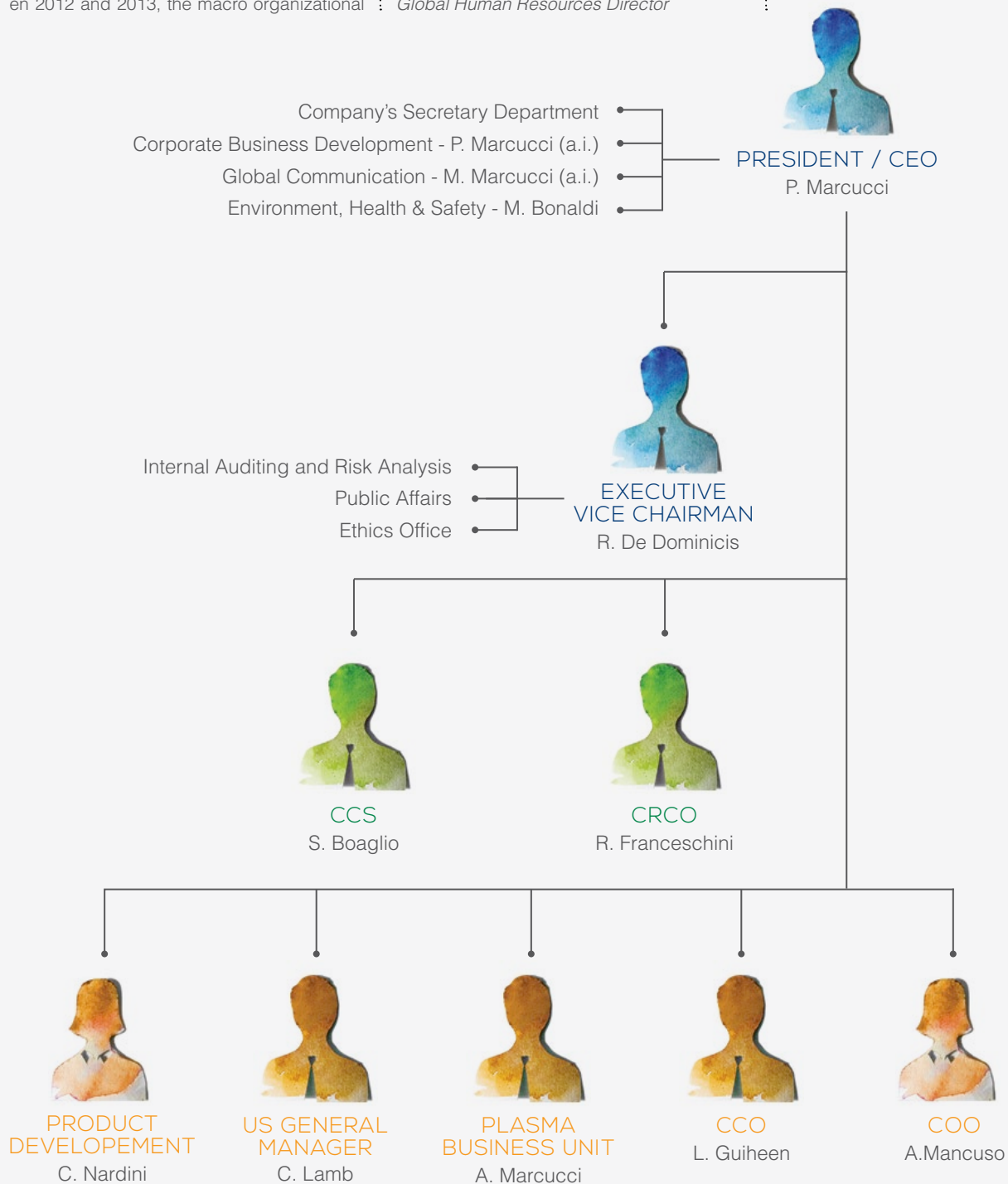


2013

"In line with the recent acceleration of the pace of Kedrion's on-going process of gradual internationalisation, corporate managerial figures are increasingly required not only to act but also to think at an international level, focusing their attention on this dimension from the formulation of strategies to the adoption of detailed operational plans. At the same time, the President and CEO is required to steer and coordinate Group strategies with the continuous support of figures with several levels of competence. For this reason, between 2012 and 2013, the macro organizational

model designed in 2008 has been re-structured in such a way as to concentrate the main responsibilities for Group guidance and management in a few positions that report directly to the CEO Paolo Marcucci. With its new organizational structure, the new Senior Management Team ensures that the Kedrion Group's transition towards a consolidated, successful, multinational dimension is smooth and expertly guided."

Giacomo Manara
Global Human Resources Director



MILESTONES 2012

JANUARY

350.000 KG OF PLASMA
PER YEAR

At the Hungarian plant in Gödöllő, the new Line 3, developed thanks to Kedrion technology, starts its GMP production. It will increase the Kedrion Group's production capacity by approximately 350.000 kg per year.

APRIL

PROJECT FIBRIN GLUE:
COMPLETED

Activities pertaining to the Fibrin Glue product development project are completed. On the one hand, industrial batches of the new product are successfully produced at the Sant'Antimo plant and, on the other, the product's clinical development for use in adults is completed.

JUNE

FSI ACQUIRES
KEDRION SHARE

Fondo Strategico Italiano (FSI) acquires Kedrion share, thanks to a financial transaction worth a total of € 150 million (€ 75 million capital increase and € 75 million to open a convertible or repayable line of credit).

JULY

2ND NATIONAL MEETING OF THE ITALIAN BLOOD SYSTEM

Supported by Kedrion, Fondazione Campus and SIMTI (the Italian Society for Transfusion Medicine and Immunohaematology) organised the 2nd National Meeting of the Italian Blood System in Lucca, attended by all of the country's Blood System's main stakeholders.

KEDRION GROUP'S NEW FINANCIAL SET UP

The holding company Kedrion Group was set up with the completion of the Fondo Strategico Italiano (FSI) transaction. 48.8% of its shares are owned by the Marcucci family's holding company Sestant, 32.6% by the Investitori Associati IV Fund, and 18.6% by FSI. Kedrion Group owns the Group headed by Kedrion S.p.A. as well as the US company Kedrion Melville, owner of the production facility based in Melville (New York, USA).

GLOBAL RIGHTS TO THE SALES OF RHOGAM™

Kedrion acquires the global rights to the sales of RhoGAM™, human anti-D immunoglobulin effective in the prevention of "haemolytic disease of the newborn" (HDN), successfully manufactured in the US for over 40 years.

OCTOBER

THE FIRST JEFFREY MODELL PAEDIATRIC IMMUNOLOGY CENTRE IN ITALY

Kedrion supports the creation of the first Jeffrey Modell Paediatric Immunology Centre in Italy with a three-year donation. The Paediatric Immunology Centre of the Meyer University Hospital in Florence joins the network of Jeffrey Modell Centres.

DECEMBER

PAOLO MARCUCCI APPOINTED NEW CHAIRMAN OF PPTA

Paolo Marcucci, CEO of Kedrion, is the new Chairman of the Global Board of Directors of the Plasma Protein Therapeutics Association (PPTA). Kedrion has been a member of the Global Board of Directors of the PPTA since 2008.

BLEEDING LISTS GO DIGITAL

Kedrion launches the "Bleeding Green" project: bleeding lists are converted from hardcopies to electronic files. This new initiative is aimed at supporting the Italian Blood System.

KEDRION SUPPORTS THE TEN PRINCIPLES OF THE GLOBAL COMPACT

Kedrion re-confirms its support of the Ten Principles of the Global Compact concerning human rights, working standards, the environment and the fight against corruption.



THE WAY FORWARD

BY PAOLO MARCUCCI

How would you rate the Company's performance in 2012, particularly in view of its considerable growth on foreign markets?

2012 was an extraordinary year, during which we maintained and consolidated our Italian market leadership and, in particular, gave further drive to our activities abroad, which at year-end accounted for 65.7 per cent of total sales. This growth was the result of the continuing presence on the US market of the three products covered by the 2011 agreements with a primary international operator, for which a new commercial organisation, with new staff and a new, US resident management team, was set up. Export growth was driven also by subsidiary Kedrion Biopharma Inc.'s acquisition on the US market of RhoGAM™, a medical specialty that has allowed the Company to target the US hyperimmune market.

To what extent did the entrance of Fondo Strategico Italiano contribute to improving company performances?

In addition to acquiring an 18.6% share, Fondo Strategico Italiano has made a € 75 million line of credit available to the Company, which allowed the acquisition of RhoGAM™, a very important operation for us. On the other

hand, because of the role it fulfils in Italy, Fondo Strategico Italiano also supports us in our strategic development decisions. The fund's mission is to identify Italian companies of major national interest that are economically and financially sound, and whose profitability prospects are adequate, and whose opportunities for development are considered significant: Kedrion, very clearly, matched these characteristics. So it is a source of great satisfaction for all of us that Fondo Strategico Italiano identified Kedrion as one of the first companies in which to invest.

Which strategic and organizational changes were needed to achieve this growth?

In the last five years we have experienced a global growth that has allowed us to go from being a single company to a Group.

At the end of 2012, we started a process of radical organizational changes that is still ongoing, made necessary by the fact that the Company has almost radically reinvented itself, with foreign sales topping domestic ones. Hence the need for a complete reorganization, achieved by means of a management structure tailored to meet the Company's new requirements. At the moment, for example, we are managing two major technology transfers. The first concerns the

Melville production plant, in the State of New York (USA), which was acquired in 2011, and the management of which we will completely take over as of July 2013. The second refers to RhoGAM™, which is currently being manufactured by the company from which we purchased it, and that, in the near future, will be manufactured by one of the Kedrion Group plants.

In addition to which, we have also started clinical trials on our new 10% liquid gammaglobulin, a product developed taking into account the characteristics of the US market, for which we will need a production site and, therefore, another technology transfer.

From the markets point of view, and also in terms of operations and investments, Kedrion has changed size, so our organizational structure had to be aligned with our new corporate reality.

Has Kedrion's development on the international market involved, or will it involve, changes in corporate vision and mission?

Both our vision and mission have firm roots, as the industry in which we operate requires a strong commitment, grounded in the social value of the transformation of plasma into pharmaceutical products: in most cases, in fact, these are live-saving drugs, which in

any case contribute to improving people's quality of life. Growth in the last five years has not changed our identity as an Italian company. If anything, becoming a global reality that operates in more than 80 countries worldwide, has been an incentive to take all the steps necessary to keep improving our products and industrial processes. We believe competition is a positive factor, which bears with it advantages in terms of culture, know-how and experience. It is an approach that has always been part of Kedrion's philosophy, and is shared by the entire management team.

The contract manufacturing regulatory framework is changing in Italy. What effects will these changes have, or which effects have they already had, on Kedrion's strategies?

