



**KEDRION**  
BIOPHARMA

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ANNUAL REPORT

2 0 1 4



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

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ANNUAL REPORT

2 0 1 4

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# CEO REVIEW



# CEO REVIEW



In 2014, Kedrion continued to grow. We are proud of the excellent results we have achieved despite the persisting unstable and challenging global macroeconomic scenario. These results are the tangible proof of the effectiveness of the strategic vision we outlined and of the abilities of our management and staff in putting such a vision in place. Even this year, we have honored all our commitments: towards the community of patients by providing an increasing number of people with access to treatments they need; towards donors by making the best use their donation; towards our partners in the health systems of the different countries in which we operate; and towards our employees and our shareholders.

Growth, Consolidation and Integration are the three key words that also in 2014 have

guided our actions. Financial indicators grew, production increased, product portfolio was expanded, plasma collection rose. At the same time, the number of markets in which we operate grew, our sales network extended even further, research activities intensified and our staff increased.

Growth also implies dialoguing with new partners. In April, we entered into the international financial market for the first time by issuing a 300 million Euro bond, which was listed on the Irish Stock Exchange, and, in November, Kedrion became part of "ELITE for Large Corporates", the program of the Italian Stock Exchange for companies that aim to strengthen their global leadership.

In order to confirm the growth targets we have set for ourselves year after year, we need to have an increasingly solid base and to nurture our roots. This is why Consolidation is our second key word. We remain committed to strengthening our leadership in the domestic market and, at the same time, to consolidating our activities in the nearly one hundred Countries where we are present, by bringing new capabilities, new energy and greater harmonization in our manufacturing operations, our management and in our employees.

This explains why Integration was and is our third key word. We have made an extraordinary effort to ensure that our production plants in Italy, the United States and Hungary were all able "to speak the same language" and, most especially, we have strived to create a harmonized

system in which each site has precise and specific production missions. With this in mind, we expanded the Melville plant and upgraded production lines in Gödöllő.

Integration does not solely concern production. The company as a whole must act in unison. For this reason, we focused on reorganizing the chain of command and the management structure; and we have worked hard to create and communicate a strong identity and shared corporate culture.

On the financial side, in 2014 Kedrion registered a turnover of 466 million Euro, an increase of about 10% on the previous year; EBITDA stood at 111 million Euro (compared to 105 million Euro in 2013); net profit was 42 million Euro; exports accounted for about 68% of total sales, with a significant turnover growth in the United States, which in 2014 became Kedrion's main market, thus outperforming the Italian one.

These numbers attest to the soundness of the strategies we have implemented and that we will continue to follow, working for the Growth, Consolidation and Integration of our company.

*Paolo Marcucci,  
Chairman and CEO of Kedrion*

# THE COMPANY

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# KEDRION BIOPHARMA AT A GLANCE

Kedrion is an international company specialized in the collection and fractionation of blood plasma for use in the treatment of patients suffering from rare diseases such as hemophilia and immune deficiencies.

People are at the core of Kedrion's activities and the very nature of our business is to help people live fuller and healthier lives. Founded in Italy, in recent years Kedrion has expanded its activities globally. The company has increased both collection and manufacturing capacities, in addition to acquiring sales and distribution rights to products such as RhoGAM®, the Anti-D human plasma immunoglobulin that for

nearly half a century has been used with great effectiveness in preventing Hemolytic Disease of the Fetus and the Newborn (HDFN).

Through KEDPlasma, Kedrion manages its plasma collection centers in Germany, Hungary and in the United States.

Manufacturing operations are concentrated in its two Italian plants in Bolognana (Lucca) and Sant'Antimo (Naples), in the Hungarian plant of Gödöllő (Budapest) and in the American facility in Melville (New York). A small production facility located in Tuscany, in Siena, specializes in the research and development of orphan drugs for the treatment of rare diseases.

In Italy, Kedrion is the primary partner of the National Health Service, with whom it actively cooperates in the pursuit of nationwide plasma and plasma-derived products self-sufficiency. At the same time, Kedrion offers its experience and commitment to communities and health systems worldwide to assist these in the achievement of that same self-sufficiency objective, thereby helping to improve the lives of people with rare diseases.

Kedrion is the bridge between donors and those in need of care, and operates globally to expand patient access to plasma-derived therapies.



PARTNER IN THE SELF-SUFFICIENCY PROGRAM IN ITALY



5 MANUFACTURING PLANTS IN 3 COUNTRIES



15 PLASMA COLLECTION CENTERS WORLDWIDE



COMMERCIAL PRESENCE IN 100 COUNTRIES



2014 TURNOVER: 466.3 MILLION EURO



ANNUAL STAFF INCREASE SINCE 2010: 13.49%



WORLD PLAYER FOR HYPER IMMUNE PLASMA COLLECTION CAPACITY



5-YEAR UNSECURED AND UNRATED 300 MILLION EURO BOND



ANNUAL GROWTH RATE SINCE 2007: 14.5%



HEADQUARTERED IN ITALY WITH SUBSIDIARIES IN EUROPE, USA, LATIN AMERICA AND ASIA



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

5<sup>TH</sup>

WORLD PLAYER AND 1<sup>ST</sup> IN ITALY IN TERMS OF REVENUES IN THE FIELD OF PLASMA-DERIVED PRODUCTS

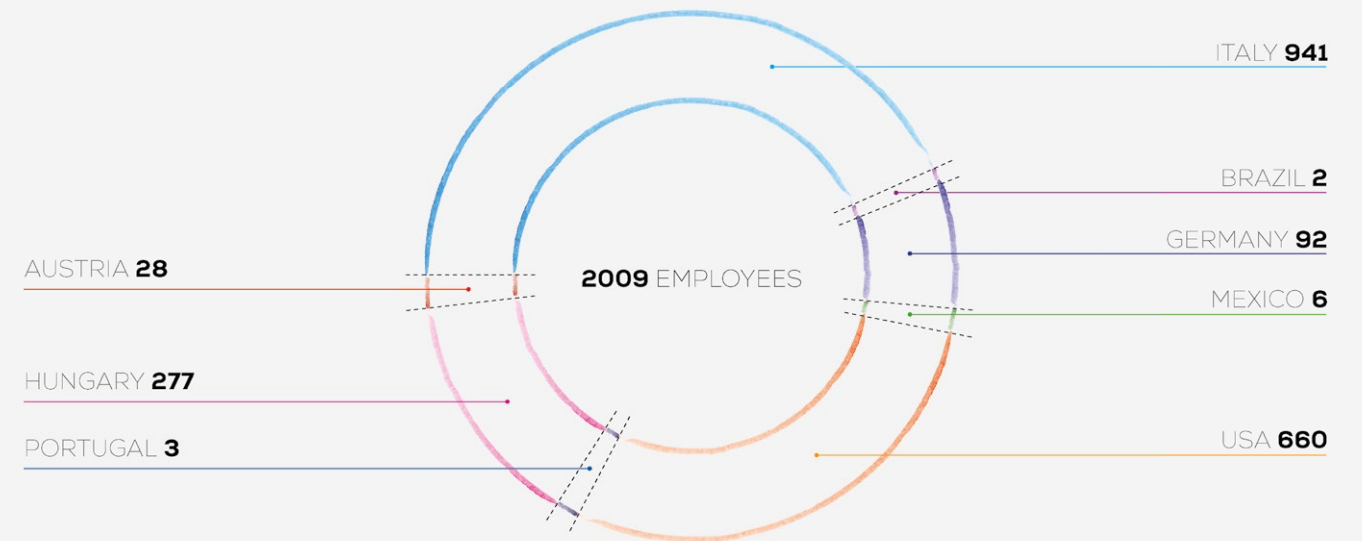


IKOD, ITALIAN FACILITY FULLY DEDICATED TO THE DEVELOPMENT OF ORPHAN DRUGS



11 VOLUNTARY CERTIFICATIONS IN MANUFACTURING, HUMAN RESOURCES, ENVIRONMENT

## STAFF



MEN 1054  
WOMEN 955

UNDER 35 670  
OVER 35 1339



# CORPORATE VISION

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People are at the core of Kedrion's activities, and the very nature of our enterprise is to help people live more full and healthy lives. This commitment extends to how we conduct our business, that is, in ways that are consistent with our mission: to benefit people, to "Keep Life Flowing". Kedrion began as a family company, intimately connected to the community in which we, and our workers, were born, live and work. Our Corporate Vision has not only been a matter of good business practices; it is based on living in our territory and on being a good neighbor. This may still seem like a rather vague and perhaps a somewhat inevitably idealistic concept. However, it may help to offer some examples of the many areas and activities in which our vision manifests itself:

- Ensuring that our workers are treated well and compensated fairly;
- Providing a safe and comfortable workplace;
- Minimizing the impact on the environment that our processes and activities have, and finding ways to improve the environment in which we operate;
- Being an active good citizen in the communities where and with which we work. For example, Kedrion establishes and maintains active collaboration with both patient and donor organizations, providing information and support;
- Ensuring that whoever operates for and on behalf of Kedrion adheres to the internationally recognized principles of best practices, as well as to national and international legislation;
- Encouraging all partners and collaborators to observe socially responsible practices, and contractually obliging partners and collaborators to conform to our Social Responsibility principles;
- Ensuring that Corporate Social Responsibility is a prominent consideration in all business transactions and decisions.

