

ANNUAL REPORT 2 0 1 6



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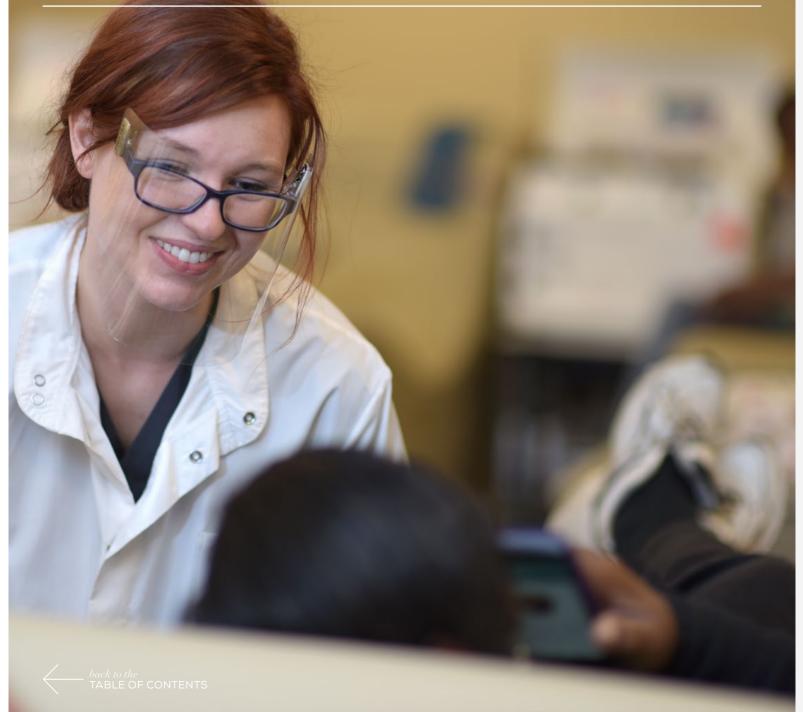
ECONOMIC AND FINANCIAL INDICATORS



### **KEDRION IN THE WORLD**



## LETTER FROM PAOLO MARCUCCI



### LETTER FROM PAOLO MARCUCCI



O16 was a successful year for Kedrion. Thanks to a set of activities - in manufacturing and plasma collection - undertaken in the second half of the year, and to the company's steady global growth, we closed the year with a 659.3 million Euro turnover (a 15.6% increase compared to the previous year) and a 106.3 million Euro EBITDA.

Melville was one of the challenges we faced in 2016: we decided to undertake a major renovation of our US manufacturing plant. This significant financial investment which will continue throughout 2017 - aims to achieve full integration of this plant with the other Kedrion facilities. A contract manufacturing agreement with an industrial partner has allowed us to carry out the total renovation of our plant while continuing to operate on the US market. In parallel, we rationalized the network of our collection centres in the United States, selling some and acquiring new ones that were logistically closer to the company's other centres.

In this spirit, in 2016 Kedrion kept expanding on the international market: approximately 75% of the overall turnover came from foreign markets. We have achieved significant growth in almost all the countries in which we sell our products. In particular, we experienced remarkable growth in Germany and Portugal, we relaunched our activities in India, and strengthened our commercial presence in Mexico, Russia and Turkey (through our subsidiary), despite the weakness of their local currencies. In Russia, we entered into a strategic partnership whereby Kedrion will transfer its technological know-how to the Russian legal entity JSC Kirov Plasma - whose joint shareholders are Kedrion S.p.A., Nacimbio (part of the Rostech Group) and Pharmstandard (a leading Russian pharmaceutical company) - with the aim of re-launching the Kirov manufacturing plant. Upon completion renovation is expected to end by 2019 - the plant will be able to process 600 tons of plasma per year.

2016 was also the year in which the Italian market opened. Kedrion is well prepared to face international competitors very determined to take over this market, and is working to extend its leadership role in Italy, in the firm belief that the Italian national self-sufficiency program - to the success of which Kedrion has always contributed - is one of the most advanced in the world in terms of plasma collection, in that it brings together voluntary donors, the public sector and the industry.

Kedrion most definitely became stronger



in 2016, because it successfully faced complex situations, proving once again its extraordinary potential for growth.

I would like to conclude by extending a special thanks to the management of Cdp Equity, the investment fund that has supported us during the last five years. Kedrion Biopharma continues to grow also thanks to their commitment.



Paolo Marcucci, Kedrion Chairman and CEO



dp Equity is a Gruppo Cassa Depositi e Prestiti investment holding that invests long-term in Italian companies of major national interest. It purchases mainly minority shares in companies with sound finances and business prospects; it invests in companies in the form of growth capital, exercising active governance rights; it provides patient capital to listed companies or companies that are planning to go public in the medium term.

Cdp Equity became a shareholder of Kedrion in 2012, investing approximately 100 million Euro in a capital increase. These funds enabled the company to carry out major acquisitions, including the OCD (Johnson&Johnson Group) business unit that manufactures and distributes a wellknown anti-D human immunoglobulin for the prevention of Hemolytic Disease of the Fetus and the Newborn (HDFN), and also to invest heavily to increase its production capacity in Italy and expand abroad.

"Over the last few years, I have seen the company – that until quite recent times has mainly processed national plasma – grow significantly on the international market, becoming to all effects a global player, capable of challenging the leaders of the highly concentrated plasma-derived industry.

Kedrion took on the market's challenges and seized growth opportunities, such as the acquisition of a manufacturing plant in the United States, thereby positioning itself as an international plasma derivatives industry leader. Its management played a key role in this.

Since Cdp Equity has invested in the company, its revenues have increased

from 277 million Euro in 2011 to 660 million Euro in 2016, with foreign sales rising from 46% to 74.6% of turnover. An outstanding result, especially in the light of the Italian industrial context.

As Kedrion shareholder and Board of Directors member, I am convinced the company has the people and the resources needed to meet further significant targets, in keeping with the achievements accomplished so far".

Guido Rivolta Cdp Equity CEO and Kedrion Board of Directors member

For information on Cdp Equity please refer to: www.cdpequity.it





# CORPORATE OVERVIEW



### **ABOUT US**

edrion Biopharma is an international company that produces and distributes plasma-derived therapeutic products for use in treating and preventing serious diseases, disorders and conditions such as hemophilia, primary immune system deficiencies and Rh sensitization, which can lead to hemolytic disease of the fetus and newborn.

Founded in Italy in 2001, over the years Kedrion has expanded its activities globally. Today, the company has more than 2,300 employees, a commercial presence in about 100 countries worldwide, and is the fifth world player and the first player in Italy in the production of plasma-derived therapies.

We manage the entire plasma transformation cycle in our production plants based in Italy, Hungary and the United States, and in our KEDPLASMA collection centers located in the USA, Germany and Hungary: from the collection of raw material to the production of plasma-derived therapies and their distribution on the market.

We actively cooperate with the Italian National Health System in the pursuit of national plasma-derived product self-sufficiency. At the same time, we are committed to offering our expertise and technologies to communities and health systems worldwide, helping other countries and other regions become less dependent on outside sources for plasma-based therapies.

People are at the core of Kedrion's activ-

ities and all of our policies and behaviors are shaped by the determination to play a positive role in the lives and communities we touch.

At Kedrion Biopharma, we think of ourselves - and want the world to see us - as "bridge builders." We are committed to making connections between donor and patient; from plasma to innovative treatment: to communities we serve and where we work.

Our ultimate goal is to expand patient access to plasma-derived therapies worldwide and to give those suffering from rare diseases the chance for a better life.