In Italy, we will continue to collaborate with the National Health Service, given that we agree with its strategy of pursuing plasma derivatives self-sufficiency. In this spirit, we are preparing to meet the new challenges that, in the near future, will arise from the regulations, decided on recently by legislators, concerning the allocation of the batches of plasma collected in Italy for the contract manufacturing of plasma-derived drugs. This new regulatory framework will open up the market to new

companies, encouraging us to improve our competitiveness further.

We view the opening up of the market as a challenge, because new developments mean new opportunities. We have already started preparing for this new scenario: our products are registered on the international market, and we have set up plasma collecting organisations in the US, Germany and Hungary, to guarantee raw material procurement. We have also tried to strengthen our production capacity in third party countries, to be less dependent on Italy. In sum, we have taken a positive view of the opening up of the Italian market, as it has encouraged us to enter the international market successfully.

What changes are to be expected in view of further consolidating the Company's position on the market, and what strategic directives will the company pursue in the short to medium term?

We will continue to focus, with increased determination, on our objectives: consolidating our national market leadership, developing our business presence abroad, increasing our production capacity and our research activities, into orphan drugs too, continuing to invest in product and process innovation, which has always characterised the way we

operate. Our main market is undeniably the US, which at the end of 2012 accounted for 33% of total sales. In general, at this moment, it is necessary to strengthen existing markets, and to achieve this objective we will be upgrading our sales force and marketing activities.

Having to sum up in a few words Kedrion's strengths, which would you underline the most?

One of our main strengths is the fact that, in terms of the global plasma-derivatives scenario, we are amongst the smallest in size. In an industry that, in terms of volumes, has been characterised in the last twenty years by constant, significant volume increases, we can only grow. Another strength is our manufacturing system, which allows for the production of at least 4-5 finished products in the same plant. Our production plants are highly technological and efficient, and regulated by tailor-made quality systems. Moreover, we can count on a fairly broad range of products. These are some of the factors that, in a highly demanding scenario, ensure that we are competitive, and will allow us to meet all the challenges the market will present us with.





THE
COMPANY



SIMONE BOAGLIO

FINANCE

*"A NEW ORGANIZATIONAL MODEL TO SUPPORT
THE ONGOING PROCESS OF KEDRION'S
INTERNATIONALIZATION"*

**IN 2012 CHIEF
FINANCIAL OFFICER,
NOW CHIEF OF
CENTRAL SERVICES**

How would you rate the Company's financial performance in 2012?

FY 2012 was a very positive year for the Group in terms of results, and also because the foundations for further development were laid. Growth in the last two years has been driven in particular by Kedrion entering the US market, which is the main market for the plasma derivatives sector.

The Company's launch in the US, highly complex with regards to regulatory aspects, was planned, but not due to take place for some years. Kedrion succeeded in gaining a foothold in the market as early as mid 2011 with excellent results, thanks to which our American subsidiary, in its first complete year of business, reported sales of over \$150 million. This success was helped also by the acquisition, last year, of RhoGAM™, a very well established product acquired from Ortho Clinical Diagnostics, a division of Johnson&Johnson.

In 2012, the Group's overall growth was driven by expansion in the US, with consolidated sales (data refers to the annualised consolidated results of Kedrion Group SpA) of € 381 million against the previous year's € 77 million, with an increase in sales of over € 100 million.

Marginality also improved: consolidated EBITDA increased from € 66 to € 82 million in a generally difficult year for most companies.

Entering the US market also had positive repercussions from a financial point of view: American customers have faster payment times, reducing the need to resort to bank loans to finance current activities.

In 2012, in fact, the Group reduced its net financial position from just over € 200 million to € 165 million; a very positive result, especially when the fact that the debt-to-equity ratio has dropped to almost two times is taken into consideration, testifying a financial stability that allows us to look to the future with greater peace of mind.

What, for Kedrion, is the weight of the foreign market compared to the Italian market?

We are an Italian company with a strong localized identity. When it was set up in 2001, Kedrion achieved 80% of sales in Italy and less than 20% abroad.

In recent years, according to precise strategic guidelines, the Company has undertaken an internationalization process, which in the pharmaceutical sector is always long and complex.

Sales in Italy have remained more or less stable, with all growth concentrated abroad: the percentages have been inverted, and 2012 closed with approx. 62% foreign sales compared to Italy's 38%.

This marked a major turning-point that required updating our organizational model to align it with the changed set-up of the Group, which owns various companies outside Italy operating with different levels of autonomy and according to different business models.

To what extent did the entry of new shareholders contribute to improving company performance?

The year 2012 saw Fondo Strategico Italiano join the Company as new shareholders.

Its financial contribution allowed the acquisition of RhoGAM™ from Johnson&Johnson, and allowed Kedrion to enter the US hyperimmune products market directly contributing to the international growth of the Company. Extending the shareholder structure to include this new, important shareholder has led to Kedrion adopting a more institutional, formal style of conducting its Board Meetings, and also for its economic and financial communications with the outside world.

What actions have been taken or are planned for the future to reinforce the expertise of Kedrion staff in dealing with new challenges on the national and international markets?

The higher percentage of foreign vs. Italian sales has changed the balance internal the Group prompting it to reconsidered the best organizational model. With the assistance of an external consultant, it was decided to maintain an operational mandate over the US, basically for the commercial part, whereas the rest the Company insourced from its Italian HQ, mostly from its corporate departments. The process is ongoing: the larger part of it has been completed at a communications level, while other aspects are still under discussion.

This is a very important phase: the new organizational model has been chosen, and now the transition needs to be managed.



RODOLFO DE DOMINICIS ETHICS

*"WE HAVE BEEN SA8000 CERTIFIED SINCE 2003 AND OUR
WORK ON ETHICS IS NOW TAILOR-MADE FOR KEDRION"*

EXECUTIVE VICE CHAIRMAN

Kedrion was one of the first companies in Italy to be awarded SA8000 certification: could you run through the history of the Company's commitment to this issue, given that Corporate Social Accountability has always been a major concern? Which steps forward were made in this direction in 2012?

As we were first awarded SA8000 certification in 2003, in 2012 all activities were mainly directed at maintaining and developing the system, which has been implemented continuously over the years. Not merely a set of rules, procedures and manuals, this system works and lives alongside the Company: employees are increasingly turning to it to address the many difficulties arising from everyday life. It has become a "safety valve" for the system, which if affected by an inconsistency seeks to re-establish stability by means of the Ethics Office.

We also carry out activities directed at identifying any infringements of the standard, through constant internal audits thank to which we ensure the system keeps working. When we started out, in 2003, I was convinced that it was not possible to implement the SA8000 system fully. I can now say that the Company is well balanced, with a generally good, cooperative climate.

Certainly, there are exceptions, which are assessed, examined, studied and corrected. Corrections are carried out by the designated organizations, which usually are those that deal with personnel or, where necessary, by the CEO.

Our work on ethics is now tailor-made for Kedrion.

Have there been any repercussions on the transparency of external stakeholders communications...

I have mainly outlined the internal aspect, which is the strong part of the company and that, thanks to its adoption of this type of "voluntary" system, builds our reputation in an intelligent manner. A reputation, in fact, is built from the inside and then developed externally. Communication is an essential element in the external interpretation of the Company. Kedrion operates within an extremely delicate system: a minor element is sufficient to shift the level of risk towards an area where this is difficult to sustain, so even minor elements must be managed, and the social accountability system is one of the factors that mitigate risk.

Kedrion has reconfirmed its compliance with the 10 principles of the United Nations Global Compact: what does this compliance imply, and what does it involve?

SA8000 is an international certification that was awarded to Kedrion also in view of its worldwide dimensions. Respecting Global Compact social accountability procedures and principles, and complying with certain standards, implies a different approach compared to that arising from a national perspective: we are moving ever more rapidly and decisively towards a global dimension also thanks to decisions such as these. The rules of the Global Compact are very stringent, and allow us to look to our internationalization with increased conviction. We have taken major steps forward in this direction, but extra momentum is needed if our aim is effectively that of becoming the best. We must avoid stalemates, and refer to strict, strong rules such as the Global Compact, which allow us to measure our performances against cases of excellence. The Company is proud of the fact that it is competitive also from this point of view, and not only commercially.



MARTA BONALDI ENVIRONMENT

"AS CONFIRMED BY THE INTERNATIONAL CERTIFICATIONS AWARDED OVER THE YEARS, A COMPANY COMMITTED TO GUARANTEEING RESPECT FOR THE SOCIAL COMMUNITY AND TO MITIGATING ITS ENVIRONMENTAL IMPACT, SUCH AS KEDRION IS, CAN CLAIM TO BE A GREEN COMPANY"

HEAD OF ENVIRONMENT, HEALTH & SAFETY

Attention to the environmental impact of company business activities has always been a mainstay of Kedrion's environmental policy. What actions were taken during the last year to pursue this goal?

For Kedrion, environmental management has never been merely a regulatory obligation but a firm, continuous commitment to constant improvement of Company instruments and processes.

The goals pursued from the outset and also during 2012 are mainly tied to saving energy, emissions, waste, wastewater drainage, noise and soil. More specifically, minor but very important steps forward were taken during the year with regards to environment-related issues.

At the Bolognana facility, a cooling system has been replaced with a more environmentally friendly ammonia-based appliance. Also at the Bolognana plant, modifying a production process has allowed a reduction not only in the quantities of drinking water purified, but also in the chemical products used and waste generated by this process.

The Company has also allocated a new resource to cover the role of Energy Manager, responsible for the rational use of energy, thus further demonstrating its commitment to environmental issues.

These policies, which will have major economic and management impacts, but that are viable and sustainable these last notwithstanding, mark the path the Company has decided to follow, identifying margins for improvement not only for the environment but also for business.

Kedrion is firmly and actively committed to protecting the environment. Can it be defined as green company? If so, why?

As confirmed by the international certifications awarded over the years, a company committed to guaranteeing respect for the social community and to mitigating its environmental impact, such as Kedrion is, can claim to be a green company. By adopting the ISO 14001 international standard, Kedrion began, in 2005, to implement an environment management system, which led, in 2006, to the certification of its Lucca sites by SGS Italia. With the acquisition of the Sant'Antimo production site, certification was also extended to the Naples facility. At the same time, the Company adopted EMAS regulations. Since 2007, the date of its EMAS registration, Kedrion issues a yearly environmental report renewing its commitment to the environment, and providing environmental performance data in accordance with the indicators set out in EMAS III. During my 13 years with the Company, I have witnessed a considerable growth in safety and environmental culture, a complete change of attitude that has raised employees' awareness of these issues, fostering the move away from the perception of safety and environmental protection as obligations and, thereby, costs to the Company, to a view that sees these as business opportunities and competitiveness factors. In 2012, many of the objectives set for our Italian sites were achieved. The time has come to open ourselves up to international realities, transferring to others our extensive experience and our know-how in the management of environmental systems. The strategy is to export an operational model that will surely allow other members of the Kedrion Group to further improve their performances in this area.



