



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

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ANNUAL REPORT

2 0 1 7

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ANNUAL REPORT

**2 0 1 7**

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# LETTER FROM PAOLO MARCUCCI



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# LETTER FROM PAOLO MARCUCCI

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**WE ENDED 2017 WITH A TURNOVER OF 602.5 MILLION EURO, DOWN 8.6% ON 2016, WHEREAS OUR ADJUSTED EBITDA GREW STEADILY FROM THE PREVIOUS YEAR'S 106.3 MILLION EURO TO 139.9 MILLION EURO. PROFITABILITY ROSE TOO, FROM 16.1% IN 2016 TO 23.2%, AND THE INCREASE IN EBIT WAS FROM 19.8 MILLION EURO IN 2016 TO 51.6 MILLION EURO IN 2017.**

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These results should be read in the context of a three-year period (from 2016) during which one of the main challenges to arise was the total refit of our Melville plant, in the United States. The investments undertaken, totaling 54.1 million Euro in 2017, aim to integrate this site fully into the Kedrion global manufacturing network. Construction work has ended and, in late 2017, the final stage of the project got underway: in 2018, in fact, it is expected that the plant will be granted the necessary regulatory approvals to become fully operational. The work carried out on the plant in the last few years has strengthened – at a global level – both our production and logistical organizations, while also growing Kedrion's technical and managerial expertise. These wide-ranging achievements will continue to create value for many years to come.

In the United States – for some years now our largest market in terms of turnover – our efforts have concentrated, on the one hand, on clawing back market share from our competitors in the Immunoglobulin segment and, on the other, on completing the reorganization of our network of plasma collection centers. I would like to restate the company's commitment to executing a plan that will ensure the long term continuity of supplies, and the quality and quantity of the vital material that raw plasma is, so as to meet the therapeutic needs of the largest possible number of patients across the world.

We registered a positive performance on the Italian market, both for Contract Manufacturing as well as commercial operations. Throughout 2017 Kedrion continued to play a central role in Italy's National Blood



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System, and submitted bids for the regional tenders that, to date, have been called.

In addition, the company consolidated or expanded its commercial presence in other markets – chief among these Austria, Germany, and Mexico – and also secured 23 new registrations for its products in 16 countries.

With regards to Research & Development (R&D), we intensified the activities of our facility in Siena, where the production of Plasminogen – one of our main new product development projects – is carried out. By the end of 2017, research staff had increased to 114 (+42.5% on the previous year), in line with the plan we launched in 2016 to provide Kedrion with a Research & Development team capable – for size and characteristics – of supporting the company’s growth ambitions. The R&D department is also an integral member of our internal Process and Product Development Committee (PPDC) that, in keeping with the “continuous improvement” approach, seeks to optimize manufacturing processes and improving products and yields management, while also rationalizing and curbing operating costs.

In 2017 we expanded and further advanced the specialization of our Medical Affairs, with a view to broadening the scientific support it provides to other departments, especially to those working at the development of new products, and are looking for the best possible uses for existing products.

In financial terms, the most important event of 2017 was our 350 million Euro bond issue in July. In the months leading up to it, we assessed market conditions reaching the conclusion that the time was right to streamline our financial structure. We initially targeted a 300 million Euro bond issue; however, following an extensive European road show and the opening of subscriptions, we drew in bids for over 700 million Euro and decided to increase the size of the bond issue to 350 million Euro. At the same time, Kedrion successfully completed another financial transaction: the repurchase, by means of a tender offer, of most of the

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outstanding notes of its 300 million Euro bond issued in 2014. Lastly, I would like to mention that in 2017 we took part in a number of meaningful initiatives in support of the communities we operate in, and of our main stakeholders, including donor and patient associations, Universities and Research centers, institutions and industry organizations, and the scientific community.

Two of these, in my opinion, were especially notable: in May, we hosted the Farindustria (national association of pharmaceutical companies) event “Innovation and Production of Value” at our Italian facility in Bologna; in the same month, with the Fondazione Carlo Erba, Milan, we established two awards in memory of Guelfo Marcucci.

The young Italian graduates specializing in non-oncology hematology who won the first edition are currently working on innovative research projects, and we look forward to awarding the “Guelfo Marcucci” bursaries again in 2018. These awards are one of the ways in which Kedrion promotes, at the same time, the values of tradition and innovation.

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**Paolo Marcucci,**  
*Kedrion Chairman and CEO*



# COMPANY OVERVIEW



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# WHO WE ARE

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KEDRION BIOPHARMA IS AN INTERNATIONAL COMPANY THAT PRODUCES AND DISTRIBUTES PLASMA-DERIVED MEDICINAL SPECIALTIES 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.

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Founded in Italy in 2001, Kedrion has continually expanded its activities globally. Today, the company has almost 2,500 employees, a commercial presence in some 100 countries, and is the fifth largest producer of plasma-derived therapies in the world, and first in Italy.

We manage the entire process from plasma collection to therapy production to product distribution. KEDPLASMA collection centers are located in the United States, Germany and Hungary and production plants operate in the United States, Hungary and Italy. Our product portfolio is distributed worldwide.

In Italy, Kedrion Biopharma has long been a partner of the Italian National Health System as it pursues national self-sufficiency in plasma derived products. We offer our special expertise and technologies to other countries, communities and healthcare systems around the world, similarly helping them to become less dependent on outside sources for plasma-based therapies.

Kedrion Biopharma builds bridges: from donor to patient; from plasma to innovative treatments; from despair to relief; between the communities we serve and where we work.

People are at the core of Kedrion's activities and all our policies and behaviors are shaped by the determination to play a positive role in the lives and communities we touch.

Our ultimate goal is to expand patient access to plasma-derived therapies worldwide to serve those suffering from rare diseases.



PARTNER IN THE SELF-SUFFICIENCY PROGRAM IN ITALY

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**6\*** MANUFACTURING PLANTS IN **3** COUNTRIES

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**24** PLASMA COLLECTION CENTERS WORLDWIDE

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COMMERCIAL PRESENCE IN APPROXIMATELY 100 COUNTRIES

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2017 TURNOVER:  
**602.5 MILLION EURO**

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PEOPLE: ANNUAL INCREASE SINCE 2010: **10.78%**

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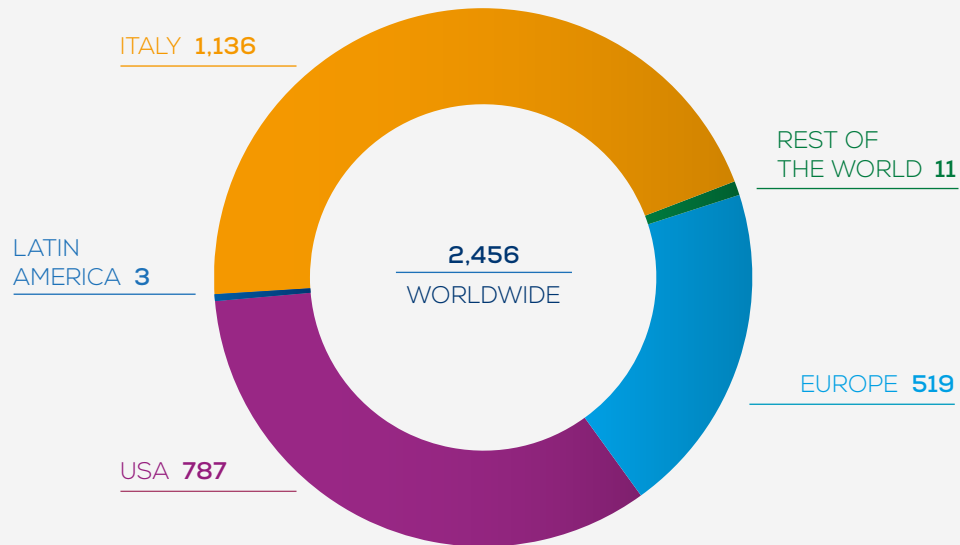


HEADQUARTERED IN ITALY WITH SUBSIDIARIES IN EUROPE, USA, LATIN AMERICA AND ASIA.

*\* The completion of our plant in Castelvecchio Pascoli, Lucca (Italy) is still ongoing*

# WHO WE ARE

## PEOPLE



MEN **1,214**  
WOMEN **1,242**



UNDER 35 **38%**  
OVER 35 **62%**



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



ANNUAL GROWTH RATE SINCE 2010: **13.5%**



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

# VISION

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**OUR MISSION IS TO BUILD BRIDGES: FROM DONOR TO PATIENT; FROM PLASMA TO TREATMENT; FROM RESEARCH TO INNOVATION. BRIDGES CONNECT PEOPLE AS WELL AS CONCEPTS AND OUR BUSINESS IS MOST FUNDAMENTALLY ABOUT PEOPLE CONNECTING TO AND HELPING OTHER PEOPLE.**

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All the Kedrion Biopharma community - in our collection centers and laboratories, in our plants and offices, our worldwide representatives – are all dedicated to this powerful idea that we can, together, help bridge the difficult waters that others face. We aspire to do this with the highest integrity, the broadest responsibility and the deepest respect for the values of the communities in which we work.

For us this means

- Ensuring that the people who work at Kedrion Biopharma are treated with care and respect; that they are compensated fairly and that they

# VISION

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- are supported and encouraged to pursue growth and advancement
- 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 corporate social responsibility is a prominent consideration in all business transactions and decisions
- Encouraging all partners and collaborators to observe socially and environmentally responsible practices and contractually obliging them to conform to our social responsibility principles.

In addition to our own ideals, principles and goals, we are guided by these CSR Standards and Certifications:

- 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.

Kedrion Biopharma cooperates with patient and donor organizations, providing them with information, practical support and expertise, and collaborating in projects that can make a difference.