# SUSTAINABILITY AND EHS

## SOCIAL PERFORMANCE

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

It is for this reason that, at Kedrion, we strive each day to ensure that special attention and care is given to our employees, to reduce environmental impact and to be an active good citizen in the communities where and with which we work.

An example of our commitment is the "Kedrion Cares" program, launched in the United States in 2012. In 2014, we were committed to leaving every place better than how we found it. We have also operated at national and local level to implement projects side by side with our communities. In February, Kedrion sponsored an after school party for elementary and middle school students in Austin, Texas. The party took place in area of town where more than 90% of children live below the poverty line. The dedication and energy the participants invested in making the event a success and in bringing a little joy to the community have

been a true source of inspiration for all of us.

Last Summer we collaborated with Fresh Start farms, wholly managed by Bantu Somali refugees, including many single mothers, in Lisbon, Maine. Kedrion was in charge of supporting infrastructure and logistics, donating tents, picnic tables and other equipment for shared use by the farmers and their families.

More recently, "Kedrion Cares" participated in a program involving the National Cemetery in Santa Fe, New Mexico, a memorial to American veterans. The opportunity of humbly offering our services to this memorial, of collaborating with Veterans' associations and of reaching out to those most in need represented yet another source of inspiration.

As in 2014, in the years ahead Kedrion will continue to encourage its employees to suggest and share ideas for projects to be carried out in their communities.

It is a privilege for us to be able to put ourselves at the service of others, contributing to the flow of life of our patients, of our customers and of our communities: *Keep Life Flowing.*

### CSR Standards and Certifications:

- Our values, principles and goals;
- The United Nation's Global Compact's ten principles in the areas of human rights, labor, the environment and anti-corruption;
- The OECD (Organization for Economic Co-operation and Development) guidelines for multinational companies;
- The ILO (International Labor Organization) principles;
- The SA8000 standards.

## ENVIRONMENT, HEALTH & SAFETY PERFORMANCE

People are at the core of Kedrion's activities: we protect the health and safety of those who work in our company, as well as the health and safety of those who generously donate their plasma, and of those who use our plasma-derived products.

In 2014, we worked on sharing globally an Environment, Health & Safety (EHS) management model capable of linking local experiences with international standards and focused on identifying common guidelines.

In addition, we worked to improve the environmental impact of our facilities, and to ensure a better quality of life in the workplace. Last year, we also conducted emergency management training linked to natural disasters and to pollution reduction.

### 2014 Activities and Results:

- To cope with natural disasters, we created an internal crisis management team that is in direct contact with the Italian government emergency management agency, Protezione Civile. The team is equipped to handle major emergencies, such as earthquakes, floods and hurricanes;
- We extended OHSAS Certification to the IKOD site in Siena;
- We initiated procedures to extend the EHS management system to the facility in Gödöllő. Our goal is to obtain OHSAS certification for the site in Hungary by the end of 2015;
- We issued a new Travel Policy, which focuses on the safety of employees who travel, and on reducing travel environmental impact. To this end, during 2014 more than 160 employees participated in practical and theoretical courses on safe driving. Additionally, to date more than 150 employees have joined our car-pooling initiative, which is also supported by a dedicated web portal.

### EHS Standards and Certifications:

- OHSAS 18001 standards;
- EMAS regulations;
- ISO 14001 standards;
- ISO 9001 standards;
- ISO26000 guidelines.



# TRAINING AND SCUOLA KEDRION

## SCUOLA KEDRION

In Kedrion, sharing ideas, experience, expertise and values is at the core of our mission. Sharing is what makes us a dynamic and efficient company.

Scuola Kedrion offers our company's managers both theory and practice-based training courses. Furthermore, the school allows us to consolidate and promote Kedrion's culture and identity, ensuring that the company's different areas share common values.

To date, over 200 Kedrion managers have benefited from the opportunity of increasing the knowledge and skills that are relevant to their activity and which they can apply to all business aspects.

Scuola Kedrion has accompanied the company's internationalization, expanding the range of training courses it offers to Kedrion companies worldwide. In 2014, approximately 30% of courses were attended also by managers from the United States, Germany, Hungary and Austria.

## CHANGING TO GROW

"Change Management" was one of the international courses held in 2014. It was aimed at showing how Kedrion's internationalization process cannot be carried out without working on both managerial skills and organizational structure and without fully appreciating the cultural differences within the company.

*"The path our company has taken towards change is also mirrored in the personal and professional lives of all Kedrion's people. Change is always an opportunity for growth. In Kedrion, the excitement over the positive change taking place is palpable. However, one needs to have a solid methodological foundation to apply to the company's world in order to make the most out of this growth phase. The course of Change Management offered me such a foundation, along with the possibility of exchanging views with international colleagues on concrete issues. Becoming aware of and managing cultural diversity was instrumental to my new appointment in Vienna".*

Silvio Audisio, Commercial Director Europe

*"Although the change process was already underway in my department, this course offered new stimulus to reflect on the methodology. What made this experience*

*unique was the direct contact with colleagues from all around the world, which in turn provided us with an opportunity to compare different cultures and approaches. The horizons of my own activities have expanded as a result. The true benefit of this learning experience? Having been able to visualize concretely the change process we needed to implement in my working group, setting it in a conceptual and theoretical framework but then dealing with these changes in the hands-on part of the course".*

Elisa Moretti, Head of Biological Safety Center BioSC

























*"Growing means changing. Either you are changed, or you manage change, and in the management of change, it is important to engage those who work with you: to make them understand that ultimately the impact of change on their professional life will always be positive. Change is a source of enrichment. If on the one hand the course has reinforced my general attitude to change, on the other it offered practical insights into how to integrate difference - cultural perspectives and backgrounds - into one company's global vision".*

Stephan Walsemann, Managing Director of KEDPlasma GmbH









# WORLDWIDE PRESENCE

## KEDRION BIOPHARMA

-  ITALY   
-  USA  
-  HUNGARY  
-  MEXICO 
-  AUSTRIA 
-  TURKEY 
-  BRAZIL 
-  SWITZERLAND 
-  PORTUGAL 
-  INDIA 

## KEDPLASMA

-  USA 
-  GERMANY 
-  HUNGARY 

### LEGENDA

-  HEADQUARTERS
-  PRODUCTION
-  DISTRIBUTION
-  PLASMA COLLECTION
-  COMMERCIAL PRESENCE



# PRODUCT PORTFOLIO

## HEMATOLOGY / HEMOPHILIA

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

**HUMAFACOR-8\*\* / HUMACLOT\*\***  
Factor VIII / von Willebrand Factor concentrate

**WILFACTIN\*\*\***  
Von Willebrand Factor concentrate

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

**EMOSINT**  
DDAVP Desmopressin

## IMMUNOLOGY / NEUROLOGY

**Ig VENA / HUMAGLOBIN / KEDRIGAMMA / Gammaked\* / GAMTEN\*\*\* / INTRATECT\*\*\***  
Standard intravenous Immunoglobulin

**OCTANORM\*\***  
Standard subcutaneous Immunoglobulin

**VENBIG / KEYVENB**  
Anti-hepatitis B intravenous Immunoglobulin\*\*\*

**IMMUNOHBs / UMAN BIG**  
Anti-hepatitis B intramuscular Immunoglobulin

**TETANUS GAMMA**  
Anti-tetanus intramuscular Immunoglobulin

**IMMUNORHO / RhoGAM / MICRhoGAM / KeyRho**  
Anti-D intramuscular Immunoglobulin

## CRITICAL CARE

**UMAN ALBUMIN / UMAN SERUM / HUMAN ALBUMIN / KEDRIALB / PLASBUMIN / KEDBUMIN\* / Albuked\***  
Human Albumin solution

**AT III KEDRION**  
Antithrombin concentrate

**K FLEBO\*\*\***  
Potassium aspartate

**PLASMASAFE\*\*\***  
Pharmaceutical grade plasma

**UMAN COMPLEX / PRONATIV\*\*\***  
Prothrombin Complex concentrate

## PRODUCTS DEDICATED TO THE ITALIAN SELF-SUFFICIENCY PROGRAM

**VENITAL**  
Standard intravenous Immunoglobulin

**ALBITAL / KALBI**  
Human Albumin solution

**ATKED**  
Antithrombin concentrate

**PLASMAGRADE**  
Pharmaceutical grade plasma

**KLOTT**  
Factor VIII concentrate

**IXED**  
Factor IX concentrate

**KEDCOM**  
Prothrombin Complex concentrate

**KEDHBs**  
Anti-hepatitis B intramuscular Immunoglobulin

**VEBIKED**  
Anti-hepatitis B intravenous Immunoglobulin

## ORPHAN DRUGS

Over the past years, Kedrion has focused strongly on researching and developing plasma-derived orphan drugs for the treatment of rare diseases.