ANDREA MARCUCCI PLASMA COLLECTION

*"IN 2012, PLASMA COLLECTION IN US CENTRES,
STRATEGICALLY ESSENTIAL FOR AMERICAN MARKET
FUTURE DEVELOPMENT PLANS, WAS STRENGTHENED"*

PLASMA BUSINESS UNIT DIRECTOR

During 2012, Kedrion further strengthened its worldwide network of plasma collection centres. Which were the most significant improvements achieved during the year?

The Kedrion Group has, since 2004, been engaged in the collection and commercialization of plasma from corporate-owned foreign collection centres. This activity, managed by the Plasma Business Unit, has been developed with the aim of guaranteeing flexible raw material procurement, ensuring the availability of specific volumes of plasma independently of market situations. 2012 was a very positive year for plasma collection, with a general growth of more than 40% in volumes. A result brought about, on the one hand, by the organic growth starting from early 2011 of existing centres, which have registered a 26% increase compared to the previous year, and, on the other hand, by the centres acquired in June 2011 from Grifols, and the new anti-D hyperimmune plasma collection centre in Buffalo, acquired in July 2012 together with the RhoGAM™ product, becoming fully operational. Six Kedrion owned US collection centres (Reseda, Johnson,

Kingsport, Bristol, Pensacola and Mobile) have increased their volumes from approx. 243 kL to around 313 kL, up 29% compared to the previous year. To these should be added the results of the centres acquired from Grifols (Mobile 2 and Winston-Salem), which achieved a 180% increase in volumes collected, from round 32 kL to approx. 88 kL, due to collection increases but also to the fact that, in 2011, these centres contributed only in the second part of the year. In just five months (from August 2012), Somerset Laboratories in Buffalo, acquired from OCD (Ortho Clinical Diagnostics) with the RhoGAM™ operation, contributed additional volumes of around 9 kL. The three German centres (Fürth, Ingolstadt and Bayreuth) increased their volumes from approx. 76 kL to around 90 kL, with an increase of 18% compared to the previous year. Hence 2012 has been a year of strong growth for the Plasma Business Unit, which has increased collections in its US centres, regarded as strategically essential to the Kedrion Group's plans for the future development of the American market. We are expecting US collections to increase further thanks to the opening, in the next 5 years, of new centres, which will allow us to improve the balance between the production capacity of the Melville plant and plasma procurement.



CLAUDIA NARDINI

R&D

"KEDRION'S COMMITMENT TO RESEARCHING AND DEVELOPING INNOVATIVE PRODUCTS IS REFLECTED IN CONSTANT, TARGETED INVESTMENTS. KEDRION IS ALSO COMMITTED TO RESEARCHING ORPHAN DRUGS USED IN THE TREATMENT OF RARE DEFICIENCIES"

PRODUCT DEVELOPMENT DIRECTOR

How would you describe the principal characteristics of the Product Development department?

Product Development embraces the entire product development chain, from basic research, pre-clinical and clinical development up to and including market launch. As Product Development Director, I coordinate the Research & Development, Clinical Operations and Medical Affairs functions, the Medical and Scientific Information, Pharmacovigilance and all those activities relating to the demonstration of the effectiveness of our production processes in the removal and/or inactivation of viral and non-viral agents.

Kedrion is also committed to researching orphan drugs for rare deficiencies: which main objectives were achieved during 2012?

The first goal achieved is ethical, as Kedrion first approached the orphan drugs sector to study these products and to provide solutions for diseases for which few treatment options, or only stop-gap therapies, are available. This activity helps to put across the high scientific levels reached by Kedrion, thereby creating an advantage also in terms of the external perception of the Company. The second objective is to optimize the use of the raw material, plasma, thereby further underlying the importance of donations.

The first orphan drug the Company intends to register is the Plasminogen Concentrate in the form of eye-drops. Kedrion regards this product as a major investment. The history of rare diseases drugs, in fact, shows that in many cases a virtuous cycle is triggered:

certain rare diseases are not diagnosed because treatments for them do not exist but, once a treatment is identified, research into these diseases increases, with a concurrent improvement in the diagnostic instruments available and an increase in demand for orphan products. Furthermore, working on unknown elements also encourages researchers to consider the problem from a different viewpoint: opportunities open up for networking, for sharing know-how inside and outside of the Company; all knowledge acquired managing unusual or highly critical situations can also be used to optimize existing products.

The second product will be Factor V; can you tell us more about it?

Research into Factor V is also proof of Kedrion's firm commitment to working with orphan drugs. Through agreements with the Regione Toscana and with Toscana Life Science, Kedrion has set up, in Siena, a dedicated production plant, the only one of its kind in Italy, for research into plasma-derived orphan drugs, leaving its other plants free to continue their registered products dedicated activities. The plant, recently inspected by the Italian Medicines Agency (AIFA), will become the plasma-derived orphan products' "scientific farm".

The continuous improvement of Kedrion products, also through substantial investments in technological innovation, is an integral aspect of the company's mission. What were the most significant results achieved in 2012?

At the moment, there are 19 projects in our product pipeline. In economic terms, lead products include immunoglobulins, and Kedrion is about to launch a standard 10% intravenous immunoglobulin and a 16% subcutaneous immunoglobulin.

Insofar as the coagulation area is concerned,

Factor VIII and Factor IX are being optimized at both technical and research levels with studies for new indications and product safety. This area also comprises the SIPPET study, in which Kedrion takes part providing its FVIII concentrate. The aim of this scientific observational study is to provide answers to the most challenging complications arising from haemophilia A treatment observed over the years of clinical practice: inhibitor development and the role of plasma-derived and recombinant Factor V in this condition.

Kedrion is also developing new products for emergency therapy, i.e. critical contexts that require immediate administration of plasma or albumin. This area also comprises the Entegriion project, which developed out of a US Department of Defence (US Army and US Navy) request, i.e. a Virus Inactivated Spray-dried Plasma treated with solvent-detergent to be used as a fresh frozen plasma substitute. Thanks to its formulation, this product is easier to store in extreme environments and situations.

Activities relating to the Fibrin Glue product development project were completed in 2012 with the successful production of industrial lots of the new product at the Sant'Antimo plant, and with the completion of the clinical development of the product for adults. Which milestones have led to the achievement of this major strategic objective?

This success was achieved thanks to a technology transfer internal to the company. Studying the "prototype" of the product and the process was followed by its industrialization. The registration dossier, presented in Italy in 2012, is currently being analyzed by the AIFA, and registration is expected by the end of the year.



RODOLFO FRANCESCHINI PRODUCTION

"YIELD IMPROVEMENT AT THE ITALIAN PLANTS OF THE KEDRION GROUP, FINALIZATION OF THE HUNGARIAN FACILITY'S NEW LINE, AND PRODUCTION CAPACITY EARMARKED FOR NEW PRODUCTS, ARE AMONGST THE MOST SIGNIFICANT RESULTS ACHIEVED IN 2012"

CHIEF OF GLOBAL OPERATIONS AND GLOBAL EXCELLENCE IN 2012, AS OF 2013 CHIEF REGULATORY AND COMPLIANCE OFFICER

Kedrion's foreign acquisitions, from Hungary to the United States, have brought about the need for major technology transfers, production rationalizations, and for plants to be renewed or extended. Could you describe the actions undertaken in this sense in 2012?

In 2008, we acquired the fractionation plant of Gödöllő, near Budapest, in Hungary. The plant had a fractionation capacity of around 200,000 litres of plasma per year. Implementation of the HuGE (Hungary Gödöllő-Expansion) project made it possible to increase production capacity by 350,000 litres, at the same time aligning process standards with those used by Kedrion at its main Bolognana facility, in the Province of Lucca. This also had the objective of meeting the need to integrate the specific activities carried out by the different plants of the Group, by means of an effective synergy between purification and fractionation capacity. The HuGE project was completed during 2012, and the new production line allows for the processing of around 90,000 litres of plasma, twice the planned quantity and one month ahead of schedule. A major result, not only in terms of economic and financial return for the Hun-

garian company that manages the Gödöllő plant, Human BioPlazma, but also in terms of engineering design. Another Hungarian project of great relevance was the Gotan project, completed thanks to a technology transfer from Bolognana that allowed the implementation of so-called dynamic, as opposed to static, thawing, which had advantageous consequences in terms of finished product yields. Lastly, a number of projects have been launched in Hungary aimed at insourcing microbiological and chemical quality control laboratory activities; these were developed to an advanced stage of completion in 2012, and will be completed during 2013. In the United States, no work was carried out on the Melville plant in 2012 as it was managed by a third party operator. An action plan will be launched in 2013-2014, and, in the same time frame, the process of internationalization of RhoGAM™ production activities will get underway.

How would you describe the performance of the two Italian production plants of the Kedrion Group in 2012?

Both the Italian plants of Bolognana (Lucca) and Sant'Antimo (Naples) achieved very good production levels, in line with expectations, also thanks to the investments made in recent years. During 2012, Bolognana's new aseptic filling area was definitively authorized, and it now operates alongside the existing five. Importantly, Bolognana has also been allocated production capacity for the manufacturing of an experimental product, next generation 10% immunoglobulin based on the chromatographic method, on which a clinical study has been started in the United

States. At the Sant'Antimo facility, the production yield of inactivated solvent detergent treated plasma, a production line specific to the Neapolitan plant, has been improved. Also, 2012 marked the successful preparation, in cooperation with the different Company departments involved, of the dossier for the registration of Fibrin Glue, a product developed in-house by Kedrion's Product Development department, and manufactured by the Sant'Antimo plant. It is expected that Fibrin Glue, which is a bio-surgery product, will be marketed in 2013.

Kedrion has a department dedicated to Global Excellence. What are its functions and which results were achieved in 2012?

Global Excellence is a department that was set up by Kedrion's CEO based on the Japanese concept of continuous improvement; it aims to provide support in raising the performance standards of all areas of the Company. In the course of 2012, the department was re-structured focusing on two main aspects: firstly, global quality, i.e. the cross-company quality system based on voluntary certification systems and quality assurance activities pertaining to pharmacovigilance and pre-clinical and clinical studies; secondly, activities relating to the process of "continuous improvement" that covers the entire company. More specifically, various "continuous improvement" projects are underway, aimed in particular at plant warehouses, while other projects that will be ongoing in 2013 concern the production, logistics and quality departments.



FERDINANDO BORGESSE MARKETING

"GEOGRAPHICAL EXPANSION HAS A POSITIVE IMPACT ON LOCAL PATIENTS COMMUNITIES, AFFORDING THEM AN EASIER, MORE DIRECT ACCESS TO TREATMENT "

INTERNATIONAL MARKETING DIRECTOR

With a three-year donation, Kedrion supported the launch of the first Jeffrey Modell Paediatric Immunology Centre in Italy, which opened in 2012 at the Paediatric Immunology Centre of the Meyer University Hospital in Florence. How did this initiative come about? What are its main objectives?