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# GROWING COMMUNITIES

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**THE MOST IMPORTANT BRIDGES WE CAN BUILD ARE TO AND BETWEEN THE COMMUNITIES WITH WHICH WE WORK: DONORS, PATIENTS, FAMILIES, HEALTHCARE WORKERS, AND RESEARCHERS AND EMPLOYEES. WE ASPIRE TO GOOD CITIZENSHIP AT ALL LEVELS OF OUR ACTIVITY, LOCAL TO GLOBAL.**

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In line with this vision, in 2017 we continued to support research initiatives and medical and scientific training, as well as volunteer activities and projects aimed at protecting human rights. In Italy, among others, we supported:

- Fondazione Veronesi (Advancement of Science initiative)
- Fondazione IRCCS Ca' Granda (MYVIP project)
- AICE - Associazione Italiana Centri Emofilia (Italian Association of Hemophilia Centers) (scholarship for young people)
- AISF - Associazione Italiana per lo Studio del Fegato (Italian Association for the Study of the Liver) (medical and scientific

# GROWING COMMUNITIES

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- professional development)
- University of Palermo - DICHIRONS department (contribution for a scholarship in hematology)
- University of Tor Vergata, of Rome (support for a Master's Degree in Advanced Pediatric Allergy and Immunology)
- Local volunteer associations (support for their activities).

We also offered our support to donor and patient associations, foundations and non-profit organizations working in our sector, among which:

- Jeffrey Modell Foundation (activities and support in favor of the JMF center at the Meyer Children's Hospital in Florence, Italy)
- FedEmo (the Federation of Italian Hemophilia Patients' Associations)
- Italian donor associations: AVIS, FIDAS, FRATRES (activities and special events)
- IFBDO (International Federation of Blood Donor Organizations)
- AMARE - Associazione Abruzzese Malattie Rare Ematologiche ("Information, assistance and awareness point" project).

Our contribution to local communities goes beyond cooperation with bodies and institutions: it also translates into neighborhood initiatives that we personally carry out to bring relief to those living in disadvantaged circumstances.

It was in this spirit, for example, that Kedrion decided to support the City Rescue Mission (CRM) of Jacksonville, Florida, in the United States, in assisting the homeless and other people in need, and the students of the LifeBuilder addiction recovery association.

Moreover, following the devastating damages caused by Hurricane Harvey in the Southern States, KEDPLASMA USA – that owns many collection centers in the stricken areas, and whose headquarters are in Atlanta, Georgia – decided to support the local population with its "Pay It Forward" initiative, by which it collected substantial cash donations from employees, plasma donors and all those willing to help the many people who lost their homes.

# GROWING COMMUNITIES

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Lastly, in November, a US Kedrion team cycled more than 250 kilometers as part of “Gears for Good”, a charity bike race that the Hemophilia Federation of America’s “Helping Hands” program sponsors every year to raise funds for children affected by coagulation disorders.

In 2017, Kedrion also confirmed its commitment to ethical and transparent projects in aid of underprivileged countries, to ensure a wider and more sustainable access to plasma-derived therapies for those in need. It did so by working together with the Italian Regions to deliver medicines to Serbia, Albania, Armenia, India and Afghanistan.

While realizing that relations with the communities in which we operate must necessarily respect local distinctive traits, one of our objectives for the future is to standardize, across the company, the Corporate Social Responsibility initiatives in which we are involved, so as to maximize ensuing benefits and outcomes.

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# CARING FOR PEOPLE AND THE ENVIRONMENT

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**OUR FOCUS AS A COMPANY IS ON PEOPLE – THOSE WHO WORK WITH AND FOR US AND THOSE WE SERVE, SO TAKING CARE OF THE HEALTH, THE SAFETY AND THE ENVIRONMENT OF OUR COMMUNITIES IS A CORE VALUE FOR KEDRION.**

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This is the reason why, year after year, we have worked, and continue to work, steadily and consistently to extend our environment and health & safety standards to all our production and administrative sites around the world. Our aim is to ensure the same high standards of quality and sustainability everywhere, whilst also respecting local specificities.

## HEALTH AND SAFETY

The safety and wellbeing of our employees are core values which we continue to invest in.

With improvement in mind, in 2017 we decided to set ourselves a number of targets, shared throughout the organization, and assessed on a monthly basis. This stringent evaluation system was supported by in-



# CARING FOR PEOPLE AND THE ENVIRONMENT

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ternal training and motivational campaigns, and meetings during which staff from our different sites could share their respective experiences. With the idea of making shared knowledge even more widespread, and of integrating the skills specific to each of the many nodes that make up our network, we established a Safety Alert System to collect and share information not only on critical issues, but also on previously implemented solutions, so as to provide our associates with a set of precedents to guide their decision making on company health and safety. Overall figures for 2017 are further proof that the policies adopted to promote and improve the culture of workplace safety are effective: compared to the previous year, injuries decreased both in terms of frequency (TIR: -17%) and severity (LWE: -39%). Finally, in keeping with the aim of standardizing company good practices, the LOTO (Lock Out Tag Out) system implemented at our Melville facility (New York, USA) was extended to our site in Gödöllő (Budapest, Hungary). This system guarantees the safety of maintenance activities, minimizes risks, and provides specific training for the operators involved.

## ENVIRONMENT

After being awarded, in 2016, the EPD® for our Factor VIII – the Environmental Product Declaration is an international voluntary certification attesting the validity and sustainability of products' Life-Cycle Assessment – in 2017 we published the report on EnvironDec's website, and have undertaken the certification process for our Albumin and Immunoglobulin products too.

In 2017, we celebrated ten years of our Italian offices and production sites being Eco-Management and Audit Scheme certified. EMAS is a voluntary certification developed by the European Community, by which Kedrion commits to assessing and improving, year after year, its environmental performances. In this case too, data is encouraging: in the last ten years we have reduced our carbon footprint by 10%, and we aim to extend this certification to all Kedrion sites and offices in Europe in the near future.

# CARING FOR PEOPLE AND THE ENVIRONMENT

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Italy also pioneered company carpooling, much appreciated by our employee community, as shown by the increasing number of users registered with the portal. Given this success, we decided to extend the program to our Melville plant employees.

## ENERGY AND RESOURCES

We took a dual approach to energy and resources: on the one hand, we continued to make small but steady improvements on our buildings, aimed at energy conservation and sustainability. For example, our new offices located in Castelvechio Pascoli (Lucca, Italy) are fitted with LED lighting – saving around 50% the energy consumed by conventional light bulbs – and with a photovoltaic system – covering 20% of the building's energy requirements.

On the other hand, we embarked on a series of more wide-ranging initiatives, the implementation and outcomes of which will be long-term. In this respect, the most important decision taken in 2017 was to start collecting data in all our sites to draw a comprehensive and reliable map of energy consumption and its uses. Our final objective is to devise an overall energy saving plan that, while taking into account the specific features of each location, will set the same targets for all our sites.

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## EHS Standards and Certifications

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- OHSAS 18001 standard
- EMAS regulations
- ISO 14001 standard
- ISO 26000 guidelines
- ISO 14025 standard

# DEVELOPING TALENT

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**TALENT IS EVERYWHERE AT KEDRION. PUTTING PEOPLE FIRST MEANS INVESTING IN THE PROFESSIONAL GROWTH AND DEVELOPMENT OF ALL EMPLOYEES, TO ENSURE THEIR TALENT - TECHNICAL, PROFESSIONAL, OR MANAGERIAL - BEARS FRUIT.**

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In 2017, to provide Kedrion with the right tools to identify and assess talent, we introduced People Review, a new multi-step employee review process that helps managers foster the professional growth of their associates by:

1. understanding - in terms of skills and organization - their unit/department's current, and future, needs
2. tracking performances, and recognizing associates' potential for future growth
3. creating development or improvement plans to share with associates
4. identifying candidates with the potential to take on leadership positions in the company.

# DEVELOPING TALENT

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The first People Review took place further to management training and briefing sessions, and involved nearly 250 employees from all company departments in the main countries in which Kedrion operates: after a preparatory stage, each department's leadership team discussed information pertaining to the points listed above, in a bottom-up process that finished in Summer with a round-table discussion at the presence of first line managers.

In 2017, Kedrion also started thinking about how best to use its technical knowledge as a means of developing talent in the company. This project aims to preserve the distinctive technical expertise linked to the specificity of several of the processes that Kedrion carries out. Its end goal, in fact, is to establish a Technical Academy - within the setting of Scuola Kedrion - that offers repeatable, modular training courses the aim of which is to turn individual know-how into shared knowledge, highlighting the work carried out by our specialists and ensuring the transfer of expertise between generations. The pilot training program, focusing on fractionation and purification, launched in Italy in April 2018.

In parallel, we are working with the academic world and educational facilities located in the communities in which we operate, to identify young talents from an early age, and attract them towards a professional future in this industry. As part of this Sourcing Talents initiative, between 2016 and 2017 Kedrion offered 24 internships, provided 135 hours of employee-led learning to local schools and universities, and took five groups of students on guided tours of its facilities. At the same time, internally to the company, we developed our Recruiting project, to identify those Kedrion trainers and managers willing to share their expertise and help colleagues to develop their recruiting skills.

In late 2017, PIN - "Città di Prato" University Centre in Italy presented "PharmaMark", its Master's Degree in Pharmaceutical Marketing developed thanks to Kedrion's unconditional support. Teaching started in the first months of 2018: the degree's multidisciplinary program offers specialized professional training in pharmaceutical marketing, the ethical drugs sector and the over-the-counter market. At the end of the course,



# DEVELOPING TALENT

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all students will be offered extracurricular internships with the pharmaceutical companies involved, including Kedrion.

Finally, we organized a number of initiatives to facilitate sharing of know-how and experience between colleagues: for instance, at our production facility in Sant'Antimo, Italy, we arranged Lunch with the Management meetings – that involved 20 plant managers for a total of 120 hours – during which key topics such as leadership, change and innovation were discussed. As of last June, on the first Wednesday of each month, US employees are able to discuss business topics with executives and sales managers during our Lunch & Learn meetings.

