

KEDRION  
B I O P H A R M A

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Keep Life *Flowing*

# ANNUAL REPORT

2013



KEDRION  
B I O P H A R M A

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Keep Life *Flowing*

# ANNUAL REPORT

2013

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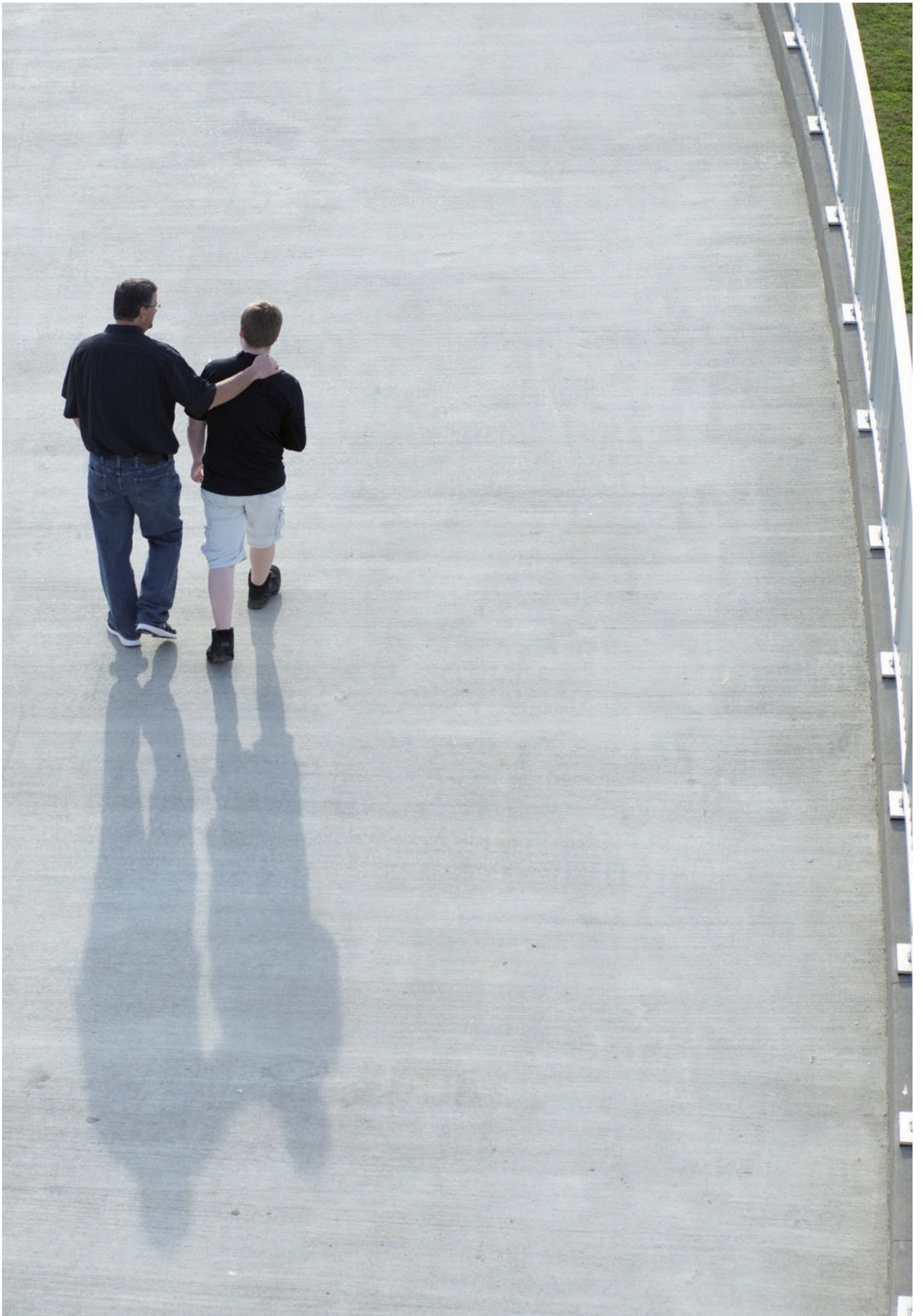
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CEO  
LETTER

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# CEO LETTER



EVER SINCE KEDRION WAS FOUNDED, OUR GOAL HAS BEEN TO ENSURE THAT AN EVER-INCREASING NUMBER OF PATIENTS AROUND THE WORLD HAS ACCESS TO THERAPIES WHICH CAN IMPROVE THEIR QUALITY OF LIFE. IN 2013, STILL GUIDED BY THIS VISION AND MISSION, WE HAVE CONTINUED TO GROW OUR BUSINESS FROM AN INDUSTRIAL, ORGANIZATIONAL AND FINANCIAL POINT OF VIEW.

In last year's Annual Report we defined 2012 as an "extraordinary year" for Kedrion; extraordinary financial results, extraordinary international growth accompanied by the consolidation of the company's domestic market presence and by the acquisition of important new products.

All signs for the year 2013 confirm that Kedrion has successfully continued on this path, on the one hand progressing even further in the process of internationalization, with exports accounting for 66% of turnover.

On the other, consolidating its leadership in Italy, with a 34% domestic market share.

Total turnover amounted to approximately 424,8 million Euro, an increase of 46,8 million over the previous year, whereas the EBITDA stood at 104,7 million Euro.

In terms of industrial production, we focused on harmonizing our different plants to make the Group's manufacturing sites homogeneous in order to start new purification lines.

Additionally in 2013, we invested in two particularly important projects: a new manufacturing plant to be constructed in Castelvecchio Pascoli, Italy, dedicated to the production of immunoglobulin; and the transfer of RhOGAM production to our Melville facility in the United States, enabling us to manufacture this essential treatment "in-house". Further impetus was given to research, with a special focus on orphan drugs.

Last year we worked on rationalizing and reorganizing the company's chain of command and management structure, bringing on new experienced managers who integrated with an already consolidated organization.

Through these steps, we initiated a process that has allowed us thus far, and more importantly will continue to allow us to further strengthen our presence in target countries such as, for example, Brazil and Russia.

On the financial side, 2013 was marked by a change in shareholder structure.

The investment fund Investitori Associati (IA),

which had been a shareholder since 2006 and held approximately 32%, sold its quota to the other two shareholders. Today, 25% of the company's shares are held by FSI and 75% by Sestant.

Once again, the years ahead look bright with promise to bring further growth in international markets and the consolidation of Kedrion's leadership in Italy.

We will continue our work with a firmness of purpose in order to expand our product offering, optimize production capacity, increase plasma collection and strengthen our management structure.

Paolo Marcucci  
Chairman and CEO of KEDRION

A handwritten signature in blue ink, appearing to read "Paolo Marcucci". The signature is fluid and cursive, with a long horizontal stroke at the end.







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COMPANY  
PROFILE

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# COMPANY PROFILE



## BY CONVERTING PLASMA INTO MEDICINES, AT KEDRION WE CONTRIBUTE TO MAKING EFFECTIVE AND REAL PEOPLE'S FUNDAMENTAL RIGHTS TO LIFE, FREEDOM AND SAFETY.

We are an international company that collects and fractionates blood plasma to produce and distribute plasma-derived medicinal products for use in treating rare conditions such as hemophilia and immune system deficiencies.

At Kedrion, our business is people: the very nature of our enterprise is to help people live fuller lives. In a way, this makes it even more obligatory that we conduct our business in ways that are consistent with that mission: to benefit people, to "Keep Life *Flowing*".

Everything we do, every decision we make, impacts the people around us: in our workforce as well as in our community worldwide. Kedrion was established in Italy in 2001, but our roots stretch back several decades in the production of blood and plasma derived products. As a partner to the Italian National He-

alth System, we have helped lead the country toward self-sufficiency in plasma-derived medicines. Today we can bring this experience and the dedication to that goal to potential partners around the world.

In recent years we have substantially expanded our operations and markets into Germany, Hungary, and the United States among other countries. We have acquired collection and production capacity as well as the rights to significant products such as RhoGAM, which effectively prevents hemolytic disease of the newborn.

## AND WHILE WE GROW, WE DO NOT FORGET OUR ROOTS IN THIS HISTORY.

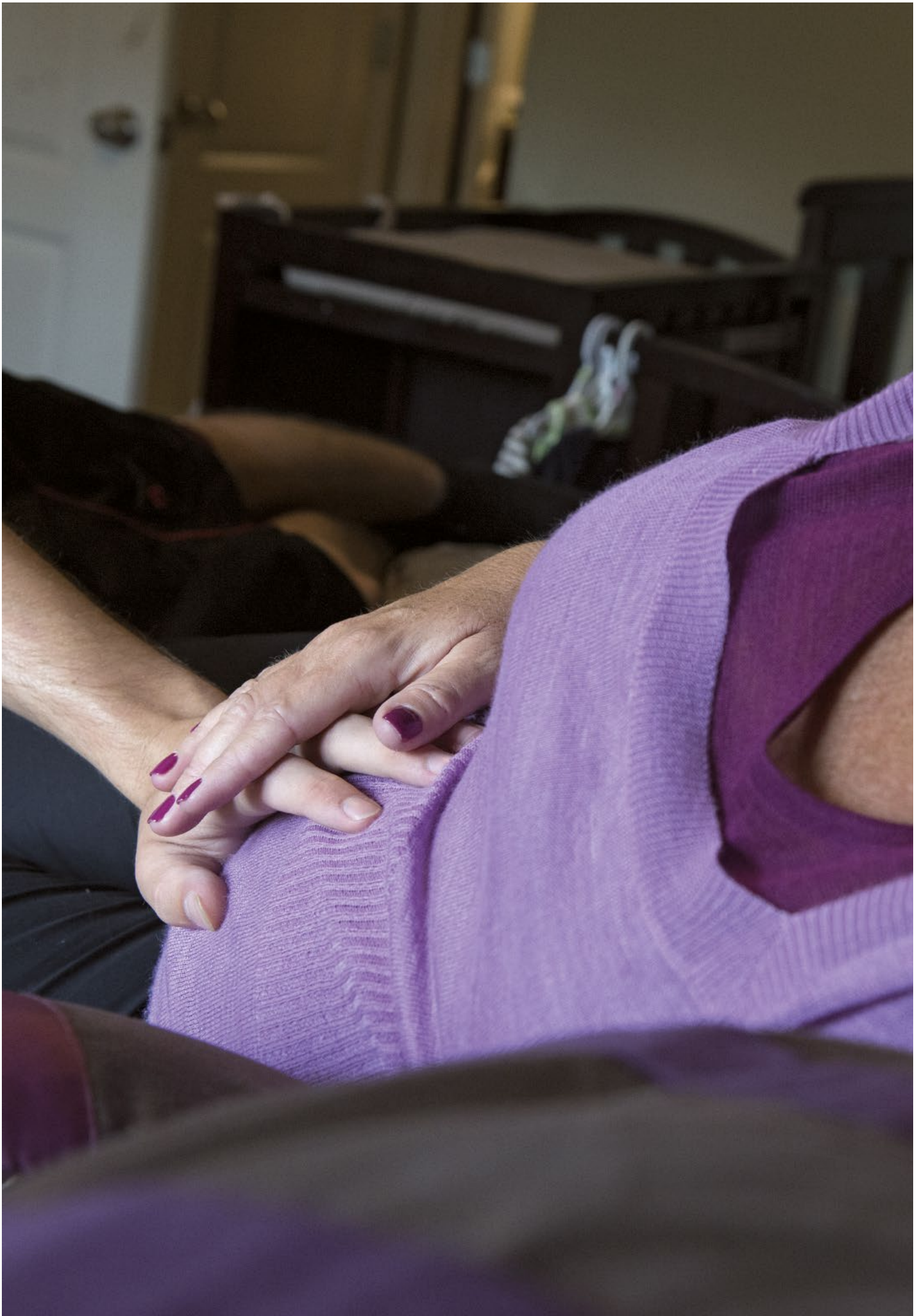
Plasma is the raw material from which all of our activities flow. Without plasma we can neither help people nor employ them. Our major activities can be traced along the path of plasma flowing from donor to patients: at Kedrion our mission is to create a bridge between donors and people who are in need of care.

Our expertise resides in a number of areas. We have built fractionation and production

facilities from the ground up as well as modernized acquired facilities. Similarly, we have developed innovative new drugs and have improved on the production of existing medicines. Moreover our commitment to researching and developing orphan drugs for the treatment of rare conditions has led us to set up a dedicated production site.

Our plants employ the most current technologies and procedures and we have instituted dedicated departments and systems to monitor and continually improve the quality, safety and innovation of our products and processes.

For us the awareness of the social value of plasma processing is the foundation of our corporate culture and the inspiration underlying our work. Using the best available technology, and thanks to the daily work of nearly 1800 people around the world, we preserve and make available the vital energy contained in blood, so that it can be safely transferred from one human being to another, thereby improving the standard of living of all those in need.





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YEAR  
IN REVIEW

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# KEDRION AT A GLANCE



**5** MANUFACTURING  
PLANTS IN  
**3** COUNTRIES



ONE CENTER SPECIALIZED  
IN COLLECTING PLASMA  
WITH A HIGH  
**ANTI-D ANTIBODY**  
CONCENTRATION LEVEL



**IKOD,**  
ITALIAN FACILITY  
FULLY DEDICATED TO  
THE DEVELOPMENT  
OF ORPHAN DRUGS



**5<sup>TH</sup>** WORLD PLAYER  
AND **1<sup>ST</sup>** IN ITALY  
IN THE PLASMA-DERIVED  
PRODUCTS FIELD



SUBSIDIARIES  
IN EUROPE, US,  
LATIN AMERICA  
AND ASIA



**11** VOLUNTARY CERTIFICATIONS  
IN MANUFACTURING, HUMAN RESOURCES,  
ENVIRONMENT



PARTNER IN THE SELF-SUFFICIENCY  
PROGRAM IN ITALY



**BIOSC,**  
THE FIRST GLP CERTIFIED  
LABORATORY IN ITALY  
FOR PATHOGEN SAFETY



**15** PLASMA  
COLLECTION  
CENTERS IN THE  
WORLD



2013 TURNOVER:  
**424,8 MILLION EURO**



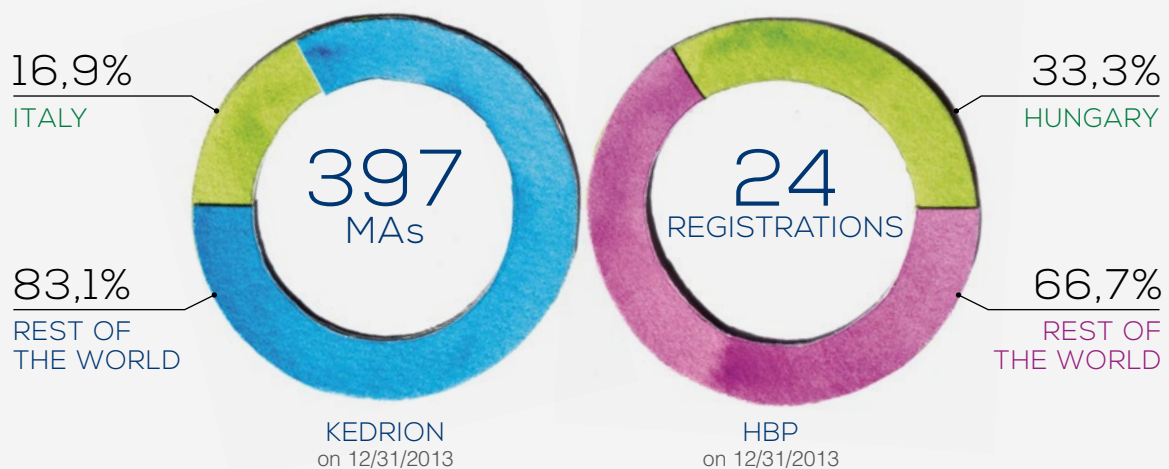
ANNUAL GROWTH  
RATE SINCE 2007:  
**15%**