The initiative grew out of direct contact with the Modell family, which is committed at a worldwide level to the prevention and treatment of Primary Immunodeficiency in children and adults. Their experience is first hand, having lost their son Jeffrey, after whom the Foundation is named, to the disease some years ago. Since then, the family has untiringly dedicated its personal and professional efforts to improving the diagnosis of this pathology, and to facilitating access to care for the families of those affected by the disease. This initiative reflects Kedrion's commitment to projects characterised by a strong social responsibility. The first Jeffrey Modell Paediatric Immunology Centre, dedicated to the diagnosis and treatment of Primary Immunodeficiency, was set up in Italy thanks to Kedrion's generous donation.

What other initiatives were launched in 2012 that confirm Kedrion's commitment to rare diseases?

One of the most important projects reflecting Kedrion's direct commitment to rare diseases

is the development of an orphan drug for the treatment of Ligneous Conjunctivitis, a disease that also affects children. Kedrion is currently developing a dedicated product in the form of plasminogen eye drops. Prior to this, the only treatment available for this very rare disorder was surgical excision. An opportunity for direct involvement came about in 2007, when the family of an Italian child affected by this disease appealed to the Ministry of Health, requesting access to experimental treatments. The Ministry of Health singled out a number of companies able to take up the challenge, but only Kedrion answered the appeal, investing human, financial and industrial resources to develop a treatment. The child was offered immediate access to the treatment, which is ongoing, as Ligneous Conjunctivitis is a chronic disease with a very high recurrence rate. This result, and the fact that the product received orphan drug designation in the EU and US, lead Kedrion to develop the plasminogen concentrate that would ensure worldwide access to the treatment. A clinical study is now being carried out on this drug, in Italy and abroad, in cooperation with the Meyer University Hospital in Florence and with specialized US hospitals.

Kedrion has always actively supported voluntary blood donations. What were the main results of this partnership in 2012?

Training and information events were organized in 2012 in conjunction with the main blood donor associations: Avis, Fidas, Fratres and the Italian Red Cross. These activities targeted the top management of the various organizations as well as young donors. In Italy, inasmuch as blood is periodically do-

nated by unpaid voluntary donors, the high ethical value and cultural aspects of donating blood were particularly emphasised. Cooperating with voluntary associations, we prioritized the corporative dynamics of belonging to an association, working together to define donors' training and information requirements, and providing access to training services through the specialized teaching delivered by the Fondazione Campus in Lucca. Another interesting aspect concerned training on the industrial process that allows the transformation of plasma from donation in to finished product: delegates from the main voluntary associations took part in introductory courses aimed at bringing them closer to the industry, visiting our production sites and also experiencing first hand personal involvement.

Which were the areas of major development in 2012?

During 2012, Kedrion continued its process of geographical expansion and consolidation, strengthening its global presence with an increase in registrations of products in new countries, mainly Asia, North Africa and the Middle East.

Apart from the positive impact this has on the solidity of the Company, it also has an equally important effect on local patients communities, gradually affording them easier, more direct access to treatments.



DANILO MEDICA DISTRIBUTION IN ITALY AND RoW

"OUR AIM IS TO RETAIN OUR LEADERSHIP OF THE ITALIAN MARKET AND TO PROMOTE KEDRION'S FURTHER GROWTH DRIVEN BY INTERNATIONAL MARKETS"

**IN 2012, DIRECTOR
OF ITALY AND ROW
MARKETS, NOW ITALY
COUNTRY MANAGER**

Kedron decided some years ago to work in close cooperation with all its stakeholders. How did Kedron implement this strategic approach in 2012?

As an integral part of the Italian Blood System, a role assigned by Italian Law No. 219/2005 to the industrial partner for the processing of national plasma, Kedron operates in close cooperation with national institutions (Ministry of Health, Istituto Superiore di Sanità), the National Blood Centre, the Italian Medicines Agency, as well as organizations operating at a regional level (Regional Blood Centres), blood donor associations and federations, professionals, scientific societies and patients' associations.

Aware of the sweeping changes currently affecting the national transfusion system, Kedron is supporting the Regions in the process of complying to the minimum structural, technological and organizational requirements imposed European legislation, making available to these its know-how and resources. Kedron has dedicated an intense training activity to blood donor associations, targeting young people in particular.

It has also contributed to the continuous update of professionals supporting their participation in international, national and regional congresses. The main highlights of the SIMTI (Italian Society of Transfusion Medicine) report refer to the organization, in cooperation with the Fondazione Campus in Lucca, of its 1st and 2nd Meetings of the Italian Blood System.

The events, which took place in May 2011 and in June 2012, provided an important occasion for discussion and debate between the stakeholders of the Italian Blood System.

Kedron fractionates the plasma collected by the Italian Regions on behalf of the national health system under a contract manufacturing agreement. What were the most significant results generated by this partnership in 2012?

In 2012, Kedron continued to improve the quality of the contract manufacturing service it provides to the Italian Regions on behalf of the national health service. For example, by implementing the regional requirement planning process, which is carried out in constant, continuous contact with the Regions, Kedron was able to respond more effectively to the demand for plasma-derived medical products, an area in which Italy is not as yet self-sufficient. Kedron was particularly committed to supporting the Regions in promoting a broader use of plasma-derived Factor VIII (from national plasma), a life-saving drug used in the treatment of a rare disease, type A haemophilia, which is still not as widely used in Italy as it is in other European countries, and the use of which would contribute to adding even more value to plasma donation.

Kedron succeeded in retaining its leadership of the Italian market in 2012 despite the generally difficult economic and financial situation. Which factors contributed to this significant result?

People determine the success of a company, and the Company owes the consolidation of its position and its growth to the men and women who work for it. The undeniable quality of the Company's products and services set Kedron apart from other players on the market; this is particularly evident in certain areas such as specific immunoglobulins.

Kedron continued to expand its international presence throughout 2012. Which main results and objectives were achieved?

Although we have achieved our goal of consolidating our leadership on the Italian market, Kedron's future development

will be driven by growth on the international market. The most significant RoW markets (Latin America, Africa, Caucasus and Balkans) results included growth in Mexico and Colombia, consolidation in the Balkans and the establishing of new partnerships in as yet unexplored markets. The Company reinforced its presence in countries where it operates through its own subsidiaries and those where it operates through distributors, leading pharmaceutical companies with all the requirements needed to qualify as our partners.

In 2012, Kedron launched the "Bleeding Green" project according to which bleeding lists have been migrated from hard-copy to computer media. This is a new activity developed by Kedron to support the Italian Blood System. How was this initiative received? What results have been achieved?

Bleeding lists contain information regarding each bag of plasma donated. In the past, this information was stored in hard-copy form; thanks to this project, it has been digitalized, thereby improving communication with the transfusion services and plasma traceability, and optimizing timing schedules. The term "green" has been adopted to stress the positive environmental impact of the project, which aims to do away with all hard-copy media in the communication between our Company and Italian transfusion centres. "Bleeding green" is part of a much broader program called Emoked, i.e. a software that will be available at the start of 2014 and is intended to simplify communication between the Italian Blood System and Kedron. Providing complete visibility over the entire production cycle, Emoked will make it possible to track all related activities: from plasma collection to its conferment to Kedron, from plasma entry at the plant to the processing of the finished product.



NEAL FITZPATRICK DISTRIBUTION IN USA

"KEDRION USA ACHIEVED CONSIDERABLE SUCCESS FOR FOUR SIMPLE REASONS: PEOPLE, FOCUS, COLLABORATION AND PASSION"

VICE PRESIDENT
OF COMMERCIAL
OPERATIONS
AT KEDRION
BIOPHARMA INC.

In 2012, in very challenging economic and financial general circumstances, Kedrion USA achieved an excellent turnover.

In your opinion, which factors contributed the most to this important result?

For Kedrion Biopharma, Inc., 2012 was the first full year of operation in the United States. This marketplace is both highly competitive and a source of great opportunity. Success in this market is essential for Kedrion Group as a whole.

Though 2012 was very challenging, both economically and in general, Kedrion USA achieved considerable success for four simple reasons: people, focus, collaboration and passion.

For the organization, 2012 was a building year in terms of bringing in highly talented, experienced and skilled people for key leadership positions. Individuals were chosen for their vast experience and accomplishments in their areas of responsibility. This enabled them to share best practices from other organizations and incorporate quickly within Kedrion.

The focus on products helped us to quickly establish Gammaked™ in the US IVIG marketplace first, then to prepare Koāte™.DVI for long-term success after more than 15 years without promotion. Finally, we prepared the organization for RhoGAM™ Brand, which we

acquired on August 1, 2012: it was important to ensure a smooth transition of RhoGAM™ from Ortho Clinical Diagnostics (OCD), which had sold the product for more than 40 years, and to quickly change the negative market share trends the product had been experiencing over the previous four years. We successfully stemmed the tide on market share loss and, in fact, showed an 8% gain from 4th quarter 2012 to 1st quarter 2013.

Even though we are a relatively small organization in the US, we needed to clearly define our responsibilities and be accountable for each of our roles. Continuous communication and collaboration were vital for us to be focused on the job at hand while at the same time understanding what each department was doing, to avoid duplicating efforts and to ensure optimal functioning collaboration. Passion is the mantra for the team we have brought on board at Kedrion Biopharma. We have gathered a group of highly experienced and committed individuals who know what it takes to be successful. We believe in the organization's mission. And we are passionate about the products we sell because we understand how they can benefit the patients who receive them. It's hard to fail with such a powerful combination.

In 2012, Kedrion acquired worldwide sales rights for RhoGAM™, human anti-D immune globulins, effective in the prevention of hemolytic disease in the fetus and newborn (HDFN).

How did this acquisition come about? How did you grow the RhoGAM™ brand in 2012?

RhoGAM™ Brand remains the gold standard in the HDFN community and is the market leader within the anti-D space. Yet it was a brand in decline - losing its custo-

mer base, market share and volume to its chief competitor, Rhophylac™, sold by CSL Behring. OCD, though the proud owner of RhoGAM™ Brand, had allowed the market to become genericized by CSL, moving RHIG from a highly differentiated sell to one focusing on cost. CSL was attempting to move the product choice from the Blood Banking department to the hospital pharmacy - a department historically more interested in cost savings than product differentiation. We knew that in order to restore the preeminence the RhoGAM™ Brand had had in the past, we needed to change the 'selling game' to one of product differentiation and superiority. We needed to show that RhoGAM™ Brand offers superior value because it provides the patient and her baby with the most benefits. This is due to its longer half-life (which means 'peace of mind' to the patient and her physician) as well as its superior purity and safety (in terms of higher IgG content, small and dedicated donor pool, lack of added albumin and coverage for West Nile virus) and its unmatched heritage. Indeed, RhoGAM™ Brand has been called "one of the greatest advances in the history of obstetrics".

It remains important to transition the conversation with decision makers and influencers away from product cost to what is best for the mother and baby. This strategy seems to be working, though there is much more work still to be done. We already have had some success in growing the volume and the market share for RhoGAM™ Brand in the short time since we acquired the brand. The entire Kedrion USA organization is committed to RhoGAM™ Brand and to giving women one less thing to worry about during pregnancy.