The ongoing training of our employees is key to how we operate: keeping our diversified and skilled workforce up-to-date is strategic to the company and its growth. It is also very important to our associates, in the full development of whose skills and talents the company invests.

To this end, we provided 22thousand hours of training, to spread technical, technological and managerial skills within our community of employees, and to ensure that everyone can benefit from this wealth of knowledge and expertise.

## SCUOLA KEDRION

Scuola Kedrion, which has been running for nearly 10 years, is a training program developed jointly with Fondazione Campus Lucca to strengthen and improve the management culture across Kedrion locations in Italy and abroad. It aims to provide the higher-level skills needed to support the achievement of the company's strategic goals, while at the same time furthering the professional and personal growth of participants by ensuring their knowledge is kept up to date.

The Scuola's plenary sessions – three in 2017, focusing on market orientation and business intelligence – were attended on average by 100 participants holding key positions within the company, and featured lectures by international speakers as well as round-table discussions in which the CEO took part.

The Scuola's initiatives have played an important role in building the

# DEVELOPING TALENT

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company's identity: as well as promoting individual growth, a shared learning experience helps to spread Kedrion's corporate culture.

In 2017, Scuola Kedrion took a step into the future: training courses are evolving into training programs, developed by first identifying internal professional categories and their specific learning requirements, then assigning these groups to the most appropriate pathways and guiding them through the various educational activities on offer (classroom training but also coaching, mentoring, collaborative projects, teamwork and distance learning). All of which in a setting that is increasingly international – with courses taught in English language and attended by participants from Kedrion sites around the world – and digitalized, using online learning tools and offering training on topics including big data, new technologies and industry 4.0.

In 2017, Scuola Kedrion launched the first edition of the Kedrion Management Development Program (KMDP): 17 top managers from five different countries exchanged views on leadership, innovation, results achieved and performances, finance and markets. Participants attended classroom-based learning sessions, webinars and workshops, and benefitted from the mentorship of Senior Management members, who generously shared their expertise.

In 2017, we also launched our People Management Journey, a pilot project involving 30 newly appointed managers, which confirms Scuola Kedrion as the company's management academy, and its chosen partner for handing down the Kedrion management and leadership model.

# DEVELOPING TALENT

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*“KMDP has allowed for new bridges to be built between the different departments that make up the Kedrion world. It has offered each of us the opportunity to experience first-hand how we are part of the same global company. Experiences such as this also increase familiarity between managers, and the human aspect of individual relationships really helps in our day-to-day work. I found this experimental training format very interesting. It also made pioneers of us all: we were encouraged to suggest changes and improvements to the program, for the benefit of those who will attend it after us. I am proud to have been asked to mentor the participants of the second edition of the program: it acknowledges both the importance of continuity, and the contribution that each one of us makes.”*

**Tommaso Paoli**, Group Plasma Quality Head



*“Being selected to participate in the 2017 Kedrion Management Development Program was a true privilege. The array of countries, cultures and professional backgrounds represented by the attendee roster created a fascinating backdrop as we learned about effective cross-cultural management communications, high performance team-building and leading in an environment centered on serving patients. New friendships forged among Program participants are certain to endure for decades. In addition, I now have a deeper appreciation for the complexities of running a global business and a reinforced view that Executive Leadership is committed to developing its people to maintain long-term success.*

*I am humbled to have participated in 2017 KMDP and hope to mentor future graduates of this excellent program.”*

**Neal Fitzpatrick**, Vice President, Commercial Head, North America



*“In 2017, I had the great pleasure of taking part in the Project Management Development Program. At the very beginning, I was a little skeptical: I regularly attend webinars, and I am used to working with digital tools, but I could hardly imagine knowledge and know-how being transferred on the web. Very soon, I changed my mind. I found it very exciting working with colleagues from the company’s locations around the world. By sharing our experiences we were able to find solutions, and make suggestions, to address the challenges of the project we were working on together.*

*In my opinion, personal dedication is crucial to completing this training program successfully. We benefitted from the enthusiastic support received and excellent learning materials, but it was each of us doing our very best that made this an invaluable opportunity for personal development.”*

**Judit Juhász**, Hungary Regulatory Manager and QPPV

# PORTFOLIO

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## HEMATOLOGY/HEMOPHILIA

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EMOCLOT/Koöte-DVI\*/EMOWIL/  
HUMACLOT\*\*/PLASMACLOT  
Factor VIII/von Willebrand Factor  
concentrate

NUWIQ\*\*\*  
Recombinant Factor VIII

WILFACTIN\*\*\*  
Von Willebrand Factor concentrate

WILATE\*\*\*  
Factor VIII/von Willebrand Factor  
concentrate in combination

AIMAFIX/KEDRIFIX  
Factor IX concentrate

EMOSINT  
DDAVP Desmopressin

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

## IMMUNOLOGY/NEUROLOGY

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Ig VENA/HUMAGLOBIN Liquid\*\*/  
KEDRIGAMMA/Gammaked\*  
Standard i.v. Immunoglobulin

NAXIGLO  
Standard s.c. Immunoglobulin

VENBIG/KEYVENB  
Anti-hepatitis B i.v. Immunoglobulin

IMMUNOHBs/UMAN BIG  
Anti-hepatitis B i.v. Immunoglobulin

TETANUS GAMMA/TETIG\*\*  
Anti-tetanus i.m. Immunoglobulin

ImmunoRHO/RhoGAM/MICRhoGAM/  
KeyRho  
Anti-D i.m. Immunoglobulin

## CRITICAL CARE

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

AT III KEDRION  
Antithrombin concentrate

K FLEBO\*\*\*  
Potassium aspartate

PLASMASAFE\*\*\*  
Pharmaceutical grade plasma

SILKETAL  
Fibrin sealant

## MEDICAL DEVICES

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CERUS INTERCEPT\*\*\*  
Small Volume platelets processing set

CERUS INTERCEPT\*\*\*  
Large Volume platelets processing set

CERUS INTERCEPT\*\*\*  
Plasma processing set

## PRODUCTS DEDICATED TO THE NATIONAL SELF-SUFFICIENCY PROGRAM IN ITALY

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VENITAL  
Standard i.v. Immunoglobulin

KEYCUTE  
Standard s.c. Immunoglobulin

ALBITAL  
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 i.m. immunoglobulin

KOLFIB  
Fibrin sealant

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\* product only available for the US market

\*\* product only available for the Hungarian market

\*\*\* product distributed by Kedrion only for the Italian market

# RESEARCH & DEVELOPMENT

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**RESEARCH IS A SIGNIFICANT ASPECT OF KEDRION'S ACTIVITIES. EACH STAGE OF PRODUCT DEVELOPMENT – FROM BASIC RESEARCH TO PRE-CLINICAL AND CLINICAL TRIALS, TO PHARMACOVIGILANCE MONITORING – CONTRIBUTES TO THE SAME OBJECTIVE: ENCOURAGING INNOVATION SO AS TO IMPROVE, ONE STEP AT A TIME, HOW WE SERVE PATIENTS WORLDWIDE.**

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Our commitment to this objective is very strong, especially in relation to extremely rare diseases for which there is still no treatment. Meeting this need is both a responsibility and a priority for us. To this end, in 2011, together with the Toscana Life Sciences (TLS) Foundation, we established IKOD, a plant in Siena (Italy) dedicated to the production of plasma-derived orphan drugs. It is the first one of its kind in Italy and Europe. The campaign *“Alla ricerca del tempo guadagnato”* (In search of time regained), promoted by TLS during 2017, describes the work that Kedrion, and the other companies and research groups housed



# RESEARCH & DEVELOPMENT

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by the Siena-based business incubator, are engaged in to develop the therapies needed to treat rare diseases.

The IKOD plant in Siena is the key player in Kedrion's orphan drug production activities. Thanks to the hard work of the team based there, much progress has been made by both the Plasminogen and Factor V projects. Kedrion is the only company that has developed a Plasminogen concentrate in the form of eye drops for the treatment of Ligneous Conjunctivitis. Clinical trials are concluded, and we are working to complete the documentation needed to apply for Marketing Authorization for the product. In the meanwhile, the company continues, on the one hand, to make the preparation available to the patients involved in the clinical trial and, on the other – within the limits of current production capacity – to provide Plasminogen for compassionate use to seven patients (four in Italy, one in Spain and two in the US) affected by Ligneous Conjunctivitis. The intention is to expand the compassionate use program, and increase the number of patients treated.

With regard to Factor V, we are planning to start the production of pre-clinical lots in Siena in 2018 and, should conditions prove favorable, progress to the production of clinical lots in 2019-20, when we would apply for Orphan Drug Designations in both Europe and the United States.

In the last months of 2017, in the United States, the Food and Drugs Administration (FDA) authorized the commercialization of the Human Rabies Immunoglobulin (HRIG) developed by Kamada and Kedrion for post-exposure prophylaxis (PEP). It was a very important step forward for the over 40,000 people exposed to rabies in the USA each year, and an important achievement for Kedrion: the company played a key role in the drug's clinical development stages, and is now entitled to exclusive marketing rights.

In 2017, the project requiring most attention and efforts was the development of our 10% Immunoglobulin (Klg10). Our entire industrial network was involved in the project, and an expert team of almost 100 professionals from the United States, Germany, Italy and other countries was

# RESEARCH & DEVELOPMENT

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also put together. This, for Kedrion, is a crucial project: it has already entered its validation phase, which will be followed by clinical trials. Kedrion most definitely is a “bridge builder”, committed to connecting research and care, but also the innovative ideas of our local partners and their realization on an industrial scale. The solid and long-standing cooperation that, over the years, we have established with doctors, researchers, public and private entities, and national and international bodies, proves just how good for research the sharing of knowledge and skills actually is. A good example of this cooperation was the scientific conference “Researching patient needs – Focusing on the future”, on the use of antiphospholipid antibodies to treat autoimmune diseases, held at our headquarters in Castelvecchio Pascoli (Lucca, Italy) in June 2017. In the near future we will be further developing this kind of partnership, in order to become an even more important reference point for talented researchers in biotechnology.