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PARTNER IN THE SELE-SUFFICIENCY **PROGRAM IN ITALY** 

6\* MANUFACTURING PLANTS IN 3 COUNTRIES



COMMERCIAL PRESENCE IN APPROXIMATELY 100 COUNTRIES



#### 2016 TURNOVER 659.3 MILLION FURO





#### PEOPLE: ANNUAL INCREASE SINCE 2010: 11.42%

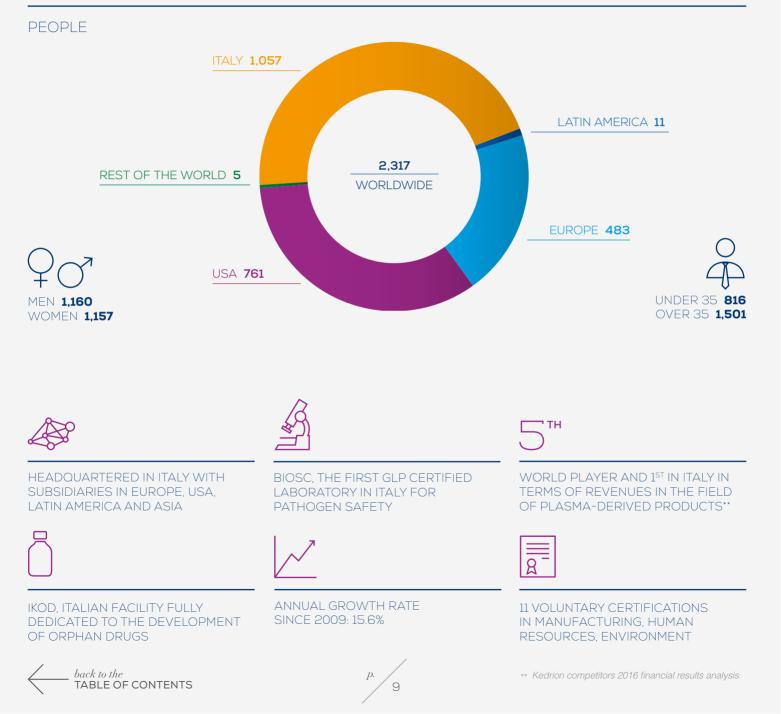
23 PLASMA COLLECTION





<sup>\*</sup> The completion of our plant in Castelvecchio

### ABOUTUS



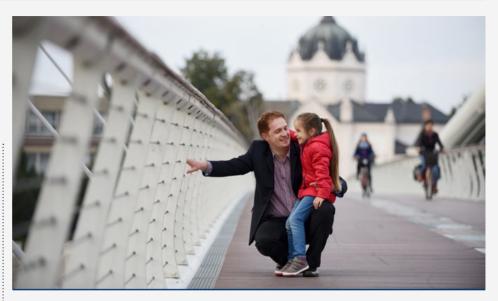
### OUR VISION

" Building bridges" means establishing connections - among donors, researchers, healthcare professionals and patients. And of course, the people who work at Kedrion Biopharma, in our collection centers, laboratories, plants and offices; those who help make our products and those who represent them worldwide are the very structure of those bridges. For them and for the communities in which and for which we work, we aspire to the highest standards of social responsibility.

We are committed to

- Providing a safe and comfortable workplace;
- Ensuring that our workers are treated well and compensated fairly, and that they are afforded training and encouragement for growth and development in their work;
- Minimizing the environmental impact of our processes and activities and finding ways to improve the environment of the communities in which we work;
- Ensuring that whoever operates for and on behalf of Kedrion adheres to internationally recognized principles of best practices, and is compliant with national and international regulations;
- Encouraging all partners and collaborators to observe socially and environmen-





tally responsible practices and contractually obliging them to conform to our social responsibility principles;

• Ensuring that corporate social responsibility is a prominent consideration in all business transactions and decisions.

Finally, we cooperate with patient and donor organizations, providing them with information, practical support and expertise, and collaborating in projects that can make a difference.

#### **Our CSR Standards and Certifications**

- Our own ideals, principles and goals;
- The Global Compact's Ten Principles regarding human rights, labour, the environment and the fight against corruption;
- The OECD (Organization for Economic Cooperation and Development) Guidelines for multinational enterprises;
- The ILO (International Labour Organization) principles;
- The SA8000 standard.



### COMMITMENT TO COMMUNITIES

uch of our work at Kedrion involves building bridges. We create connections: between donor and patient, research and innovation, health need and solution. We carry that idea of bridge building to the communities we work with and within - finding ways to express the ideals of good citizenship at the local level to the global.

In 2016, we backed initiatives aimed at scientific research, protection of human rights, commitment in volunteer work and in medical professional development. In this framework, for example, we supported:

- Fondazione Veronesi (Advancement of Science initiative)
- Robert F. Kennedy Foundation of Europe (activities and special events)
- OXFAM (fund-raising events for developing countries)
- University of Tor Vergata, Rome (medical and scientific professional development)
- Local care services such as Misericordia and volunteer associations in the province of Lucca (support volunteer activities)

At the same time, we offered our contribution to donor and patient associations, to foundations and to non-profit organizations working in the field of medical and



scientific research. Among others, we supported:

- Italian Blood Donor Associations: AVIS, FIDAS, FRATRES (activities and special events)
- IFBDO, International Federation of Blood Donor Organizations (activities and campaigns)
- A.C.E.P. "Massimo Chesta" Onlus (statutory activities)
- Angelo Bianchi Bonomi Foundation (statutory activities)
- Associazione Bambini e Giovani con Emofilia - Association for Children and Youth with Hemophilia (clinical trial implementation)
- Fondazione EMO (statutory activities)
- Associazione AEL Lazio Hemophilia Patient Association (statutory activities)
- Vite-Onlus (information campaign)
- Jeffrey Modell Foundation (activities and

support in favor of JMF center at Meyer Children's Hospital in Florence, Italy)

- Fondazione Paracelso ONLUS (statutory activities)
- Fondazione IRCCS Ca' Granda (MYVIP project)
- AINP ONLUS (statutory activities)

In the United States, we strengthened our commitment in supporting the community with our *Kedrion Cares* program, working closely with local and national partners to promote charitable activities, with the ultimate goal of "leaving every place better than how we found it". For example, during our participation at the 2016 National Hospital Pharmacy Conference in Chicago last October, we made a donation to the Chicago HOPES for Kids organization, which aims to provide education to children living in homeless shelters. Furthermore, during



the International Plasma Awareness Week, KEDPLASMA USA engaged employees and donors in an initiative geared at supporting the Feeding America hunger-relief organization, working to connect people with food and end hunger in the United States.

In Hungary, Kedrion Biopharma employees were awarded the annual prize "For the City of Gödöllő 2016", given to individuals and communities whose work has benefited the city and its inhabitants. In addition, in 2016 Kedrion renewed its active commitment in supporting Hungarian patients and made a donation in favor of the two main hospitals in Budapest to assist in purchasing technological instrumentation and toys for children undergoing medical treatment.

In Italy, as in past years, we worked side by side with Donors' Associations to

raise awareness of the gift of blood and blood-derived products and to promote knowledge of different forms of donation. Among the activities, we partnered FIDAS - the Italian Federation of Blood Donors Association - during one of Italy's most popular sporting events, the Giro d'Italia cycling race contributing to the campaign "Blood is thicker than water. #DissetaLa-Vita"; and we supported AVIS Toscana for the production of its promotional spot "Donating blood, a beautiful thing".

Finally, in 2016, we renewed our commitment to ethical, transparent and sustainable projects addressed to disadvantaged countries, to maximize the use of a valuable resource such as plasma and to ensure those in need a wider and more equitable access to plasma-derived therapies. For example, we confirmed our unconditional support to WISH, the humanitarian aid program endorsed by the World Federation of Hemophilia (WFH) and by the Italian National Blood Centre (CNS), which is aimed at reducing global differences in access to clotting factor concentrates; and we supported the Italian Regions by contributing to the delivery of medicines to Albania and India. Additionally, in summer 2016, we donated 145 vials of Factor IX to the Kabul Hemophilia Center in Afghanistan to make up for a temporary shortage of the product in the country and to ensure the continuity of treatment for 30 children with hemophilia B - two of whom are in critical condition - being assisted at the Hemophilia Center in the Esteglal Hospital located in the Afghan capital.



### ENVIRONMENT, HEALTH AND SAFETY

or us, to Keep Life *Flowing* has always meant putting people at the center of our business. Giving back - in social, economic and environmental terms - to those who work for us and with us, and to the communities in which we operate, is one of Kedrion's core values.

In line with this principle, we are working to extend our environment, health & safety standards to all our production sites, so that local distinctive traits are retained, and enhanced, within a shared management model capable of ensuring the same high standards of quality, and the same environmental impact.

### ENVIRONMENT

Our procedures are carefully monitored, so as to ensure the highest environmental standards.

In 2015, we completed the Environmental Product Declaration (EPD®) for the Factor VIII we produce in Bolognana, Lucca. Between the end of the previous year and early 2016, we were awarded the certification, which is international, and voluntary, and certifies the validity and sustainability of this product's Life Cycle Assessment (LCA). Moreover, in an industry that as yet has no specific standards to refer to, we decided to



take a proactive stance: in a groundbreaking move, we drafted - with the help of a consulting firm - the first Product Category Rules (PCRs) for plasma-derived products. This protocol was examined and approved by the International EPD® System in Stockholm, and has now become the benchmark for this industry's players. From now on, all Environmental Product Declarations for plasma-derived products will be guided by, and have to conform to, these regulations.

 In Italy, the carpooling company program was particularly appreciated by our internal community, so much so that - for effort shown, results obtained and CO<sub>2</sub> emissions saved - Kedrion Biopharma won the Best Carpooling Company award for 2015. These results were confirmed and improved in

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2016: the 178 Italian employees registered with the website shared a total of 533 commutes (+33% compared to the previous year), resulting in a saving of 1377 kg of  $CO_{2}$  (+77%).

### HEALTH & SAFETY

We strongly believe that safety in the workplace is a value to uphold and strengthen.