ROBERT LEFEBVRE

DISTRIBUTION IN EU, ASIA AND MIDDLE EAST

"IN 2012, THE PRESENCE OF THE KEDRION GROUP IN EUROPE, MIDDLE EAST AND ASIA WAS CONSIDERABLY STRENGTHENED. A NEW MANAGEMENT STRUCTURE CREATES A CLEAR ACCOUNTABILITY FOR THE COMMERCIAL SUCCESS OF ALL THE PRODUCTS"

EU, MIDDLE EAST AND ASIA SALES DIRECTOR

Kedron International has played an important role in the Group's expansion in the EU, Middle East and Asian markets in 2012: which are the main results achieved?

In 2012, the presence of the Kedron Group in Europe, Middle East and Asia was considerably strengthened. A new Kedron brand identity was implemented with a change in the name of the operating unit from Ked Pharmaceuticals to Kedron International GmbH (KIG). This means that this year onwards, all activities in this region will be conducted under the name of Kedron International.

Additionally, the region was re-organized under a new management structure aimed at creating a clear and more geographically aligned accountability for the commercial success of all Kedron Group products, whether they are manufactured in Hungary by the subsidiary Human BioPlazma or by the Group's manufacturing facilities in Italy. According to this re-organization, Kedron International has three distinct regions under its management: Europe, the Middle East and Asia, each now managed by experienced and seasoned commercial executives. In particular, the new structure helped us to strengthen our direct commercial presence in Germany and to achieve a strong growth in total turnover; to realize very strong sales performances in Poland, the Middle East region and in Asia; and to perform a successful

return to the Greek market.


Besides, we launched our Hepatitis franchise in Germany, Poland and the Nordic territories.

In 2012, the new Kedron International GmbH team was able to overachieve budget targets for the year, both in total turnover and in profitability. In addition, KIG recorded strong growth of over 18% in turnover compared to 2011 results. Due to these results, Kedron International contributed close to 10% of overall Group turnover in 2012.

Do you see Eastern Europe as a real emerging market for Kedron in general?

Absolutely. As the markets of countries like Poland, Romania, Bulgaria and the Czech Republic continue to evolve and their healthcare systems strengthen and mature, their ability to start accessing rare disease products that we make is growing. They need to be able to access them in a way that allows stable and consistent supply.

The Balkan states, which for Kedron are run out of Italy, are also growing at a rapid pace and export relationships have been solidly established. For Russia, the Far East and CIS states, I think there is an opportunity, but it needs to be managed carefully. Kedron is taking its time to evaluate what can be done; there is huge demand and it is just a matter of finding the right way to penetrate those markets, be it through a joint venture, a wholly owned subsidiary, distributorship or a combination of the three.



ECONOMIC
AND
FINANCIAL
INDICATORS

FINANCIAL INDICATORS

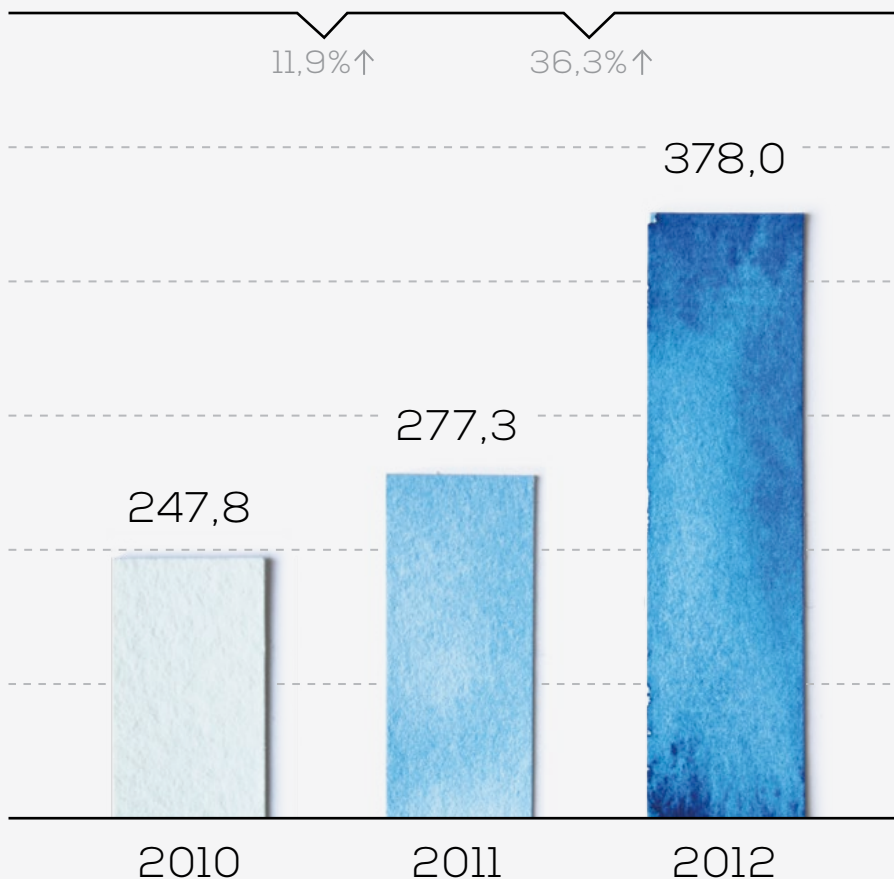
DURING THE FINANCIAL YEAR 2012 THE KEDRION GROUP COMPLETED ITS INTERNATIONALISATION PROCESS BY REACHING AN EXPORTS QUOTA OF ABOUT 62% OF THE OVERALL TURNOVER BY FURTHER DEVELOPING THE AMERICAN MARKET AND OTHER STRATEGIC MARKETS.

This growth, which especially concerns volumes and which developed in a highly aggressive competitive scenario, has increased the turnover by about 36%, achieving € 378.0 million. Continuing a trend that started during the previous years, 2012 too was characterised by a drop in sales prices, especially of immunoglobulin and albumin, in some markets, while the raw material, namely plasma, recorded a rise in price (particularly in the American market) after a long period of stability. Said developments generated a slight dilution of the gross industrial margin (40.7% vs. 41.2% of the previous financial year), and

the Group faced it through continuous focus on improving efficiency in all business areas, achieving a corrected Ebitda of € 79.0 million (20.9% of the turnover). The business outcome (Ebit) recorded € 60.4 million (16.0% of the turnover), while the net income for the financial year rose to € 32.2 million vs. € 15.1 million for the operating year 2011.

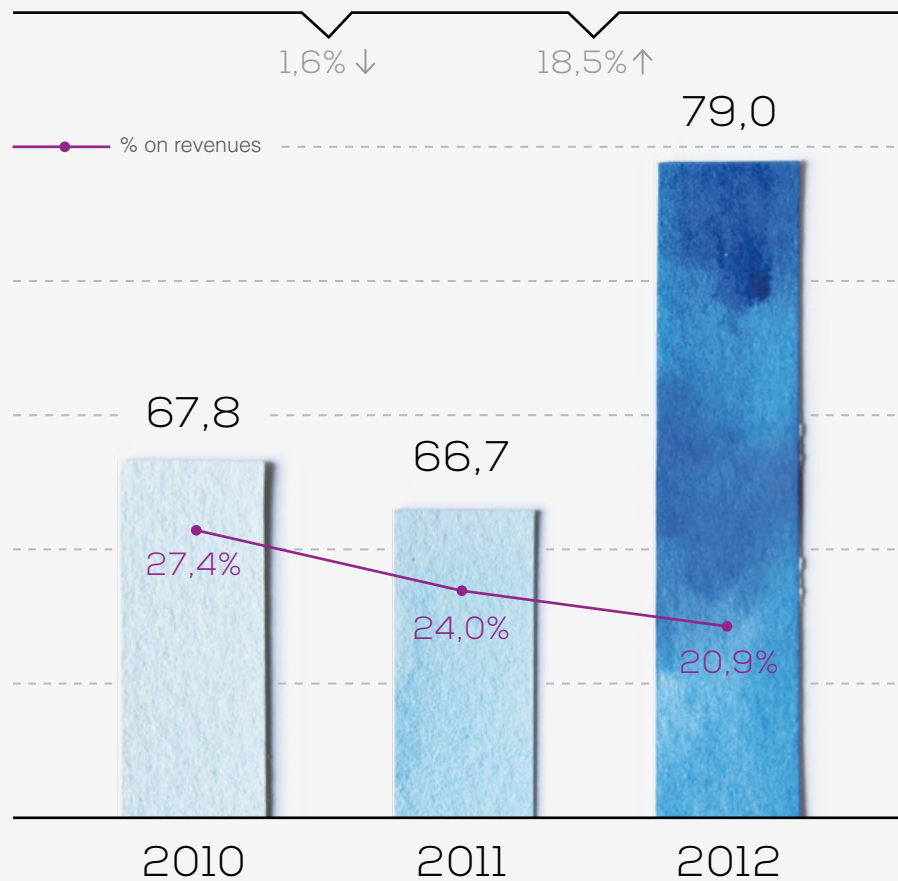
REVENUES (€ MLN)

CAGR 23,5%↑



EBITDA ADJUSTED (€ MLN) AND
ADJUSTED EBITDA MARGIN (%)

CAGR 8,0%↑

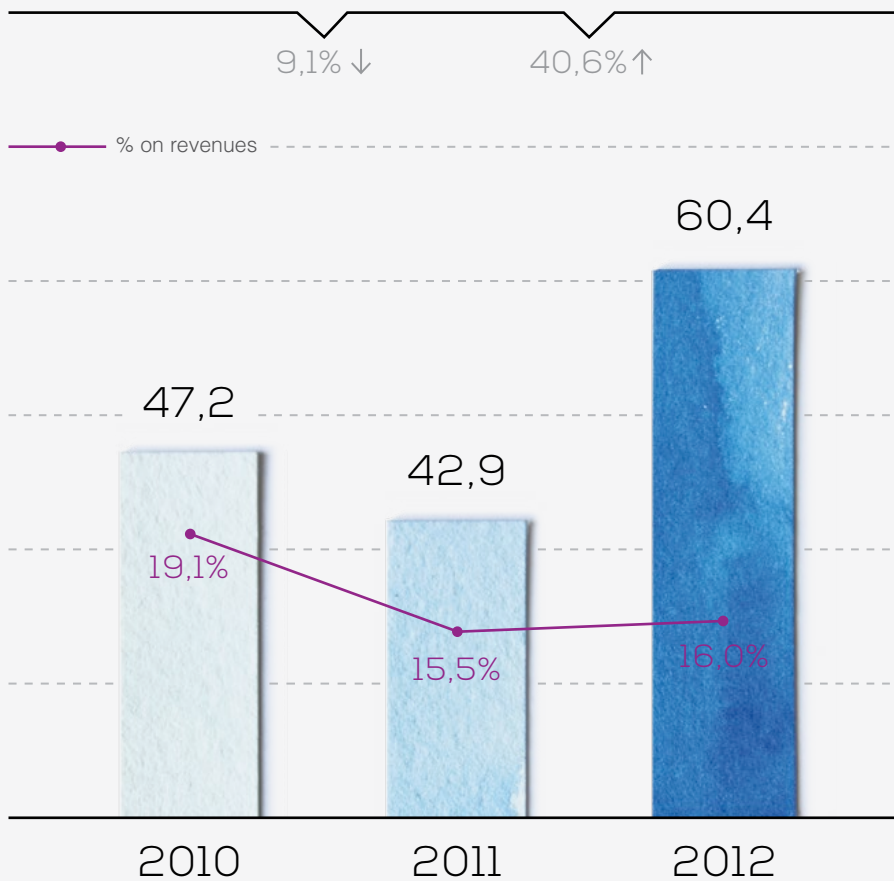


The strong reduction in the incidence of net working capital and the good progress of business allowed to reduce the Net Financial Position, which recorded a considerable improvement by dropping to € 33.3 million and stabilising at € 170.0 million with a contraction in short-term debts as a result of the greater liquidity generated, and of the middle-long term debt, which diminishes as the instalments envisaged by the Euro Term are paid. The improvement in relations between Net Financial Indebtedness and Net Equity is significant, and drops to 0.68.