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# WHERE WE ARE



## MAP LEGEND

- 🎯 HEADQUARTERS
- 🏭 PRODUCTION
- 📦 DISTRIBUTION
- 💧 PLASMA COLLECTION
- COMMERCIAL PRESENCE



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# THE YEAR AT A GLANCE

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## **JANUARY** - KEDPLASMA: PARTNERSHIP WITH IMMUNOTEK IN THE USA IS EXPANDED

In addition to the acquisition of two new plasma collection centers located in Shreveport (Louisiana) and Ocala (Florida) – certified by the FDA and approved by the European Authorities – the agreement provides that ImmunoTek Bio Centers will develop 28 collection centers for KEDPLASMA in the United States, ensuring a significant increase in plasma volumes in the next five years.



## **JANUARY** - AT STANFORD, IN THE UNITED STATES, THE ANNUAL MEETING OF CURhE

Possible advocacy strategies for the introduction of blood group screening in Nigeria are discussed at Stanford University during the annual meeting of CURhE (Consortium for Universal Rh Disease Elimination), the global alliance between the academic world and industry promoted and supported by Kedrion Biopharma.



## **FEBRUARY** - “ALLA RICERCA DEL TEMPO GUADAGNATO” (IN SEARCH OF TIME REGAINED): A CAMPAIGN TO FIGHT RARE DISEASES

An information campaign supported by the Toscana Life Sciences Foundation highlights the work of companies and research groups engaged in the development of therapies for the treatment of rare disorders. Kedrion describes the experience of its Kedrion Orphan Drugs plant (IKOD) in Siena, Italy.



## **FEBRUARY** - SIPPET STUDY IS PRESENTED IN INDIA

At the “Meeting the Expert” initiative in Mumbai, organized by Kedrion and attended by Indian doctors and patient associations, the results of the SIPPET Study are presented, and the topic of inhibitors in hemophilia are addressed.



## **MARCH** - PLASMA-DERIVED DRUGS PICTOGRAM: KEDRION SUPPORTS THE REGION OF TUSCANY

In Italy, Kedrion supports the Region of Tuscany – the first Italian Region to do so – in the implementation of the Ministry of Health recommendation that the packaging of plasma-derived products manufactured under the self-sufficiency program should feature the pictogram of a superimposed heart and plasma drop, to indicate that the raw material used comes from non-remunerated and voluntary donations.



## **APRIL** - KEDRION UNDERSIGNS THE EHC “PARTNERS” PROGRAM

To mark World Hemophilia Day, the European Hemophilia Consortium officially presents its “PARTNERS” (Procurement of Affordable Replacement Therapies - Network of European Relevant Stakeholders) program. This project – which Kedrion is very keen to join in – aims at ensuring sustainable access to treatment in those European countries that currently do not meet hemophilia care minimum standards.



# THE YEAR AT A GLANCE

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## **APRIL** - HUMANITARIAN DONATION OF FACTOR VIII TO SERBIA

Kedrion manages the delivery to Belgrade of 3 million Factor VIII IUs provided by the Italian Region of Lombardy. The exportation of plasma-derived products for humanitarian purposes falls within the scope of the 2013 Accordo Stato-Regioni, an agreement underwritten by the Italian State and its Regions thanks to which over 10 million units of coagulation factors have been donated to countries including Afghanistan, Albania, Armenia and India.



## **APRIL** - NEW KEDPLASMA CENTERS IN HUNGARY AND THE UNITED STATES

The new center opened in Debrecen is the fifth in Hungary for KEDPLASMA, and the second in the small town in the east of the country.

In the USA, the acquisition from ImmunoTek of centers in Kissimmee (Florida) and Burlington (North Carolina) is in line with the corporate growth plan aimed at doubling the number of centers by 2020.



## **MAY**- BOLOGNANA PRODUCTION PLANT HOSTS A STAGE OF FARMINDUSTRIA'S "INNOVATION AND PRODUCTION OF VALUE" ROADSHOW

Over 200 guests, including representatives of institutions, economy, industry and science, attend the event entitled "The pharmaceutical industry: an asset Italy can't afford to lose", during which Kedrion and the Florence-based Menarini Group highlight the many strengths of the Tuscan pharmaceutical industry whilst underlying Italy's role in the international pharmaceutical context.



## **MAY** - EPATEAM CONFIRMS KEDRION'S COMMITMENT TO LIVER TRANSPLANTOLOGY IN ITALY

Believing strongly that education is an integral part of patient treatment and care, Kedrion Biopharma commits its unrestricted support to Epateam, a large-scale educational campaign aimed at improving awareness of liver pathologies, transplantation and pre- and post-transplant patient care management.



## **JUNE** - HUMANITARIAN DONATION OF FACTOR VIII TO ARMENIA

Within the framework of the technical cooperation agreement between the Italian National Blood Center and the Armenian Hematology Center, Kedrion manages the delivery to Yerevan of the 790thousand Factor VIII IUs made available by the Region of Lombardy.



## **JUNE** - KEDRION SUPPORTS THE CURhE CONSENSUS CONFERENCE IN NIGERIA

In Abuja, CURhE representatives meet institutions, newborn intensive care units professionals, gynecologists and members of the Rhesus Solution Initiative association. The introduction of neonatal prophylaxis in Nigeria, and possible strategies to extend access to treatment with Anti-D Immunoglobulin, are debated during the conference.

# THE YEAR AT A GLANCE

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## **JULY** - KEDRION LAUNCHES A NEW 350 MILLION EURO BOND

On July 12, a 350 million Euro bond due July 12, 2022 and paying 3% per annum is issued and listed on the Irish Stock Exchange. In addition, Kedrion repurchases, by means of a tender offer, a large part of the outstanding notes of its 300 million Euro bond issued in 2014. The objective is to extend the average duration of the company's loans, optimizing costs and securing new resources for growth.



## **JULY** - KEDPLASMA OPENS SIXTH COLLECTION CENTER IN HUNGARY

This new facility is the first donation center to open in Miskolc, a small town located in the north-west of the country, and the sixth for KEDPLASMA in Hungary.



## **AUGUST** - FDA AUTHORIZES NEW HUMAN RABIES IMMUNOGLOBULIN (HRIG) DEVELOPED BY KAMADA AND KEDRION

Kedrion collaborated with the Israeli company Kamada in the clinical development of the product – approved for post-exposure prophylaxis (PEP) by the Food and Drugs Administration – and will be the exclusive distributor in the United States where, according to estimates, over 40,000 people are exposed to rabies each year.



## **AUGUST** - HUMANITARIAN DONATION OF COAGULATION FACTORS TO AFGHANISTAN

Kedrion supports the delivery, to the "Indira Gandhi" Hospital in Kabul, of 1,500 vials of Factor VIII – made available by the Italian Region of Emilia-Romagna – and 300 vials of Factor IX donated by the Italian Region of Marche. The donation is part of a project aimed at helping the hospital to increase the number of children (currently around 300) that it is treating.



## **SEPTEMBER** - EPADAY IN TURIN, ITALY, LAUNCHES THE EPATEAM CAMPAIGN

Turin – where a record-breaking 3,000 liver transplants have been carried out – is chosen to host the first Epaday (a national workshop dedicated to liver transplantology) and the official launch of the Kedrion promoted and supported Epateam educational campaign.



## **SEPTEMBER** - START OF THE SECOND EDITION OF SCUOLA FEDEMO

Twenty young association managers from all over Italy attend the three training modules dedicated to management, the right to health, and the third sector. Scuola FedEmo is run by Fondazione Campus for the Italian Federation of Hemophilic Patients' Associations (FedEmo) and benefits from Kedrion Biopharma's unconditional support.

# THE YEAR AT A GLANCE

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## **OCTOBER** - AGREEMENT WITH CERUS FOR THE DISTRIBUTION IN ITALY OF INTERCEPT BLOOD SYSTEM®

Kedrion and Cerus Corporation enter into an agreement for the distribution in Italy of the full portfolio of INTERCEPT Blood System® products. Kedrion will initially distribute INTERCEPT for platelets and plasma.



## **OCTOBER** - START OF THE THIRD EDITION OF SCUOLA AVIS

Twenty-five young association managers from all over Italy attend Scuola AVIS, established and promoted by Kedrion together with the AVIS blood donors association (one of three in Italy) and with Fondazione Campus Lucca. Training addresses topics including the ethical value of donation, management in the not-for-profit sector, and institutional relations.



## **NOVEMBER** - IPOPI LAUNCHES PID GENIUS

At the IPIC Congress in Dubai, IPOPI (the International Patient Organization for Primary Immunodeficiencies) presents its mobile application PID Genius, designed and developed thanks to Kedrion's technical and economic support, which is very well received. This app is designed to work as an all-round personal assistant for patients to help them in the management of their disease and in their interactions with medical specialists.



## **NOVEMBER** - OFFICIAL PRESENTATION TO THE EUROPEAN PARLIAMENT OF THE "PARTNERS" PROJECT

Kedrion is one of the members of the "PARTNERS" program, which the EHC (European Hemophilia Consortium) presents in the course of an institutional meeting in Brussels on November 28. "PARTNERS" identifies 14 European countries in which to take action to ensure compliance with the treatment levels recommended by international guidelines. This is expected to have a positive impact on the quality of life of around 5,000 hemophilic patients.



## **NOVEMBER** - KEDPLASMA REACHES 13 CENTERS IN THE UNITED STATES

With the acquisition of the center in Greenville (North Carolina) and the construction from scratch of the center in Tucker (Georgia), KEDPLASMA collection centers in the USA are now 13.