ITALIAN COMPANY  
PRESENT IN OVER  
**90** COUNTRIES  
WORLDWIDE



ANNUAL STAFF  
INCREASE  
SINCE 2010:  
**14,48%**

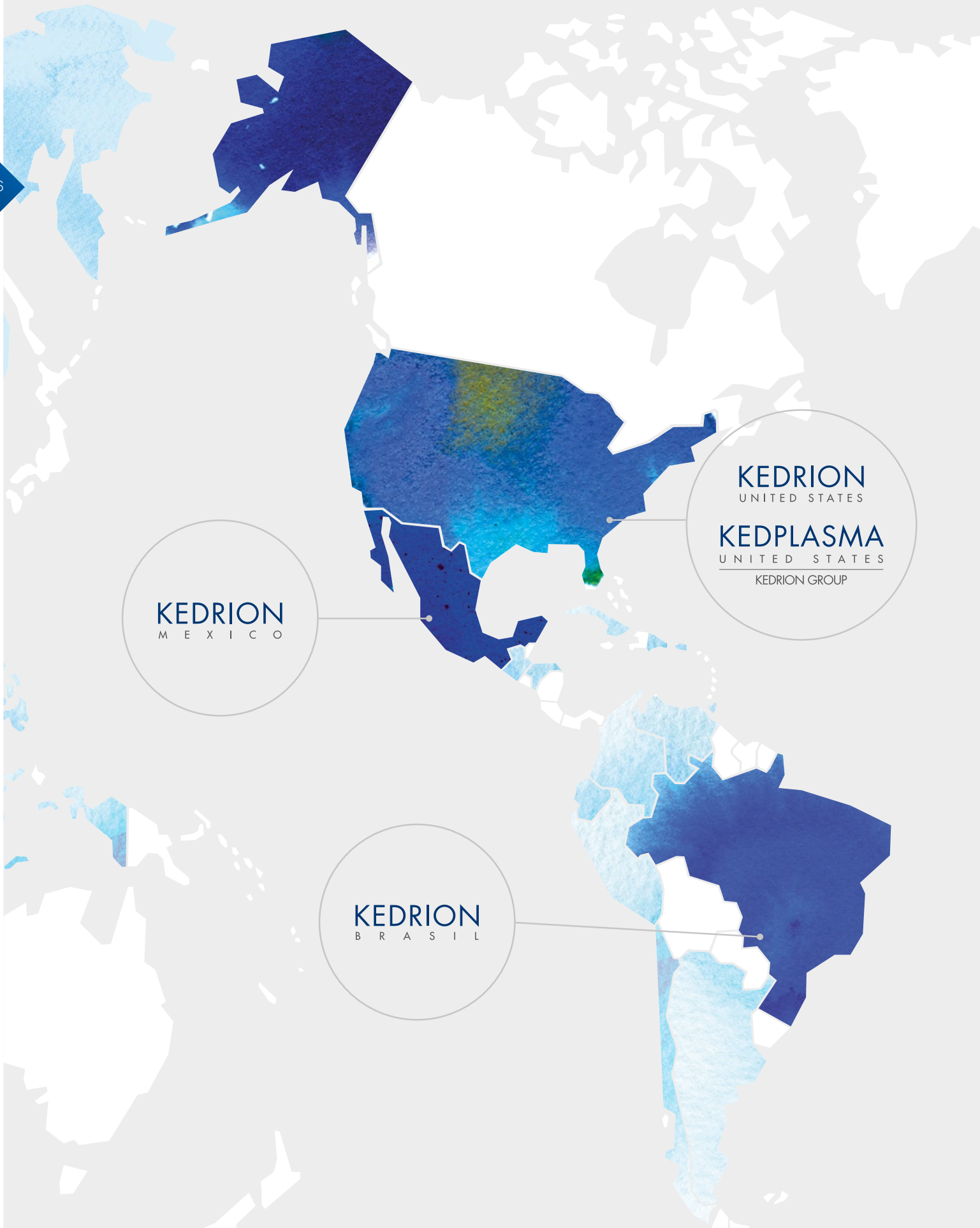
## MARKETING AUTHORIZATIONS (MAS) NUMBER



## TOTAL NUMBER OF EMPLOYEES



# WORLDWIDE PRESENCE



KEDRION  
MEXICO

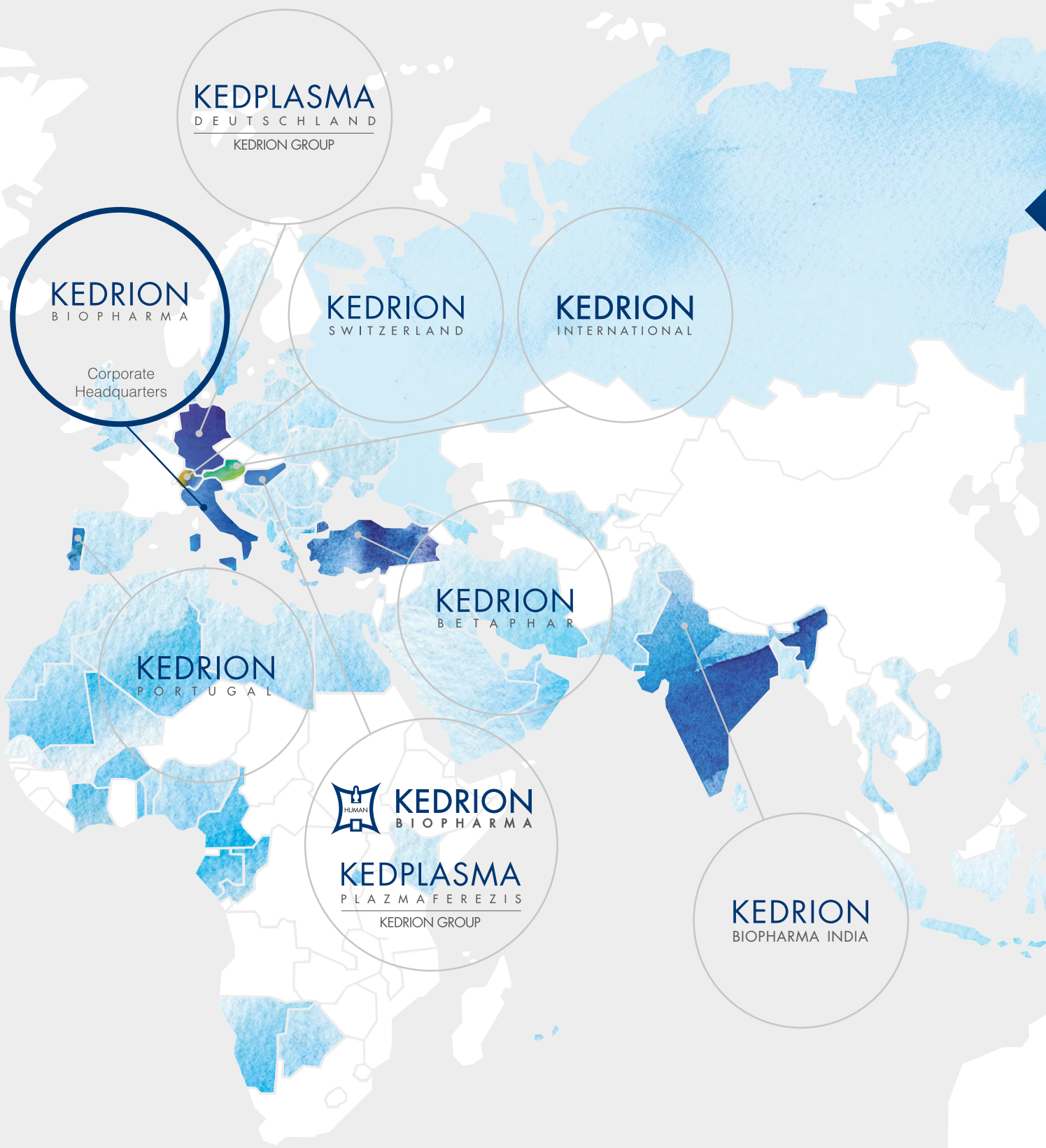
KEDRION  
UNITED STATES

KEDPLASMA  
UNITED STATES

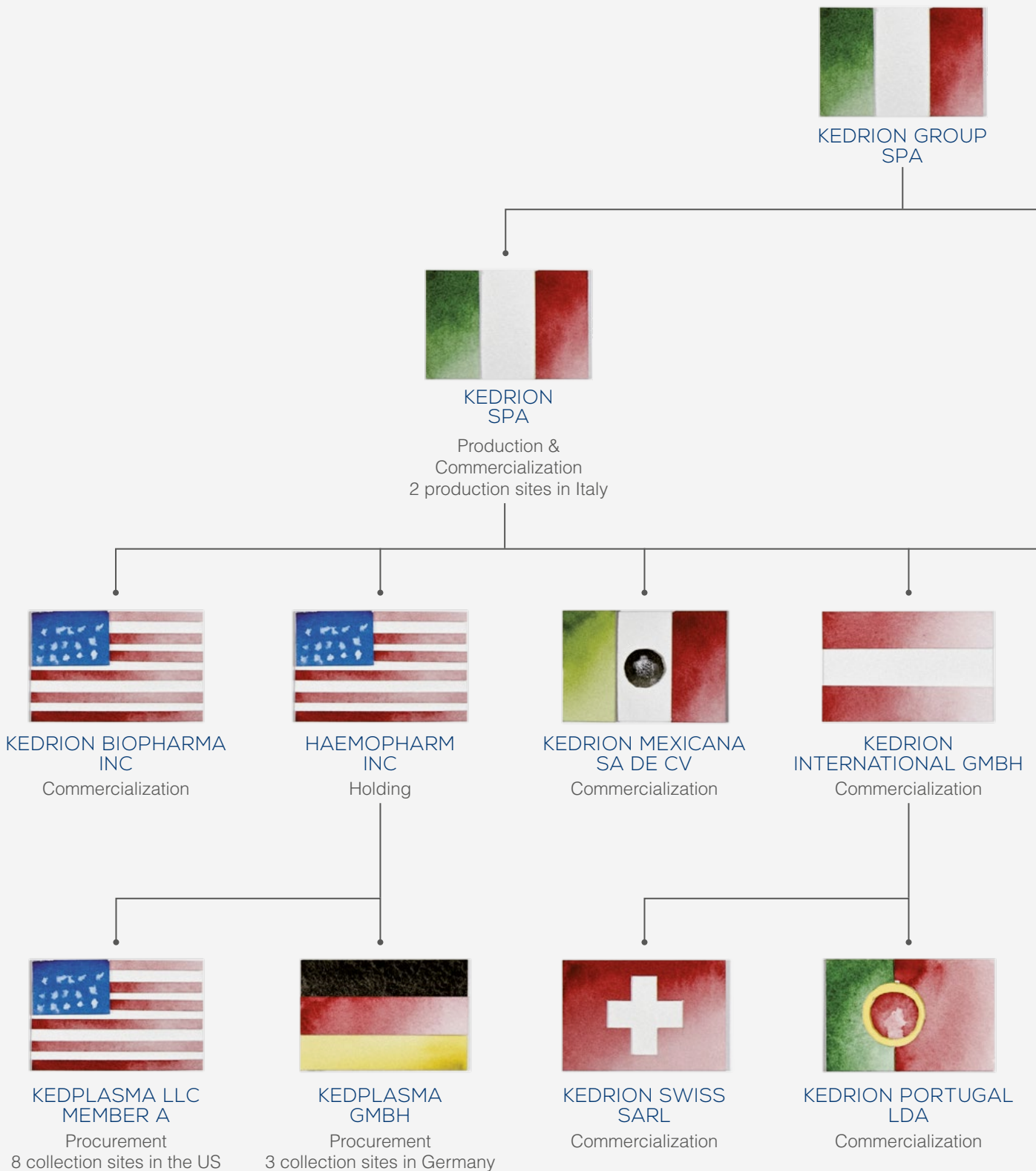
KEDRION GROUP

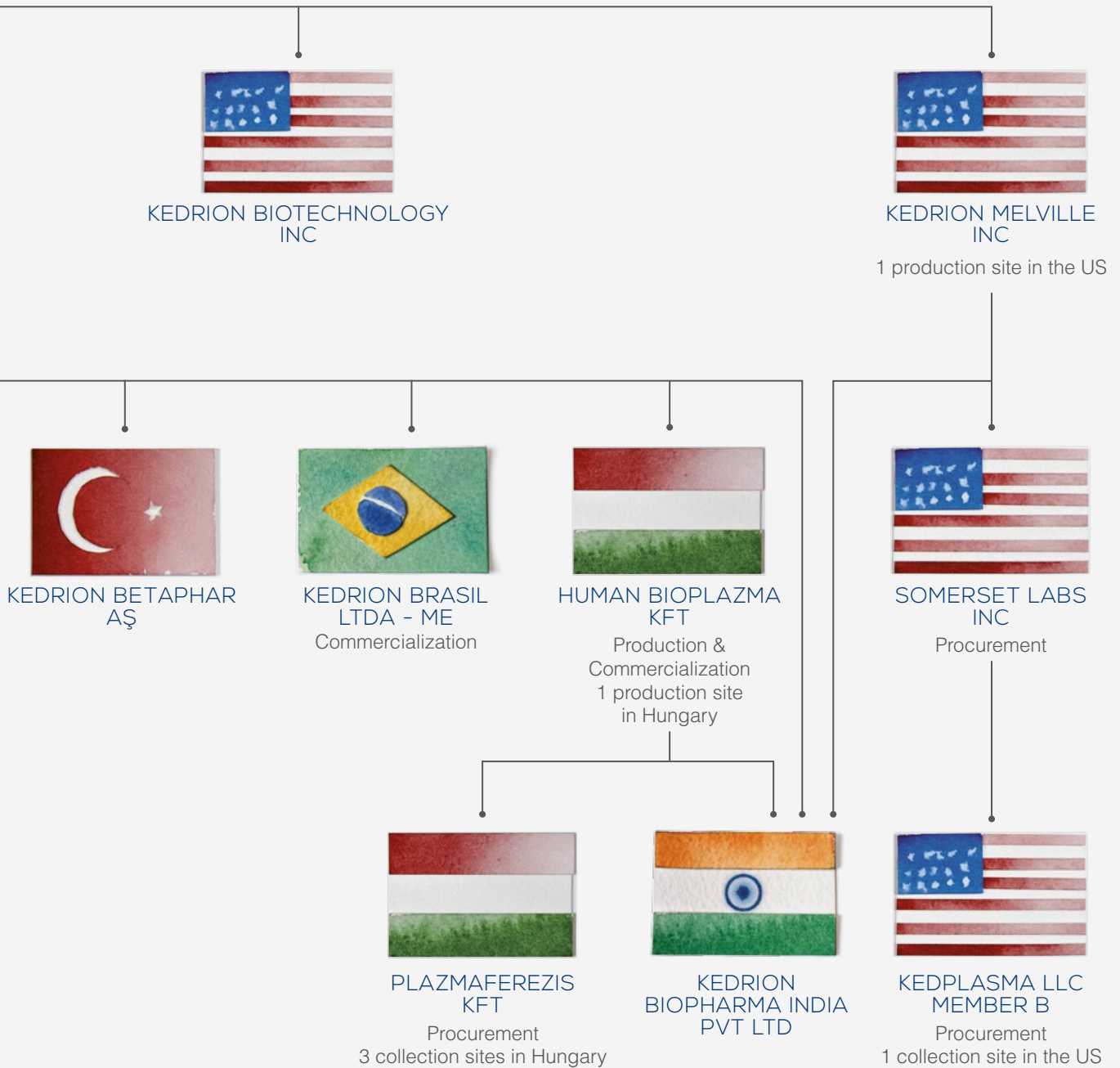
KEDRION  
BRASIL





# GROUP STRUCTURE





# KEDRION IN THE WORLD

## KEDRION SPA CORPORATE HEADQUARTERS

Registered Office:  
Loc. Ai Conti, Castelvecchio Pascoli  
55051 Barga, Lucca (Italy)