The product that is in the most advanced trial stage is human Plasminogen concentrate based eye-drops for the treatment of Conjunctivitis Ligna.

Phase II of the clinical study was concluded successfully, and the product has already obtained Orphan Drug designation in both Europe (from EMA, European Medicines Agency) and the United States (from FDA, Food and Drug Administration).

During 2014, the first clinical scale batches of Factor V, on which to carry out stability and characterization studies, were produced in Kedrion's pilot plant in Siena. Our aim is to request Orphan Drug designation, for the treatment of congenital Factor V deficiency, as soon as possible in both Europe and the United States for this product too.

Other major projects concern the development of Factor H for the treatment of Atypical Hemolytic-Uremic Syndrome (HUS), and of a Factor IX concentrate to be used as replacement therapy when this coagulation factor is deficient.

\* product only available for the US market

\*\* product only available for the Hungarian market

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

# KEY 2014 EVENTS



## **FEBRUARY** - PROF. MANNUCCI SPEAKS ON THE FUTURE OF HEMOPHILIA AT CONFERENCE IN COLOMBIA

Professor Pier Mannuccio Mannucci, one of the world's leading experts of hemophilia, held a conference in Medellín, Columbia, entitled "Pasado, presente y futuro de la hemofilia". Kedrion promoted the conference in collaboration with the Pablo Tobón Uribe Hospital.



## **APRIL** - NEW KEDRION WEBSITE NETWORK LAUNCHED

Kedrion Biopharma's online presence is completely renovated with the launch of the corporate website [www.kedrion.com](http://www.kedrion.com), immediately followed by the websites of the eight subsidiaries.



## **APRIL** - HUNGARIAN KEDPLASMA CENTERS AWARDED IQPP CERTIFICATION

Kedrion's three plasma collection centers are the first to receive the PPTA (Plasma Protein Therapeutics Association) IQPP (International Quality Plasma Program) certification in Hungary.



## **JULY** - KEDRION ANNOUNCES LAUNCH OF PLASMACLOT® IN MEXICO

Kedrion Mexicana starts distribution of Factor VIII Plasmaclot® 250 IU on the Mexican market.



## **SEPTEMBER** - ANVISA AUTHORIZES IMPORT OF BIOLOGICAL PRODUCTS IN BRAZIL

The Brazilian Drug Agency (ANVISA) authorizes Kedrion to import and distribute biological products in Brazil.



## **SEPTEMBER** - ROUNDTABLE ON SELF-SUFFICIENCY AT THE FESTIVAL DELLA SALUTE - HEALTH FESTIVAL

Kedrion supports and organizes the roundtable "How to achieve self-sufficiency in plasma-derived medicinal products. A new model for plasma collection" during the VII Festival della Salute in Viareggio, Italy's most important event dedicated to health and wellness.



## **APRIL** - KEDRION LAUNCHES ITS FIRST 5-YEAR 300 MILLION EURO BOND

Kedrion successfully issues senior, unsecured and unrated bonds for 300 million Euro, maturing in April 2019. The bonds are placed with leading international institutional investors. Banca IMI SpA and Natixis acted as Joint Lead Managers.



## **MAY** - EMOKED ONLINE PLATFORM CREATED TO SUPPORT ITALIAN SYSTEM

Kedrion launches EmoKed, a web accessible validated software that can be integrated with systems used by transfusion centers and that is designed to ensure better plasma traceability.



## **MAY** - KEDRION SUPPORTS WISH PROJECT LAUNCHED BY WFH AND CNS

Kedrion promotes the development and implementation of the WISH Project, a humanitarian program set up by the World Federation of Hemophilia (WFH) and the Italian National Blood Centre (CNS). The initiative aims to make optimum use of surplus Italian plasma-derived Factor VIII.



## **OCTOBER** - CLINICAL STUDY ON PLASMINOGEN SUCCESSFULLY COMPLETED

The clinical study on human Plasminogen-based eye-drops for the treatment of Conjunctivitis Lignea comes to a successful conclusion. This is the first orphan drug developed by Kedrion.



## **OCTOBER** - 3<sup>RD</sup> NATIONAL CONFERENCE OF THE ITALIAN BLOOD SYSTEM

The 3rd National Conference of the Italian Blood System is organized, in Bologna, by SIMTI and the Fondazione Campus of Lucca in collaboration with Kedrion. The theme is "The frontiers of self-sufficiency. Ethics, Economy, Responsibility".



## **NOVEMBER** - KEDRION ENTERS "ELITE FOR LARGE CORPORATES"

Kedrion is admitted to the "ELITE for Large Corporates" program, which is promoted by the Italian Stock Exchange and geared to companies that want to consolidate their internationalization and strengthen their global leadership.



## **JUNE** - KEDRION IMMUNOGLOBULINS OBTAIN CIDP INDICATION IN ITALY

AIFA (Italian Medicines Agency) officially approves the therapeutic extension of Kedrion's polyvalent immunoglobulin for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP).



## **JULY** - KEDRION AT THE FOREFRONT IN ERADICATING HDFN

A seminar marks the partnership between Kedrion and the Programme for Global Paediatric Research (PGPR). The joint program aims at eradicating Hemolytic Disease of the Fetus and the Newborn (HDFN) globally. The CURhE Project (Consortium for Universal Rh disease Elimination) is set up.



## **JULY** - KEDRION FOR HUMANITARIAN INITIATIVES

Kedrion's commitment to humanitarian initiatives and collaboration with the Italian Blood System is confirmed once again by the company lending its support to the donation of Factor VIII and Factor IX from Italian plasma to Afghanistan.



## **NOVEMBER** - THE "KEDRION MEETS ..." PROGRAM IS COMPLETED

The program of 11 visits that brought donor associations and other representatives of the Italian Blood System to Kedrion and its Bolognana plant is completed. Its aim was to increase visitors' awareness of plasma's journey from donor to patient, and of the industrial role Kedrion plays in it.



## **NOVEMBER** - VEDOGREEN AWARD FOR SUSTAINABLE DEVELOPMENT

Kedrion wins the "VedoGreen Green Excellence Award" that honors the best Italian companies in the fields of eco-friendly innovation, technological expertise and sustainable business models.



## **DECEMBER** - BLA FOR RHO GAM® AND MICRHO GAM® TRANSFERRED TO KEDRION

The US Food and Drug Administration (FDA) formalizes the transfer to Kedrion of the Biologics License Application (BLA) for RhoGAM® Ultra-Filtered PLUS and for MICRhoGAM® Ultra-Filtered PLUS

# 2014 HIGHLIGHTS

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# FROM PLASMA TO PRODUCT



Plasma is the very fluid of life, the raw material from which it all starts. Plasma is at the core of all Kedrion activities. By transforming plasma into medicine products, Kedrion adds value to the donation process and makes plasma-derived therapies available worldwide. We are a bridge, a vital connection between donors and recipients; and it is thanks to plasma that we can help people in need of care.

Based on a vertical integration business model, Kedrion manages the entire plasma transformation cycle. Plasma procurement takes place in the 15 collection centers managed by our KEDPlasma division (9 centers in the United States and 6 in Europe) which in 2014 collected over 558K liters of plasma (a 3% growth compared to 2013). Kedrion has four major production sites, two in Italy, one in Hungary and

one in the United States. In 2014, the four plants fractionated a total of 2,5 million liters of plasma (a 29% growth compared to 2013, considering that the management of US production started in July 2013).

Optimizing plasma collection is one of the main objectives of Kedrion's growth plan. We strive to increase the number of collection centers, to boost plasma volumes, to reduce costs across the board and to develop strategic partnerships.