## **DECEMBER** - TENTH ANNIVERSARY OF EMAS CERTIFICATION CONFIRMS KEDRION'S ECO-FRIENDLY MISSION

Kedrion celebrates 10 years of EMAS (Eco-Management and Audit Scheme) voluntary certification for its Italian facilities. The scheme certifies the company's commitment to improving, year after year, its environmental performance. The company aims to extend EMAS to all of its European locations in the near future.



EVERY DAY,  
KEDRION'S WOMEN  
AND MEN MEET THE  
CHALLENGE OF  
PLAYING A POSITIVE  
ROLE IN PEOPLE'S  
LIVES



# BUILDING BRIDGES

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# FROM DONORS TO THE WORLD

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THE GENEROUS DONOR STANDS AT ONE END OF A BRIDGE TO THE REST OF THE WORLD. HIS OR HER PLASMA IS TRANSFORMED BY KEDRION BIOPHARMA INTO THE PRODUCTS THAT WILL HELP PEOPLE WHO NEED THEM, THEIR NEIGHBORS AS WELL AS GRATEFUL STRANGERS AROUND THE WORLD.

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Kedron is privileged to build this bridge and is indebted to those donors and that generosity. Our capacity to help others is based on this vital resource.

Our state-of-the-art centers - clean, comfortable, efficient and safe - in the United States and Europe ensure an adequate supply of plasma - this precious raw material - so we are less dependent on outside sources. In 2017, we have experienced notable growth in all countries.

In Germany, our Augsburg center recorded a significant increase in plasma collection as did the Ingolstadt center, which was renovated



*“I actually look forward to going – says Keith Malough, who donates at the Somerset Labs in Williamsville, New York – because each time I feel good knowing that, through a small act, I have contributed to make the world a better place.”*

# FROM DONORS TO THE WORLD

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and expanded. KEDPLASMA promoted “KED-Club” with the purpose of fostering a sense of community and to give the donors of the Bavarian centers of Ingolstadt, Fürth, Bayreuth and Augsburg the opportunity to share their experience.

Despite heavy competition in Hungary as well as a new cap on compensation to donors, the volume of collected plasma increased in 2017 over the previous year. This was achieved mostly thanks to the noteworthy performance of our two new centers in Debrecen and Miskolc.

In the United States growth was exceptionally strong last year, thanks in large part to the partnership with ImmunoTek BioCenters LLC, from which we acquired five centers and with which we entered into an agreement for the development of another 28 centers over the next five years. In addition, we built a new center in Tucker, Georgia and broke ground for another in Atlanta. Our Mobile, Alabama center was moved to new premises.

A new IT system for the management of donations is being implemented in all US centers toward our goal to become paperless by the end of 2018. The loyalty program, KEDREWARDS, which allows all the KED-PLASMA donors in the USA to view their donation history and donor profile directly on their personal smartphones, is another step in that direction.

In Italy, where we continued to support the National Blood System's self-sufficiency program, plasma collection recorded a national increase in volumes of 1.8% over 2016.

During the year, Kedrion supported the Region of Tuscany – the first Italian Region to do so – in the implementation of the Ministry of Health recommendation that the packaging of plasma-derived products manufactured under the self-sufficiency program should feature the pictogram of a superimposed heart and plasma drop, to indicate that the raw material used was from non-remunerated and voluntary donations.



*“I have always known that, with my donations, I was helping others – states German donor Helmut Kreipl – but then I had the chance to meet a patient and everything suddenly took on a totally new meaning.”*



*“When you donate plasma, each drop is important” – says Ernő László Nyíri, from Debrecen, who has donated plasma more than 350 times. “We are not doctors, but we too can help people in need. Our only motivation is to help others.”*

# FROM DONORS TO THE WORLD

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We have organized or supported a series of projects aimed at expanding donation awareness and at describing the plasma's amazing journey from donor to patient. For instance, as part of the much appreciated "Kedrion Incontra" (Kedrion Meets) program, we continued to share our knowledge and expertise with our stakeholders, such as donor associations and institutions, either by welcoming them to our production and administrative sites or by reaching out to local volunteer associations. This initiative allows us to communicate also with those who have not yet decided to donate, such as the young people doing Civilian Service with the associations.

These are learning opportunities Kedrion offers especially to younger people, with the aim of providing them with the best possible tools to take on management roles and carry the Italian donor community into the future. This is also the goal of the Scuola Nazionale di formazione AVIS (AVIS School), which we established for and with the AVIS blood donors association (one of three in Italy) and with Fondazione Campus Lucca.

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*“Education is important, it is an investment for the future” – states Raffaele Raguso, an AVIS Martina Franca member, after attending Scuola AVIS’ third edition in 2017. “I believe that volunteers too need educating, and it is great that a company like Kedrion works side by side with voluntary associations to offer this. Scuola AVIS provided me with insights into topics such as ethics, donation and Third Sector, showing me how they are interrelated: this understanding will help me to improve the ways in which I will be pursuing, both locally and at a national level, the AVIS mission.”*

# FROM PLASMA TO THERAPIES

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**OUR INDUSTRIAL ACTIVITIES – THAT ARE CENTRAL TO KEDRION’S BUSINESS – ENSURE OUR COMMITMENT TO BUILDING BRIDGES BETWEEN DONORS AND PATIENTS WORLDWIDE IS ACTED ON EVERY SINGLE DAY. THIS COMMITMENT, WHICH WE PURSUE WITH GREAT SENSE OF RESPONSIBILITY, MAKES OUR WAY OF DOING BUSINESS UNIQUE AND DISTINCTIVE.**

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Daily, the women and men working in Kedrion’s manufacturing plants in Italy, Hungary and the United States welcome the challenge of living up to the company’s international reputation as a key player in the plasma-derivatives industry. We face this exciting challenge – that is inspired by the quest for excellence and continuous improvement – to help people affected by rare disorders lead healthier and fuller lives.

In the past two years, our production plant in Melville (New York, USA) has been one of the main challenges to face: in April 2016, the company decided to undertake a major refitting of the plant, with the aim of fully integrating it in the Kedrion manufacturing network. This investment

# FROM PLASMA TO THERAPIES

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is proof of Kedrion's determination to maintain its position as a leading player on the US market as well as in the rest of the world.

Another major ongoing project is the development of our new 10% Immunoglobulin (Klg10). The current phase of the product's development is being carried out in our Gödöllő plant, in Hungary, following renovation - between March and April 2017 - of the purification area in which clinical batches are prepared. The next stage of Klg10's development – the manufacturing of qualification batches – is instead expected to take place in Castelvechio Pascoli (Lucca, Italy). Works to adapt the plant to the new process are needed in this case too. This investment will be made over a three year period starting from the end of 2017.

Our Bolognana plant (Lucca, Italy) – the company's industrial hub – increased its fractionation capacity by about 30 thousand liters, thanks to continuous process improvements. We also started work on the fractionation department upgrade, which will be completed in the next few years.

As to Sant'Antimo (Naples, Italy), we allocated additional resources to the pharmaceutical grade plasma manufacturing area, improving both production facilities and processes.

Meanwhile, with a view to the continual improvement of our processes, we kept working at the integration of all our production facilities: for example, we identified some common indicators that each plant will monitor on a monthly basis, which will then be consolidated at a network level. Moreover, in 2017, a "network team" of experts from our different plants was set up, the first meeting of which was held in Gödöllő. The team will share expertise and best practices, and offer its members a setting in which to discuss potential problems and optimizations, and find solutions to bring about continual improvement in every process.

In 2017, Kedrion also consolidated its position as a global pharmaceutical industry player. As one of the leading companies of the Tuscan pharmaceutical hub, we were proud to host "Innovation and Production of Value", the roadshow organized by Farmindustria (the national association of pharmaceutical companies), in our Bolognana plant. In addition



# FROM PLASMA TO THERAPIES

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to which, we were included in the 2016 top ten list of Italian companies advancing research and development.

For us, in fact, innovation is so much more than an abstract concept: it is both a starting point, and an objective that is also pursuable at a local level. With this in mind, we strengthened our partnership of local research centers, and our involvement in local education, by helping to develop training programs that meet the needs of the job market, as in the case of the two-year courses organized by “Fondazione VITA Istituto Tecnico Superiore per le Nuove Scienze della Vita” in Tuscany, and of PharmaMark, the Masters Degree in Pharmaceutical Marketing run by PIN – the City of Prato University campus.

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# FROM KEDRION TO PATIENTS

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**PATIENTS ARE THE FOCUS OF OUR WORK. ALL THE WAY ACROSS THE BRIDGE, FROM THE FIRST DROP OF PLASMA COLLECTED TO THE LAST BOX OF PRODUCTS DISTRIBUTED ON THE MARKET, KEDRION PUTS PEOPLE LIVING WITH RARE DISEASES AND IN NEED OF PLASMA-DERIVED THERAPIES AT THE CENTER.**

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It is to patients, to their families and to their communities that we are committed, working with expertise and passion to provide tangible help, and to ensure fair access to therapies in those countries where therapeutic needs are still unmet.

In keeping with these objectives, throughout 2017 Kedrion continued to pursue growth in Italy and on the international markets, because growing - for us - means reaching out to even more patients worldwide.

Italy continues to be the foundation of our business: its commercial result for 2017 was 164 million Euro, representing 27% of the com-

# FROM KEDRION TO PATIENTS

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pany's global turnover. The Italian national plasma-derived product self-sufficiency program – to which Kedrion has always been proud to contribute in partnership with the Blood System – continues to grow and, as a consequence, the commercial market is shrinking. This notwithstanding, in 2017 we managed to strengthen our position, achieving our best performance in the last four years.

At the same time, we are doing our part in the ongoing process of opening up of the Contract Manufacturing market, and are submitting bids for the tenders that award the processing of regional plasma. Our tender bids reflect our long-held beliefs in careful attention to quality, and in the importance of donating, which ensure we optimize each liter of plasma collected so that it yields the greatest possible number of products. This commitment also highlights donation, bringing great visibility to donors and the gift of life they contribute. Moreover, the expansion of our product portfolio to include a medical device for the viral inactivation of pathogens, strengthens our value proposition to the Italian Transfusion System, whilst at the same time offering a solution for the critical situations arising from the appearance of new emerging viruses.