Head Office:  
Loc. Il Ciocco, Castelvecchio Pascoli  
55051 Barga, Lucca (Italy)  
Tel: +39 0583 19691  
Fax: +39 0583 766121  
info@kedrion.com  
www.kedrion.com

## COMMERCIAL AREAS

Africa  
Asia  
Europe  
Latin America  
Middle East  
Russia & CIS  
US

## KEDRION SPA

Loc. Il Ciocco, Castelvecchio Pascoli  
55051 Barga, Lucca (Italy)  
Tel: +39 0583 19691  
Fax: +39 0583 766121  
info@kedrion.com

## HUMAN BIOPLAZMA KFT

Táncsics Mihály út 80,  
H-2100 Gödöllő (Hungary)  
Tel: +36 (28) 532200  
Fax: +36 (28) 532201  
info@humanked.com

## KEDRION BIOPHARMA INC

400 Kelby Street, 11<sup>th</sup> Floor  
07024 Fort Lee, NJ (USA)  
Tel: +01 (201) 242 8900  
Fax: +01 (201) 242 8913

#### KEDRION INTERNATIONAL GMBH

Kärntner Ring 5-7, Top 501,  
1010 Wien (Austria)  
Tel: +43 1 513 29 44 12  
Fax: +43 1 513 29 44 22  
office@kedrioninternational.com

#### KEDRION PORTUGAL - DISTRIBUIÇÃO DE PRODUTOS FARMACÊUTICOS LDA

Av. José Gomes Ferreira 15, Edifício Atlas IV  
Piso 5 Fracção Q, Miraflores 1495-139  
Algés (Portugal)  
Tel: +351 (214) 107 246  
Fax: +351 (214) 100 645  
office@kedrioninternational.com

#### KEDRION SWISS SARL

Obmoos 4, CH-6301  
Zug (Switzerland)  
Tel: +41 (79) 2195867  
office@kedrioninternational.com

#### KEDRION MEXICANA SA DE CV

Adolfo Prieto 1427, Col. del Valle  
03100 México, D.F. (México)  
Tel: +52 (55) 53403493  
j.hernandez@kedrion.com.mx

#### KEDRION BETAPHAR BIYOFARMASÖTİK İLAÇ SANAYİ VE TİCARET ANONİM ŞİRKETİ

Meşrutiyet Mahallesi Konur Sokak No: 50/4,  
Bakanlıklar - Çankaya/Ankara (Turkey)

#### KEDRION BRASIL DISTRIBUIDORA DE PRODUTOS HOSPITALARES LTDA - ME

Rua Desvio Bucarest 615,  
Qd. 255, Lt. 11, Jd. Novo Mundo  
74.703-100 Goiânia, Estado de Goiás (Brazil)  
Tel: +55 (62) 32069044  
a.silva@kedrion.com

#### KEDRION BIOPHARMA INDIA PRIVATE LIMITED

901-905, Naurang House,  
21 Kasturba Gandhi Marg, Connaught Place  
New Delhi 110001 (India)  
Tel: +91 (124) 2803391/92  
office@kedrioninternational.com

#### KEDPLASMA GMBH

Bahnhofstrasse 96  
82166 Gräfelfing, BA (Germany)  
Tel: +49 (89) 7167715-0  
Fax: +49 (89) 7167715-98  
info@kedplasma.com

#### PLAZMAFEREZIS ÁLLOMÁS KÖZHASZNÚ NONPROFIT KFT

Táncsics Mihály út 80,  
H-2100 Gödöllő (Hungary)  
Tel: +36 (28) 532248  
Fax: +36 (28) 532201  
Email: i.kiss@humanked.com

#### KEDPLASMA LLC

400 Kelby Street, 11<sup>th</sup> Floor  
07024 Fort Lee, NJ (USA)  
Tel: +01 (201) 461-5558  
Fax: +01 (201) 461-2353  
Email: contactus@kedplasmausa.com

# PRODUCT PORTFOLIO

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## HEMATOLOGY HEMOPHILIA

EMOCLOT / Koāte-DVI\* / EMOWIL  
Factor VIII / von Willebrand Factor  
concentrate

HUMAFactor-8\*\*/ HUMACLOT\*\*  
Factor VIII / von Willebrand Factor  
Concentrate

WILFACTIN\*\*\*  
Von Willebrand Factor concentrate

AIMAFIX / HUMAFactor-9\*\*  
Factor IX concentrate

EMOSINT  
DDAVP Desmopressin

UMAN COMPLEX  
Prothrombin Complex concentrate

## IMMUNOLOGY NEUROLOGY

Ig VENA / HUMAGLOBIN/  
KEDRIGAMMA / Gammaked\*  
Standard intra venous Immunoglobulin

VENBIG / KEYVENB  
Anti-hepatitis B intra venous  
Immunoglobulin

IMMUNOHBs / UMAN BIG  
Anti-hepatitis B intra venous  
Immunoglobulin

TETANUS GAMMA  
Anti-tetanus intra muscular  
Immunoglobulin

ImmunoRHO / RhoGAM /  
MICRhoGAM / KeyRho  
Anti-D intra muscular Immunoglobulin

## 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

PRODUCTS  
DEDICATED  
TO THE ITALIAN  
SELF-SUFFICIENCY  
PROGRAM

VENITAL

Standard intra venous Immunoglobulin

ALBITAL / KALBI\*\*\*\*

Human Albumin solution

AT III KEDRION / ATKED\*\*\*\*

Antithrombin concentrate

PLASMASAFE / PLASMAGRADE\*\*\*\*

Pharmaceutical grade plasma

EMOCLOT / KLOTT\*\*\*\*

Factor VIII concentrate

AIMAFIX / IXED\*\*\*\*

Factor IX concentrate

UMAN COMPLEX / KEDCOM\*\*\*\*

Prothrombin Complex concentrate

KEDHBs\*\*\*\*

Anti-hepatitis B intra muscular  
Immunoglobulin

VEBIKED\*\*\*\*

Anti-hepatitis B intra venous  
Immunoglobulin

ORPHAN DRUGS

Kedrion Human Plasminogen: a sterile human plasma-derived plasminogen preparation in the pharmaceutical form of eye drops for the treatment of ligneous conjunctivitis, currently under development.

The product has obtained the designation of orphan drug by the US Food and Drug Administration (FDA) and by the European Medicines Agency (EMA). Clinical trials are still underway to obtain Marketing Authorization in the United States and in Europe (EU).

\* product only available for the US market

\*\* product only available for the Hungarian market

\*\*\* product only available for the Italian market

\*\*\*\* not yet available for distribution

# ORGANIZATION CHART



**CHAIRMAN / CEO**

P. Marcucci

- ▶ Corporate Secretariat
- ▶ Corporate Business Development - P. Marcucci (a.i.)
- ▶ Environment, Health and Safety - M. Bonaldi



**GLOBAL COMMUNICATION**

M. Marcucci (a.i.)



**CHIEF OF CENTRAL SERVICES**

S. Boaglio



**CHIEF REGULATORY & COMPLIANCE OFFICER**

R. Franceschini



**CHIEF COMMERCIAL OFFICER**

L. Guiheen



**US GENERAL MANAGER**

C. Lamb



**CHIEF OPERATING OFFICER**

A. Mancuso



IN 2013, KEDRION CONSOLIDATED AN ORGANIZATIONAL MODEL IN WHICH THE MAIN RESPONSIBILITIES FOR THE GROUP'S GUIDANCE AND MANAGEMENT ARE CONCENTRATED IN A FEW POSITIONS THAT REPORT DIRECTLY TO THE CEO. WHILE CONTINUING TO GROW INTERNATIONALLY, WE NURTURE AND VALUE OUR ITALIAN ROOTS BY STRENGTHENING THE ROLE OF OUR CORPORATE HEADQUARTERS BASED IN CASTELVECCHIO PASCOLI, IN THE PROVINCE OF LUCCA, ITALY.



- ▶ Internal Audit & Risk Analysis
- ▶ Public Affairs
- ▶ Ethics Office

## VICE CHAIRMAN & ETHICS OFFICER

R. De Dominicis



## PRODUCT DEVELOPMENT

C. Nardini



## PLASMA BUSINESS UNIT

A. Marcucci

# 2013 KEY EVENTS

## CORPORATE

APRIL

**PLASMA-DERIVED  
PRODUCTS FROM  
NATIONAL PLASMA  
FOR HUMANITARIAN  
DONATIONS**



In support of the Italian National Blood System, Kedrion makes two shipments of national plasma-derived products: Afghanistan and Albania receive factor VIII and factor IX to support the medical needs of patients with hemophilia.

JULY

**KEDRION  
TAKES OVER  
MANAGEMENT OF  
MELVILLE PLANT**



Grifols transfers to Kedrion management of the US Melville plant operations a year ahead of schedule. The transfer enables the Group to optimize the production capacity of its plants with a view to mainstreaming production activities.

JULY

**KEDPLASMA  
DEUTSCHLAND  
CELEBRATES ITS 5<sup>TH</sup>  
ANNIVERSARY**



KEDPlasma GmbH celebrates its 5th anniversary. Founded in 2008, the Gräfelfing company, based in Munich, now owns three plasma collection centers in Fürth, Ingolstadt and in Bayreuth, in Germany. All collection centers are IQPP certified by the Plasma Protein Therapeutics Association.

JUNE-JULY

**SPEARHEADING  
EFFORTS  
IN HELPING  
DISADVANTAGED  
COUNTRIES**

Kedrion gives more than 1.500.000 international units of coagulation factor IX to disadvantaged countries, such as Pakistan and Afghanistan, to broaden hemophilia patients' access to the treatments they need.

## PLASMA & BIOTHERAPIES

APRIL

**RhoGAM AND  
MICRhoGAM IN  
US MEDICAID  
REIMBURSEMENT  
PROGRAM**

In the United States, anti-D human immunoglobulin concentrates RhoGAM and MICRhoGAM are listed among the reimbursable drugs covered by the Medicaid Drug Rebate Program, the US government social health program.

APRIL

**NEW ALBUMIN  
FORMAT ON SALE  
IN THE US**

The Food and Drug Administration (FDA) authorizes the launch on the US market of the new 100ml size for Kedbumin 25%. The product is manufactured in Bolognana using intermediate plasma fractions from the United States. This new format is the first example of integration between the Melville plant and the Italian production facilities.



Sestant, the holding company of the Marcucci family, and the Fondo Strategico Italiano buy back Kedrion shares held by Investitori Associati, investors who after nearly 7 years of invaluable consulting and financial contributions, decide to exit the company. Sestant now holds more than 75% of the Kedrion Group capital while Fondo Strategico Italiano SpA owns the remaining shares.



Kedrion Brasil Distribuidora de Produtos Hospitalares LTDA-ME is born from the joint venture agreement between Kedrion SpA (51%), and FBM Pharma Pharmaceutical Industry LTDA (49%). Immunoglobulin will be the first product to be registered in Brazil.



Kedrion implements the new Global Medical Information System, a structured and centralized system of information aimed at sharing medical and scientific information. The service has its roots in Kedrion commitment to the welfare of patients and provides health care professionals with prompt, specific and non-commercial information in response to all inquiries.



In order to respond to the continuing development of international markets, Kedrion Biopharma India Private Limited is registered in Delhi. It is made up of three Kedrion Group companies: Kedrion SpA (60%), HUMAN BioPlazma Kft (20%) and Kedrion Melville Inc (20%).



Thanks to an agreement with Octapharma, for the next ten years Kedrion will distribute in Italy the first human cell-derived recombinant factor VIII, which is produced by the Swiss company. Kedrion reaffirms its commitment to the development of treatments for patients suffering from hemophilia.

# 2013 KEY EVENTS

## R&D

28

MARCH  
DEVELOPMENT OF  
AN INNOVATIVE  
SPRAY-DRIED  
PLASMA



Kedrion Melville Inc signs an agreement with Entegriion Inc for the development and exclusive global rights for the sale of Resusix, an innovative virus inactivated spray-dried plasma that can substitute fresh frozen plasma. The project is supported by the US Department of Defense, which has grasped its potential use in first aid.

APRIL  
KEDRION  
ANNOUNCES  
COLLABORATION  
WITH RESIST  
STUDY

Over the next three years, Kedrion Biopharma Inc will collaborate with RESIST (Rescue Immune Tolerance Study). The US company's support makes the continuation of this project possible, a study aimed at defining the role of the von Willebrand factor combined with factor VIII inhibitors in the treatment of hemophilia A.

## EVENTS

APRIL  
FIRST  
INTERNATIONAL  
WORKSHOP ON  
HEPATITIS

Kedrion and Kedrion International gather opinion leaders from around the world during the European Association for the Study of the Liver Congress (EASL) in Amsterdam for a workshop on the treatment of hepatitis at a global level.

JUNE  
LATAM MEETING  
ON IMMUNO-  
DEFICIENCIES

Kedrion and the Latin American Society for Immunodeficiencies (LASID) organize the LatAm Expert Meeting on primary immunodeficiencies in Miami. The goal is to broaden and share knowledge of these diseases and to strengthen Kedrion's position in Latin American markets.

SEPTEMBER  
SEMINAR ON THE  
ITALIAN BLOOD  
SYSTEM AT THE  
HEALTH FESTIVAL



Kedrion collaborates in the organization of the workshop "The Italian Blood System towards self-sufficiency in plasma-derived products" held in Pietrasanta (Lucca, Italy) during the 6th Festival della Salute, Health Festival. All major players of the Italian Blood System meet to discuss the regulatory changes taking place.

JUNE  
SUPPORT FOR THE  
WORLD BLOOD  
DONOR DAY



Kedrion confirms its support to associations and federations of blood donors taking part in World Blood Donor Day, first celebrated by the World Health Organization in 2004, now at its tenth edition.



**MAY**  
**CLINICAL STUDY  
ON PLASMINOGEN  
KICKS OFF**

The trial phase of human plasminogen eye drops kicks off. This is the first orphan drug developed by Kedrion and the only product that has been proven effective in the treatment of ligneous conjunctivitis.



**OCTOBER**  
**Ig VENA, NEW  
APPROVAL FOR  
TREATMENT  
OF CIPD**

In Germany, Poland, Portugal, Greece, Austria and Switzerland, Ig VENA is approved for the treatment of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), a neurological disease whose treatment is estimated to account for about 30% of world consumption of intravenous immunoglobulin.



**OCTOBER**  
**KEDRION ONE OF  
THE ACTORS AT  
FIODS SEMINAR  
IN LUCCA**

The 2013 edition of the International Federation of Blood Donor Organizations seminar takes place at the Fondazione Campus in Lucca. Kedrion reaffirms its role as the "Fourth Pillar of the Italian Blood System", sharing concrete examples of activities carried out to support Italian stakeholders.



**OCTOBER**  
**PRIMARY IMMUNO-  
DEFICIENCIES  
CONGRESS IN CHILE**

Kedrion is one of the main sponsors of the international meeting organized by the Latin American Society for Immunodeficiencies (LASID). The congress held in Santiago, Chile brings together the world's top experts in the field of primary immunodeficiencies.



**OCTOBER**  
**FIRST AWARENESS  
WEEK ON PLASMA  
COLLECTION**

KEDPlasma Deutschland and KEDPlasma US actively take part in the first International Plasma Awareness Week (IPAW) organized by the Plasma Protein Therapeutics Association (PPTA). A week dedicated to raising global awareness about the importance of plasma collection.



**OCTOBER**  
**FIRST  
INTERREGIONAL  
SEMINAR ON THE  
ITALIAN BLOOD  
SYSTEM**

The first Interregional Seminar on the Italian Blood System focuses on the topic "Regions exchange views to deal with change". The Region of Tuscany, Blood Donor Associations and Fondazione Campus of Lucca organize with Kedrion's support this important meeting held in Florence.



An aerial photograph of a blue waterway or coastline, possibly a fjord or a narrow channel, with a central text overlay. The water is a deep blue, and the surrounding land is a lighter blue. The text "THE WAY FORWARD" is centered in a dark blue, sans-serif font, flanked by two horizontal lines.