FINANCIAL INDICATORS

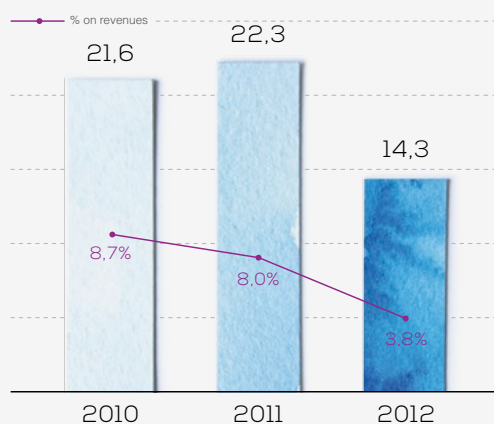
EBIT (€ MLN) AND EBIT MARGIN (%)

CAGR 13,0%↑

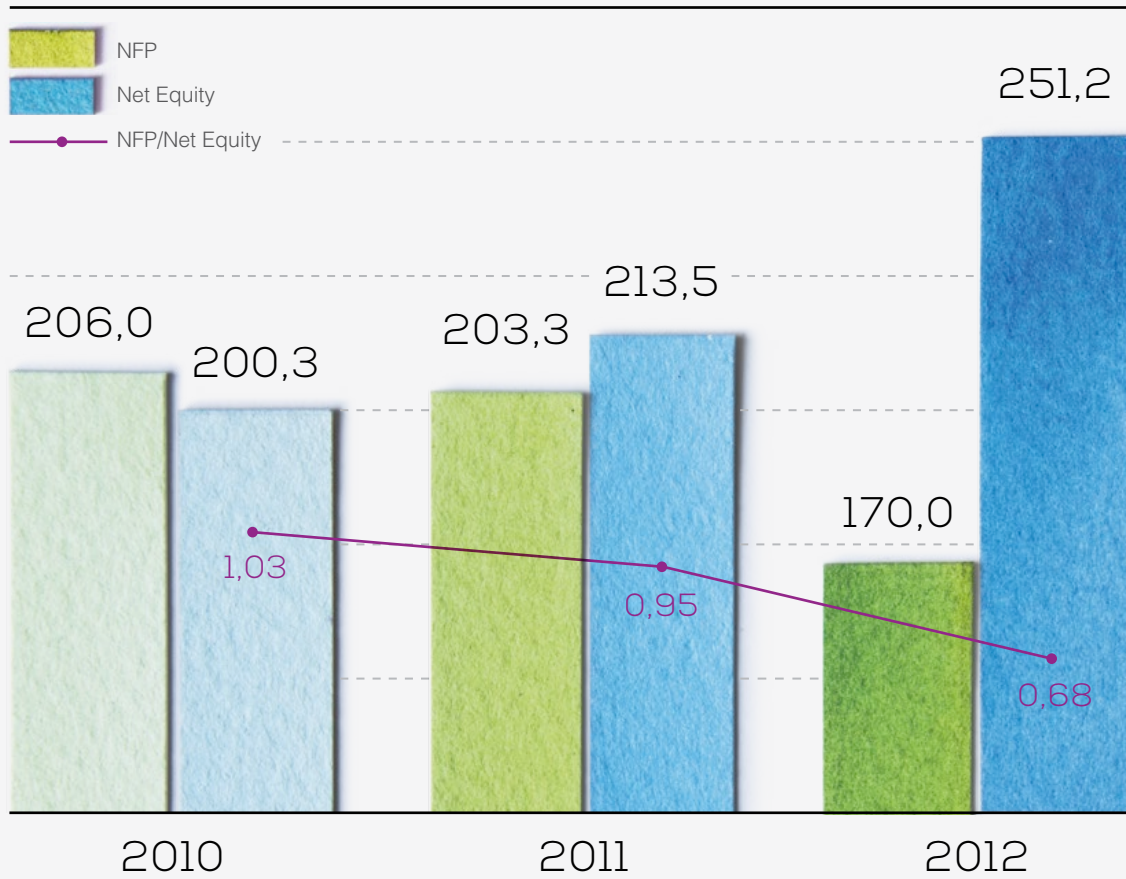


NET INVESTMENTS (€ MLN)

In 2012 total investments dropped compared to the previous financial years because some projects for the development and expansion of productive capacity came to a close, and during the current financial year the production plants were prevalently subjected to periodic servicing to improve efficiency to ensure, at all production levels, higher safety standards than those envisaged by current regulations and optimal levels of usage. The above has led to a level of global investments that is always significant, namely of € 14.6 million excluding M&A transactions.

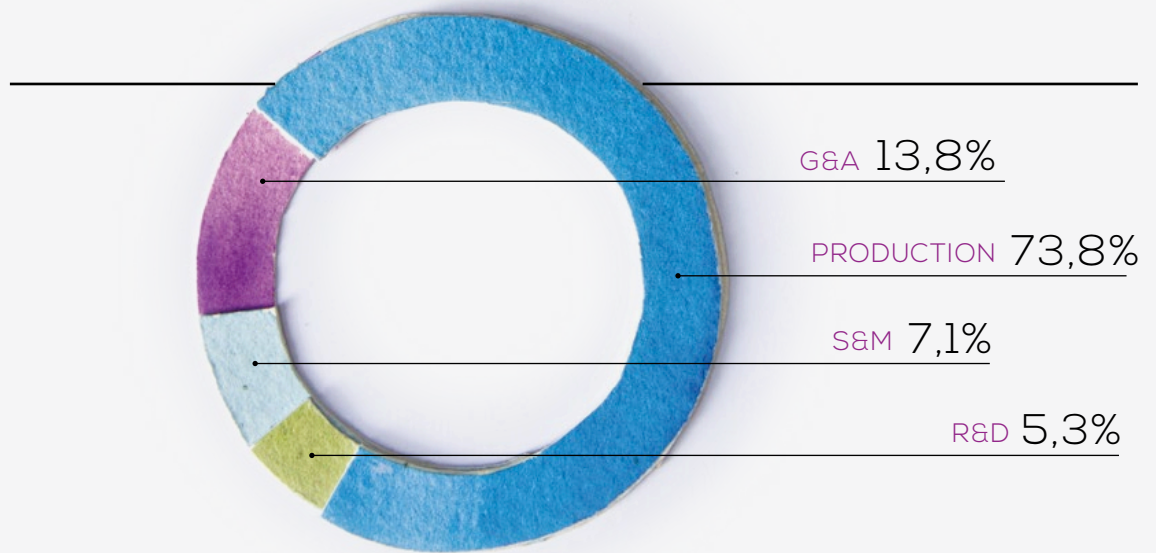


NET FINANCIAL POSITION (NFP) AND NET EQUITY (€ MLN)