In the United States too, where all efforts were focused on the Melville plant resuming its operations, we scored several commercial successes, including FDA approval of the new Human Rabies Immunoglobulin (HRIG) that we developed alongside Kamada, and are now exclusively distributing on the American market. The US market represents 40.6% of our revenues.

Kedrion once again recorded excellent growth rates on the European markets, thanks to the strong performances of a number of key countries (Germany, Austria and Switzerland achieved +16% compared to 2016; good results were achieved in Hungary too). We also consolidated our position in Latin America: the markets in Columbia and Mexico, especially, underwent considerable development. Finally,

# FROM KEDRION TO PATIENTS

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significant growth was achieved in Russia and the CIS (+50% compared to the previous year), and in Vietnam (+60%).

Growing also means developing and strengthening our partnership with the medical and scientific community and the associations working in our sector. In this respect, 2017 was a very intense year. We went to Nigeria several times to support the CURhE (Consortium for Universal Rh-disease Elimination) project, confirming our commitment to the introduction of prophylaxis with Anti-D Immunoglobulins in that country, and all the while worked to improve awareness of the disparities - in the access to treatment – that currently exist between the various regions of the world.

With regards to Hemophilia, we joined the EHC - European Haemophilia Consortium's "PARTNERS" program (Procurement of Affordable Replacement Therapies – Network of European Relevant Stakeholders), an innovative and sustainable procurement plan aimed at improving access to coagulation disorders replacement therapies in those European countries where the recommended minimum treatment levels are currently not met.

Last July we attended the ISTH (International Society on Thrombosis and Hemostasis) conference in Berlin, during which Hemophilia and the results of the SIPPET study were discussed. SIPPET is the first randomized study designed to compare the immunogenicity of recombinant and plasma-derived Factor VIII concentrates.

We provided technical and economic support to IPOPI (the International Patient Association for Primary Immunodeficiencies) for the design and development of PID Genius, a mobile application that aims to make the lives of patients living with PID easier.



*“The risk of developing inhibitors, today, is by far the most important critical factor in the decision to start treating a new patient with Hemophilia, and there are many aspects that should be considered to prevent and reduce this risk”*  
– stated Professor Giancarlo Castaman, hematologist at the Careggi University Hospital of Florence, Italy. *“We know that the risk decreases with plasma-derived products, so it is necessary to discuss this therapeutic option with the parents of the patient at the beginning of the treatment.”*



*Johan Prevot, IPOPI Executive Director, stressed the added value of “an app created by patients for patients, which is a leap forward, and an important innovation that will both extend the awareness of Primary Immunodeficiencies, and offer a comprehensive management tool for the disease.”*

# FROM KEDRION TO PATIENTS

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In Italy we supported Epateam, a large-scale educational campaign - currently also available online - dedicated to liver transplantology.

Finally, we supported Scuola FedEmo again. Now in its second consecutive year, the School is a FedEmo (the Federation of Hemophilic Patients' Associations) initiative run in collaboration with the Fondazione Campus Lucca. It is a very high-profile training experience – as past attendees have pointed out – bringing together local associations that are very different from each other, and allowing for participants to debate issues such as the ethical basis of volunteerism, associations' aims and the scope of their activities, and patients' rights.

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*“Providing the most updated, complete and multidisciplinary information – explained Professor Renato Romagnoli, a surgeon working at the Transplantation Centre in Turin, and Epateam faculty member – is necessary in order to bring transplantation centers closer to the outside world, shortening their distance from non-specialists and patients.”*



IN 2018  
WE WILL BE  
MARKING SEVERAL  
SIGNIFICANT  
ANNIVERSARIES





# GLANCING AT 2018

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# GLANCING AT 2018

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**2018 IS A YEAR OF CELEBRATIONS FOR KEDRION BIOPHARMA, AS WE MARK SEVERAL SIGNIFICANT ANNIVERSARIES.**

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## 50 YEARS OF ANTI-D

Most noteworthy is the Golden Jubilee of the discovery of Anti-D Immunoglobulins for the prevention of Rh sensitization. The work of several groups of researchers around the world – in England, Canada and the United States – came together in 1968, when Drs. John Gorman and Vincent Freda of Columbia University College of Physicians and Surgeons, and William Pollack of Ortho Labs, developed this breakthrough prophylactic treatment.

In pregnant women who are Rh negative, Rh sensitization may lead to Hemolytic Disease of the Fetus and Newborn (HDFN), which is often fatal to a fetus or newborn. It can also result in miscarriage, stillbirth, early post-natal death and life-long disabilities in surviving babies.

Prior to 1968, approximately 10,000 infants succumbed to HDFN each

# GLANCING AT 2018

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year in the USA. By the 1970s, routine antenatal care for mothers in the US and UK included screening of all expectant mothers to find those whose pregnancy may be at risk of HDFN, and giving preventative treatment accordingly. Such steps have led to a dramatic decrease in the incidence of HDFN in these geographies and others, and, in particular, in the number of severe cases of the type once responsible for stillbirth and neonatal death.

Today, few cases of HDFN due to Anti-D are reported each year in the most developed countries, and Anti-D Immunoglobulins are considered the standard of care for its prevention across North America, Europe, and Australia.

Though there is clear reason to celebrate, the recognition of this 50-year old breakthrough illuminates the unacceptable fact that half the women in the world who need this protection still have no access to the drug. That is why Kedrion has helped to found and fund an organization committed to bringing Anti-D Immunoglobulins to every woman in the world who needs it: the Consortium for Universal Rh Disease Eradication (CURhE).

We are teaming with such institutions as Stanford and Columbia universities, Toronto's Hospital for Sick Kids, and the International Federation of Gynecologists and Obstetricians (FIGO), among others with the aim of establishing a veritable alliance to celebrate the past and campaign for the future. Planned events include awareness-raising conferences in Dubai, Rome, Toronto, Moscow and Rio de Janeiro, which will culminate in an international scientific symposium in New York, at the Columbia University College of Physicians and Surgeons.

## 10 YEARS IN HUNGARY

In 2018, we are also celebrating the 10th anniversary of Kedrion's direct presence in Hungary - a presence that dates back to 1st January 2008, when the company acquired a production plant in Gödöllő, near Budapest. Since then, and for the last ten years, Kedrion has carried out its production and sales activities in Hungary through its



# GLANCING AT 2018

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subsidiary HUMAN BioPlazma, and has collected plasma through its KEDPLASMA division.

In these ten years, Kedrion has invested heavily in the Gödöllő site, in which around 3.4 million liters of plasma have been fractionated for the manufacturing of plasma-derived medicinal products, and over half a million donations have been collected in its KEDPLASMA centers throughout the country.

To celebrate these achievements and mark the 10th anniversary, Kedrion Biopharma is organizing a series of events and initiatives that will take place in Hungary in 2018.

## 10 YEARS OF KEDPLASMA IN GERMANY

Ten years ago, in October 2008, KEDPLASMA collected its first plasma donation in Germany. It took place in KEDPLASMA's center in Fürth, marking the beginning – in the country – of a new, modern approach to donating and collecting plasma. In December 2008, the company purchased two more centers in Bayreuth and Ingolstadt and, in 2015, it opened its Augsburg plasma center.

Over the years, confidence in KEDPLASMA has increased steadily, as have the volumes of raw material collected and the number of donations carried out: from around 5,000 in 2008, to almost 150,000 in 2017. This growth trend is set to continue, thanks to state-of-the-art collection centers that are clean, comfortable, efficient and safe, and are turning plasma donation into an “everyday experience” for many people in Germany.

The donor community that in the last ten years has grown around our four collection centers in Southern Germany, together with the staff that works in these – to date 116 people – represents one of the pillars of the bridge from plasma to medicinal product that Kedrion helps to build. This connection between donors and patients was further strengthened in the last three years by the presence, within the KEDPLASMA organizational structure, of a team dedicated to making Kedrion therapies available in the region.



# ECONOMIC & FINANCIAL INDICATORS

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# ECONOMIC & FINANCIAL INDICATORS

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## RELEVANT EVENTS OF THE YEAR

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Kedrion ended 2017 with Euro 602.5 million in turnover, declining by 8.6% from the prior year. Revenues from the sale of plasma derivatives totaled Euro 490.0 million, down slightly due to the shortage of products for the American market following the temporary shutdown of operations at the plant in Melville, United States - partially offset by the production outsourced to a third party - as well as the termination of the distribution agreement for Bivigam®. Even though the US remained the group's main market - followed by Italy - it fell by 9% compared to 2016. In line with the gradual internationalization process aimed at consolidating Kedrion's presence in the largest global markets, turnover continues rising in the other countries where the company operates – led by Russia and Germany.

The plasma segment generated Euro 93.1 million in revenues, down from the previous year because of the sharp reduction in the amount of plasma supplied by third parties: although partially offset by the growth in plasma collected at the group's centers in the United States and Europe, this caused sales to decline in order to secure the volumes necessary for production purposes.

Despite the slight decrease in turnover, in 2017 Kedrion saw its margin rise to 23.2% (16.1% in 2016) and reported an adjusted EBITDA of Euro 139.9 million, thanks to the proceeds from the sale of plasma collection centers as well as the group's relentless pursuit of operational efficiency through specific cost control and reduction efforts.

## REFITTING OF THE MELVILLE PLANT

During the year, work continued on the refitting of the Melville plant, which involves renovating the existing fractionation line in order to fully align and integrate it with the other plants of the Kedrion group as well as building a fractionation and purification line for the Anti-D Immuno-globulin (RhoGAM®). From an industrial perspective, this key initiative, for which the group has invested Euro 54.1 million in 2017 (on top of the



# ECONOMIC & FINANCIAL INDICATORS

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approximately Euro 29.5 million already invested in 2016), is now complete. The plant is to resume operations in the first half of 2018 following the necessary validation and regulatory phases.