THE WAY  
FORWARD





# THE WAY FORWARD

PAOLO MARCUCCI



IN 2014 AND FOR THE YEARS TO COME, KEDRION WILL CONTINUE ON ITS SUCCESSFUL PATH: CONSTANT INCREASE IN THE PRODUCTION CAPACITY, AN EXPANDING PRODUCT PORTFOLIO, THE HARMONIZATION OF INDUSTRIAL PROCESSES, OPENING UP NEW MARKETS.

In past years, especially in 2012 and 2013, we laid the foundations to make our project come true. We worked on a vertical integration model and we gave notable impetus to plasma collection, the precious resource needed to manufacture our medicinal products. We believe that over the next three to five years, the following goals will be achievable: to increase our fractionation capacity and to more than double our capacity for plasma collection. In addition to increased manufacturing, we will register new products that will enrich our portfolio even further.

In particular, our new standard immunoglobulin will play a key role.

We will continue our partnership with the Italian National Health System, with the goal of maintaining our existing volumes in the domestic market which, as we know, is gradually opening up to other competitors. Italy is still central to our business; and it is due to this that today 76% of new company investments are still made in this country. At the same time, we will expand our presence in strategic markets such as Turkey, Mexico, Germany, Austria and Poland and in emerging markets such as Russia, India, Brazil and China, where we plan to operate with local partners.

Furthermore, we are developing medicines intended for the treatment of rare diseases, which are also known as orphan drugs. For this reason, we have decided to strengthen our research activities even more: in our Siena laboratories. Researchers will explore new and challenging frontiers that will also result in the development of scientific knowledge, likely to have a defining impact on the improvement of quality and development of traditional pharmaceutical products.

THE WAY FORWARD IS CLEAR, THE HORIZON VISIBLE. ALL WE NEED TO DO IS TO SET OUT ON OUR JOURNEY, KNOWING THAT WE CAN COUNT ON THE EFFICIENCY OF OUR MANUFACTURING FACILITIES, ON THE EXPERTISE OF OUR RESEARCHERS, EMPLOYEES AND MANAGEMENT, ALWAYS BEARING IN MIND THAT OUR MAIN OBJECTIVES ARE TO ENSURE THAT AN EVER-INCREASING NUMBER OF PATIENTS HAVE ACCESS TO CARE AND, AT THE SAME TIME, TO GENERATE INCOME FOR FAMILIES AND PROFITS FOR THE COMPANY.





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THE  
COMPANY

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# FINANCE

EFFICIENCY · INTEGRATION · HARMONIZATION · GROWTH



THE KEY TO CONTINUE TO MOVE FORWARD ON OUR PATH OF INTERNATIONAL GROWTH IS TO STRENGTHEN OUR COMPETITIVENESS AND EFFICIENCY WHILE MAINTAINING QUALITY AT THE CORE OF THE PROCESS.

WE INVEST IN INNOVATIVE PRODUCT RESEARCH AND DEVELOPMENT. IN 2013, WE INCREASED INVESTMENTS IN THIS FIELD AND ARE COMMITTED TO CONTINUE DOING SO IN THE FUTURE.

In 2013, Kedrion continued its international development process. This is a course of action that we have been actively pursuing over the recent years and that has yielded good results. Last year, export accounted for 66,1% of total turnover; Kedrion consolidated its presence in the US market; strategic markets such as Germany, Austria, Poland, Portugal, Turkey and Mexico developed notably; and at the same time, we laid a solid foundation for expansion into emerging markets, namely India, Brazil and Russia.

The year 2013 saw an increase of over 10% in turnover, from 378 million Euro in 2012 to 424,8 million Euro in 2013. Likewise, profitability grew with EBITDA increasing from 20,9% to 24,7 %. This result was supported by a slight recovery in prices and made possible by the development of internal efficien-

cies, which in turn allowed us to optimize the integration process among the Group's production plants. In particular, the new production line "Huge" is now operating at full capacity in our Hungarian facility in Gödöllő, while the US plant in Melville now carries out fractionation internally and therefore at a lower cost, a process that was previously outsourced.

"Bologna continues to be the Group's production hub, but at the same time we are working on ensuring maximum horizontal integration between facilities in order to reach an ever-increasing production capability," explains Simone Boaglio, Chief of Central Services. "On the one hand, thanks to our improved internal efficiency, we have been able to reduce operating costs. On the other hand, we have boosted investment in rese-

arch and development to support our two ongoing clinical studies concerning new generation immunoglobulins and plasminogen eye drops".

"In order to achieve the turnover and profit margin goals we have set for ourselves, Kedrion's priority is to internalize all production processes. The strategic plan for the next five years includes the construction of a new production plant in Castelvecchio Pascoli, near Lucca in Italy, and the creation of additional plasma collection centers in Europe and the United States. Our ultimate goal is to increase our strategic production capacity and to become increasingly autonomous in the procurement of raw material", concludes Simone Boaglio.

# BUSINESS DEVELOPMENT

ACCESS · EXPANSION · PROFITABILITY · DILIGENCE

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WE HAVE BECOME A TRULY GLOBAL PLAYER WITH PLANTS IN THREE COUNTRIES AND A COMMERCIAL FOCUS ON A NUMBER OF KEY STRATEGIC NATIONS.

PATIENTS ARE THE CORE OF OUR ACTIVITIES AND EXISTENCE. THEIR WELL-BEING AND SAFETY IS WHAT DRIVES US. WE BELIEVE THAT NO PATIENT SHOULD GO UNTREATED; AND WE STRIVE TO ENSURE AND ENABLE ACCESS TO OUR PRODUCTS THROUGHOUT THE WORLD.

In 2013, Kedrion continued growing, consolidating its presence in key international markets. Kedrion's US operations played an important role, and sales increased worldwide as a result of establishing new subsidiaries, joint ventures and strategic partnerships with local players. The company is very active in evaluating new opportunities as they present themselves on the market and is always searching for ways to grow organically and also to expand through transactions with third parties. In 2011, the company acquired the Melville plant and two plasma centers from Grifols and in 2012 the RhoGAM product line and a plasma center from Ortho-Clinical Diagnostics in the USA. 2013 marked the first calendar year in which Kedrion owned the RhoGAM brand for a full cycle and the Group's revenues benefitted from the additional turnover associated with this product line.

Technology transfer has been and will continue to be a strategic activity for Kedrion. In 2013, Kedrion's new fractionation line in Gödöllő, Hungary, became operational following large investments and a highly complex technology transfer effort.

Kedrion is currently focused on two important projects involving technology transfer: a state-of-the-art purification plant in Italy for Kedrion's new generation immunoglobulin and a new production area at the US Melville facility for the "in-house" production of RhoGAM, which is now being manufactured by Ortho-Clinical Diagnostics.

As the company expands its manufacturing capacity, it also needs to increase its plasma availability: one of Kedrion's key strategic initiatives over the next years is to enhance collection capacity in its existing centers and to open new ones.

The expansion of our product portfolio is at the heart of Kedrion's Business Development and is a result of our internal Research & Development efforts and of our strategic acquisitions and distribution agreements.

In the next few years the plan is to launch a number of new products developed internally. In addition, Kedrion will launch and be exclusive distributor of two products manufactured by strategic partners: a spray-dried solvent detergent treated plasma and an anti-rabies immunoglobulin.

# SOCIAL RESPONSIBILITY

FORESIGHT · DEDICATION · CONTINUOUS LEARNING · SHARING

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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 from 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.

## 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.



BEING SOCIALLY RESPONSIBLE MEANS NOT ONLY MAKING QUALITY PRODUCTS AND PLACING THEM ON THE MARKET AT THE RIGHT PRICE, BUT ALSO ENTERING THESE MARKETS PROPERLY. THIS IS THE ONLY METHOD OF DOING BUSINESS IN A LONG-LASTING WAY. IT IS NOT EASY OR TRIVIAL, BUT IT IS WHAT WE WANT.



[www.kedrion.com/corporate-social-responsibility](http://www.kedrion.com/corporate-social-responsibility)

Corporate Social Responsibility has undergone a fundamental evolution in Kedrion over the more than ten years of the company's life. Originally CSR stemmed from our desire to be SA8000 certified, a benchmark standard, and now has become a fundamental guideline on how we do business, how we behave internally towards our employees and externally towards our stakeholders.

For us, being responsible is a matter of understanding that we do not exist or operate in a vacuum. Everything we do, every decision we make, impacts the people around us: our workforce, our community and the world.

It is for this reason that at Kedrion we strive every day to ensure that special attention and care is given to our employees, to reduce the environmental impact and to be an

active good citizen in the communities where and with which we work.

We ensure that whoever operates for and on behalf of Kedrion adheres to internationally recognized principles of best practices, as well as to national and international legislation. In addition, we encourage all partners and collaborators to observe socially responsible practices and contractually obligate partners and collaborators to conform to our Social Responsibility principles.

"Even in 2013 we verified that all our activities were in compliance with the Social Accountability System and with our Code of Ethical Conduct. We also measured our performance against some voluntary standards we have adopted", states Rodolfo De Dominicis, Vice Chairman & Ethics Officer.

Kedrion's rapid international growth in recent years has also had an inevitable impact on Social Responsibility. "We are putting a strategy in place which will allow each company within the Group, anywhere in the world, to be ethically and socially responsible. To this end, we are creating an International Strategic Board tasked with drafting our ethical policy at a global level. Four super-partes experts will be at our side on this path to internationalization and will assist us in aligning our practices to the ethical principles we have set as well as to external regulation" concludes Rodolfo De Dominicis.

## OUR STANDARDS AND CERTIFICATIONS

- Our own ideals, principles and goals
- The Global Compact's Ten Principles regarding human rights, labor, the environment and the fight against corruption
- The OECD (Organisation for Economic Co-operation and Development) Guidelines for Multinational Enterprises
- The ILO (International Labour Organization) Principles
- The SA8000 Standards

# SOCIAL RESPONSIBILITY



THROUGH OUR WORK, WE COMMIT TO TREATING OUR PEOPLE IN THE BEST WAY POSSIBLE. WE ARE OPEN TO EACH OTHER'S SENSIBILITIES AND SENSITIVITIES; WE COLLECT IDEAS, SUGGESTIONS, AND EXPECTATIONS AND INCORPORATE THEM SYSTEMATICALLY SO THEY BECOME TANGIBLE ASPECTS OF OUR WAY OF DOING BUSINESS.

At Kedrion, our business is people: we protect the health and safety of those who work with us, of those who generously give their plasma and of those who use our plasma-derived products.

"In 2013 we reduced our plants' environmental impact and pollution, worked towards a higher quality of life in our working environment and organized emergency management training activities tied to natural disaster scenarios" states Marta Bonaldi, Head of Environment, Health & Safety. "One of our most important goals for 2014 is to share globally an EHS management model that will be able to link local experiences with international standards and identify common guidelines" Bonaldi concludes.



[www.kedrion.com/environment-health-safety](http://www.kedrion.com/environment-health-safety)

## OUR STANDARDS AND CERTIFICATIONS

- The ISO 14001 Standards
- The OHSAS 18001 Standards
- The EMAS Regulation

# SCUOLA KEDRION

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At Kedrion, the communication of ideas, experiences, practices and values is essential to our mission as well as to the development of a vibrant and effective company. The Scuola Kedrion provides Kedrion's managers access to academic, theoretical and practical training. It also provides a means to develop and communicate corporate awareness, identity and culture, ensuring that common values and consistent practices can be assumed throughout the corporation.

Currently more than 200 Kedrion leaders take advantage of the opportunity to learn and refine concepts and skills directly relevant to their careers at Kedrion but applicable across the broader business world.

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# PLASMA COLLECTION

DONORS · BRIDGE · *FLOWING* · RESPONSIBILITY

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PLASMA IS AT THE HEART OF ALL KEDRION'S ACTIVITIES, FROM RESEARCH TO PRODUCTION. OUR MISSION IS TO CREATE A LIFE-SUSTAINING BRIDGE BETWEEN DONORS AND RECIPIENTS BY COLLECTING PLASMA AND TRANSFORMING IT INTO MEDICINES AND THERAPIES THAT IMPROVE THE QUALITY OF LIFE OF THOSE WHO NEED IT.

OUR SOMERSET LABORATORIES IN BUFFALO, NEW YORK, COLLECT HYPER-IMMUNE ANTI-D HUMAN PLASMA FOR THE MANUFACTURING OF RHOGAM, USED IN PREVENTING HEMOLYTIC DISEASE OF THE NEWBORN. IN 2013, THE VOLUME OF ANTI-D PLASMA HAS DOUBLED COMPARED TO THE PREVIOUS YEAR.



[www.kedrion.com/donors](http://www.kedrion.com/donors)

When we say *Keep Life Flowing*, the agent of that commitment is plasma, the very fluid of life. Kedrion's mission is to establish a vital connection between donor and recipient by collecting and transforming plasma. Kedrion works with donors in Germany, Hungary and the United States, collecting plasma in state-of-the-art plasma collection centers. In Italy, Kedrion collaborates with donor associations and federations and with the Italian National Health System.

In 2013, global growth for the Kedrion Plasma Business Unit was notable and served to lay the groundwork for the further development of the Group's collection centers.

"One of the main goals of Kedrion's growth plan is the optimization of plasma collection", states Andrea Marcucci, Plasma Business Unit Director. "We are working on boosting the number of our collection centers, which will in turn lead to a significant increase in the volume of plasma collected, to a general re-

duction of costs and to the development of strategic partnerships".

About 620.000 liters of plasma were collected overall in 2013, up 16% over the previous year. This significant growth was achieved thanks to the US centers, where donations increased by 17%, and to the European centers in Germany and Hungary, where plasma collection was up by 11%.

Last year, the continuous upgrades implemented in the "historic" Kedrion centers of Reseda, Johnson City, Kingsport, Bristol, Pensacola and Mobile produced excellent results as did our most recent centers of Mobile 2 and Winston-Salem, acquired from Grifols in 2011. In particular, the collection of standard plasma through plasmapheresis was quite remarkable, with a 34% recorded increase in the US and 9% growth in Germany. Plasma collection in Hungary also improved, up 18% compared to 2012 with more than 37.000 liters.

The collection of hyper-immune Anti-D human plasma doubled in 2013, reaching close to 28.000 liters. This result is due to the twelve-month contribution of Somerset Laboratories in Buffalo, New York, acquired from Ortho-Clinical Diagnostics during the RhoGAM operation (in 2012, they had only been operative for five months) and due to collection increase across the board in all other centers.

"For the foreseeable future, we will be focusing on opening new centers in the US because plasma collection in North America is, and will always be, an essential key to achieve the goals we have identified in Kedrion's growth strategy", states Andrea Marcucci.

# RESEARCH & DEVELOPMENT

PATIENT · VISION · INNOVATION · INTEGRATION



WE LISTEN TO OUR COMMUNITIES AND STRIVE TO INTEGRATE FULLY WITH OUR PATIENTS, CONVERTING THEIR NEEDS INTO NEW PRODUCTS. THROUGHOUT OUR PRODUCT DEVELOPMENT PROCESS, OUR FOCUS IS ALWAYS THE PATIENT.

FOR KEDRION, DEALING WITH ORPHAN DISEASES IS BOTH A CHALLENGE AND AN OPPORTUNITY. ALSO IN THIS FIELD, WE HAVE THE OPPORTUNITY TO LIVE UP TO OUR IDEALS, TO PROMOTE INTERACTION BETWEEN THE WORLD OF RESEARCH AND THE WORLD OF BUSINESS AND TO INSPIRE A GLOBAL VISION.



[www.kedrion.com/product-development](http://www.kedrion.com/product-development)

Research and Development is present in all the stages linking donors to patients. From basic research to industrial development, from pre-clinical and clinical development to market launch and Pharmacovigilance activities, we make every effort to help those in need of our products.

"Our priority is to integrate fully with the patient, whose needs are recognized and then translated into new products," states Claudia Nardini, Product Development Director.