In 2016, with the aim of testing the effectiveness of the training provided so far, and of tailoring future training to the company's actual needs, we started mapping out the proficiencies - in relation to environment, health and safety - of each of our plants. The auditing process has already been completed for the Bolognana and Castelvecchio Pascoli (Italy) sites, and results have



shown significant employee uptake. More than 97% of staff - about 600 people - voluntarily completed personalized online surveys aimed at assessing technical and behavioral skills in relation to their respective professional roles. A clear testimony of how important the issues of safety and the environment are held by all.

In 2015, the production site in Gödöllő and the Plasma Operation Center in Üllő (Hungary) obtained OHSAS 18001 certification for workplace health and safety management. Last year, the two sites underwent a further monitoring audit to confirm the validity of the system. This took place at the same time as Kedrion's plants in Italy were being inspected, and its outcome was positive. Moreover, this systembased approach - working at the same integrated way, sharing knowledge, experiences and results, so as to start a virtuous circle that has positive effects on all production sites involved - was especially appreciated.

In line with our vision of sharing good practices as much as possible, and taking our plant in Melville (USA) as an example, we are currently extending to all other Kedrion facilities - the LOTO (Lock Out Tag Out) system, which ensures maximum safety during maintenance activities, minimizes risks, and provides specific training activities aimed at increasing operators' awareness. By 2017, LOTO implementation will be completed in all Kedrion production sites worldwide.

### time across multiple locations in an ERESOURCES AND ENERGY

We believe that energy management activities - to map out consumption levels, and to identify those areas where the company's energy performances need to improve - are strategic.

- In Gödöllő (Hungary), the energy diagnosis of the plant completed the energy pre-audit undertaken in 2015. This allowed us to measure, and subsequently improve, the plant's energy performance and efficiency, which in turn had a positive impact on manufacturing as well as the environment.
- In our Bolognana plant (Italy), traditional light bulbs are being replaced with LED lighting, which is more efficient and sustainable. The first phase of this project has been completed, and energy consumption for lighting has been





reduced by 200,000 kWh (or 15% of total consumption).

At the Sant'Antimo site, in Italy, a significant reduction in natural gas consumption - a decrease in excess of 25% compared to the previous year - has been achieved by improving the efficiency of the boilers used to produce steam.

#### **EHS Standards and Certifications**

OHSAS 18001 standard; EMAS regulations; ISO 14001 standard; ISO26000 guidelines.



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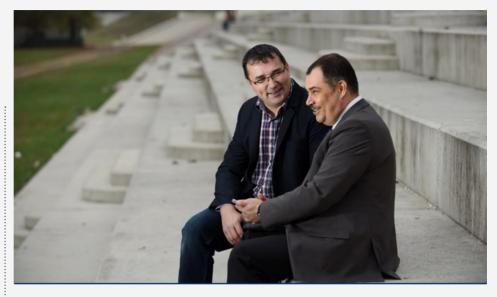
### DEVELOPING TALENT

### CREATING VALUE. WITH PEOPLE. FOR PEOPLE.

n Kedrion Biopharma, we put people at the center of our actions and invest in the development of knowledge and skills.

For us, creating value means striving daily to offer our employees continuous professional development. A commitment we renewed and expanded in 2016, with the goal of building a diverse and professional workforce, while offering job opportunities to external talents and new inspiration to those already working within our company. We accomplished this by upgrading and sharing technical, professional and managerial skills, and by means of ongoing training programs that have helped to enrich the wealth of knowledge and experience needed to meet new business challenges, and to address the requirements of a fast growing company such as Kedrion. In 2016, almost 800 employees worldwide attended a total of approximately 20,000 hours of training, averaging 25 hours of training per person.

Special attention was given to managerial-behavioral training programs, aimed at improving the effectiveness of staff management, and of interpersonal and interdepartmental communication, and at developing project management



and leadership skills. Moreover, with the increasing internationalization of the company, language training has taken on a key role. Employees, managers and executives attended English, Arabic and Italian language courses - the latter reserved to foreign managers - organized in collaboration with, and held at, the Fondazione Campus in Lucca. Technical and operational training was the focus of a number of courses aimed at updating and consolidating the skills and technical knowledge associated with the different professional roles, particularly in relation to projects promoting competitiveness and business growth.

Believing firmly that it is essential to provide young people with the tools to decide their professional paths mindfully, in 2016 Kedrion took part in job fairs and career days held at various Italian universities. We also strengthened our cooperation with the Fondazione VITA, the New Technologies for Life Technical Institute, in Tuscany, which has launched four two-year training courses for young people.

Together with the Fondazione Campus and the training agency Per-Corso, Kedrion supported FA.BENE.CHI.SA, a project developed by the "E. Ferrari" Technical and Technological Institute in Borgo a Mozzano, near Lucca, and funded by the Regional Operational Program-Regione Toscana 2014-2020, which aims to expand and improve vocational training for the chemical-pharmaceutical industry.

At the end of 2016, Kedrion also launched a pilot smart working project: using an objectives driven approach, approximately 20 employees will work from home from a minimum of four, to a maximum of six, days per month.



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### SCUOLA KEDRION

Scuola Kedrion, with the support of the Fondazione Campus in Lucca, develops advanced training courses to consolidate and improve management culture in all Kedrion Biopharma offices in Italy and around the world. Scuola Kedrion is an environment that fosters skill and talent development to support the achievement of the company's strate-

gic goals, promoting the personal growth of its alumni, who are thus able to continue learning and updating their knowledge.

Insofar as it encourages the sharing of common values, and discussion, Scuola Kedrion also represents an important means of consolidating corporate identity. Learning together encourages individual growth as much as it strengthens Kedrion's corporate culture, which is the result of many national cultures coming together. In the name of multiculturalism, in 2016 Scuola Kedrion completed its internationalization plan, delivering all its courses in English to address the requirements of an international audience.

Educational innovation played an important role. Alongside more traditional didactic tools such as conferences, lectures and seminars, digital modules taught using collaboration work platforms were also introduced, to help develop attitudes and behaviors that improve teamwork, digital innovation and virtual leadership.

### LEARNING TOGETHER TO GROW TOGETHER

uring 2016, Scuola Kedrion activities developed along three lines: management development, business intelligence and project management.

In terms of management development, the Kedrion Management Development Program, designed in collaboration with Global Human Resources, got underway. For the first time in Kedrion's history, 18 managers from around the world were put to work discussing topics including leadership, innovation and quality of results. The program featured mentoring activities carried out by the company's senior management, who are also - alongside the CEO - members of the course's steering committee.

With regards to business intelligence, around 80 managers took part in plenary training sessions focusing on the importance of market analysis and of comparing to competitors, and on business intelligence in general, in line with the compa-



ny's business plans to become increasingly competitive on the global market. Lastly, the training program focusing on project management involved approximately 100 Kedrion employees. Alternating different learning tools - lectures, webinars, group work and collaborative learning - helped to enhance skills and raise awareness of the importance of working on a project basis, especially in a company that is growing as rapidly as Kedrion is.

Articipants in the training module dedicated to market analysis, and to what is commonly known as business intelligence, came from many different departments within Kedrion. This was key to its success, as it meant that even staff not used to measuring their work according to purely commercial criteria were able to understand these logics and dynamics. The results of the Kedrion Management Development Program were surprising: we worked with directors coming from different backgrounds, experiences and roles, who achieved an almost complete synergy on the topics of leadership and teamwork. The final outcome was a very interesting document that took into account the experiences and approaches of all participants in respect of these issues.

> Ferdinando Borgese, Global Marketing Director, Kedrion Biopharma

he "Scuola" is a program of which we at Kedrion can be proud. On an ongoing basis, it provides updates on developing business trends and individual growth for Kedrion employees. It also plays a crucial role in Kedrion's internal cultural integration. I thought specific lessons to improve on this aspect were needed and instead I realized that integrating "on the field " - in the classroom - was much more effective and inspiring. People learn to work together, to get to know and understand one another, and as a result, at the end of the training course, what emerges is a cohesive group rather than single individuals. I learned so much from my experience at Scuola Kedrion and I especially appreciated the high quality of training offered. Moreover, meeting colleagues I had never known before and comparing different cultures and approaches enriched





me tremendously. The Scuola provided a growth factor that was professional, as well as personal, for myself and for the entire working group.

> Helen Nasser, Managing Director, **KEDPLASMA USA**

raining on a topic such as project management is never ending, and it is never easy to apply in practice what has been learned in theory. What counts, though, is that people are aware of the existence of a specific method, and that this method is gradually put in place. I found the training tools offered by Scuola Kedrion effective, because they allow people to learn together even if they are

not physically close by. This approach encourages interaction and collaboration, and participants feel involved because they are required to express themselves. It also offers the opportunity to get to know colleagues better, providing a different and more direct perception of what is happening in the company.