## KIG10

In 2017, work continued also on the construction, in Castelvecchio Pascoli (Lucca, Italy), of the facility for the purification of 10% Immunoglobulin (Klg10) with the chromatographic method, but the protracted halt of operations at Melville will delay the start-up of the plant.

## PROPRIETARY PLASMA COLLECTION CENTERS

On the one hand, Kedrion sold six centers not considered strategic, and on the other hand, it purchased/opened five new centers in the United States and two in Hungary during the year. As a result, at the end of 2017 the group's network included 24 proprietary centers.

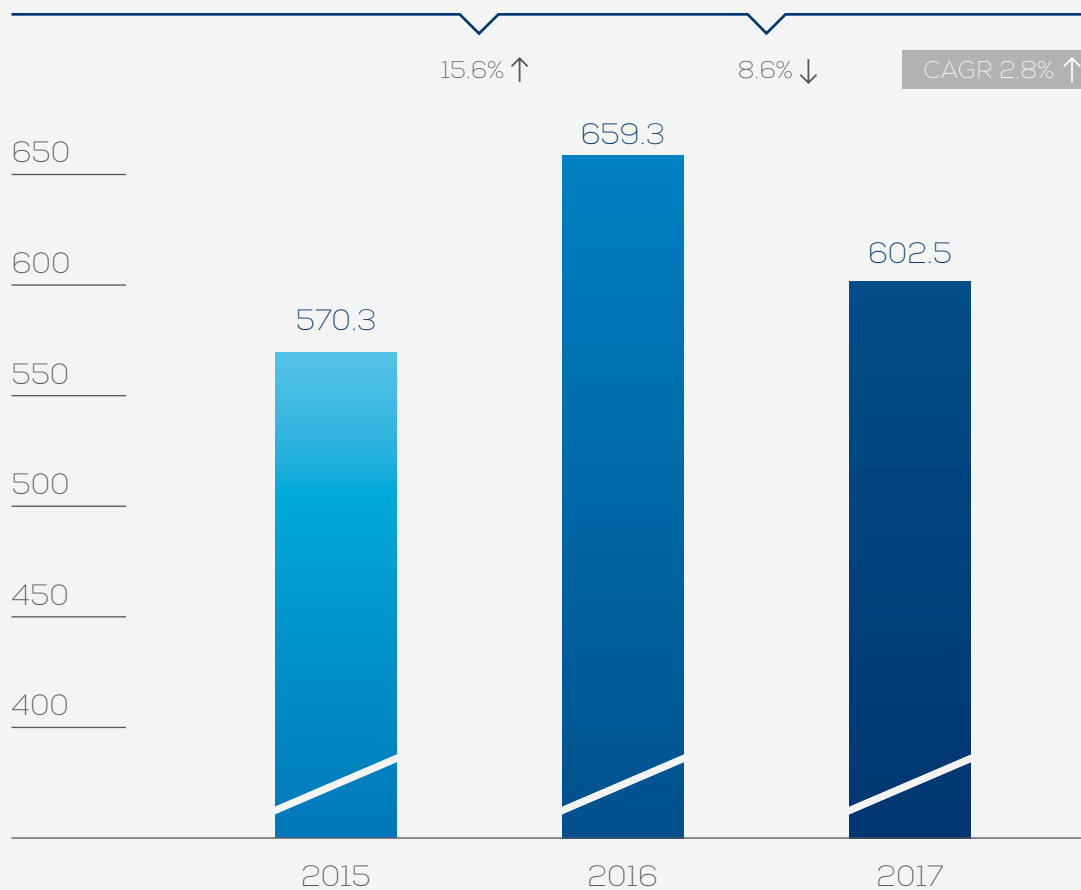
## DEBT REFINANCING

Taking advantage of favorable market conditions, in 2017 the group carried out a series of transactions to refinance a significant portion of its medium/long-term debt, eventually issuing a new Euro 350 million bond with maturity in 2022 and a coupon of 3%. Kedrion used part of the proceeds to repurchase Euro 91 million of the bond with maturity in 2019 and a coupon of 4.625%. In addition, it extended the maturity of two credit facilities for a total amount of Euro 188 million from April 2019 to 2022 as well as took out a new Euro 60 million revolving line of credit after repaying other outstanding loans. Overall, this allowed Kedrion to lengthen the average maturity of its debt in order to support its growth plan.

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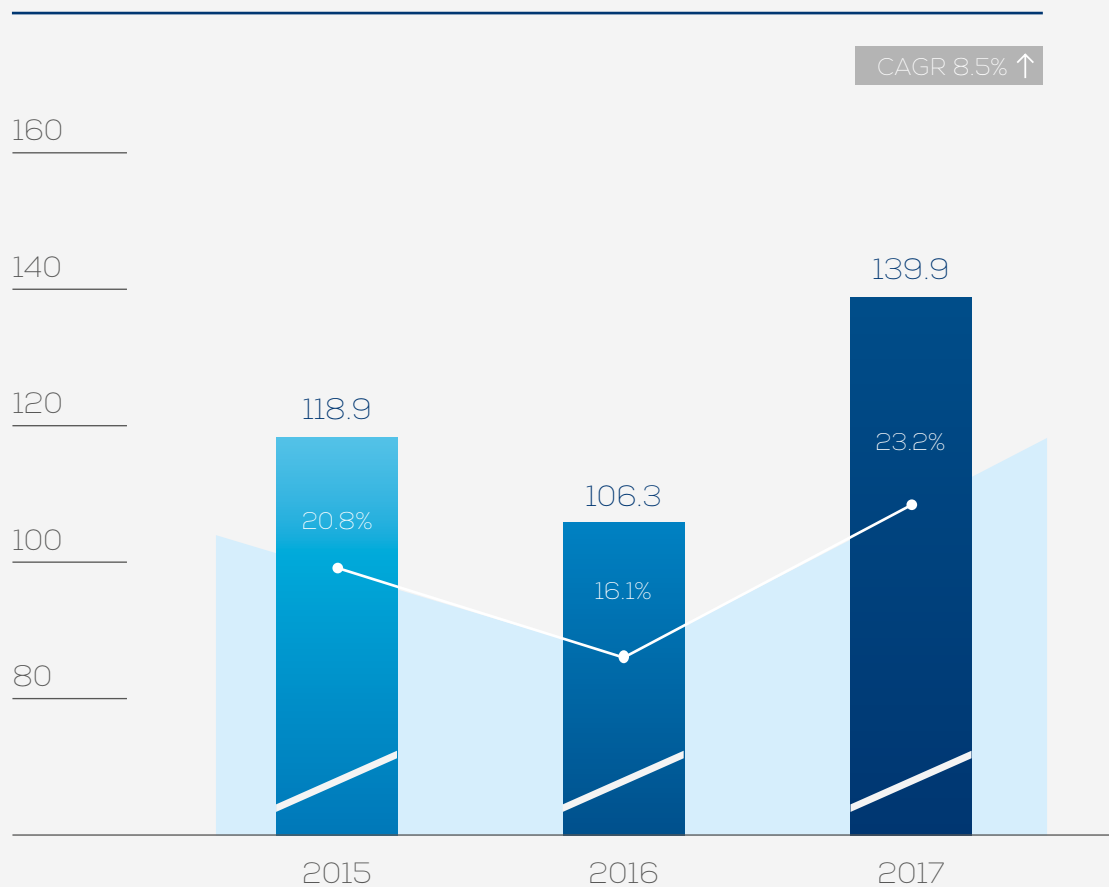
# ECONOMIC & FINANCIAL INDICATORS

REVENUES (€ MLN)



# ECONOMIC & FINANCIAL INDICATORS

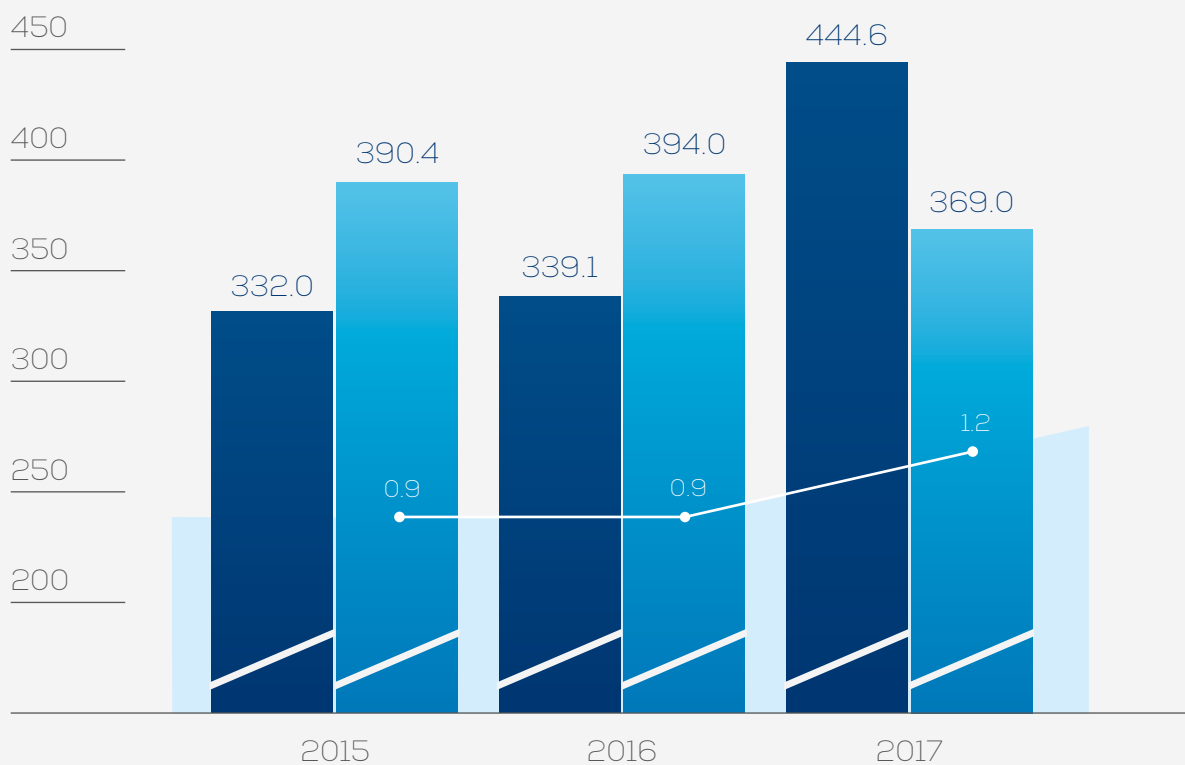
EBITDA ADJUSTED (€ MLN) AND  
ADJUSTED EBITDA/REVENUES %