For example, Pharmacovigilance is not only about complying with monitoring activities and regulation. It also represents an invaluable source of information allowing us to collect data concerning patient safety which then becomes an integral part of the product development process.

Similarly, Kedrion's Global Medical Informa-

tion Management offers a structured global system that shares medical and scientific information and that provides prompt answers to health care professionals' inquiries about our products. A service that is deeply rooted in our commitment to the well-being of patients.

In the near future, Kedrion plans to establish Scientific Advisory Boards, made up of world-renowned physicians and opinion leaders.

The Advisory Boards will constitute an additional tool to gather every useful input from the medical community in order to develop our product portfolio, including the development of orphan drugs that are essential in the treatment of particularly rare diseases.

"We talk about "rare" diseases but patients suffering from these diseases are many", explains Claudia Nardini. "For this reason

we established IKOD, a manufacturing plant in Siena, for small plasma-derived product quantities. This facility is wholly dedicated to the research and development of orphan drugs". IKOD will focus on producing batches used in clinical trials on factor V concentrate and the commercial production of plasminogen concentrate in the form of eye drops. Trials for both products are currently underway.

Kedrion's strong commitment to research is demonstrated by an increased investment in R&D compared to previous years. Products currently in the development pipeline include the new generation immunoglobulin.

## BIOLOGICAL SAFETY CENTER (BIOSC)

Kedrion's dedication to the safety of its products, as well as to the safety and well-being of the people it serves, led it to establish its Biological Safety Center (BioSC). The Center specializes in the protection from viral pathogens and has been operating at the Bolognana (Lucca) plant since 2010. The GLP certified laboratories conduct studies on the inactivation and removal of pathogens.

The inactivation and removal of pathogens are a part of Kedrion's Quality Program which is at the core of all our production processes. In 2013, part of BioSC activities focused on two of the

[www.kedrion.com/biological-safety-centre](http://www.kedrion.com/biological-safety-centre)

company's strategic projects: the new generation immunoglobulin and Resusix, an innovative virus inactivated spray-dried plasma.

BioSC aims to become an international benchmark and point of reference in the field of safety for all those who, by putting the patient first, need to and have the obligation of understanding products better, protecting them from biological risk. A service offered not only to the pharmaceutical industry but also to the scientific community and to institutions involved in research.



# COMPLIANCE & REGULATORY

GLOBAL VISION · SAFETY · BROAD REACH · INTEGRATION

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WHEN WE SAY THAT IN KEDRION QUALITY ASSURANCE IS "GLOBAL", WE MEAN THAT THIS APPLIES NOT ONLY TO OUR OPERATIONS AROUND THE WORLD, BUT TO ALL DECISIONS AND ACTIVITIES THAT HAVE AN IMPACT ON THE QUALITY OF OUR SERVICES AND PRODUCTS.

OUR GLOBAL QUALITY ASSURANCE PROGRAM INCLUDES THE GOAL OF RESPECTING THE COMMUNITIES WE WORK WITH, ESPECIALLY THE DONORS AND THE ULTIMATE USERS OF OUR PRODUCTS.



[www.kedrion.com/quality-safety](http://www.kedrion.com/quality-safety)

In Kedrion, our Global Quality Assurance program seeks to ensure that all parts of the company and all people working in those parts – from Bolognana to Budapest, from Fort Lee to Fürth; from plasma collection to plasma-derivative development – understand and respect the same resolute standards of quality.

For us, quality is a "system" which includes the safety and effectiveness of our products and that extends to the quality of our services and business practices, always bearing in mind the needs of the ultimate users of our medicinal products. Kedrion's strategy aims to create a perfect synergy among the Group production plants located around the world. This is obtained on the one hand by integrating the facilities and on the other by cherishing and valuing our diverse cultures. "A good example of how we are pursuing our

harmonization goal is the use of intermediate products" states Rodolfo Franceschini, Chief Regulatory and Compliance Officer. "In 2013 we received permission to use intermediate products from our Hungarian plant to produce plasma derivatives in the other Group facilities. This ensures production capacity optimization and greater business flexibility. Similarly, in 2014 we are going to focus on integrating our new plant located in Melville, US, into the Group's industrial process".

In order to continue growing in global markets, close cooperation between the Authorities of different countries and Kedrion, mainly the Regulatory department, is a key factor.

"In 2013, in the United States we received authorization to market our new 100ml format of 25% albumin which is produced at the Bolognana plant, while in many European countries we have obtained a new therapeutic

indication for the use of Ig VENA in the treatment of CIDP, a neurological disease. It is estimated that the treatment of CIDP accounts for 30% of the world consumption of intravenous immunoglobulin," concludes Rodolfo Franceschini.

In Kedrion, quality is a broad and cross-reaching concept, ranging from international regulation compliance to the creation of value and reputation building - an essential prerequisite for continued company growth – also encompassing new product development and ever-increasing presence in international markets.

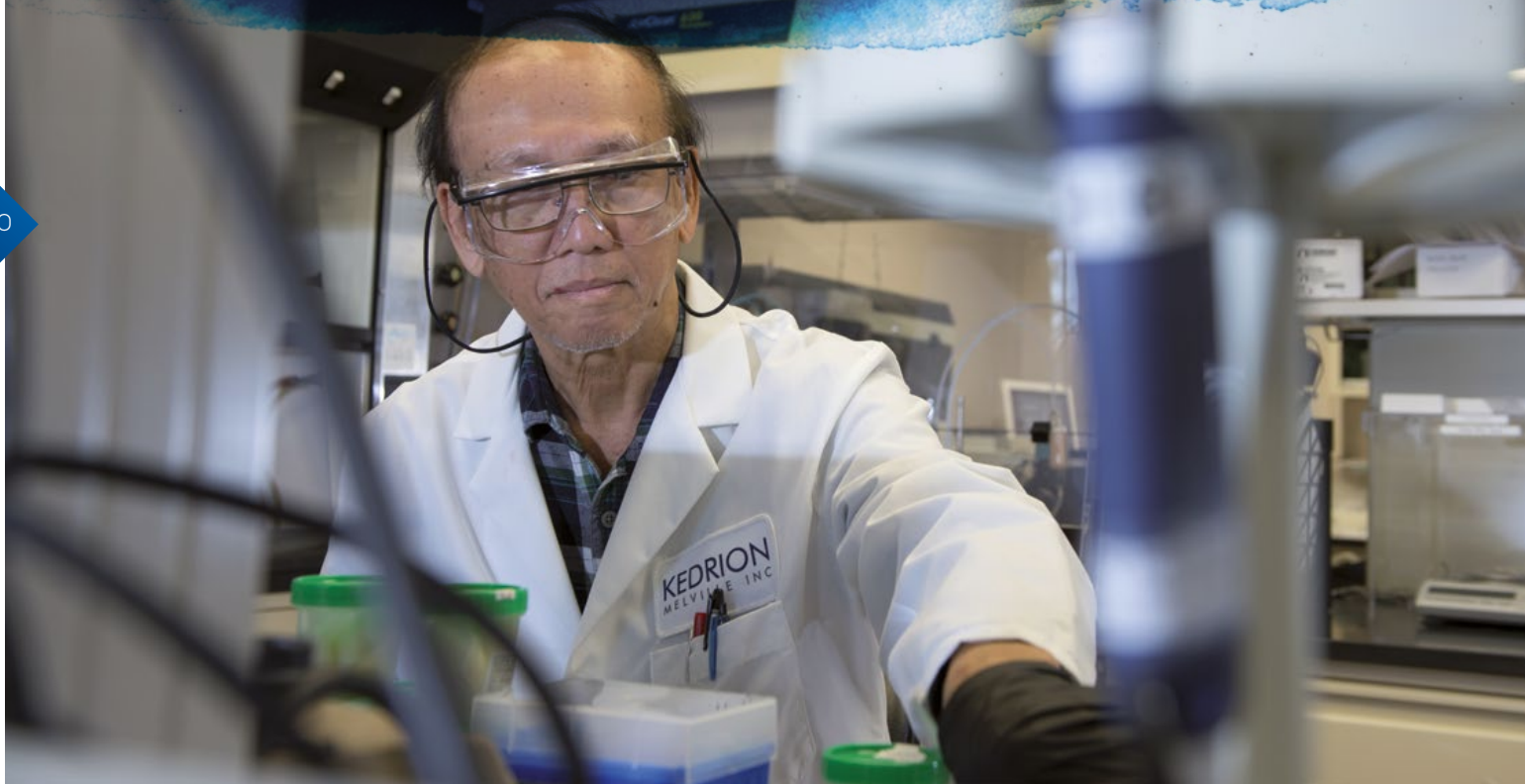
## OUR STANDARDS AND CERTIFICATIONS

- Good Manufacturing Practices
- Farmindustria Certification
- ISO 9001 Standards
- Quality Standards of Excellence, Assurance and Leadership (Plasma Protein Therapeutics Association)
- International Quality Plasma Program (Plasma Protein Therapeutics Association)

# PRODUCTION

PEOPLE · PASSION · TRUST · TRANSPARENCY

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FOR KEDRION,  
PEOPLE ARE THE MOST  
IMPORTANT ASSET.

HORIZONTAL  
INTEGRATION OF  
ACTIVITIES CARRIED  
OUT IN OUR PLANTS  
FACILITATES THE  
SHARING OF KNOWLEDGE  
AND OF EXPERTISE  
WITHIN THE GROUP.



[www.kedrion.com/expertise](http://www.kedrion.com/expertise)

Our expertise has its roots in the long experience of the companies from which Kedrion was born. Nowadays, our plants use the most advanced procedures and technologies. In Kedrion, every activity is carried out observing the highest standards of safety, quality and innovation.

The ever-growing Group's international presence calls for the harmonization of activities and processes in our plants located throughout the world. This will allow us to optimize plasma collection and our production capacity.

Kedrion has four production sites: Bologna and St. Antimo, in Italy; Gödöllő in Hungary; and Melville in the United States. In addition to these facilities, we have a plant in Siena, Italy, dedicated to researching and developing orphan drugs. In 2013, the foundations for the future expansion of the plants were laid. The Kedrion five-year strategic

plan sets the final production capacity and outlines which plants to invest in.

Production capacity optimization is one of the main guidelines of our growth plan. Following Kedrion's goal to harmonize production sites, in 2013 we initiated a technology transfer in the Gödöllő plant in order to modernize fractionation line 1, an investment that in the short term will lead to economic benefits and greater flexibility. "We believe that the transfer of technology is a set of processes and procedures which are integrated into our quality system: a transfer of both technological know-how and of expertise", explains Antonella Mancuso, Chief Operating Officer. A second objective is to internalize strategic production: some projects have already been started in 2013 to meet this goal. Among the most important ones has been the transfer of the fractionation and purification processes necessary to produce RhoGAM into the

Melville plant in the US; in Castelveccchio Pascoli, near Lucca, Italy, we are building a new facility for the production of the new generation immunoglobulin. "This second project, in particular, has led us to build a multi-functional and cross-functional work team in order to share experience and expertise. We firmly believe that the horizontal integration of our resources into our production system is a necessary prerequisite to continue growing and to be able to compete in a highly competitive global scenario", Antonella Mancuso concludes.

# SALES & MARKETING

PATIENT · QUALITY · GROWTH · RESPONSIBILITY



KEDRION'S GOAL IS TO EXPAND GLOBALLY TO DELIVER HIGH QUALITY PATIENT CARE IN COUNTRIES WHERE COMMUNITIES ARE UNDERSERVED.

OUR OBJECTIVE IS TO CONTINUE TO GROW OUR BUSINESS, BOTH WITHIN OUR PRODUCT PORTFOLIO AND GEOGRAPHICALLY IN A FINANCIALLY SUSTAINABLE WAY WHILE FULFILLING OUR KEY RESPONSIBILITIES. THESE RESPONSIBILITIES ARE TO OUR PATIENTS, OUR EMPLOYEES AND OUR INVESTORS.

In 2013, Kedrion continued to expand worldwide with the United States becoming a key market place. Growth was also central to our European operations, with expansion into Germany, Poland and Hungary. We established a dedicated business unit in Latin America and are establishing a strong presence in Russia.

Strategically we are focused on expanding our presence in countries where we currently have a market position while establishing positions in new countries. In Africa and the Middle East, Kedrion has continued to increase opportunities to deliver high quality patient care in countries where communities are underserved. In Turkey and Iran, our position is well established and Kedrion will expand further.

Our activities in Italy represent the foundation of the Kedrion business. "The focus in Italy is to continue to enlarge our product portfolio in order to grow our business and to create a service level that is hard to compete with. This will differentiate us from the competition," states Larry Guiheen, Chief Commercial Officer.

Double-digit growth over the past years in both Europe and the United States has been the result of the implementation and development of Kedrion's strategic plan.

In establishing our growth targets, we have focused on two factors: product and country. A product therapy approach looks at how we develop and position existing and future products, whereas a geographic approach is based on which countries offer the greatest opportunities for our therapies.

"The vision of the company over the next 5 years", explains Larry Guiheen "is to improve our current products, develop innovative therapies and expand geographically".

"The harmonization of our marketing campaigns is a strategic goal for the future," comments Guiheen. "We plan to optimize our approach to the diseases and conditions that our products treat and to have a unified marketing approach across the globe. This will enable us to transform our brands into global brands and to ensure we deliver the best treatments".

Around the world, the quality of care, be it within hemophilia, primary immunodeficiency or neurology, varies greatly. Kedrion's goal is to bring the best-demonstrated practices from Europe and the United States to other countries that are just beginning to develop biopharmaceutical treatments. Education is at the core of our effort in order to guarantee quality of care worldwide. In developing countries, Kedrion is organizing training

programs and ensuring that reimbursement policies are supported by national healthcare policy by working in conjunction with our industry associations.

Kedrion Global Marketing supports the company's worldwide needs from a marketing perspective. They work with R&D on the prioritization of our products, product harmonization and unified marketing approaches worldwide. In 2013, Global Marketing developed and initiated a Brand Team focus to determine the best way to face the worldwide challenges for each brand. Coordination of our efforts and team organization will be key factors to ensure optimization in all of our initiatives.

# COMMUNICATION

STRENGTH · ALLIANCE · INITIATIVE · SUPPORT

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## SUPPORT TO COMMUNITIES

Kedrion's commitment to Social Responsibility extends to all the communities we work with, from the sites of our operations to the environment in the broadest sense, from the community of donors to the community of patients.

Our goal is to raise global awareness of the diseases we treat and to improve diagnosis, treatment and access to care worldwide.

We pursue our objective by supporting projects locally, by making significant product donations all over the world, by closely collaborating with organizations that focus on educating and supporting patients like the Jeffrey Modell Foundation and the World Federation of Hemophilia.

## SUPPORT TO DONOR AND PATIENT FOUNDATIONS & ASSOCIATIONS

- Blood Donor Associations in Italy: AVIS , FIDAS , FRATRES, ITALIAN RED CROSS , FIODS
- Fondazione Paracelso ONLUS
- FedEmo
- World Federation of Hemophilia
- LA Kelley – Communication
- Pakistan Hemophilia Patients Welfare Society
- Jeffrey Modell Foundation

THE IMAGE WITH WHICH WE LIKE TO DESCRIBE OUR COMPANY IS A BRIDGE; ONE WHICH HELPS US BUILD RELATIONSHIPS, SHARE EXPERIENCES, OVERCOME DIFFERENCES AND PROMOTE COMMON INTERESTS.

OUR CORE VALUES GUIDE US IN HOW WE COMMUNICATE. OPENNESS AND TRANSPARENCY ENABLE US TO SHARE THE EVER-INCREASING KNOWLEDGE AND EXPERTISE WE HAVE GAINED OVER THE YEARS WITH PATIENT AND DONOR ASSOCIATIONS, INSTITUTIONS AND SCIENTIFIC COMMUNITIES.