I believe that Scuola Kedrion is also an important means of social interaction, especially for people who have just come on-board. It is an aggregator that helps to build relationships, allowing people to showcase their skills and abilities.

> Cristina Pagliaccia, R&D Project Planning Manager, Kedrion Biopharma





## PRODUCT PORTFOLIO

### HEMATOLOGY / HEMOPHILIA

EMOCLOT/ PLASMACLOT\*\*\*\*/ Koāte-DVI\*/WILATE\*\*\* 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

NUWIQ\*\*\* Recombinant Factor FVIII concentrate from human cell line

### IMMUNOLOGY / NEUROLOGY

lg VENA/HUMAGLOBIN/KEDRIGAMMA/ Gammaked\*/GAMTEN\*\*\* Standard intravenous Immunoglobulin

NAXIGLO Standard subcutaneous 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

BIVIGAM\*\*\*\*\* Polyvalent 10% intravenous 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

KEYCUTE Standard subcutaneous Immunoglobulin

ALBITAL/KALBI Human Albumin solution

ATKED Antithrombin concentrate

PLASMAGRADE Pharmaceutical grade plasma

KLOTT Factor VIII/von Willebrand Factor concentrate

IXED Factor IX concentrate

KEDCOM Prothrombin Complex concentrate

KEDHBs Anti-hepatitis B intramuscular Immunoglobulin

VEBIKED

Anti-hepatitis B intravenous Immunoglobulin

product only available for the US market

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

<sup>\*\*\*\*</sup> product only available for the mexican market \*\*\*\*\* product for the US market only; no longer available

### RESEARCH & DEVELOPMENT

### FIGHTING AGAINST RARE DISEASES AND CREATING VALUE IN THE FIELD OF ORPHAN DRUGS

edrion Biopharma makes available a wide range of products, used in the treatment of rare and often serious diseases such as hemophilia and primary immunodeficiencies. For this reason, we are committed to developing new medicines and to improving existing ones.

Each stage of product development from basic research, and clinical pre-trial and trial phases, to Pharmacovigilance monitoring - pursues the same objective: to encourage innovation to improve, one step at a time - the quality of patients' lives.

One of our main priorities is our commitment to plasma-derived orphan drugs. To this end, in 2011 - in collaboration with the Fondazione Toscana Life Sciences in Siena - we set up a dedicated plant, the first of its kind in Italy and in Europe. The facility was renamed IKOD (Kedrion Orphan Drugs Plant) and, in October 2015, it was authorized to manufacture small batches of plasma-derived experimental therapies by the Italian Drug Agency (AIFA, Agenzia Italiana del Farmaco) for use in clinical studies. This achievement, together with



the Quality Control authorization obtained in May 2016, have made the Siena site completely independent insofar as the production and control of plasma-derived experimental therapies are concerned.

In recent years, the R&D department at IKOD has focused its efforts on the study of human Plasminogen concentrate. This product has obtained Orphan Drug designation in both Europe (from EMA, European Medicines Agency) and in the United States (from FDA, Food and Drug Administration). Now, our goal is to begin its commercialization by 2018.

In this field, we believe that research is an essential part of what we do. In the words of the father of an Italian child affected by Ligneous Conjunctivitis, who is now being treated with Plasminogen eye drops: 'Rare disease specialists at the Ospedale Bambino Gesù in Rome told us "you're in luck because your daughter's disease has a name and a therapy, whereas in this ward there are diseases that only have a number" ... we cannot turn the tap off on research'. Every day, we do our best to honor this commitment, especially with regards to extremely rare diseases that are still without a cure.

In terms of orphan drugs, in 2016 we made notable progress in the process of characterization and optimization of plasma Factor V to treat hemorrhaging in patients who are deficient in this factor. This project is particularly important to Kedrion because of its therapeutic value, and because it is the end result of a long collaboration - supported by the Regione Toscana - with national and international doctors, researchers, and public and private institutions.

This collaboration is also a tangible



demonstration of the extent to which sharing knowledge and skills benefits research; a practical example of the collaborative model we are developing in order to become a reference point for talented researchers working in the biotech industry, and for the communities in which we operate.

Our R&D department works closely with the Biological Safety Center (BioSC), the first laboratory in Italy to be awarded GLP (Good Laboratory Practices) certification for pathogen inactivation and removal studies in biological and biotechnological products by the Italian Ministry of Health. A true center of excellence that, in the course of 2016, proved to be essential in the startup phase of the 10% immunoglobulin (KIg10) project: at first, in the definition of the "Pathogen Safety Strategy", that is, the identification of the steps to be added to the production process to ensure compliance in terms of safety from product pathogen agents; and later in the preliminary investigation of the aforementioned steps.

For Kedrion, having internal access to a highly specialized laboratory such as the Biological Safety Center (BioSC) means being able to ensure extremely high safety and quality standards. It enables us to work completely independently, without having to rely on the services provided by external centers, which allows for faster and more effective processes.

Currently, Kedrion Biopharma is the only Italian company - and one of the few in Europe - that can pride itself with such a distinguishing feature. For this reason, BioSC has become - for any organization needing to carrying out viral validation studies on its processes and products - a national and international reference point for safety. In addition to which, the expertise gained over the years has enabled Kedrion, and its Pathogen Safety specialists, to become active players in those international working groups where key aspects for the safety of plasma-derived products are monitored and discussed.



### EXPANDING WORLDWIDE





## 2016 MILESTONES



#### **JANUARY** - PLASMA COLLECTION NETWORK EXPANDS: KEDPLASMA ACQUIRES TWO NEW CENTERS IN THE UNITED STATES

The two new plasma collection centers are located in Dothan (Alabama) and Hattiesburg (Mississippi) and were previously operated by ImmunoTek Bio Centers LLC.



#### JANUARY - SUPPORTING DONORS: NEW HEADQUARTERS FOR KEDPLASMA CENTER IN FÜRTH, GERMANY

Inaugurated on 14 January 2016, the headquarters are located on the second floor of the *Neue Mitte Fürth*, a newly constructed building in the historic city center.



#### **FEBRUARY** - SUPPORTING THE ITALIAN BLOOD SYSTEM: THE *KEDRION INCONTRA* PROJECT RESUMES

From donation to industrial processing, and to the final distribution of plasmaderived medicinal products: in February, our *Kedrion Incontra* plant visits resumed, aimed at increasing our stakeholders' awareness of the different milestones that make up plasma's "journey" from donor to patient.



#### **MARCH** - PATIENTS FIRST: CURHE CONSORTIUM KICK-OFF MEFTING

CURhE (Consortium for Universal Rh disease Elimination) held its inaugural and programmatic meeting at Stanford University, California. Members of the Global Alliance for the eradication of Hemolytic Disease of the Fetus and the Newborn (HDFN), which is strongly supported by Kedrion Biopharma, gathered to formulate a global strategic plan jointly with the International Federation of Gynecology and Obstetrics (FIGO) and the International Pediatric Association (IPA).



#### MARCH - HUNGARIAN SITES AWARDED OHSAS 18001 CERTIFICATION

Further to the positive outcome of the energetic diagnosis carried out on the production site in Gödöllő and on the central warehouse in Üllő, Human BioPlazma is awarded OHSAS 18001 certification. A result that confirms Kedrion's commitment to adopting the same environmental and health & safety standards in all company plants.

### **APRIL** - PRODUCT PORTFOLIO EXPANSION: HUMAGLOBIN LIQUID® LAUNCHED IN HUNGARY

The first liquid immunoglobulin made entirely from Hungarian plasma -HUMAGLOBIN LIQUID® - was officially launched in Budapest in the course of a dedicated symposium in which eminent world experts in the fields of immunology and neurology took part.





## 2016 MILESTONES



#### MAY - FIGHT AGAINST INHIBITOR DEVELOPMENT IN HEMOPHILIA: NEW ENGLAND JOURNAL OF MEDICINE PUBLISHES SIPPET STUDY RESULTS

Results of the SIPPET Study, the first multicenter, randomized and controlled study on hemophilia A are published by the prestigious journal edited by the Massachusetts Medical Society. The study addresses the key clinical issue of the role played in inhibitor development by the source of the replacement Factor VIII. The study was sponsored by the Angelo Bianchi Bonomi Foundation, with financial support from the Italian Ministry of Health and unrestricted grants from Grifols, Kedrion and LFB.



#### MAY - PLASMA COLLECTION CENTER NETWORK EXPANDS: KEDPLASMA OPENS 4<sup>TH</sup> CENTER IN HUNGARY

KEDPLASMA opens its 4<sup>th</sup> plasma collection center in Pécs, Hungary, at the end of May. The center has 15 donation beds, which it intends to increase to 40 over the next three years.