Through KEDPlasma, Kedrion collaborates with donors in the United States, Germany and Hungary welcoming them in its state-of-the-art collection centers. Their outstanding quality was confirmed once again in February 2014, when our Hungarian centers of Budapest and Debrecen received the highest certification in the field of plasma collection, and were included in the International Quality

Plasma Program (IQPP) developed by the Plasma Protein Therapeutics Association (PPTA).

In the US, Somerset Laboratories in Buffalo, New York, are the feather in our cap. This collection center focuses on hyperimmune anti-D plasma, which is used to produce RhoGAM®, a medicinal product that, after nearly half a century, continues to be used with great effectiveness in preventing Hemolytic Disease of the Fetus and the Newborn. In this field, Kedrion aims to confirm its leadership position as the world's top collector of hyperimmune plasma (anti-D, anti-rabies and anti-tetanus), a prerequisite to reaffirming the company's role as the main global player in the anti-D market.

In Italy, Kedrion is the leading industrial partner of the Italian National Health System, with which it has collaborated for

many years in the pursuit of nationwide self-sufficiency in plasma-derivatives. The Italian model is a benchmark of excellence in the world: plasma donation is at its core, as is the social contribution and strategic role of approximately 1.8 million donors, who donate on a voluntary, anonymous and non-remunerated basis.

Kedrion continues to operate in its neighboring communities to raise plasma donation awareness. The company has taken part in dedicated campaigns such as the International Plasma Awareness Week sponsored each year by PPTA. This means an active commitment to being a strong local presence that brings the community into its life and activities; and to promoting an increased individual awareness of issues related to donation and plasma-derived therapies.

A continuous improvement in plasma collection is the prerequisite to increasing our production capacity. Kedrion's global presence requires the harmonization of all our worldwide activities. In 2014, the company invested heavily to strengthen this integrated system.

In the United States, the Melville plant in New York State was expanded.

Here, at the end of 2014, the new manufacturing line for the in-house production of RhoGAM® was completed from the mechanical point of view, and its final testing and validation phases started. During the year, tangible progress was made in the process of cultural and operational integration of the Melville site into the Kedrion system, increasingly harmonizing the American plant's activities with Kedrion's Italian facilities.

In 2014, integration of the Hungarian plant of Gödöllő with the Italian sites progressed

largely in line with the company's strategic guidelines: fractionation capability increased by 15% and the product portfolio was upgraded, also thanks to the technology transfer that aligned the fractionation and purification production line (Line 1) to Kedrion standards.

In 2014, the infrastructures and procedures of each plant have continued to benefit from Kedrion's focus on Global Quality in all areas. In particular, the strengthening of the Global Quality Assurance department in the United States has allowed the improvement of activities supervision across the board: from plasma collection to distribution of the finished product.

A clear-cut philosophy supports this effort: to operate using a more comprehensive approach, which at the same time encompasses both the United States and Europe. At Kedrion, quality is a unifying and wide-ranging concept, which starts from compliance with international regulations and extends to the creation of value and good reputation, the prerequisite for continuous company growth.

## A LIFE SPENT DONATING PLASMA

Heinz Kühlein, age: 65  
Bayreuth, Bavaria (Germany)

*"Donating is part of my life," observes Heinz Kühlein. And he means it: Heinz has been donating blood or blood plasma since 1970, when he was doing his army service. Ten years later he was donating at the Bavarian Red Cross in Bayreuth and that is where he met Angela Beck, who was working there. Angie (as Heinz calls her) now works at KEDPlasma and that is one of the reasons he has been donating plasma there since 2008.*

*In Germany plasma donors are limited to a maximum of 45 donations per year and Heinz nearly always achieves the maximum. If he is getting close as October approaches, he slows down a bit so he will be there on his birthday on the 10th. He likes the birthday present given to all active donors. He has donated well over 200 times.*

*He is actually responsible for even more donations because he has inspired many of his friends to donate as well. He sometimes has to reassure them that the little needle prick is nothing to worry about and reminds them that they will walk away feeling good about themselves and with a little extra Trinkgeld in their pockets.*

*Heinz is retired after 28 years with the Bundesbahn, the German train system. He doesn't really need the money he gets as reimbursement for his donations, but he does appreciate it: he gives 5 Euros to his grandson and buys a little something – a treat he wouldn't otherwise buy – for himself. Recently, that was a nice watch, which he says reminds him every time he looks at it that he is helping people with his donation of plasma.*

*While the idea of helping others is the most powerful motivation for Heinz, he admits to enjoying the time to read magazines and enjoy a cup of cappuccino. And then of course, there is Angie.*

# BROADENING ACCESS TO THERAPIES



In recent years, Kedrion has expanded its activities, starting from Italy and then developing and consolidating its international presence through subsidiaries in Europe, the United States, Latin America and Asia.

Today we are present in 100 countries worldwide, and our aim is to pursue the welfare of those who benefit from our products as well as that of the communities where we operate, and of the people with whom we work.

Kedrion is committed to satisfying as yet unmet therapeutic needs by broadening, as much as possible, patient access to plasma-derived therapies.

In 2014, Kedrion continued growing with revenues rising by 10.8% compared to the previous year. The company also continued to strengthen its positioning in Italy, and further grew its market share in

the United States, which today represents the most important market for Kedrion and accounts for 34% of total revenue.

In Italy, Kedrion works in partnership with the Italian National Health Service. Regions collect the plasma in approximately 300 transfusion centers and then transfer it to Kedrion, whose role, as the industrial partner of the system, is to add further value to the donation. Kedrion transforms the Italian national plasma into medicinal products that are then returned to hospitals to ensure the population's therapeutic requirements are met.

In 2014, the challenge for Kedrion was to maintain, and if possible strengthen, its position on the Italian market. With a growth of over 6% compared to 2013, this objective was achieved. This result was mainly due to our immunoglobulin, contract manufactured or commercially

distributed, being the first in Italy to be granted the new indication for the treatment of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).

The process of opening up the market for the fractionation of Italian plasma continued throughout 2014. In December, the decree identifying the companies that will be able to take part in local tenders issued by the Regions was signed. Kedrion stood by the Italian Transfusion System throughout this significant change of scenario, greatly contributing to the achievement of the structural, technical and organizational requirements called for by new EU regulations.

Further evidence of the company's commitment to active partnership with the Italian Health System is that, in 2014, Kedrion was granted specific Marketing Authorizations for the products made

by processing national plasma, and production based on these Marketing Authorizations has since begun.

Kedrion's dedication to raising plasma donation awareness has been unwavering in Italy too, particularly since, for the first time, 2014 saw a decrease in collections. In order to make the objective of national self-sufficiency in plasma and plasma-derived products reachable, the full commitment of all the National Health System's players is required. As in previous years, in 2014 Kedrion supported or promoted institutional events, such as the Health Festival (Festival della Salute) in Viareggio (Tuscany, Italy), with the aim of gathering politicians and technicians around the same table, thereby facilitating a fruitful discussion on self-sufficiency. Our commitment to an ongoing conversation with donor associations is also steadfast; our aim is to increase associations' awareness that their donations are converted into life-enhancing therapies.

In the United States, the industry's largest market in the world, our primary objective is to increase Kedrion brand awareness and recognition. In 2014, we continued to grow (+14% compared to 2013), by especially focusing on immunoglobulins for the treatment of primary immune deficiencies and of neurological diseases, and on specific anti-D immunoglobulins. In this category, RhoGAM® is a well-established brand that strives for safety and effectiveness in the prevention of Hemolytic Disease of the Fetus and Newborn (HDFN), and already enjoys a market leadership position, currently with 52% market share in the United States. Our duty is to maintain this position, so that an ever increasing number of mothers

worldwide has access to these much needed therapies.

In Europe, Germany, Austria and Poland registered the highest growth rates (cumulatively +62% compared to 2013). Russia, Turkey and Iran followed. Africa is an emerging area of great interest to Kedrion that produced very good results in 2014. In Latin America, Kedrion benefited from being granted the marketing authorization for a new Factor VIII for the Mexican market, from the opening of a sales office in Brazil, and from the continued growth of established markets such as Colombia.

At the same time, Kedrion has continued to support the humanitarian projects promoted by the National Blood Center (CNS) and by the Italian blood transfusion system as a whole for an ethical use of Factor VIII. The company took care of both the administrative and logistic aspects of making available, and delivering, to other countries surplus plasma-derived products manufactured under the national self-sufficiency program. This bears witness to Kedrion's, and the entire Italian Blood System's, commitment to broadening - globally, and to the greatest degree - access to plasma-derived therapies.