[www.kedron.com/news-rooms](http://www.kedron.com/news-rooms)

In Kedrion, communicating means opening up to the world that surrounds us to share who we are, what we do, our knowledge and our goals. Communication is the tool with which we create and consolidate our community made up by patients, donors, staff, health care professionals and scientific researchers.

"The best way to describe our company is to envision a bridge. Kedrion helps build relationships, share experiences, overcome differences and promote common interests; we do all this mainly through communication", states Marialina Marcucci, Global Communication Director. "We always start from the premise that listening is as important as speaking, that learning is as important as teaching, thus establishing a steadfast relationship of mutual exchange".

Through its communication activities, Kedrion disseminates steady and dependable

information on the company's projects in Italy and throughout the world. By taking part in specific training, information and outreach campaigns, we contribute to raising awareness and knowledge of the importance of donation, particularly focusing on youth programs. Kedrion promotes, facilitates and supports dialogue between institutions, associations and scientific communities; and we unwaveringly stand by humanitarian aid programs so that they can obtain maximum media visibility.

In 2013, Kedrion kicked off a project aimed at redesigning its global websites. The network will become Kedrion's main communication tool, as it is able to mirror and reinforce the company's identity, its changes and its worldwide growth on the internet. At the beginning of 2014, the new Corporate website was launched with the subsidiaries' sites following shortly thereafter.

In Kedrion, we are about people. The new websites show pictures of real members of our broad community and tell the stories of donors who give to others, of people whose lives have been improved by our products and of employees who are well aware of the importance of their work.

"Similarly to Kedrion, which owes its continued success to the combination of innovation and quality, we envisioned our network of websites as a work-in-progress that will grow with the company," explains Marialina Marcucci. "We want our sites to become a place where people can meet, get to know and learn from one other: a place where life flows through communication and that invites everyone to participate. To Keep Life Flowing, as our claim states".

SUPPORT TO FOUNDATIONS AND ASSOCIATIONS ON HUMAN RIGHTS, VOLUNTEERING, UNIVERSITY, OTHER

- Fondazione Humanitas ONLUS
- CIDP Italia ONLUS
- AISF (Italian Liver Studies Association), Rome
- Prometeo AITF ONLUS (Italian Liver Transplantees Association) – Sardegna delegation
- ASTRA (Liver Transplantees Association), Gagnano
- AITF (Italian Liver Transplantees Association), Caserta

- Robert F. Kennedy Foundation of Europe ONLUS
- Global Compact
- Children in Crisis
- International Women's Coalition
- Muhura Mission in Rwanda
- Progetto Sorriso nel Mondo ONLUS (Smile in the World Project)
- Università di Tor Vergata, Rome
- ERASMUS MC Universitair Medisch Centrum Rotterdam (Support for Peripheral Neuropathies research)







ECONOMIC  
& FINANCIAL  
INDICATORS

# FINANCIAL INDICATORS

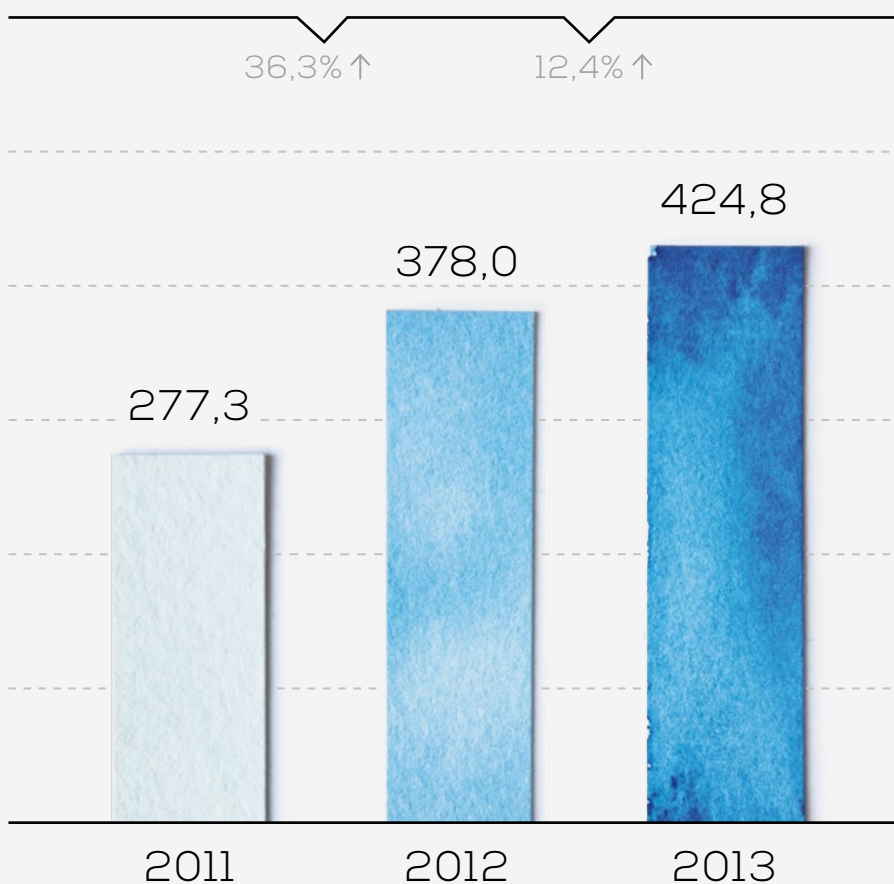
DATA IN THE 2011 AND 2012 CONSOLIDATED FINANCIAL STATEMENTS ONLY REFER TO KEDRION SPA AND THEREFORE DO NOT INCLUDE KEDRION MELVILLE, SOMERSET LABS AND KEDPLASMA MEMBER B.

DURING THE 2013 FINANCIAL YEAR, KEDRION COMPLETED A MAJOR INTERNATIONALIZATION PROCESS AIMED AT INCREASING THE GROUP'S PRESENCE IN KEY INTERNATIONAL MARKETS.

Thanks to the development of the US market and of other strategic areas, in 2013 export accounted for about 66,1% of total turnover. This result was achieved in a highly aggressive scenario. It has allowed us to reach a turnover of about 424,8 million Euro with a 24,7% profitability. The adjusted EBITDA is 104,7 million Euro while EBIT stands at 79,4 million Euro, equal to 18,7% of turnover. The net profit for the financial cycle amounts to 34,2 million, equal to 8,0% of turnover.

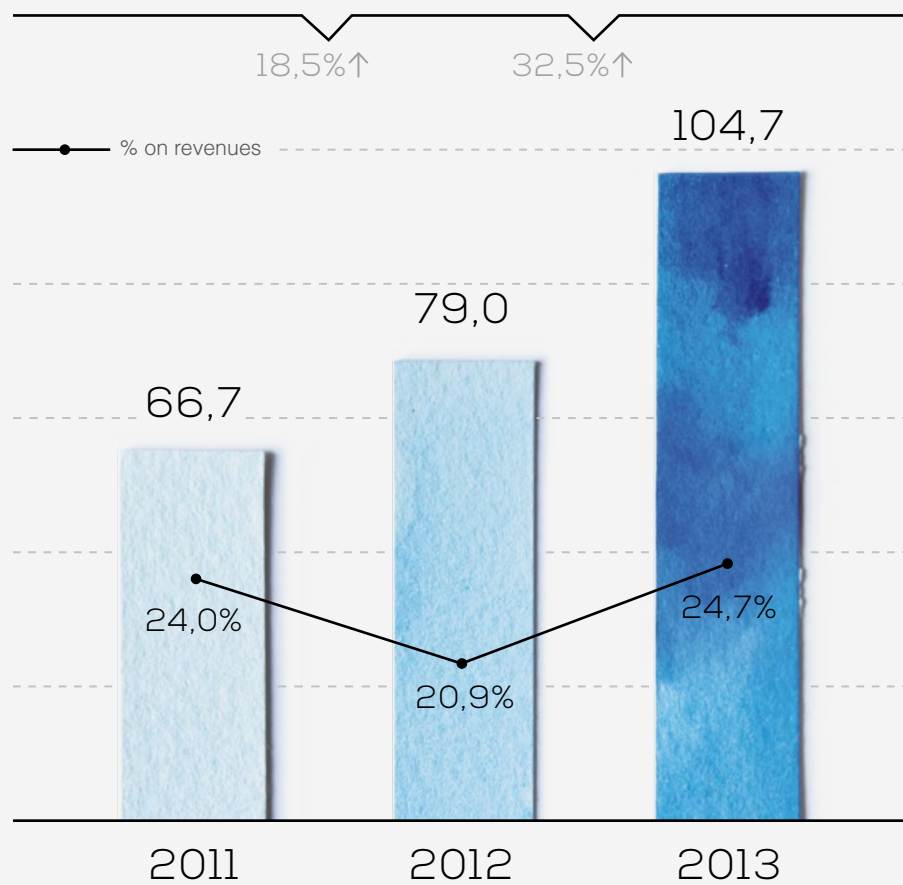
REVENUES (€ MLN)

CAGR 23,8%↑



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

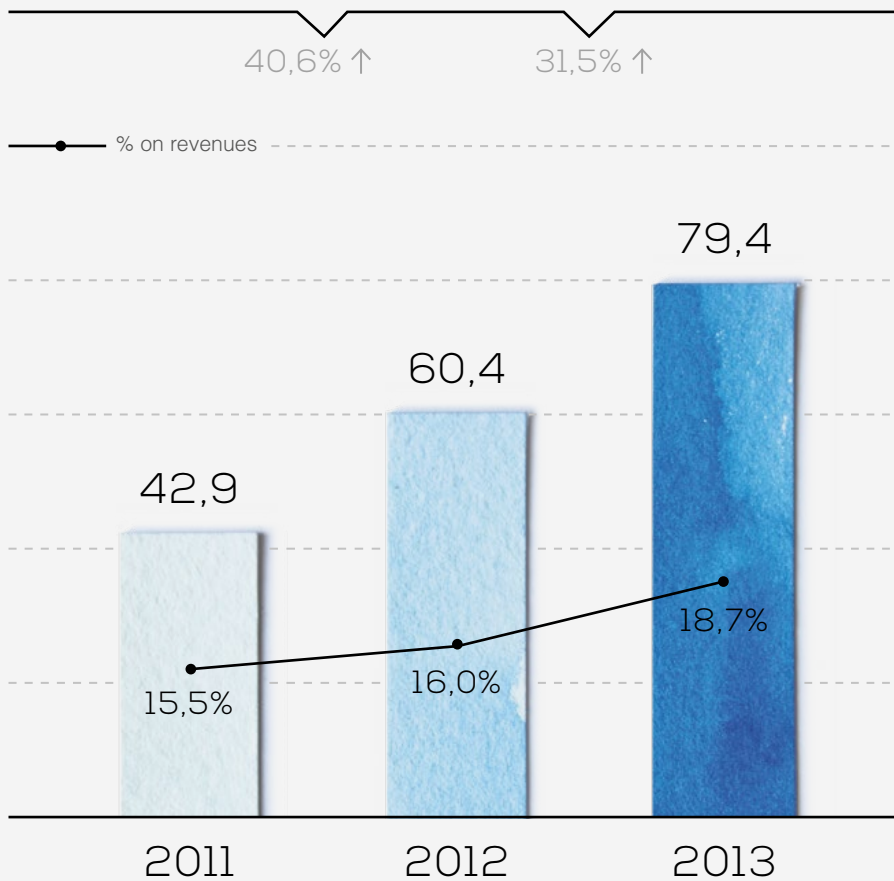
CAGR 25,3%↑



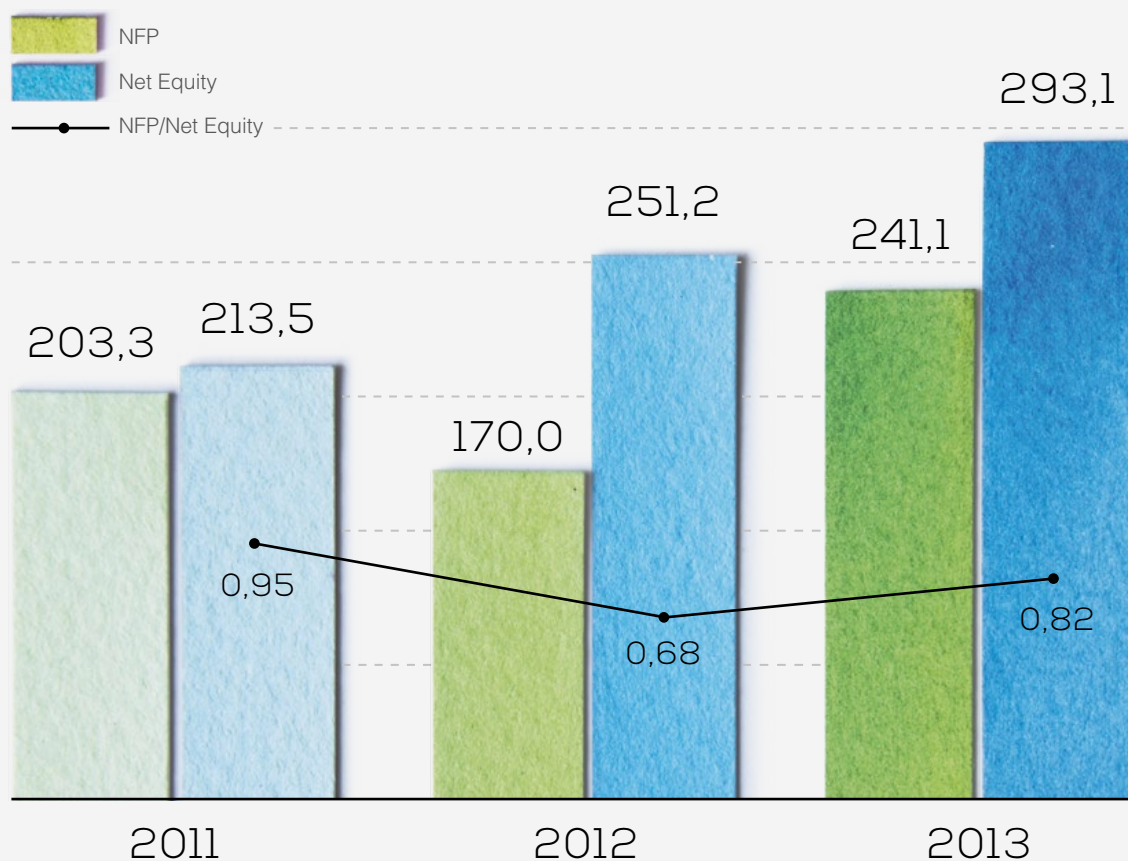
# FINANCIAL INDICATORS

EBIT (€ MLN) AND EBIT MARGIN (%)

CAGR 36,0% ↑



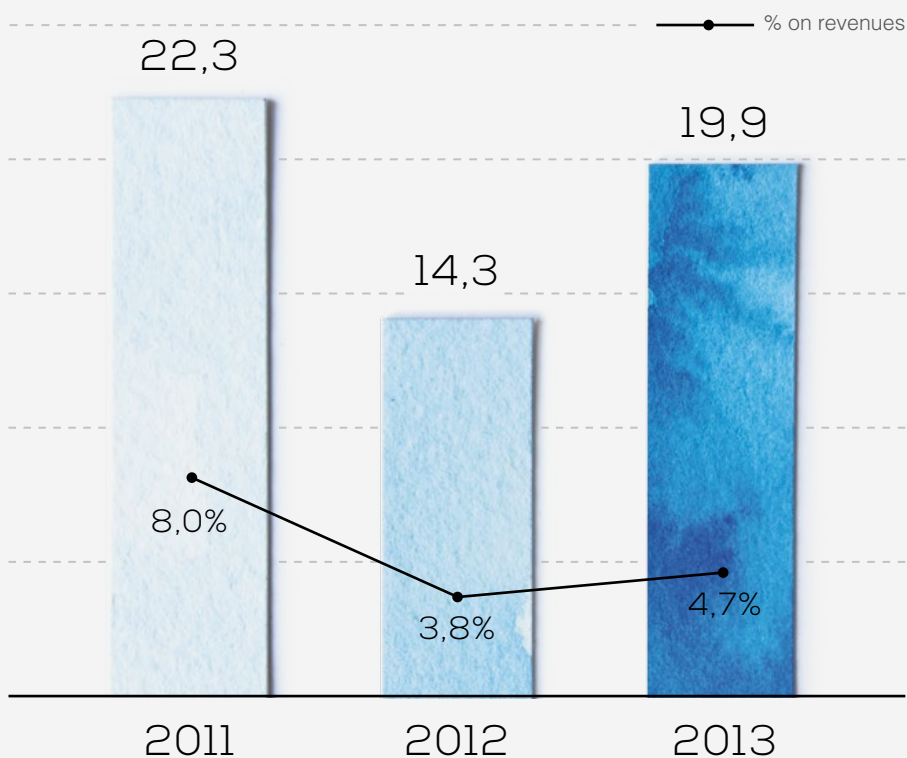
NET FINANCIAL POSITION (NFP) AND NET EQUITY (€ MLN)



In 2013, the Group's net financial position grew to 241,1 million Euro compared to 170 million Euro in 2012. In addition to the positive impact resulting from operating efficiency, investments and working capital performance, a key factor was the remarkable buy-back transaction completed in July 2013. At the exit of one of our financial Partners, the Investitori Associati fund, Kedrion Group SpA bought back shares for a value of 80 million Euro. The purchase was financed in part through existing Partners' share capital increase (for a total amount of 27,8 million Euro) and in part by opening of a new credit line with Natixis.