#### JUNE - INTERNATIONAL GROWTH: AGREEMENT WITH NACIMBIO E PHARMSTANDARD

Kedrion signs an agreement to relaunch the Russian plant in Kirov that will manufacture plasma-derived drugs. The deal with the Russian National Immunobiological Company (Nacimbio) was made the object of a memorandum signed in December further to Pharmstandard entering the joint venture. According to the agreement, the facility will be operational in 2019, once plant renovation, installation of new manufacturing equipment and all activities - including the transfer of experience, skills and technologies from Kedrion - have been concluded. The Kirov plant will process 600 tons of plasma per vear.



#### **JUNE** - PLASMA COLLECTION CENTER NETWORK EXPANDS: KEDPLASMA OPENS NEW CENTER IN THE USA

KEDPLASMA USA inaugurates its latest collection center in Gastonia, North Carolina. The new facility, which can accommodate up to 60 donors at a time, is run using the latest and most advanced technologies, such as Next Gen, a donor management web application.



#### **SEPTEMBER** - MAKING THERAPIES MORE ACCESSIBLE: FACTOR IX DONATION TO AFGHANISTAN

Kedrion - a long standing supporter of the Italian Regions' humanitarian projects - donates 115 thousand IU of Factor IX to the Kabul Hemophilia Center in Afghanistan, to help address the temporary shortage of coagulation factors need to treat 30 children suffering from hemophilia B. The children are being treated at the Hemophilia Center of the Esteqlal Hospital, in the Afghan capital.



#### **SEPTEMBER** - INNOVATION FOR PATIENTS: KEDRION SUPPORTS FEDEMO TO LAUNCH WEEMO FREE APPLICATION

Developed with Kedrion Biopharma's unconditional support, Weemo is the FedEmo free app designed for hemophilia patients and their families. It offers lifestyle suggestions aimed at improving their quality of life. The app can be download free of charge from http://weemo.fedemo.it.





### 2016 MILESTONES



#### **OCTOBER** - PATIENTS FIRST: "MY FIRST FACTOR" OR HEMOPHILIA SEEN THROUGH THE EYES OF A CHILD

The "My First Factor Creation" series of children's books is the result of Kedrion's long standing collaboration with LA Kelley Communications. The three books aim to help the young patients, and their families, learn to live with hemophilia. They are available in six languages - English, Russian, Turkish, Italian, Spanish and Hungarian - and can be downloaded free of charge from Kedrion's websites.



#### **NOVEMBER** - I FAVING EVERY PLACE BETTER THAN HOW WE FOUND IT: WE DONATE TO CHICAGO HOPES FOR KIDS

In keeping with our commitment to give back to the communities in which we operate, the *Kedrion Cares* program makes a donation to Chicago HOPES for Kids, an organization that provides educational support for children living in Chicago's homeless shelters



#### **NOVEMBER - MAKING** THERAPIES MORE ACCESSIBLE: CURHE ADVOCACY IN NIGERIA. MOROCCO AND RUSSIA

Kedrion supports the CURhE Consortium in the global advocacy and Rh disease awareness campaigns launched in Nigeria. Morocco and Russia. The goal is to ensure the widest possible access to prevention and treatment of this disease in order to eradicate the Hemolytic Disease of the Fetus and Newborn (HDFN).



#### **NOVEMBER - PRODUCT** PORTFOLIO EXPANSION: FDA ACCEPTS BLA SUBMISSION FOR NEW RABIES IMMUNOGLOBULIN DEVELOPED BY KAMADA AND **KEDRION**

The request for marketing authorization is based on the results of a clinical trial on 118 healthy subjects completed in December 2015. Following FDA approval, expected by August 2017, Kamada will retain the product license, whereas Kedrion will hold exclusive US marketing rights.



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### **DECEMBER** - MAKING THERAPIES MORE ACCESSIBLE: ALBANIA OFFICIALLY JOINS THE WISH HUMANITARIAN PROGRAM

Albania becomes a part of the WISH humanitarian program following a meeting in Tirana between the Albanian Health Minister, and representatives of the Regione Toscana and Regione Umbria, and of the Italian National Blood Center. The Albanian Health System now has access to coagulation Factor concentrates - for the treatment of the country's hemophilia patients manufactured from plasma collected from Italian donors.



### **DECEMBER** - LEAVING EVERY PLACE BETTER THAN HOW WE FOUND IT: SUPPORTING HOSPITALS IN BUDAPEST

Kedrion and KEDPLASMA employees donate plasma in Hungary, and the remuneration collected – increased by an additional corporate contribution - is donated to the Szt. Làszlò - Szt. Istvàn e Heim Pàl hospitals in Budapest. Funds are used funds to purchase technical equipment and to buy toys for young patients.

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### **BUILDING BRIDGES**



### **DONORS**:

*II* ponating plasma is more than just saving lives. It's changing them - says Autumn Clifton, a college student who donates at a KED-PLASMA center in Mobile, Alabama, USA. Knowing in my mind that my donation not only saves people, but also changes the way they look at life is why I choose to be a donor."

To carry out our mission at Kedrion Biopharma, we rely on the thousands of people who are willing to donate plasma, the raw material we turn into life-saving and life-enhancing therapies. Our donors come from all walks of life; they are young and old, urban and rural - diverse in almost every way. What they have in common is the desire to help others. Even in the US, where donors receive a small compensation for their time and effort, altruism remains a major motivating factor.

Mildred Benton donates twice a week in our new facility in Gastonia, North Carolina, USA. So do her three sons and daughter. So do her daughter-in-law and her son's girlfriend. "I tell them, 'Don't think about the money; think about the people you are helping. We're not doctors, but we can help people feel better."

We owe it to our donors to make the donating experience as safe, efficient and comfortable as possible.







### THE FOUNDATION OF OUR WORK

"I actually look forward to going," says Mildred. "The staff is super nice. They explain everything to you and take care of anything you need. And the facility is super clean and comfortable."

This attention to the comfort of our donors helps to explain why collection in the US increased by 26% in 2016. Some of that increase is also due to the addition of five new centers, including the one in Gastonia. Increases were also noted in Germany (+13%) and Hungary (+20%), where a new center was opened in the southern city of Pécs.

Opening and improving centers accounted for much of the 15 million Dollar investment made in 2016, in KEDPLASMA. Significant expansion of our plasma collection potential is a major constituent of our projected business activities.

In addition to adding collection centers,

we are committed to continued increase in collected plasma volumes, enhanced efficiencies and cost reduction, and the development of long term strategic partnerships. A major element of our growth depends on recruiting and retaining a strong and talented workforce, and in the next few years we plan to invest heavily in the search for new professionals to join Kedrion Biopharma's Plasma Business Unit.

In Italy, our historic partnership with the national Blood System allows us to keep being a significant and reliable supplier of plasma products. In 2016, we continued to support and collaborate with donor associations and federations: fostering public campaigns to raise general awareness of the need to donate blood and plasma; working to extend general knowledge of "plasma's journey (from donor to patient)" by welcoming our stakeholders - as part of the much appreciated *Kedrion Meets* program - into our production plant in Bolognana; contributing to offer specific educational paths to young donors - like we did with Scuola AVIS - so as to provide them with the best possible tools to take over and carry the Italian donor community into the future.

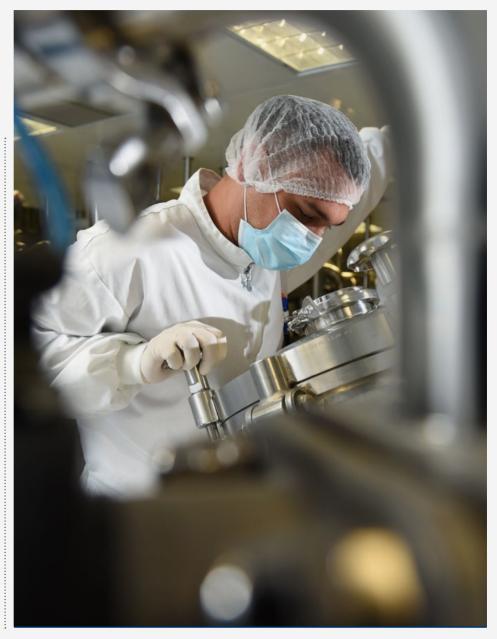
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### **INDUSTRY**:

t Kedrion, we like to think of ourselves as people who help to build bridges: bringing donors and the people benefitting from their donations together in a growing community; creating pathways from donation to research, from product development to the relief of suffering.