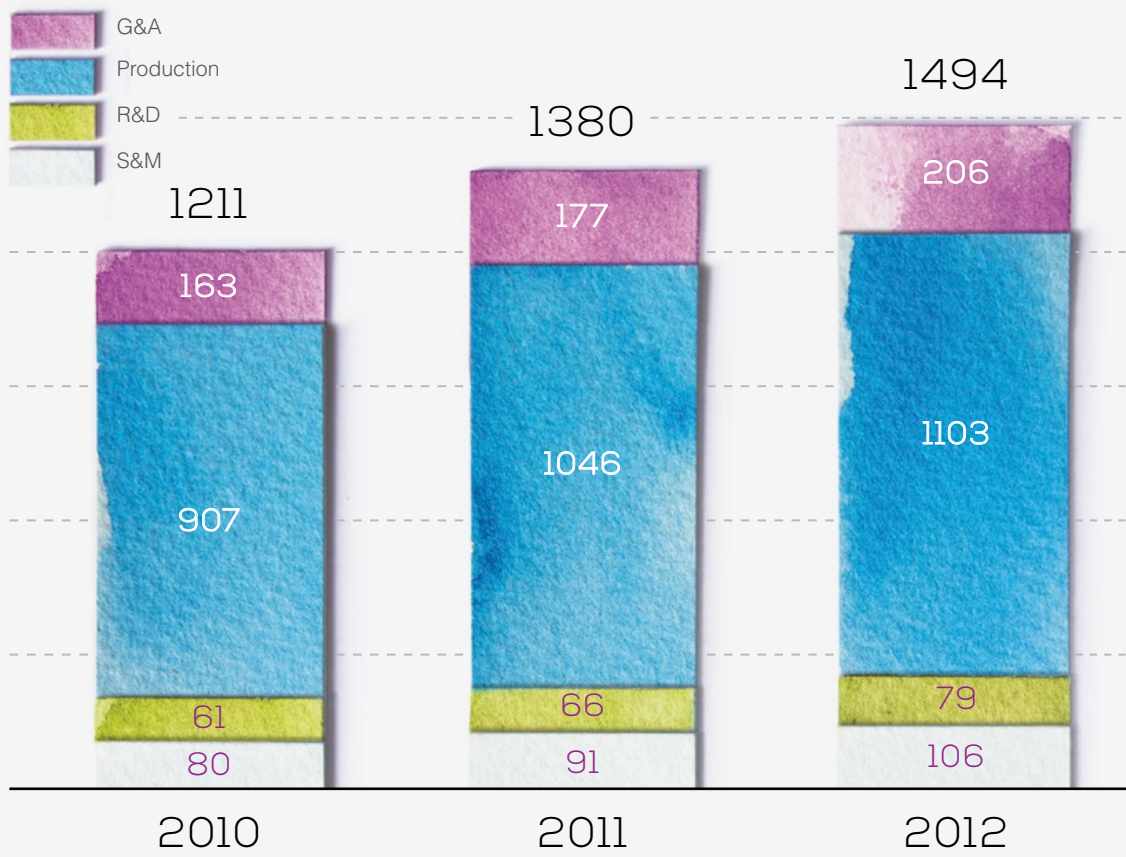
FINANCIAL INDICATORS

2012 STAFF DISTRIBUTION



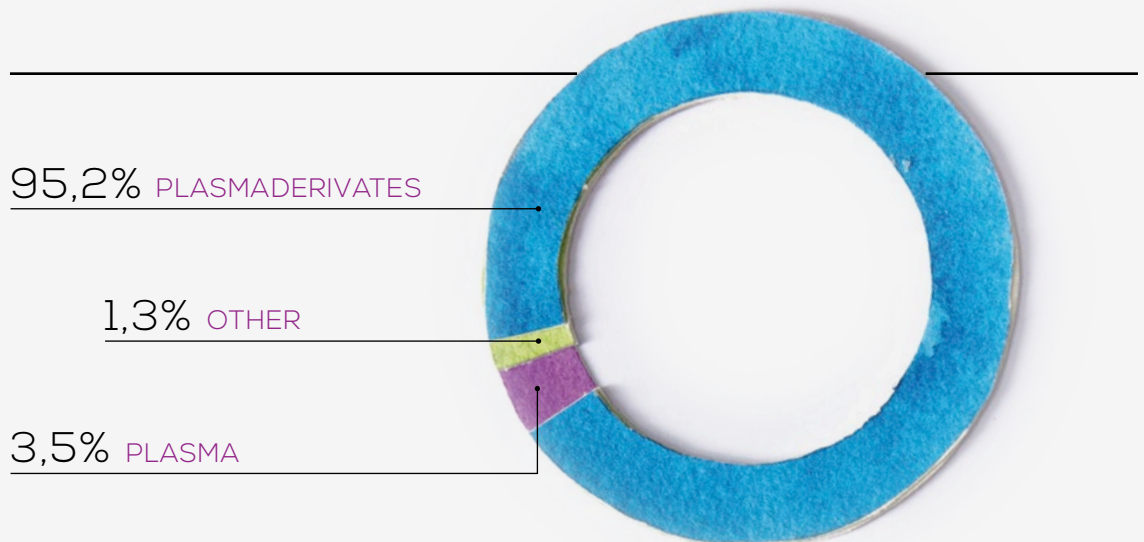
Unlike the previous year, 2012 has registered a more homogeneous unity growth among the different divisions. In relative terms, the division that has had the greatest increase appears to be that related to Research and Development and RAO, due to the enhancement of the relevant structures.

STAFF (UNIT)



BUSINESS AREAS

2012 DISTRIBUTION OF REVENUE
BY BUSINESS AREA



Kedrion Group activities can be divided into three different segments, namely:

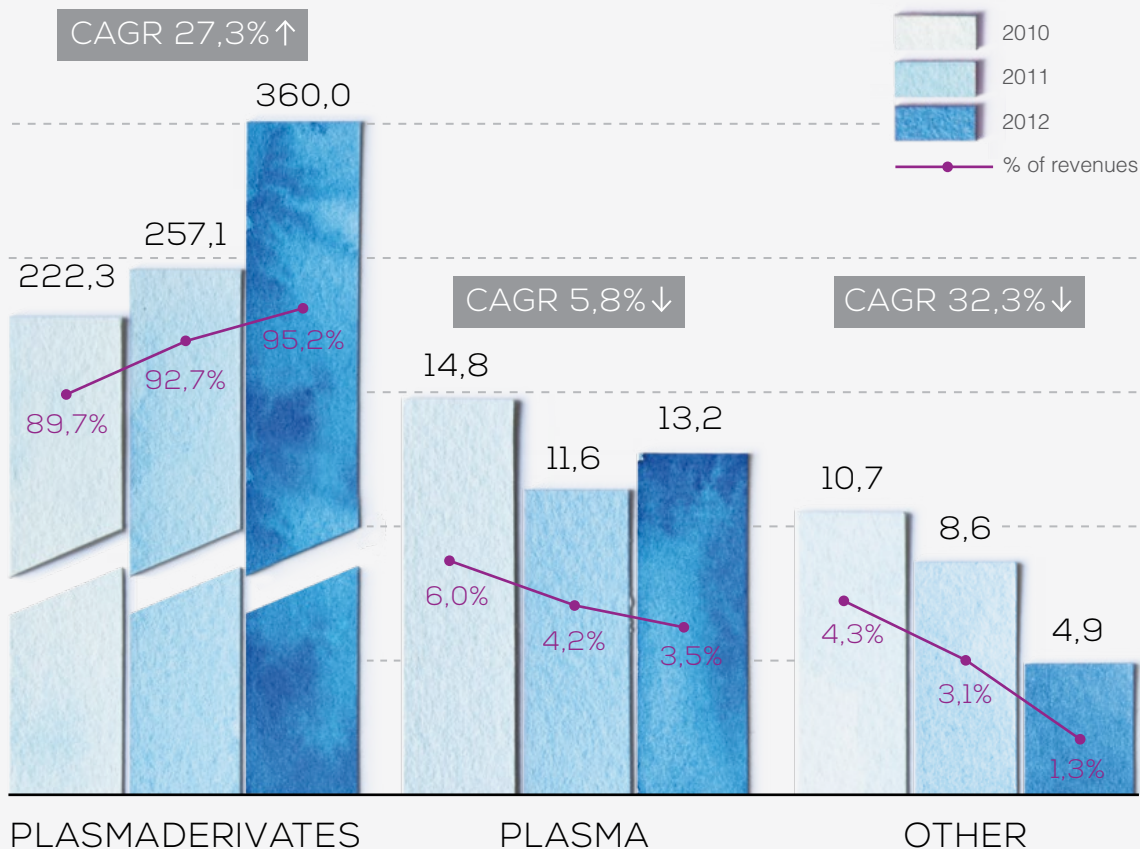
- Production and marketing of plasma-derived medicinal products resulting from the fractionating process of plasma
- Collection and marketing of plasma
- Other activities

PRODUCTION AND MARKETING OF PLASMA-DERIVED MEDICINAL PRODUCTS

The profits of the production and marketing segment of plasma-derived medicinal products on 31 December 2012 amount to € 359,957 thousand (95.2% of total profits) and record a 40.0% increase compared to the corresponding period of the year 2011. This growth leads to growing focus on this business segment; becoming fully operational on the US market, after entering it in mid-2011, with standard immunoglobulin,

albumin and Factor VIII; and, the acquisition of the new brand (RhoGam™) in August 2012, which has considerably increased the market shares of Kedrion in the anti-D immunoglobulin sector. The increase in volumes sold in European markets and in the rest of the world compensates for price dilutions required by a very aggressive competitive scenario. While the net income for the financial year rose to € 32.2 million vs. € 15.1 million for the operating year 2011.

DISTRIBUTION OF SALES BY BUSINESS AREA (€ MLN)



COLLECTION AND MARKETING OF PLASMA

The profits of plasma collection and marketing on 31 December 2012 amount to € 13,184 thousand vs. € 11,561 thousand in 2011 with a 14% increase that was achieved through the rise in plasma collection in proprietary centres based both in the US and in Europe. In fact, improving the efficiency of its centres in 2012 allowed this segment, managed by the Plasma Business Unit, which includes Haemopharm, Ked Plasma LLC and Ked Plasma GmbH, both to cover the rising

demand in the segment of plasma-derived medicinal products and to increase plasma sales to third party operators.

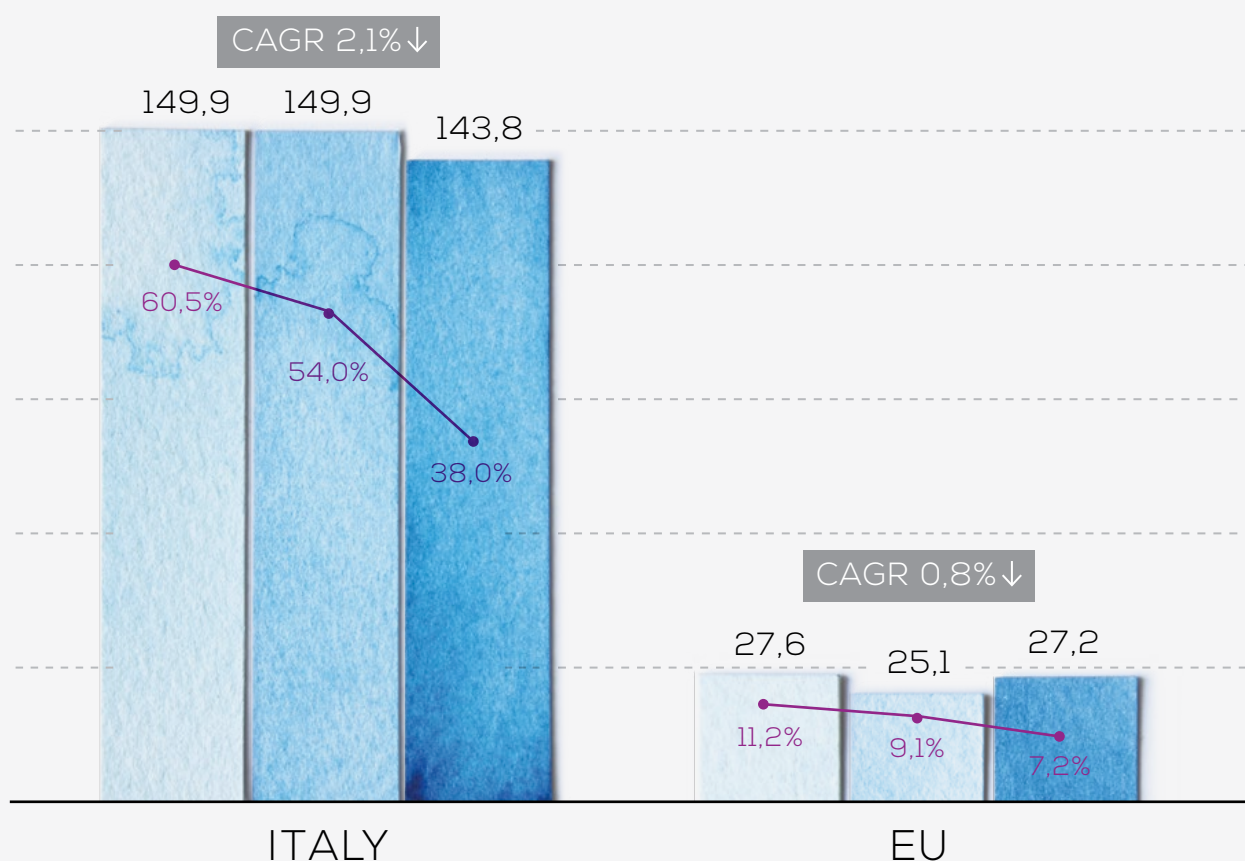
OTHER ACTIVITIES

The profits of this segment on 31 December 2012 are € 4,888 thousand with a 43.5% decrement compared to the corresponding period of the previous financial year to be principally traced to the strong reduction in sales of the anti-influenza vaccine due to production problems involving the principal

supplier of Kedrion and partly due to a drop in volumes intended by Human Bioplazma for the contract manufacturing of an operator in the sector, considering the increased demand of the segment of plasma-derived medicinal products.