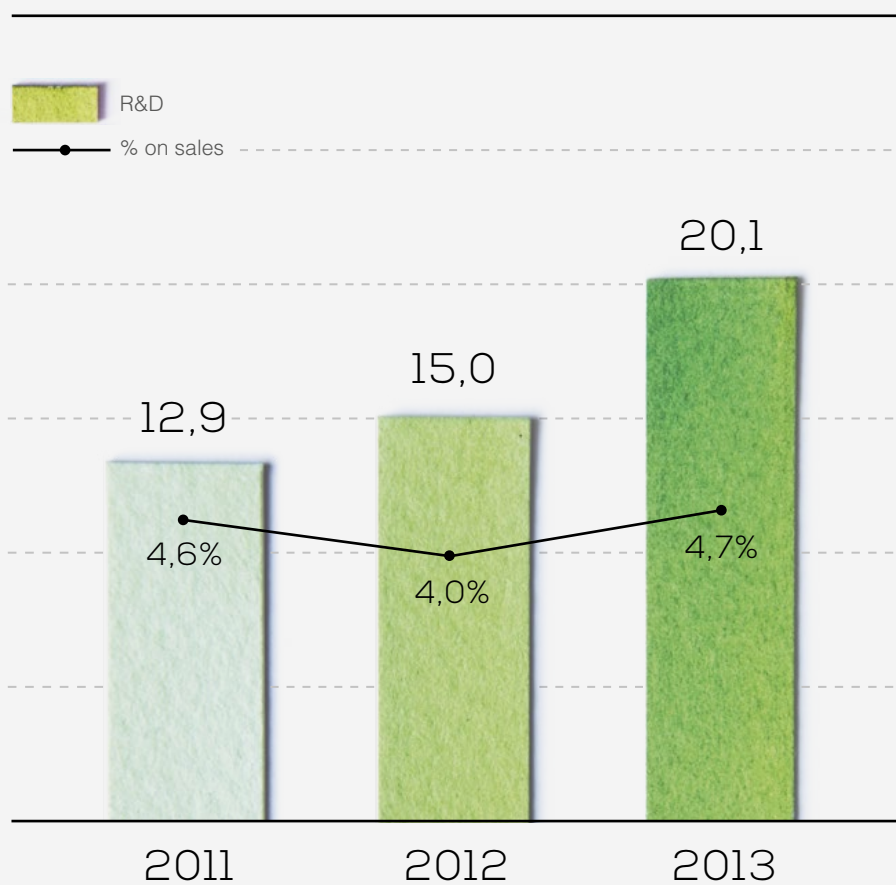
# FINANCIAL INDICATORS

NET INVESTMENTS (€ MLN)



In 2013, capital expenditure (excluding acquisitions) increased in order to support the Group's growth in terms of both volume and profitability. To this end, Kedrion initiated two important internalization projects of relevant production processes: a new line for the production of RhoGAM and one for the production of new generation immunoglobulins.

R&D TOTAL EXPENDITURE AND INVESTMENTS (€ MLN)



# FINANCIAL INDICATORS

2013 STAFF DISTRIBUTION

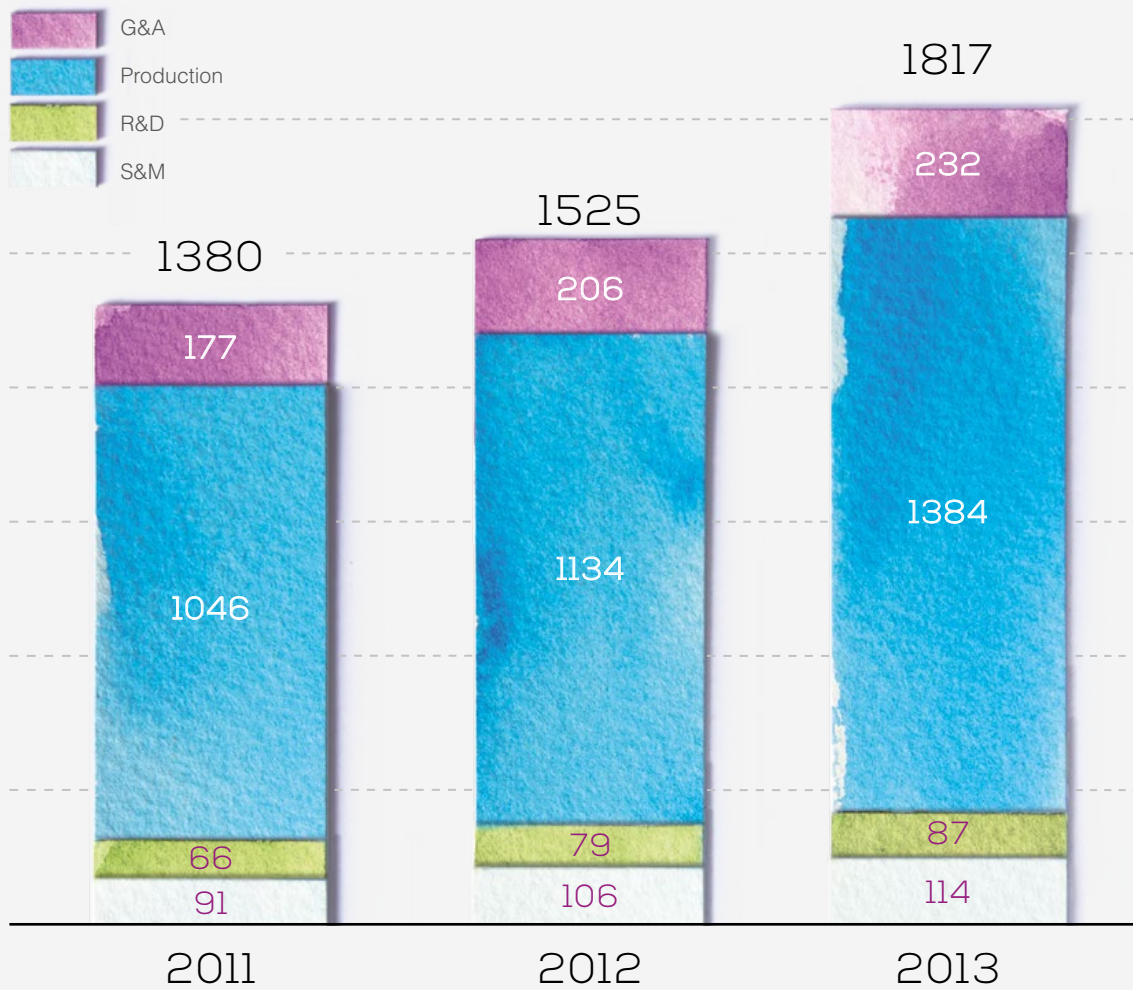


The inclusion of staff from the Melville plant at the beginning of the second semester characterized 2013. The addition led to a significant increase in overall staffing, particularly in the manufacturing area.

Other areas were also affected by this general growth trend, with a uniform staffing increase in the Sales & Marketing and the R & D departments and more remarkable development in the administrative area.

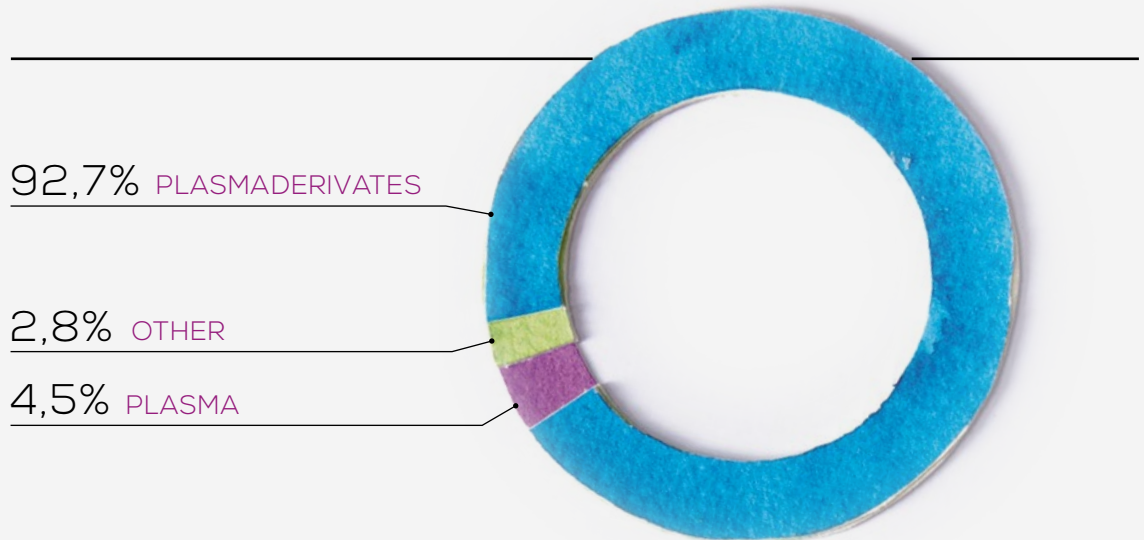


STAFF (UNIT)



# BUSINESS AREAS

2013 DISTRIBUTION OF REVENUE  
BY BUSINESS AREAS



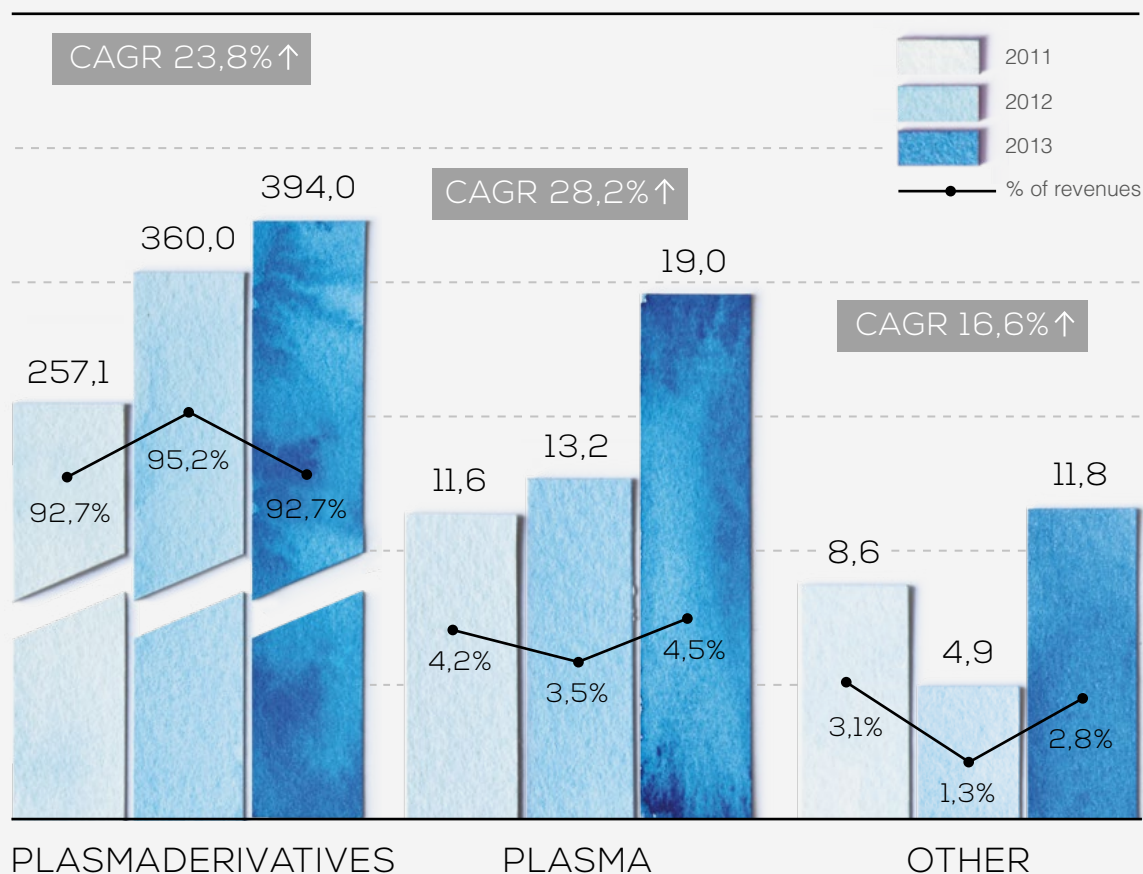
Kedrion Group's activities can be divided into three different segments:

- Production and sales of plasma-derived therapeutic products obtained from the plasma fractionation process;
- Plasma collection and sales;
- Other activities.

## PRODUCTION AND SALES OF PLASMA-DERIVED THERAPEUTIC PRODUCTS

On 31 December 2013, earnings in the "Production and sales of plasma-derived therapeutic products" segment stood at 394.035 Euro (92,8% of total earnings). Kedrion continues to maintain a very strong focus in this area as it represents the Group's core business. In 2013 the "Other activities" segment grew as percentage of total revenue. This was due to initiating contract manufacturing in the Melville plant. A slight decrease in percentage was registered in the other two segments.