Each day in our manufacturing plants in Italy, in Hungary and in the United States we welcome the challenge to maintain the highest standards of industrial excellence; to establish leadership in the domestic market while expanding our global presence. And whilst, on the one hand, Kedrion actively promotes the distribution of its plasma-derived therapies abroad, on the other it is committed to transferring its expertise, know-how and technology, so as to create value for the health systems of other countries that are pursuing self-sufficiency in plasma collection and fractionation. With this is mind, in 2016, we entered into a partnership with the Russian National Immunobiological Company (Nacimbio, Rostech Group) and Pharmstandard to re-launch the Kirov plasma-derived therapies manufacturing plant. In 2019, when the renovation of the plant is completed, new manufacturing equipment is installed, and all the ope-







rations included in Kedrion's technology transfer have been implemented, the plant will be able to process 600 tons of plasma a year. Kedrion will transfer its know-how to the Russian legal entity JSC Kirov Plasma, in which Kedrion S.p.A., Nacimbio and Pharmstandard are joint shareholders.

In 2016, the company invested heavily in its more strategic projects, and to continue its Research & Development activities – all with the aim of creating value for the communities in which we operate. For instance, we started work on the complete renovation of the plant in Melville (USA) thanks to an investment – which will continue throughout 2017 – to achieve its full integration with the other Kedrion facilities. These same principles apply to the investments – almost completed in respect of the engineering phase (to be followed by the validation, inspection and regulatory phases) – in the new anti-D

immunoglobulin (RhoGAM<sup>®</sup>) fractionation and purification line at the Melville plant, and the purification line of 10% immunoglobulin (Klg10) with the chromatographic method at the plant in Castelvecchio Pascoli (Italy). Kedrion further strengthened its position as a leading player in the global pharmaceutical industry.

In Italy, for instance, we took part in events including "The future of the Italian health system. Challenges and opportunities", organised in September by the Aspen Institute, during which our CEO delivered a presentation illustrating his industry-owner perspective, and two institutional events, held in Florence and Siena, in which we represented Farmindustria and were invited to speak about our commitment to research and to the life sciences.

At a Regional level, in Italy, we took on larger roles in both education and research, by supporting the two-year life sciences vocational courses organized by the "Fondazione VITA. Istituto Tecnico Superiore per le Nuove Scienze della Vita", and the Biochemistry and Molecular Biology doctoral degree program run by the University of Siena, which we believe to be of great scientific value, and fully in line with the projects and activities our company is currently pursuing.

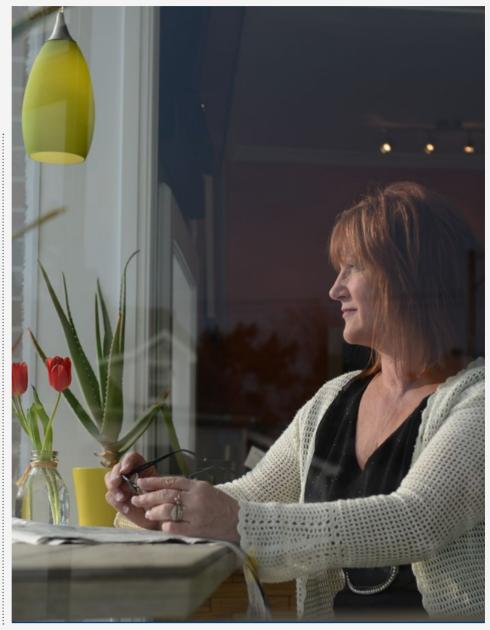


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### **PATIENTS**:

or Kedrion, growing means reaching out to an increasing number of patients across the world, by extending access to plasma-derived therapies wherever there is an unmet need. In 2016, we renewed our commitment to support local communities and the health systems of countries worldwide, and to raise patients' and physicians' awareness of diseases and the therapies available for their treatment, carrying out training and educational activities jointly with patients' associations and key opinion leaders.

In 2016, we yet again experienced very positive growth figures. Alongside the United States (+17.6% sales on 2015), Italy represents the foundation of our business. In Italy, in 2016, turnover reached an all-time high (167.5 million Euro, or +14%), mainly thanks to the remarkable rise in the volumes of plasma fractionated on behalf of the Regions we work for as contract manufacturers. The collection of plasma for contract fractionation is in fact growing again (+3.1% on 2015, and in line with the average growth of the previous decade), mostly thanks to the increased volumes of apheresis-donated plasma (approximately 7% more than in 2015) resulting from a change of direction operated by the entire







Italian Transfusion System. By reacting – to revert this downward trend – consequences that could have negatively affected the achievement of plasma-derived products national self-sufficiency have been avoided. Exchanges of plasma-derived medicines between Regions, which have finally become true thanks to recent legislation and are now ratified by the "Piano Plasma 2016-2020", have also contributed to achieving this objective.

2016 was the year in which the Italian market opened. Kedrion is ready to compete in this new national scenario, as it continues to pursue the Italian Blood System's strategic objectives. In the course of the year, all stakeholders – but especially donors – encouraged discussion and debate on the topic of recent legislation changes: opportunities to do so included the IFBDO Congress in the Vatican City

("Plasma-derivatives and self-sufficiency: which outlooks for Europe?"), and the Second Interregional Workshop held during the Health Festival that took place in Montecatini (Pistoia, Italy), organized by the Regione Toscana with the aim of providing the Italian Regions with a setting in which to compare their respective experiences of this shift. In the course of this last event, the Italian Transfusion System's merit, and the importance of the ethical principles underlying it, were restated.

Kedrion has also experienced remarkable growth in other EU countries (+36.5%), and in the Rest of the World (+6.3%). Germany, in particular, continued the positive trend first seen in 2015, confirming itself as the fastest growing country followed by Portugal. In addition to which, Kedrion relaunched its activities in India, and consolidated its commercial presence in Mexico, Russia and Turkey (through Kedrion Betaphar), despite these countries' weak local currencies.

In 2016, we upheld our commitment to support projects and initiatives that help create value for the communities in which we work. These include CURhE, the Consortium for Univer¬sal Rh-disease Elimination, developed jointly with world-class research centres and international companies, for the global eradication of the Haemolytic Disease of the Fetus and Newborn (HDFN).

"In Nigeria, where infant mortality is extremely high, less than 40% of women avail themselves of official health care and are fortunate enough to have access to a hospital; even fewer are covered by any form of insurance whatsoever", explains Prof. Angela Okolo, Distinguished Pediatri-



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cian for Africa in 2013. "Neonatal jaundice is a major problem: almost 6 million children are born every year in this country, but 6-7% of mothers are Rh negative and therefore at risk of developing Hemolytic Disease of the Fetus and the Newborn." To reach those in need of treatment, Kedrion is partnering the CURhE Consortium in the launch of a new blood group-screening program, in relation to which several Nigerian regional administrations have already expressed an interest in starting their own pilot projects.

As mentioned earlier, Kedrion is also committed to supporting patient associations in raising patients' awareness of specific diseases, working to broaden and improve knowledge of the plasma-derived treatments available by taking part in dedicated events, such as the Congress of the European Society for Immunodeficiencies (ESID), which in 2016 took place in Barcelona. "I decided to bring my disease and my artistic talent together – said 18 years old Dominik Skiba, the creator of ImmunoWorld, a comic strip that aims to offer a scientific explanation of immunodeficiencies that is also simple, and direct, whom we met at the ESID event – to create something that will help other children improve their understanding of immunodeficiency related problems."

Kedrion is proud to partner Dominik, the International Patient Organization for Primary Immunodeficiencies (IPOPI) and the Jeffrey Modell Foundation (JMF), in their daily efforts to help Primary Immunodeficiency (PID) patient communities.

And it is always ready to support projects that work to raise awareness, such as the re-issue of the "My First Factor" children's book series on hemophilia, published by LA Kelley Communications, and now available worldwide in six different languages; or such as the "Weemo" web app developed with FedEmo (the Federation of Italian Hemophilia Patients' Associations) to provide digital support to all Italian hemophilia patients and their families, helping improve the quality of their lives.



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## RELEVANT EVENTS OF THE YEAR

he significant revenue growth experienced during the 2016 fiscal year was supported by an increase in the volume of available plasma, due to a rise in the volumes of plasma collected, and by a decrease - resulting from the plant's shutdown for revamping operations - in the volumes of plasma processed at the Melville plant (USA). These factors allowed the plasma segment to jump from 9.6% to 21.5% of our total turnover, amounting to a 157% increase, compared to the previous year. On the other hand, the plasma-derivative segment grew by just 1.1% as a result of the limited availability of the US plant, offset - in the last months of the year - by outsourcing production to a third-party fractionator.

During the fiscal year, sales prices were characterized by a significant increase in the plasma segment and an overall stability in plasma- derivatives. In the latter segment, the US market registered an upward trend, whereas markets such as Russia, Mexico and Turkey suffered significantly due to the weakness of their local currencies.

Analyzing our final markets, it is the steady growth of our turnover in the US, the industry's main market, stands out. The US consolidated its position - ahead of Italy, Kedrion's historical market - as the company's most important market, primarily thanks to the plasma segment's very positive performance. This is the direct result of an ongoing internationalization process, aimed at strengthening Kedrion's presence on all major international markets. The excellent results achieved in other important markets such as Germany, Russia, Austria and Mexico, are consistent with this process of internationalization that, in 2016, has resulted in exports to accounting for 74.6% of our total turnover.