## I TRIUMPHED IN MY RACE FOR LIFE!

Ferenc Nagy, age: 39 - Eger (Hungary)

*I was about six months old when I was diagnosed with severe hemophilia A.*

*At the time, each hemorrhage required hospitalization. Sadly, by the time I was treated, the affected joints had been invaded by blood and were unbearably painful. It was a difficult childhood, but I did not give up, and from my adolescence on I have striven to live as full a life as possible, making sure that I also lead a healthy, active lifestyle.*

*Due to the long periods spent in hospital, I completed secondary school thanks to distance education. I had few aspirations for my future, until, in 1992, thanks to a patient organization, I attended a Summer camp where, for the first time in my life, I was treated with a Factor VIII replacement product. Its effects were incredible, and I continued the treatment on my return home. This broadened my horizons and I started to think bigger.*

*And my biggest adventure yet was taking part, last January, in the Budapest-Bamako Rally, the motto of which is "Anybody, with anything, anyhow". The contest is open to amateur car racers and professional adventurers. It is nearly 9000 kms long, and it crosses 4 countries in Europe and 3 in Africa.*

*En route, we distributed the donations we had collected back home amongst schools, hospitals and spectators. I may not have changed lives, but it was an uplifting experience to see so many happy, smiling faces.*

*I have always enjoyed challenge, and the desire to live up to my expectations and those of my fellow patients was enormous. This race enabled me to channel my inner strength. I still don't know whether I completed the race thanks to the powers above or to adrenalin: whichever the case, I made it home in good health, and so much richer in spirit.*

## CURhE

A global program for the eradication of Rh disease

*Stanford University experts have proposed a Consortium for Universal Rh disease Elimination (CURhE) to galvanize medical communities and lead, launch and replicate model programs for societal partnerships. Concurrently, industry partners (Kedrion among them) have been invited to co-lead this global outreach to eradicate Rh sensitization of all pregnant women through the use of affordable screening and prevention technologies (including anti-D immunoglobulin therapies) embedded in existing maternal child health and adolescent services facilitating the implementation of an endorsed and evidence-based "global standard of care".*

*Prof Dr Vinod K. Bhutani's call to action aims to create a global program for the prevention of Rh disease condition. Currently, 3 pregnant women among every 1000 who give birth (worldwide) are Rh sensitized, and the ensuing Rh disease can be deadly to the baby before birth. This is a well-established, well-proven and most easily preventable cause for newborn disease and mortality in countries with unrestricted health care access. The call is to develop replicable and scalable models that screen and prevent Rh sensitization, and are supported by concomitant national outreach and awareness campaigns in resource-constrained communities. Maternal empowerment strategies, adapted to community culture and values, are a key component of the program's mission, such that families of Rh sensitized newborns can self-navigate their access to expert care at regional facilities, and can be counseled for potential safe outcomes.*

*The principle family message is that "every woman knows her blood type" within the context of a societal message that everyone should know their blood type for emergencies and pregnancies, as well as mandate a clinical practice to verify every woman's blood type at the time of birthing or reproductive loss.*

*Prof. Bhutani is of the opinion that, through a social-media initiative ("Know Rh"), a global health consortium will endorse a universal*

*curricula for parent, societal and provider champions that will screen for an individual's Rh status by point-of-care technologies, primary prevention of sensitization at birthing or fetal loss, jaundice recognition of infants at birth, use of effective phototherapy and, if needed, referrals for higher level care under medical supervision through a program that is accountable and patient centered as promoted by the Institute of Medicine.*

*Interview with Prof Dr. Vinod K. Bhutani, Professor of Pediatrics at Stanford University School and a newborn specialist at the Stanford Children's Health of Lucile Packard Children's Hospital*



# RESEARCHING TO DEVELOP



Kedrion's constant commitment to Research and Development is one of the key factors in the company's success. On the one hand, our dedication enables us to expand the product portfolio. On the other hand, it has allowed for the further improvement of existing specialty therapies, thereby meeting the needs of the patients we serve in over 100 countries worldwide with a wide range of innovative treatments.

In 2014, R&D activities continued on new products including Resusix®, a virus inactivated spray-dried plasma developed for the American military by Kedrion in collaboration with a US-based company Entegron. Additionally, Kedrion has requested Marketing Authorizations for subcutaneous 16% immunoglobulin and for fibrin glue. Procedures to obtain the necessary authorizations to manufacture these two products at the Kedrion plant in Sant'Antimo, near Naples, are underway.

Our production site in Siena, renamed IKOD (Kedrion Orphan Drugs Plant), mainly hosts research and development activities focused on plasma-derived orphan drugs for the treatment of rare diseases.

In particular, in 2014, the first clinical scale batches of Factor V concentrate were manufactured for stability and characterization studies in view of obtaining, over the coming months, Orphan Drug designations both in Europe and in the United States.

Small, select production runs were also transferred to this plant and, in 2014, a number of research projects in collaboration with the CNR (Italian National Research Center) and the University of Pisa, financially supported by the Region of Tuscany, were undertaken. One project, in particular, focuses on 10% immunoglobulins.

The activities carried out by Global Medical Affairs - invariably aimed at meeting

patients' needs - have led to the creation of a web-based global system for the management of medical and scientific information requests coming from patients and physicians. In late 2014, two advisory boards - bringing together American and European immunology and hemophilia specialists - were established.

Finally, a team made up of staff members from Global Medical Affairs, Global IT and Global Human Resources developed the PAK project - Pharmacovigilance Awareness by Kedrion. This campaign, which will be launched in 2015, aims to increase - among Kedrion employees worldwide - knowledge of what Pharmacovigilance is, and awareness of the active role that each of us plays in its success.

# ECONOMIC AND FINANCIAL INDICATORS

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# FINANCIAL INDICATORS

## RELEVANT EVENTS OF THE YEAR

The higher volumes available supported revenue growth during the 2014 fiscal year. This was the result of further development and optimization of the additional fractionation capacity at the Hungarian plant of Gödöllő and of the full use of the US Melville facility, whose direct management began in mid-2013 after the plant had been leased from an industry third party.

Regarding sales prices, 2014 was characterized by an overall stability with a growth trend for albumin and immunoglobulin, particularly in some markets.

Analyzing our final markets, what stands out is the continuous increase of US turnover, the main market in our industry, which has become Kedrion's most important market, overtaking Italy's historical role. This result stems from a gradual internationalization process aimed at boosting Kedrion's presence in all the main international

markets. The excellent results achieved in other major markets such as Turkey, Mexico, Russia and Poland should also be interpreted in this context. In 2014, these markets allowed exports to account for 67.9% of total revenue.

Additionally, during the year Kedrion continued to pursue further operating efficiencies through the internalization of relevant production processes that had been previously entrusted to third parties. In particular, thanks to the significant investments made in 2014, two new production lines are close to completion from an industrial point of view: the new fractionation and purification line for Anti-D immunoglobulin (RhoGAM®) at the Melville plant in the United States, and the 10% immunoglobulin purification line.

Funding of these investments was secured by issuing a 300 million Euro Eurobond. It should also be noted that, during 2014, significant non-recurring operations were

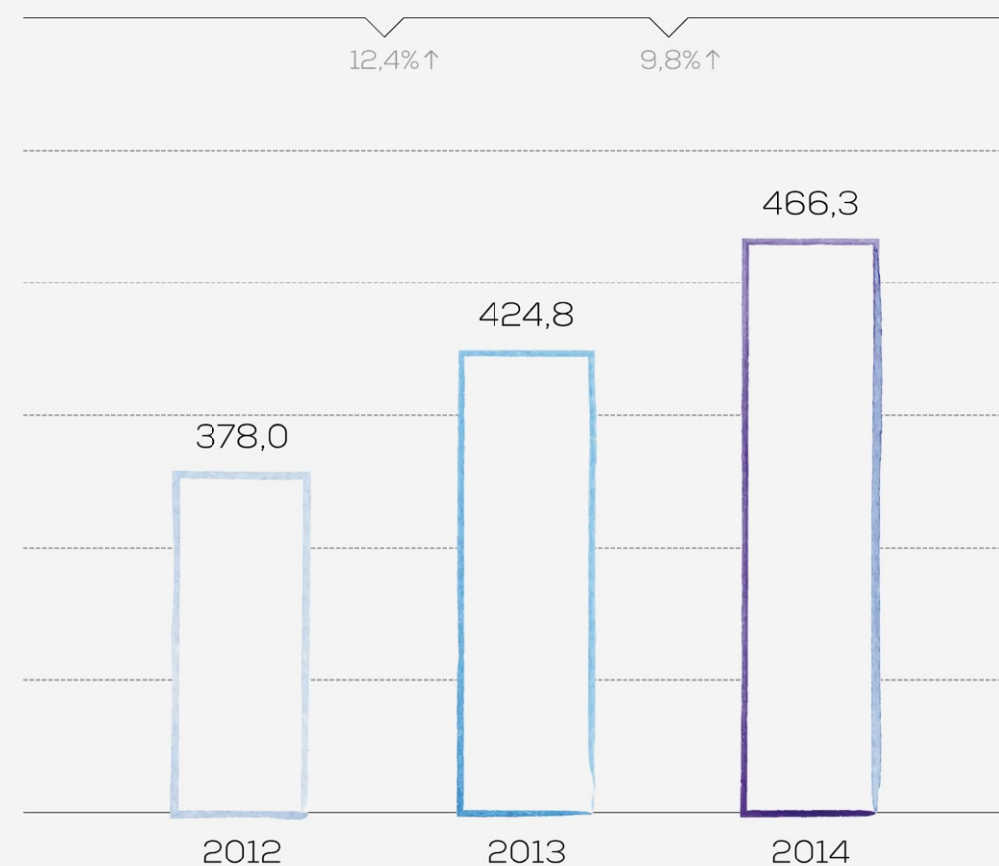
put in place for a total value of 13.4 million Euro. Among these, the aforementioned construction of the new fractionation and purification line for the production of RhoGAM® at the Melville facility, the opening of a number of new plasma collection centers, and Kedrion's facility in Siena dedicated to the production of orphan drugs.