DISTRIBUTION OF SALES BY BUSINESS AREAS (€ MLN)



PLASMA COLLECTION AND SALES

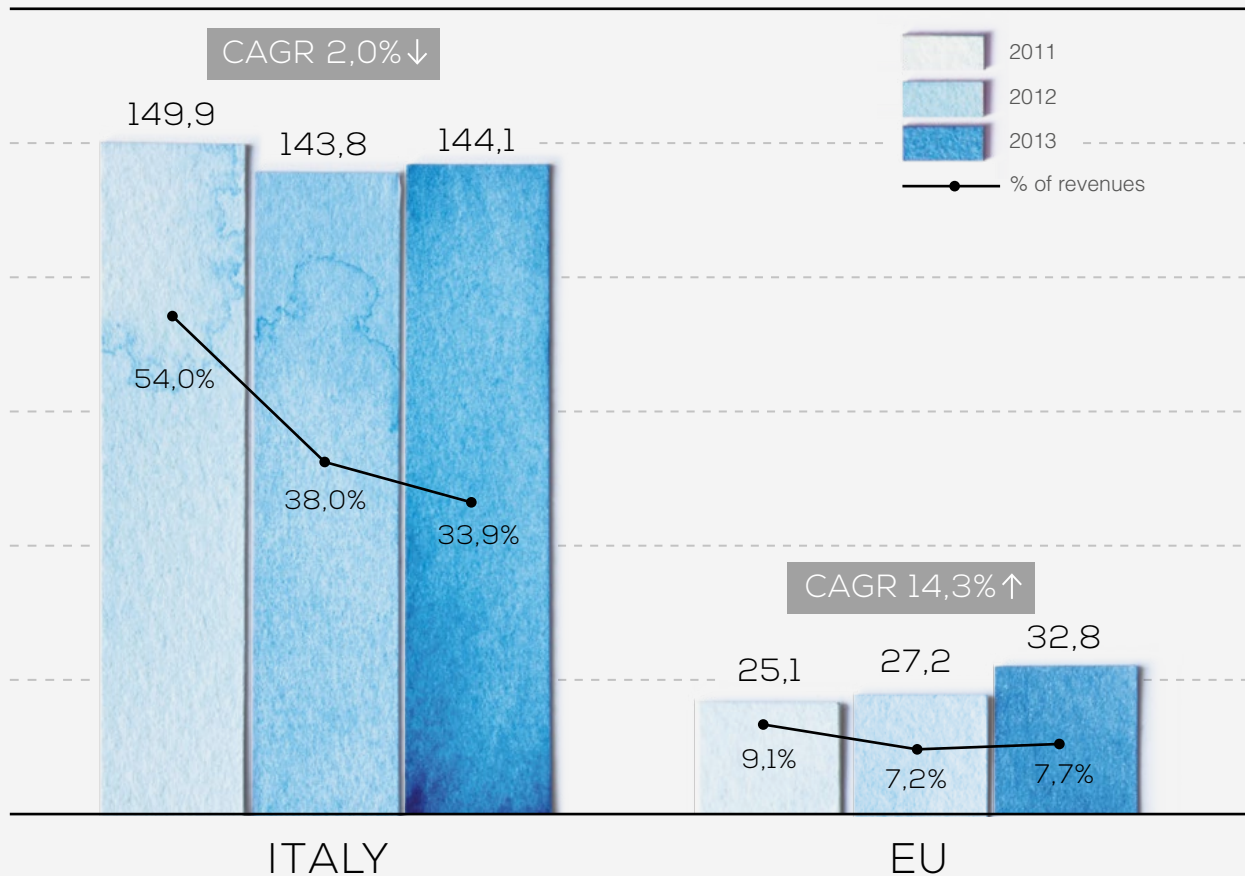
On 31 December 2013, earnings in the “Plasma collection and sales” segment stood at 19.010 Euro. The result was due to the performance of American and European company-owned collection centers managed by the Plasma Business Unit, which include Haemopharm Inc, KEDPlasma LLC, KEDPlasma GmbH and Plazmaferézis Kft. Our plasma collection centers have allowed us to meet the ever-growing needs of the plasma-derived segment and to increase, in absolute terms, the plasma sales value to third party operators.

OTHER ACTIVITIES

On 31 December 2013, earnings in the “Other activities” segment stood at 11.766 Euro. This result is mainly linked to contract manufacturing carried out at the Melville and Gödöllő plants and to the sale of two chemical products.

# GEOGRAPHICAL AREAS

DISTRIBUTION OF SALES BY GEOGRAPHIC AREAS (€ MLN)

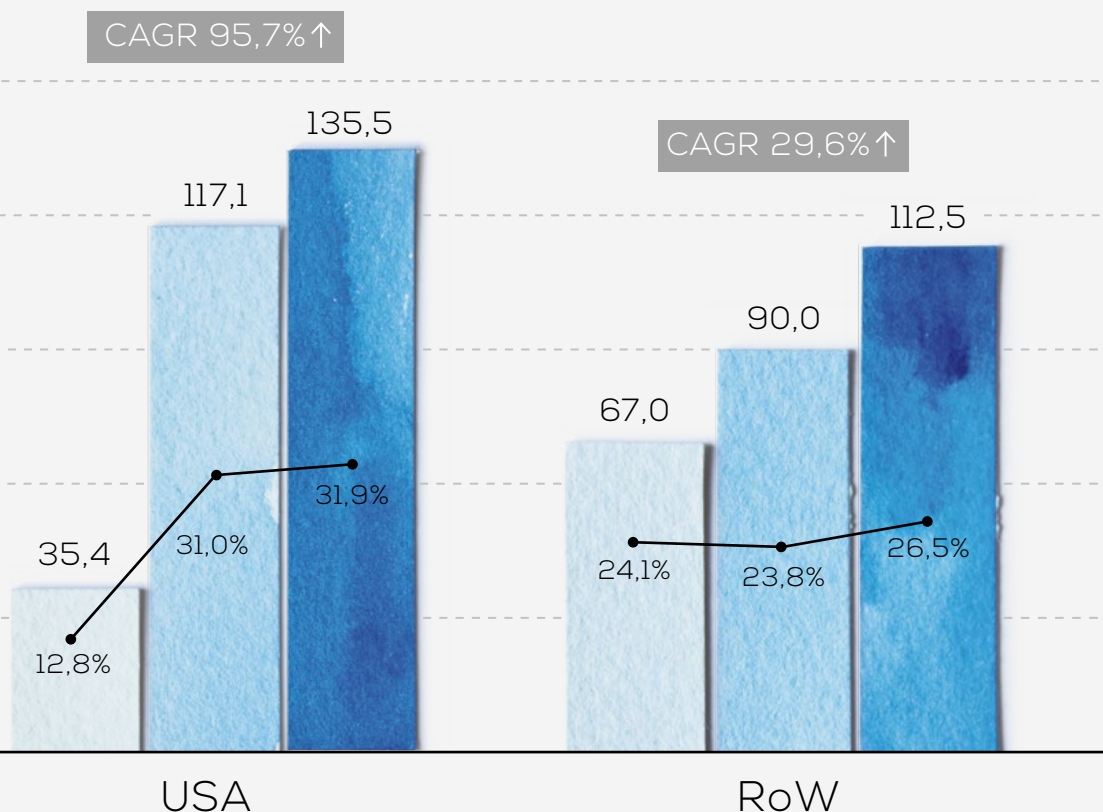


## ITALY

On 31 December 2013, Italy remains the main target market with a turnover of 144.073 Euro that accounts for 33,9% of total earnings. This was accomplished through finished product sales and contract manufacturing for the Italian National Health System.

## EUROPEAN UNION

On 31 December 2013, earnings in the European Union amounted to 32.815 Euro, representing 7,7% of total earnings. The result was primarily due to Kedrion International Group sales in Greece, Poland, Austria, Portugal and Germany and to sales through HUMAN BioPlazma in Hungary and Germany. The main European markets in 2013 were Hungary, Greece, Poland, Germany, Austria and Portugal.



### USA

In 2013, turnover in the United States reached 135,5 million Euro after having entered the American market in mid-2011 thanks to a major strategic agreement with Grifols and following the acquisition of RhoGAM from Johnson & Johnson in August 2012. RhoGAM was registered as the first anti-D immunoglobulin in the US market over 40 years ago and is the frontrunner in this market. In this geographical area, the leading product is standard immunoglobulin followed by anti-D immunoglobulin (RhoGAM), by factor VIII and by albumin. In addition to plasma-derived therapeutic product sales, US turnover was also constituted by contract manufacturing at the Melville plant and by a small share of plasma sales.

### REST OF THE WORLD

On 31 December 2013, earnings for the "Rest of the world" geographic area amounted to 112.456 Euro, representing 26,5% of total earnings. Our leading markets in terms of sales are Turkey, Mexico, Iran, South Korea (mainly sales of plasma), Vietnam, Colombia, Venezuela, Russia, Ukraine and Serbia.

# CONSOLIDATED FINANCIAL STATEMENTS

AT DECEMBER 2013

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CONSOLIDATED INCOME STATEMENT  
(IN THOUSANDS OF EURO)

YEAR ENDED AT 31 DECEMBER

2013

Revenues from sales and services	424.811
Cost of sales	239.151
<b>GROSS OPERATING MARGIN</b>	<b>185.660</b>
Other revenues	9.813
General and administrative expense	61.065
Sales and marketing expense	34.160
Research and development expense	15.794
Other operating costs	5.104
<b>OPERATING RESULT</b>	<b>79.350</b>
Financial charges	23.748
Financial income	4.189
<b>RESULT BEFORE TAX</b>	<b>59.791</b>
Income taxes	25.606
<b>NET RESULT FOR THE PERIOD</b>	<b>34.185</b>
<b>OF WHICH:</b>	
<b>GROUP RESULT</b>	<b>32.274</b>
<b>MINORITIES RESULT</b>	<b>1.911</b>

OTHER COMPREHENSIVE INCOME  
(IN THOUSANDS OF EURO)

YEAR ENDED AT 31 DECEMBER  
2013

PROFIT FOR THE PERIOD	34.185
OTHER COMPREHENSIVE INCOME TO BE RECLASSIFIED TO PROFIT OR LOSS IN SUBSEQUENT PERIODS:	
Net movement on cash flow hedges	2.186
Income tax effect	(601)
	1.585
Exchange differences on translation of foreign operations	(3.212)
Income tax effect	0
	(3.212)
NET OTHER COMPREHENSIVE INCOME TO BE RECLASSIFIED TO PROFIT OR LOSS IN SUBSEQUENT PERIODS	(1.627)
OTHER COMPREHENSIVE INCOME NOT TO BE RECLASSIFIED TO PROFIT OR LOSS IN SUBSEQUENT PERIODS:	
Re-measurement gains (losses) on defined benefit plans	333
Income tax effect	(91)
	242
NET OTHER COMPREHENSIVE INCOME NOT TO BE RECLASSIFIED TO PROFIT OR LOSS IN SUBSEQUENT PERIODS	242
OTHER COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX	(1.385)
TOTAL COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX	32.800
ATTRIBUTABLE TO:	
EQUITY HOLDERS OF THE PARENT	30.889
NON-CONTROLLING INTERESTS	1.911

# CONSOLIDATED FINANCIAL STATEMENTS

AT DECEMBER 2013

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CONSOLIDATED STATEMENT OF FINANCIAL POSITION  
(IN THOUSANDS OF EURO)

YEAR ENDED AT 31 DECEMBER

2013

## NON CURRENT ASSETS

Property, plant and equipment	118.104
Investment property	1.685
Goodwill	198.387
Fixed term intangible assets	41.799
Investments in associated companies	23
Investments in other companies	1.451
Other non current financial assets	837
Deferred tax assets	10.085
Non current trade receivables	762
Other non current assets	228

**TOTAL NON CURRENT ASSETS** 373.361

## CURRENT ASSETS

Inventories	157.392
Trade receivables	110.829
Current tax credits	1.667
Other current assets	16.285
Other financial current assets	9
Cash and cash equivalents	52.618

**TOTAL CURRENT ASSETS** 338.800

**TOTAL ASSETS** 712.161



CONSOLIDATED STATEMENT OF FINANCIAL POSITION  
(IN THOUSANDS OF EURO)

YEAR ENDED AT 31 DECEMBER

2013

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GROUP SHAREHOLDERS' EQUITY

Share capital	86.060
Reserves	174.211
Group net income	30.889

**TOTAL GROUP SHAREHOLDERS' EQUITY 291.160**

MINORITIES SHAREHOLDERS' EQUITY

Minorities capital and reserves	55
Minorities net income	1.911

**TOTAL MINORITIES SHAREHOLDERS' EQUITY 1.966**

**TOTAL SHAREHOLDERS' EQUITY 293.126**

NON CURRENT LIABILITIES

Medium/long-term debt	87.958
Provisions for risks and charges	46
Payables for employee benefits	4.554
Other non current liabilities	8.918

**TOTAL NON CURRENT LIABILITIES 101.476**

CURRENT LIABILITIES

Payables to banks and other lenders	149.280
Current portion of medium/long-term debt	57.364
Provisions for risks and charges	774
Trade payables	76.325
Current tax payables	2.858
Other current liabilities	30.958

**TOTAL CURRENT LIABILITIES 317.559**

**TOTAL LIABILITIES 419.035**

**TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES 712.161**

# CONSOLIDATED FINANCIAL STATEMENTS

AT DECEMBER 2013

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CONSOLIDATED CASH FLOW STATEMENT  
(IN THOUSANDS OF EURO)

YEAR ENDED AT 31 DECEMBER

2013

Net cash flow generated by operating activities (A)	21.183
Net cash flow absorbed by investment activities (B)	(95.972)
Net cash flow generated/(absorbed) by financing activities (C)	97.957
<b>TOTAL NET CASH FLOW D=(A+B+C)</b>	<b>23.168</b>
Cash and cash equivalents opening balance (E)	29.300
Net effect of conversion of foreign currencies on cash and cash equivalents (F)	74
<b>CASH AND CASH EQUIVALENTS CLOSING BALANCE G=(D+E+F)</b>	<b>52.542</b>



Reconta Ernst & Young S.p.A.  
Piazza della Libertà, 9  
50125 Firenze

Tel: +39 055 552451  
Fax: +39 055 5524850  
ey.com

**Independent auditors' report  
pursuant to art. 14 of Legislative Decree n. 39 dated 27 January 2010  
(Translation from the original Italian text)**

To the Shareholders of Kedrion Group S.p.A.

1. We have audited the consolidated financial statements of Kedrion Group S.p.A. and its subsidiaries, (the "Group") as of 31 December 2013 and for the year then ended, comprising the statement of financial position, the statement of profit or loss, the statement of profit or loss and other comprehensive income, the statement of changes in consolidated shareholders' equity, the statement of cash flow and the related explanatory notes. The preparation of these financial statements in compliance with International Financial Reporting Standards as adopted by the European Union is the responsibility of Kedrion Group S.p.A.'s Directors. Our responsibility is to express an opinion on these financial statements based on our audit.
2. We conducted our audit in accordance with auditing standards issued by the Italian Accounting Profession (CNDCEC) and recommended by the Italian Stock Exchange Regulatory Agency (CONSOB). In accordance with such standards, we planned and performed our audit to obtain the information necessary to determine whether the consolidated financial statements are materially misstated and if such financial statements, taken as a whole, may be relied upon. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, as well as assessing the appropriateness of the accounting principles applied and the reasonableness of the estimates made by Directors. We believe that our audit provides a reasonable basis for our opinion.

For the opinion on the consolidated financial statements of the prior year, which are presented for comparative purposes, reference should be made to our report dated April 12<sup>th</sup>, 2013.

3. In our opinion, the consolidated financial statements of the Kedrion Group S.p.A. at 31 December 2013 have been prepared in accordance with International Financial Reporting Standards as adopted by the European Union; accordingly, they present clearly and give a true and fair view of the financial position, the results of operations and the cash flows of the Group for the year then ended.
4. The Directors of Kedrion Group S.p.A. are responsible for the preparation of the Report on Operations in accordance with the applicable laws. Our responsibility is to express an opinion on the consistency of the Report on Operations with the financial statements as required by law. For this purpose, we have performed the procedures required under Auditing Standard 001 issued by the Italian Accounting Profession (CNDCEC) and recommended by CONSOB. In our opinion, the Report on Operations is consistent with the consolidated financial statements of the Kedrion Group S.p.A. at 31 December 2013.

Florence, March 28<sup>th</sup>, 2014

Reconta Ernst & Young S.p.A.

Signed by: Lorenzo Signorini, partner

*This report has been translated into the English language solely for the convenience of international readers.*

Reconta Ernst & Young S.p.A.  
Sede Legale: 00198 Roma - Via Po, 32  
Capitale Sociale € 1.400.000,00 I.v.  
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## CREDITS

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Luigi Casentini: photo on page 5

Alessandro Puccinelli: photo on page 9

Gigi Lusini: photo on page 31

Frankenstein - Progetti di Vita Digitale: photo on page 41

Christian Sinibaldi: all the other photos

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Agenzia Teseo

(design: Aimone Bonucci / Francesco Ciardi)

**KEDRION**  
B I O P H A R M A

**Kedrion**

Loc. Ai Conti - 55051 Castelvecchio Pascoli, Barga (Lucca) - Italy  
Tel +39 0583 19691 - Fax +39 0583 766121  
[www.kedrion.com](http://www.kedrion.com)