Furthermore, during the 2016 fiscal year, Kedrion continued to pursue additional operating efficiencies by increasing the amount of plasma collected directly in the centers it owns (it is more economical to collect plasma than it is to purchase it from third parties), and by proceeding in the internalization of key production processes that had previously been outsourced.

Insofar as the plasma segment is concerned, we signed an important new agreement to double the number of Kedrion owned centers in the US, which has already resulted in major investments in the course of 2016, the most significant being the purchase of two new centers at year end.



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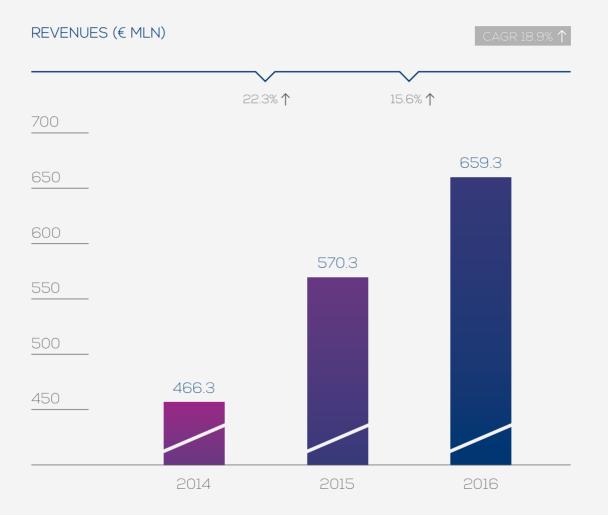
With regards to production, the Melville plant renovation project got underway. The facility is expected to be operational again in the last guarter of 2017. The restructuring calls for a total investment of approximately 100 million Dollar. It will be carried out between this fiscal year and the next one, with the aim of achieving the integration and harmonization of this plant with the other Kedrion group facilities, so as to increase industrial optimization and further improve production synergies.

These principles have also guided the investments - almost completed in respect of the engineering phase (validation, inspection and regulatory phases will follow) - in the new anti-D Immunoglobulin (RhoGAM<sup>®</sup>) fractionation and purification line at the Melville plant, and in the 10% immunoglobulin (Klg10) chromatographic method purification line at our site in Castelvecchio Pascoli (Italy). The shutdown of the plant in Melville will inevitably result in the late start of both projects.

Financial coverage of these investments was obtained through the issue of a Euro 300 million Eurobond in April 2014, which - during financial restructuring carried out in the 2015 fiscal year - was partially repurchased against a new credit facility. In addition to which, during 2016, the new Euro 90 million credit facility (detailed in the financial section of this report) was secured, from a pool of banks, to partially meet the financial requirements of the Melville renovation project.

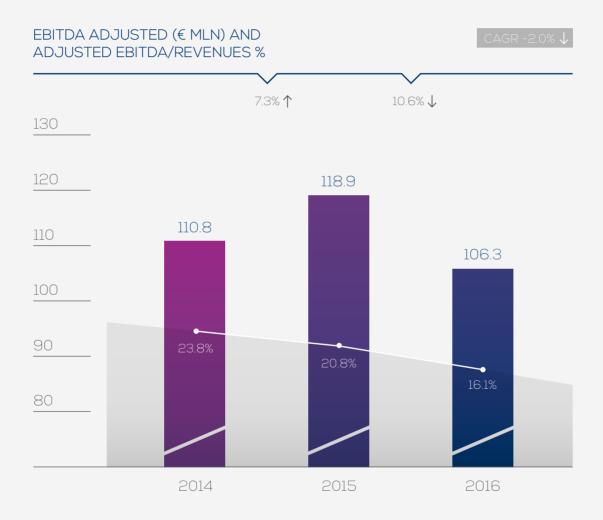






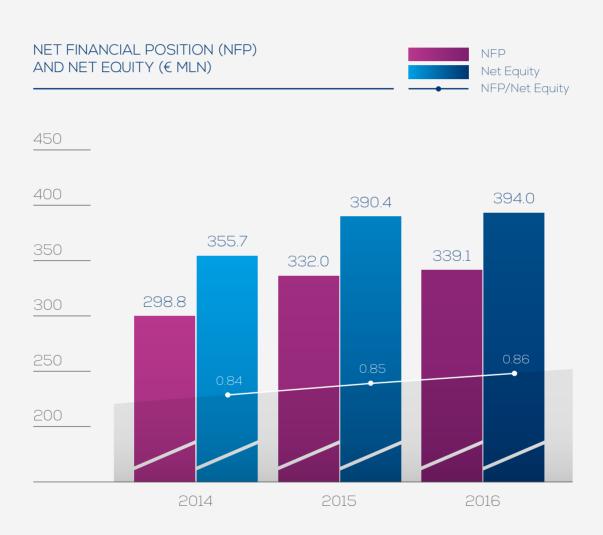








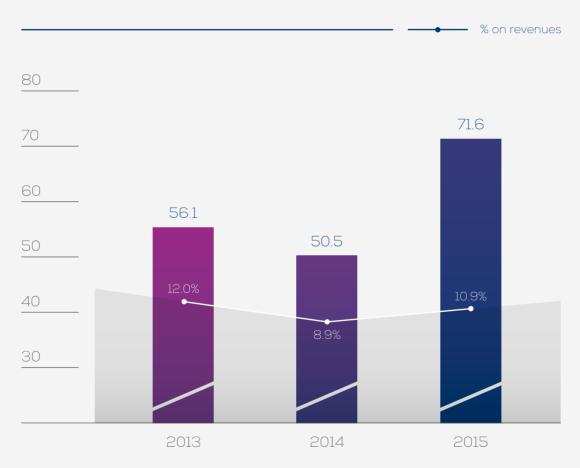




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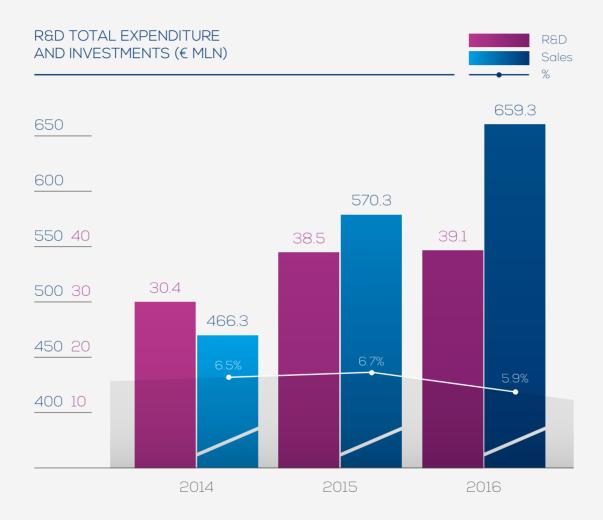


## NET INVESTMENTS (€ MLN)













## USA

After entering the US market in mid-2011, following a strategic agreement with a third party, and after the acquisition in August 2012 of RhoGAM® - the first anti-D immunoglobulin registered in the US and a market leader - turnover for this country has continued to grow, reaching Euro 297 million and registering a 17.6% increase on the previous year. The US consolidated its position as the company's main market, accounting for 45.1% of total revenues. Plasma sales were the fiscal year's main growth drivers, followed by standard Immunoglobulin, growing steadily thanks to Bivigam<sup>®</sup>, a product obtained in distribution from Biotest\*. Conversely, anti-D immunoglobulin (Rho-GAM®), Factor VIII and Albumin sales declined compared to the previous year, mainly due to the shutdown of the Melville plant. In addition to plasma-derivatives sales, US turnover also includes revenues from third party contract manufacturing carried out in Melville.

## ITALY

Figures at 31 December 2016 show that the Italian market grew by 14.0% compared to the previous year, reaching a turnover of Euro 167.5 million or 25.4% of total revenues. This was achieved thanks to sales of finished products and contract manufacturing for the Italian National Health System. The increase compared to the previous year is mainly due to the higher volumes of plasma fractionated for the Italian National Health System.