Finally, in October 2014, we completed the reverse merger of Kedrion Group S.p.A. in Kedrion S.p.A. Accounting and tax effects of the merger began on the first day of the fiscal year during which the merger took place.

Following this merger, Kedrion Melville Inc., previously 100% controlled by Kedrion Group S.p.A., has become part of Kedrion S.p.A..

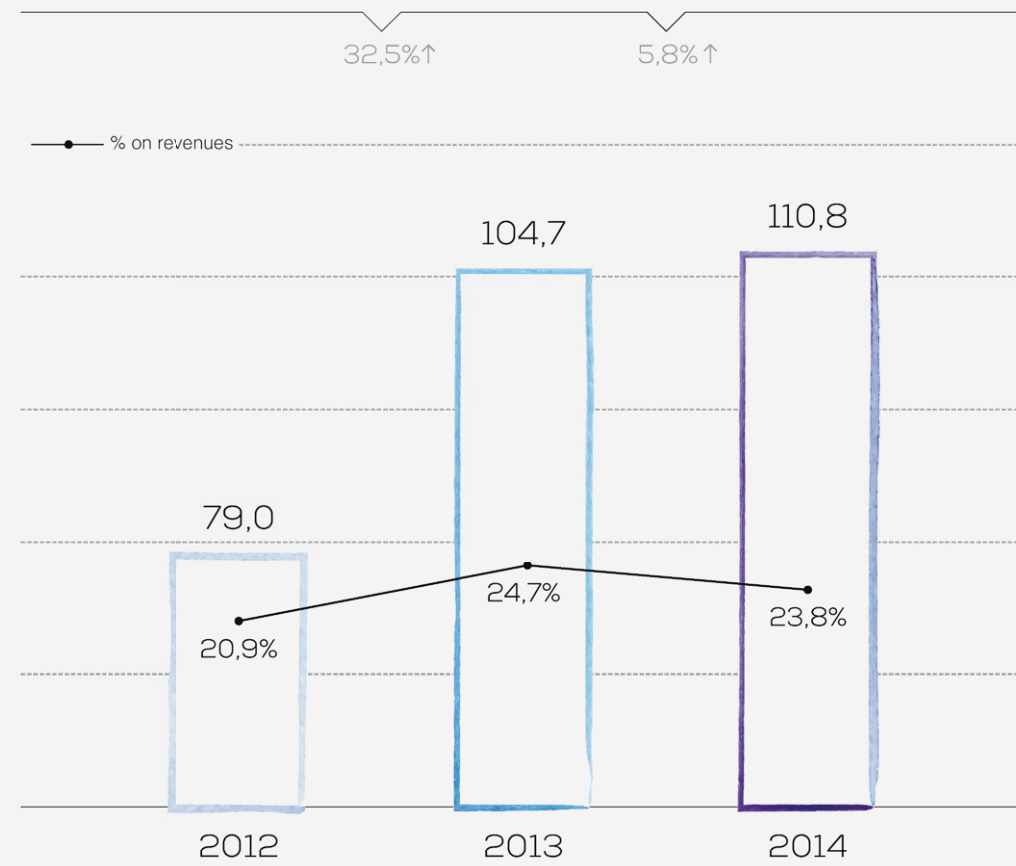
## REVENUES (€ MNL)

CAGR 11,1% ↑

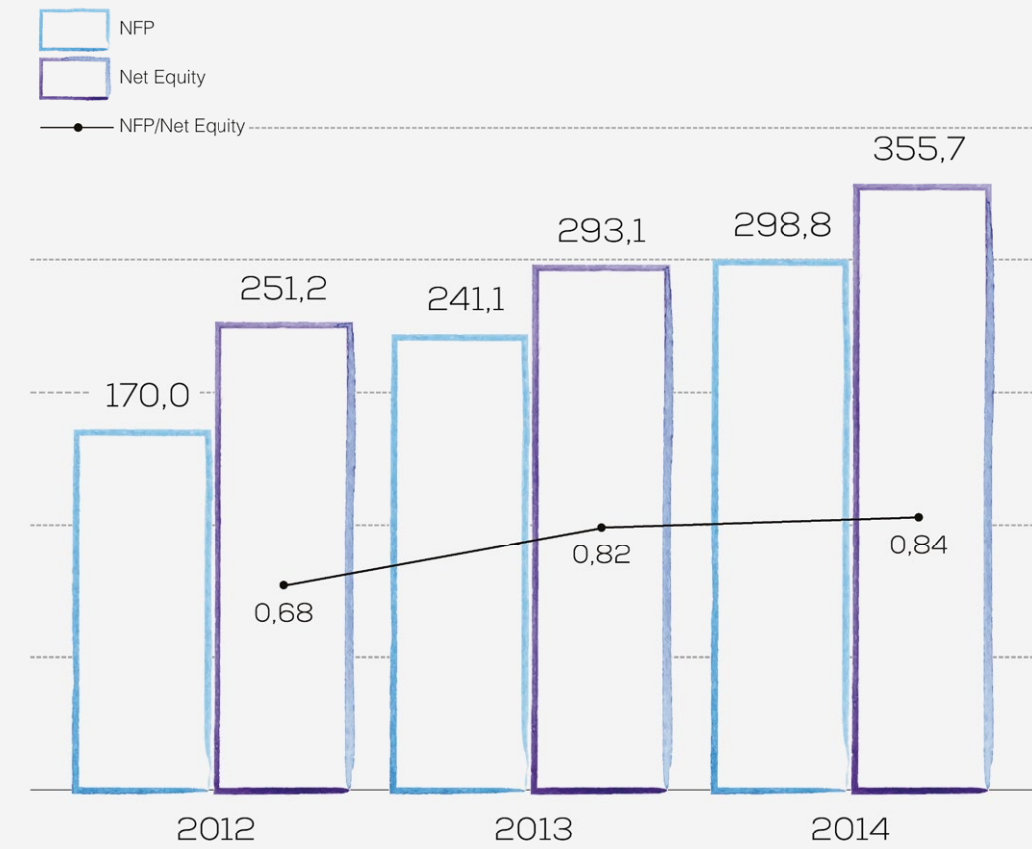


EBITDA ADJUSTED (€ MNL) AND  
ADJUSTED EBITDA MARGIN (%)