GEOGRAPHICAL AREAS

DISTRIBUTION OF SALES BY GEOGRAPHIC AREA (€ MLN)



ITALY

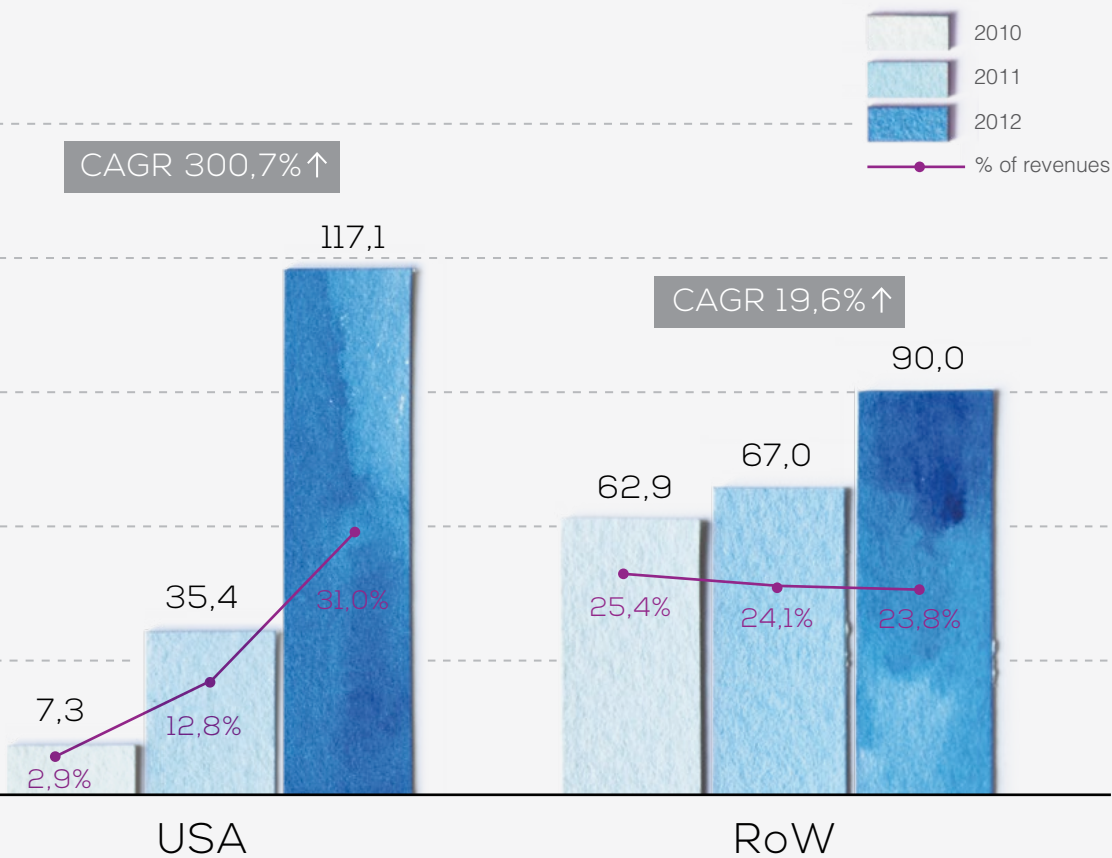
On 31 December 2012 the Italian market remains the principal reference market with a turnover of € 143,761 thousand, corresponding to 38% of overall profits. Compared to the previous financial year, product volumes supplied in Italy remain stable overall with the growing importance of Italian plasma processing on behalf of Italian Regions, compared to the commercial market, which suffered fluctuations in the price of the principal products.

EUROPEAN UNION

Profits from business in the European Union amounts to € 27,208 thousand, equal to 7.2% of overall profits on 31 December 2012, with an approximate 8.3% increase compared to the previous financial year principally due to the rise in sales in Greece and Poland through the company Kedrion International, and in Hungary through Human Bioplazma. The principal European markets in 2012 are, therefore, Hungary, Germany, Poland, Austria, Greece and Portugal.

USA

After penetrating the US market in 2011 as a result of an important strategic agreement with Grifols that enabled the Kedrion Group to enter the American market in advance through the company Kedrion Biopharma by marketing standard immunoglobulin, albumin and Factor VIII, expansion in this crucial market continued in 2012. In fact, the turnover of this area reached € 117 million with standard immunoglobulin as leading product, followed by Factor VIII and



albumin. Regarding albumin, it must be said that besides sales made with the product supplied by Grifols, a turnover of € 3.7 million was recorded with the product (Kedbumin) purified at the Bolognana production facility. In addition to this structural development, in August 2012 Kedrion Melville Inc. (100% subsidiary of Kedrion Group S.p.A.), acquired from Johnson&Johnson RhoGam™ the first anti-D immunoglobulin registered on the American market more than 40 years ago. It is a leading product in this market. This was a positive contribution to the strong growth as it was given to Kedrion Biopharma Inc.

for distribution in 2012. Besides the sales of plasma-derived medicinal products, this area also has a small quota of plasma sales.

REST OF THE WORLD

The profits for this geographical area on 31 December 2012 amounts to € 89,957 thousand, corresponding to 23.8% of total profits. The growth compared to 2011 is 34.3% underpinned by the greater product availability and by new registrations. Turkey remains the leading market in terms of

turnover and accounts for over 80% of total profits, along with Mexico (intensive growth), South Korea, Vietnam, Iran, Columbia, Russia and Serbia.

CONSOLIDATED FINANCIAL STATEMENTS

AT DECEMBER 2011 AND 2012

CONSOLIDATED CASH FLOW STATEMENT
(IN THOUSANDS OF €)

YEAR ENDED AT 31 DECEMBER

	2011	2012
Net cash flow generated by operating activities (A)	40.473	54.066
Net cash flow absorbed by investment activities (B)	(16.397)	(9.551)
Net cash flow generated / (absorbed) by financing activities (C)	(15.456)	(42.880)
TOTAL NET CASH FLOW D=(A+B+C)	8.620	1.636
Cash and cash equivalents opening balance (E)	13.154	21.666
Net effect of conversion of foreign currencies on cash and cash equivalents (F)	(107)	(3)
CASH AND CASH EQUIVALENTS CLOSING BALANCE G=(D+E+F)	21.666	23.298

CONSOLIDATED CASH FLOW STATEMENT
(IN THOUSANDS OF €)

YEAR ENDED AT 31 DECEMBER

2011 2012
RESTATED*

CONSOLIDATED BALANCE SHEET
(IN THOUSANDS OF €)

Property, plant and equipment	99.013	100.847
Investment property	1.754	1.700
Goodwill	168.680	168.704
Fixed term intangible assets	7.249	5.282
Investments in associated companies	0	23
Investments in other companies	1	1
Other non current financial assets	399	552
Deferred tax assets	0	1.495
Non current trade receivables	0	858
Other non current assets	467	341
TOTAL NON CURRENT ASSETS	277.563	279.803
CURRENT ASSETS		
Inventories	139.398	131.101
Trade receivables	97.811	87.354
Current tax credits	1.600	3.487
Other current assets	10.576	11.999
Other financial current assets	184	1.678
Cash and cash equivalents	21.757	23.326
TOTAL CURRENT ASSETS	271.326	258.945
TOTAL ASSETS	548.889	538.748

CONSOLIDATED FINANCIAL STATEMENTS

AT DECEMBER 2011 AND 2012

CONSOLIDATED CASH FLOW STATEMENT
(IN THOUSANDS OF €)

YEAR ENDED AT 31 DECEMBER

2011
RESTATED*

2012

CONSOLIDATED BALANCE SHEET (IN THOUSANDS OF €)

Share capital	52.116	52.116
Reserves	147.722	165.526
Group net income	12.804	30.780
TOTAL GROUP SHAREHOLDERS' EQUITY	212.642	248.422
MINORITIES SHAREHOLDERS' EQUITY		
Minorities capital and reserves	390	895
Minorities net income	505	1.852
TOTAL MINORITIES SHAREHOLDERS' EQUITY	895	2.747
TOTAL SHAREHOLDERS' EQUITY	213.536	251.169
NON CURRENT LIABILITIES		
Medium-/long-term debt	160.276	137.391
Provisions for risks and charges	395	51
Payables for employee benefits	3.867	4.583
Deferred tax liabilities	128	0
Other non current liabilities	2.653	2.289
TOTAL NON CURRENT LIABILITIES	167.319	144.314
CURRENT LIABILITIES		
Payables to banks and other lenders	30.509	23.972
Current portion of medium-/long-term debt	34.876	34.219
Provisions for risks and charges	1.674	275
Trade payables	70.217	59.051
Current tax payables	6.766	2.774
Other current liabilities	23.991	22.974
TOTAL CURRENT LIABILITIES	168.033	143.265
TOTAL LIABILITIES	335.352	287.579
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES	548.888	538.748

CONSOLIDATED INCOME STATEMENT
(IN THOUSANDS OF €)

YEAR ENDED AT 31 DECEMBER

	2011 RESTATED*	2012
Revenues from sales and services	277.334	378.029
Cost of sales	163.091	224.225
GROSS OPERATING MARGIN	114.243	153.804
Other revenues	7.835	4.908
General and administrative expense	45.559	48.875
Sales and marketing expense	20.587	34.164
Research and development expense	9.370	11.209
Other operating costs	3.640	4.106
OPERATING RESULT	42.922	60.358
Financial charges	21.007	18.264
Financial income	5.723	6.866
RESULT BEFORE TAX	27.638	48.960
Income taxes	12.570	16.800
NET RESULT FOR THE PERIODX	15.068	32.160
OF WHICH:		
GROUP RESULT	14.563	30.308
MINORITIES RESULT	505	1.852

CONSOLIDATED FINANCIAL STATEMENTS

AT DECEMBER 2011 AND 2012

OTHER COMPREHENSIVE INCOME
(IN THOUSANDS OF €)

YEAR ENDED AT 31 DECEMBER

	2011 RESTATED*	2012
NET INCOME OF THE PERIOD	15.068	32.160
(Loss) / profit net of actuarial defined benefit plans	(48)	(471)
Translation differences	(1.536)	501
(Loss) / profit on cash flow hedges	(175)	442
OTHER NET COMPREHENSIVE INCOME OF THE YEAR	13.309	32.632
OF WHICH:		
NET GROUP COMPREHENSIVE INCOME	12.804	30.780
NET COMPREHENSIVE INCOME OF MINORITY INTERESTS	505	1.852

* CERTAIN AMOUNTS REPORTED IN THIS COLUMN DO NOT MATCH THOSE OF THE 2011 BALANCE SHEET, AS THEY REFLECT ADJUSTMENTS MADE AS DETAILED IN PARAGRAPH 2.7



Plant of Bolognana near Lucca where the headquarter is located

KEDRION
B I O P H A R M A

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