## EUROPEAN UNION

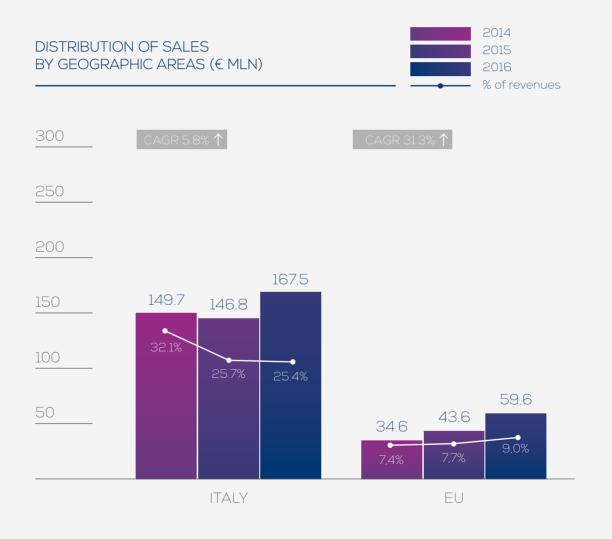
European Union revenues at 31 December 2016 amounted to Euro 59 million, representing 9% of total earnings and a 36.5% increase compared to the previous year. This positive result was achieved primarily thanks to Kedrion International sales in Germany, Poland, Austria and Portugal, and to Human BioPlazma sales in Hungary and Germany. In 2016, our main European markets were Germany, Poland, Hungary, Austria and Portugal.

## REST OF THE WORLD

This geographic area's revenues at 31 December 2016 amounted to Euro 134.9 million, or a 6.3% growth on 2015 accounting for 20.5% of total turnover. In terms of sales, Turkey strengthened its leadership thanks to the availability of a complete product portfolio, closely followed by Mexico. Both countries, however, suffered the weakness of their local currencies. Together with Russia, Vietnam, Iran, Israel and India, they account for 65% of this area's total revenues.

\* This footnote refers to an event that took place in the fiscal year 2017. It is included in this chapter because of its relevance: Due to unexpected difficulties in the manufacture of Bivigam<sup>®</sup> encountered by Biotest Pharmaceuticals Corporation, the agreement for distribution rights of Bivigam<sup>®</sup> in the United States between Biotest and Kedrion Biopharma has been terminated. Bivigam<sup>®</sup> is no longer available for sale or distribution in 2017.















## CONSOLIDATED INCOME STATEMENT (IN THOUSANDS OF EURO)

YEAR ENDED AT 31 DECEMBER

2016

	LOIO
Revenues from sales and services	659,349
Cost of sales	469,927
GROSS OPERATING MARGIN	189,422
Other revenues	5,827
General and administrative expenses	83,085
Sales and marketing expenses	50,836
Research and Development expenses	33,089
Other operating costs	8,447
OPERATING RESULT	19,792
Financial charges	20,560
Financial incomes	11,296
RESULT BEFORE TAX	10,528
Income taxes	(1,230)
NET RESULT FOR THE PERIOD	11,758
OF WHICH:	
GROUP RESULT	10,722
MINORITIES RESULT	1,036

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OTHER COMPREHENSIVE INCOME (IN THOUSANDS OF EURO)	YEAR ENDED AT 31 DECEMBER
PROFIT FOR THE PERIOD	11,758
OTHER COMPREHENSIVE INCOME TO BE RECLASSIFIED TO PROFIT OR LOSS IN SUBSEQUENT	PERIODS:
Net movement on cash flow hedges	(560)
Income tax effect	105
	(455)
Exchange differences on translation of foreign operations	4,536
	4,536
NET OTHER COMPREHENSIVE INCOME TO BE RECLASSIFIED TO PROFIT OR LO SUBSEQUENT PERIODS	955 IN 4,081
OTHER COMPREHENSIVE INCOME NOT TO BE RECLASSIFIED TO PROFIT OR LOSSI N SUBSEQUPERIODS:	JENT
Re-measurement gains (losses) on defined benefit plans	(194)
Income tax effect	42
	(152)
NET OTHER COMPREHENSIVE INCOME NOT TO BE RECLASSIFIED TO PROFIT C	PR LOSS (152)
OTHER COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX	3,929
TOTAL COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX	15,687
EQUITY HOLDERS OF THE PARENT	14,651
NON-CONTROLLING INTERESTS	1,036

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## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

## YEAR ENDED AT 31 DECEMBER

(IN THOUSANDS OF EURO)

2016
------

NON CURRENT ASSETS	
Property, plant and equipment	210,012
Investment property	2,445
Goodwill	218,979
Fixed term intangible assets	58,330
Investments in other companies	2,382
Other non current financial assets	6,539
Deferred tax assets	8,708
Other non current assets	1,159
TOTAL NON CURRENT ASSETS	508,554

## CURRENT ASSETS

	1044 575
Assets held for sales	12,468
TOTAL CURRENT ASSETS	523,553
Cash and cash equivalents	66,510
Other financial current assets	111
Other current assets	30,748
Current tax credits	9,248
Trade receivables	136,056
Inventories	280,880

1,044,575

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### CONSOLIDATED STATEMENT OF FINANCIAL POSITION YEAR ENDED AT 31 DECEMBER (IN THOUSANDS OF EURO) 2016 GROUP SHAREHOLDERS' EQUITY Share capital 55.186 325.568 Reserves Group net income 10.722 TOTAL GROUP SHAREHOLDERS' EQUITY 391.476 MINORITIES SHAREHOLDERS' FOULTY Minorities capital and reserves 1.481 Minorities net income 1.036 TOTAL MINORITIES SHAREHOLDERS' EQUITY 2.517 TOTAL SHAREHOLDERS' EQUITY 393.993 NON CURRENT LIABILITIES Medium/long-term debt 355.557 Payables to banks and other lenders 801 Provisions for risks and charges 652 Payables for employee benefits 5,157 Other non current liabilities 6.706 TOTAL NON CURRENT LIABILITIES 368.873 CURRENT LIABILITIES Payables to banks and other lenders 37,031 Current portion of medium/long-term debt 18.856 Provisions for risks and charges 3.487 Trade payables 162.586 Current tax payables 2.027 Other current liabilities 57.722 TOTAL CURRENT LIABILITIES 281,709 TOTAL LIABILITIES 650.582 TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES 1,044,575

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## CONSOLIDATED CASH FLOW STATEMENT (IN THOUSANDS OF EURO)

YEAR ENDED AT 31 DECEMBER

2016

	2010
Net cash flow generated by operating activities (A)	80,879
Net cash flow absorbed by investment activities (B)	(65,130)
Net cash flow generated / (absorbed) by financing activities (C)	(8,462)
TOTAL NET CASH FLOW D=(A+B+C)	7,287
Cash and cash equivalents opening balance (E)	59,208
Net effect of conversion of foreign currencies on cash and cash equivalents (F)	14
CASH AND CASH EQUIVALENTS CLOSING BALANCE G=(D+E+F)	66,508

CASH AND CASH EQUIVALENTS CLOSING BALANCE G=(D+E+F)







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Independent auditor's report in accordance with articles 14 and 16 of Legislative Decree n. 39, dated 27 January 2010

(Translation from the original Italian text)

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

#### Report on the consolidated financial statements

We have audited the accompanying consolidated financial statements of Kedrion S.p.A. (together with Its subsidiaries "Kedrion Group"), which comprise the statement of financial position as at 31 December 2016, 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 for the year then ended, and a summary of significant accounting policies and other explanatory information.

#### Directors' responsibility for the consolidated financial statements

The Directors of Kedrion S.p.A. are responsible for the preparation of these consolidated financial statements that give a true and fair view in accordance with International Financial Reporting Standards as adopted by the European Union as well as with the regulations issued to implement article 9 of Legislative Decree n. 38, dated 28 February 2005.

#### Auditor's responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with International Standards on Auditing (ISA Italia) implemented in accordance with article 11, paragraph 3 of Legislative Decreen. 39, dated 27 January 2010. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's professional judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation of the consolidated financial statements that give a true and fair view in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriates of accounting policies

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used and the reasonableness of accounting estimates made by Directors, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

#### Opinion

In our opinion, the consolidated financial statements give a true and fair view of the financial position of Kedrion Group as at 31 December 2016, and of its financial performance and its cash flows for the year then ended in accordance with International Financial Reporting Standards as adopted by the European Union as well as with the regulations issued to implement article 9 of Legislative Decree n. 38, dated 28 February 2005.

#### Report on other legal and regulatory requirements

Opinion on the consistency of the Report on Operations with the consolidated financial statements

We have performed the procedures required under audit standard SA Italia n. 720B in order to express an opinion, as required by law, on the consistency of the Report on Operations and of its corporate governance section, solely for the information included therein in compliance with art. 123bis of Legislative Decree n. 58/1998, paragraph 2, letter b), with the consolidated financial statements. The Directors of Kedrion S.p.A. are responsible for the preparation of the Report on Operations and of its corporate governance section in accordance with the applicable laws and regulations. In our opinion the Report on Operations and the specific information included therein in compliance with art. 123-bis of Legislative Decree n. 58/1998, paragraph 2, letter b), presented in the specific section of the Report on Operations, are consistent with the consolidated financial statements of Kedrion Group as at 31 December 2016.

Florence, April 12<sup>th</sup>, 2017 EY S.p.A. Signed by: Lapo Ercoli, partner

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



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