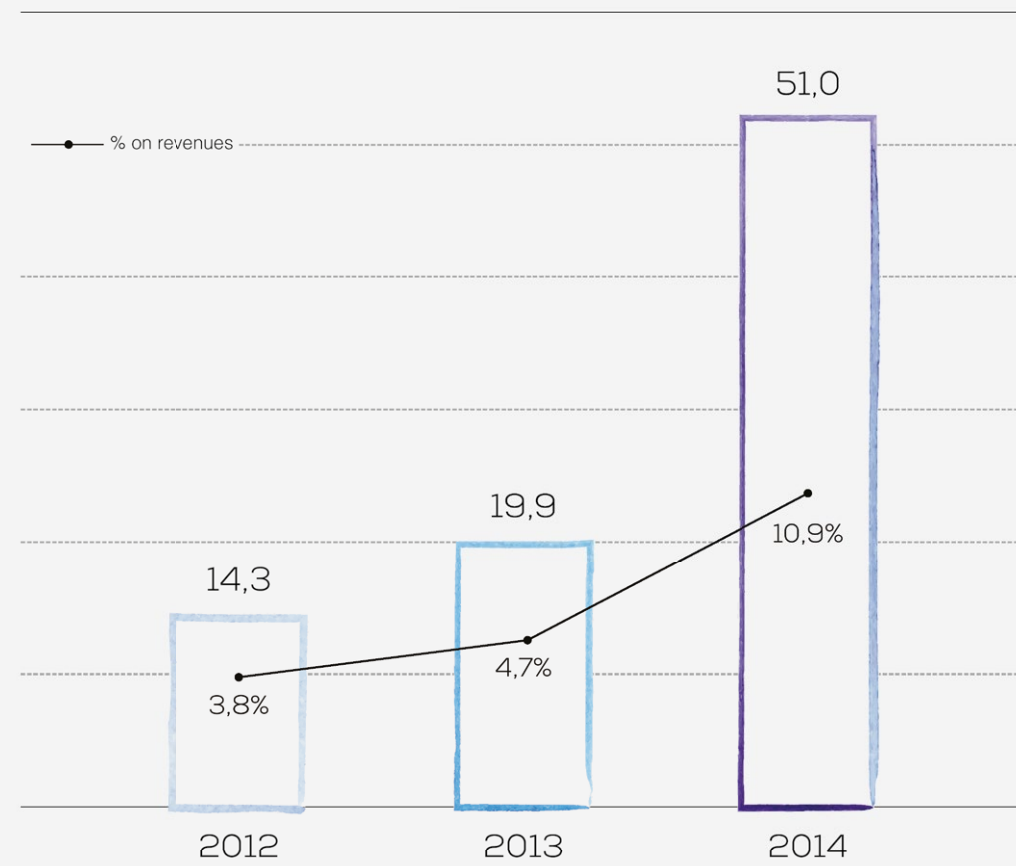
CAGR 18,4% ↑



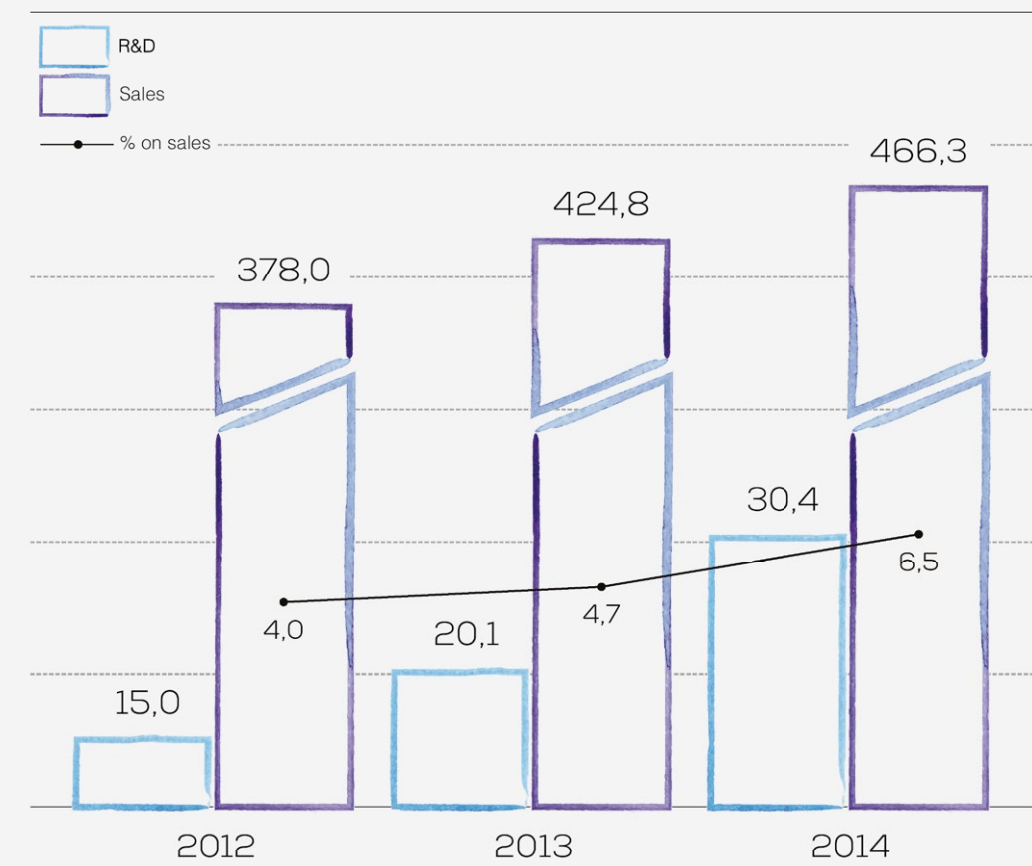
NET FINANCIAL POSITION (NFP) AND NET EQUITY (€ MNL)



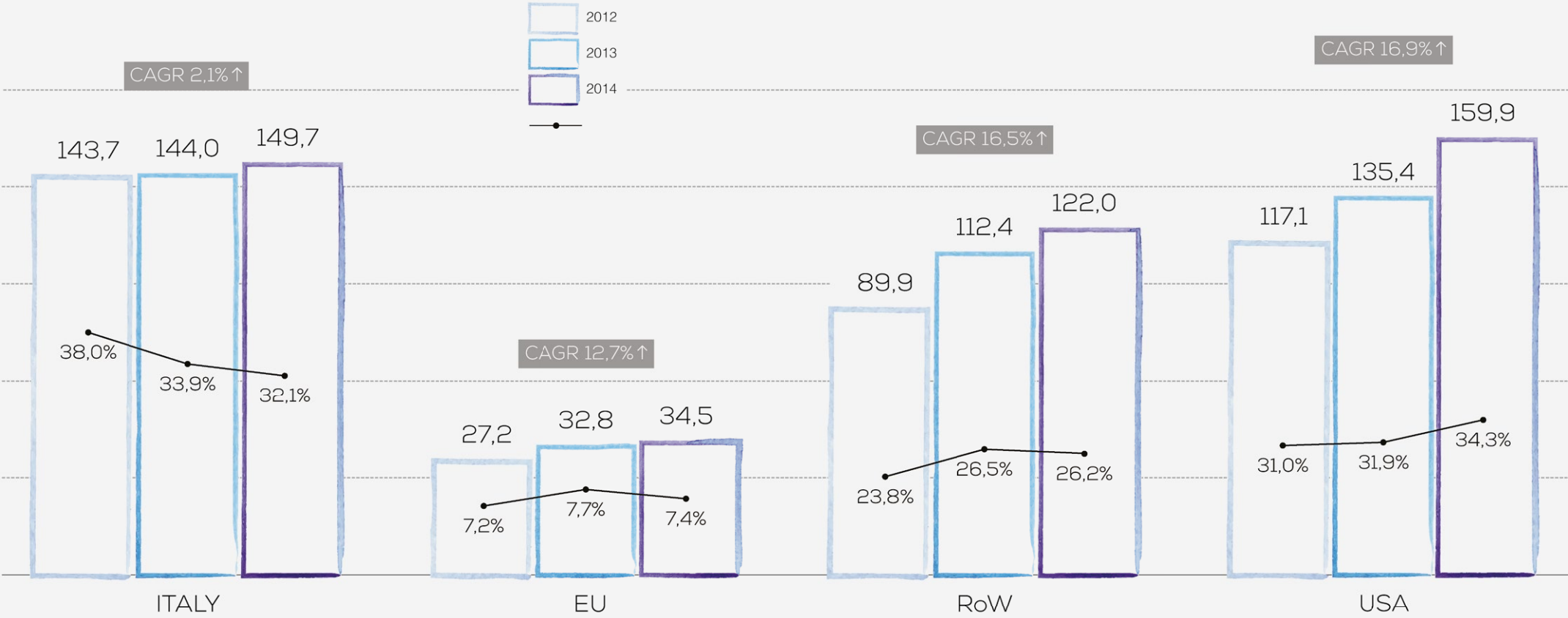
NET INVESTMENTS EXCLUDING M&A (€ MNL)



R&D TOTAL EXPENDITURE AND INVESTMENTS (€ MLN)



DISTRIBUTION OF SALES BY GEOGRAPHIC AREAS (€ MLN)



CONSOLIDATED INCOME STATEMENT  
(IN THOUSANDS OF EURO)

YEAR ENDED AT 31 DECEMBER  
2014

Revenues from sales and services	466.299
Cost of sales	263.263
<b>GROSS OPERATING MARGIN</b>	<b>203.036</b>
Other revenues	8.062
General and administrative expense	64.486
Sales and marketing expense	38.863
Research and development expense	23.766
Other operating costs	6.454
<b>OPERATING RESULT</b>	<b>77.529</b>
Financial charges	26.848
Financial income	16.989
<b>RESULT BEFORE TAX</b>	<b>67.670</b>
Income taxes	25.740
<b>NET RESULT FOR THE PERIOD</b>	<b>41.930</b>
OF WHICH:	
GROUP RESULT	40.040
MINORITIES RESULT	1.890

OTHER COMPREHENSIVE INCOME  
(IN THOUSANDS OF EURO)

YEAR ENDED AT 31 DECEMBER  
2014

<b>PROFIT FOR THE PERIOD</b>	<b>41.930</b>
OTHER COMPREHENSIVE INCOME TO BE RECLASSIFIED TO PROFIT OR LOSS IN SUBSEQUENT PERIODS:	
Net movement on cash flow hedges	0
Income tax effect	0
Exchange differences on translation of foreign operations	9.956
Income tax effect	0
<b>NET OTHER COMPREHENSIVE INCOME TO BE RECLASSIFIED TO PROFIT OR LOSS IN SUBSEQUENT PERIODS</b>	<b>9.956</b>
OTHER COMPREHENSIVE INCOME NOT TO BE RECLASSIFIED TO PROFIT OR LOSS IN SUBSEQUENT PERIODS:	
Re-measurement gains (losses) on defined benefit plans	(525)
Income tax effect	144
<b>NET OTHER COMPREHENSIVE INCOME NOT TO BE RECLASSIFIED TO PROFIT OR LOSS IN SUBSEQUENT PERIODS</b>	<b>(381)</b>
<b>OTHER COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX</b>	<b>9.575</b>
<b>TOTAL COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX</b>	<b>51.505</b>
ATTRIBUTABLE TO:	
EQUITY HOLDERS OF THE PARENT	49.615
NON-CONTROLLING INTERESTS	1.890

CONSOLIDATED STATEMENT OF FINANCIAL POSITION  
(IN THOUSANDS OF EURO)

YEAR ENDED AT 31 DECEMBER

2014

NON CURRENT ASSETS

Property, plant and equipment	150.626
Investment property	2.565
Goodwill	203.734
Fixed term intangible assets	49.032
Investments in associated companies	23
Investments in other companies	2.098
Other non current financial assets	2.236
Deferred tax assets	3.683
Non current trade receivables	0
Other non current assets	498
<b>TOTAL NON CURRENT ASSETS</b>	<b>414.495</b>

CURRENT ASSETS

Inventories	231.145
Trade receivables	144.920
Current tax credits	5.807
Other current assets	18.313
Other financial current assets	0
Cash and cash equivalents	39.641
<b>TOTAL CURRENT ASSETS</b>	<b>439.826</b>

**TOTAL ASSETS** 854.321

GROUP SHAREHOLDERS' EQUITY

Share capital	55.186
Reserves	258.526
Group net income	40.040
<b>TOTAL GROUP SHAREHOLDERS' EQUITY</b>	<b>353.752</b>

MINORITIES SHAREHOLDERS' EQUITY

Minorities capital and reserves	60
Minorities net income	1.890
<b>TOTAL MINORITIES SHAREHOLDERS' EQUITY</b>	<b>1.950</b>

**TOTAL SHAREHOLDERS' EQUITY** 355.702

NON CURRENT LIABILITIES

Medium/long-term debt	313.383
Provisions for risks and charges	278
Payables for employee benefits	4.669
Other non current liabilities	7.848
<b>TOTAL NON CURRENT LIABILITIES</b>	<b>326.178</b>

CURRENT LIABILITIES

Payables to banks and other lenders	18.454
Current portion of medium/long-term debt	8.816
Provisions for risks and charges	176
Trade payables	105.304
Current tax payables	4.906
Other current liabilities	34.785

**TOTAL CURRENT LIABILITIES** 172.441

**TOTAL LIABILITIES** 498.619

**TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES** 854.321



CONSOLIDATED CASH FLOW STATEMENT  
(IN THOUSANDS OF EURO)

YEAR ENDED AT 31 DECEMBER  
2014

Net cash flow generated by operating activities (A)	(2.545)
Net cash flow absorbed by investment activities (B)	(46.977)
Net cash flow generated / (absorbed) by financing activities (C)	36.520
<b>TOTAL NET CASH FLOW D=(A+B+C)</b>	<b>(13.002)</b>
Cash and cash equivalents opening balance (E)	52.542
Net effect of conversion of foreign currencies on cash and cash equivalents (F)	32
<b>CASH AND CASH EQUIVALENTS CLOSING BALANCE G=(D+E+F)</b>	<b>39.572</b>



Reconta Ernst & Young S.p.A.  
Piazza della Libertà, 9  
50129 Firenze  
Tel: +39 055 552451  
Fax: +39 055 5524850  
ey.com

Independent auditors' report  
pursuant to art. 14 and 16 of D.Lgs. 27.1.2010, n. 39  
(Translation from the original Italian text)

To the Shareholders of  
Kedrion S.p.A.

1. We have audited the consolidated financial statements of Kedrion S.p.A. and its subsidiaries, (the "Kedrion Group") as of 31 December 2014 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 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 recommended by CONSOB (the Italian Stock Exchange Regulatory Agency). 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.  
  
The consolidated financial statements present for comparative purposes the data related to the prior year of the consolidated financial statements of Kedrion Group S.p.A. and its subsidiaries, on which we issued our auditor's report dated March 28<sup>th</sup>, 2014.
3. In our opinion, the consolidated financial statements of the Kedrion Group at 31 December 2014 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 Kedrion Group for the year then ended.
4. The Directors of Kedrion S.p.A. are responsible for the preparation of the Report on Operations in accordance with the applicable laws and regulations. Our responsibility is to express an opinion on the consistency with the financial statements of the Report on Operations and the specific section on corporate governance regarding the information included therein in compliance with art. 123-bis of Legislative Decree n. 58/1998, paragraph 2, letter b), as required by the 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 and the information included therein in compliance with art. 123-bis of Legislative Decree n. 58/1998, paragraph 2), letter b) included in the specific section on corporate governance, are consistent with the consolidated financial statements of the Kedrion Group at 31 December 2014.

Florence, April 10<sup>th</sup>, 2015

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: 02198 Roma - Via Po, 32  
Capitale Sociale € 1.402.500,00 i.v.  
Iscritta alla S.O. del Registro delle Imprese presso la C.C.I.A.A. di Roma  
Codice Fiscale numero di iscrizione 10444000584  
P.IVA 00897231003  
Iscritta all'Albo Revisori Contabili al n. 70945 Pubblicato sulla G.U. Suppl. 13 - IV Serie Speciale del 17/2/1998  
Iscritta all'Albo Speciale delle società di revisione  
Consob al progressivo n. 2 delibera n.10831 del 16/7/1997  
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# CONTACT 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  
Balkans  
Central EU  
Eastern EU  
Italy  
Latin America  
Middle East  
North America

## 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) 532201  
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 0  
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 Fração Q, Miraflores 1495-139  
Algés (Portugal)  
Tel: +351 (214) 107 246  
Fax: +351 (214) 100 645  
safonso@kedrionportugal.com

## KEDRION SWISS SARL

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

## KEDRION MEXICANA SA DE CV

Torre de los Parques  
Insurgentes Sur 1196 9° Piso  
Col. Tlacoquemécatl Del Valle  
México D.F. CP 03200 (Mexico)  
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

House No. R-265C,  
Ground Floor Greater Kailash Part-I,  
New Delhi 110048 (India)  
Tel: +91 (124) 4069391/92  
Fax: +91 (124) 2567301  
n.madan@kedrionindia.com

## KEDPLASMA GMBH

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

## PLAZMAFEREZIS ÁLLOMÁS NONPROFIT KFT

Táncsics Mihály út 80,  
H-2100 Gödöllő (Hungary)  
Tel: +36 (28) 532248  
Fax: +36 (28) 532201  
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  
contactus@kedplasmausa.com

## CREDITS

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Alessandro Stefani: photo on page 7

Federica Piacentini: photo on page 34/35

Christian Sinibaldi: all other photos

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Agency: Teseo  
(design: Aimone Bonucci / Francesco Ciardi)

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

**Kedrion S.p.a.**

Loc. Ai Conti - 55051 Castelvecchio Pascoli, Barga (Lucca) - Italy

Tel +39 0583 19691 - Fax +39 0583 766121

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