# ECONOMIC & FINANCIAL INDICATORS

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

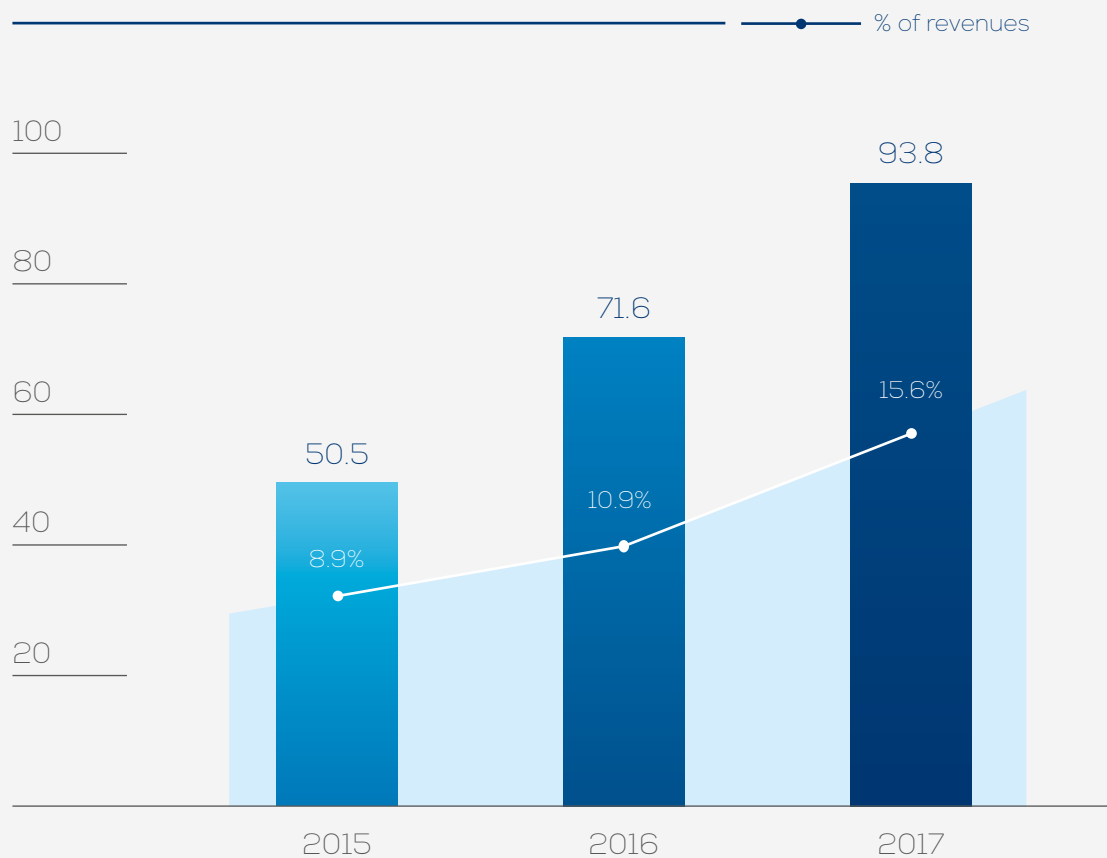
■ NFP  
■ Net Equity  
—●— NFP/Net Equity



# ECONOMIC & FINANCIAL INDICATORS

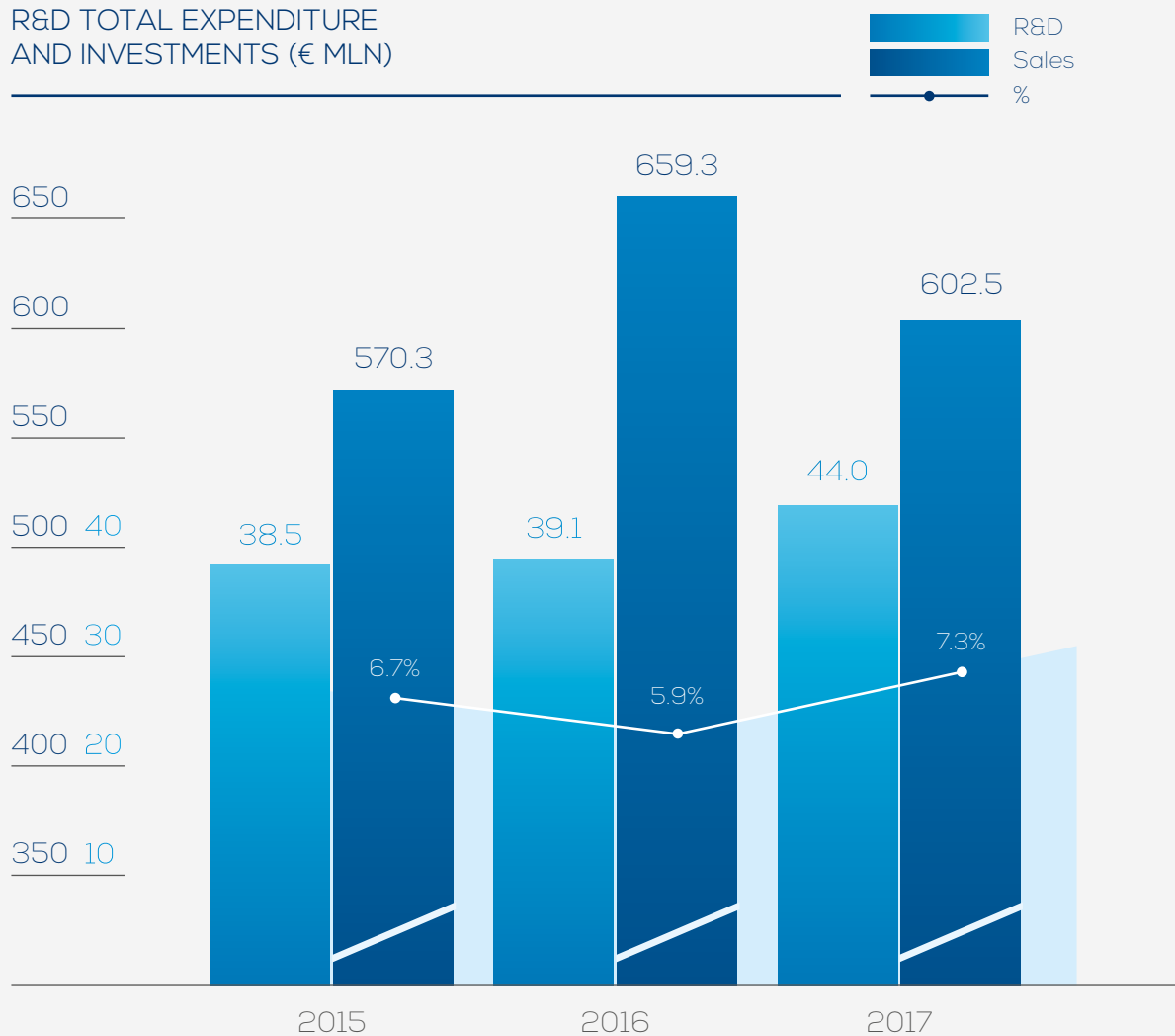
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## NET INVESTMENTS (€ MLN)



# ECONOMIC & FINANCIAL INDICATORS

R&D TOTAL EXPENDITURE  
AND INVESTMENTS (€ MLN)





# ECONOMIC & FINANCIAL INDICATORS

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## REVENUES

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### USA

Even though it was down 17.8% from the previous year, the area generated Euro 244.4 million in turnover and remained Kedrion's main market, accounting for 40.6% of total revenues. Plasma sales were the main driver of the reduction in revenues during the year because of the shortage in the supply of plasma from third parties, followed by standard Immunglobulin, the Anti-D Immunglobulin (RhoGAM®), Factor VIII, and Albumin, which all declined year-on-year largely because the group suspended operations at the Melville plant and discontinued the sale of Bivigam®. Besides the sales of plasma derivatives, the area also includes the revenues generated by contract manufacturing operations at the Melville plant, which were down slightly because of the end of manufacturing operations on behalf of Grifols.

### ITALY

At 31 December 2017, the Italian market was down 2.3% from the previous year, generating Euro 163.6 million in turnover - 27.1% of total revenues - from the sales of finished products on the commercial market and contract manufacturing operations on behalf of Italy's National Health System. The year-on-year decline was largely attributable to the reduction in the volumes of contract manufacturing performed on behalf of Italy's National Health System, partially offset by the increase in the revenues from Nuwiq® sales.

### EUROPEAN UNION

At 31 December 2017, turnover in the European Union amounted to Euro 58.4 million, accounting for 9.7% of total revenues and down 1.9% compared to 2016 because of the lower sales of plasma to third parties. This was almost offset by the growing sales of plasma derivatives, specifically in Germany, Hungary, Poland, Austria, and Portugal, which represented the group's main European markets in 2017.

# ECONOMIC & FINANCIAL INDICATORS

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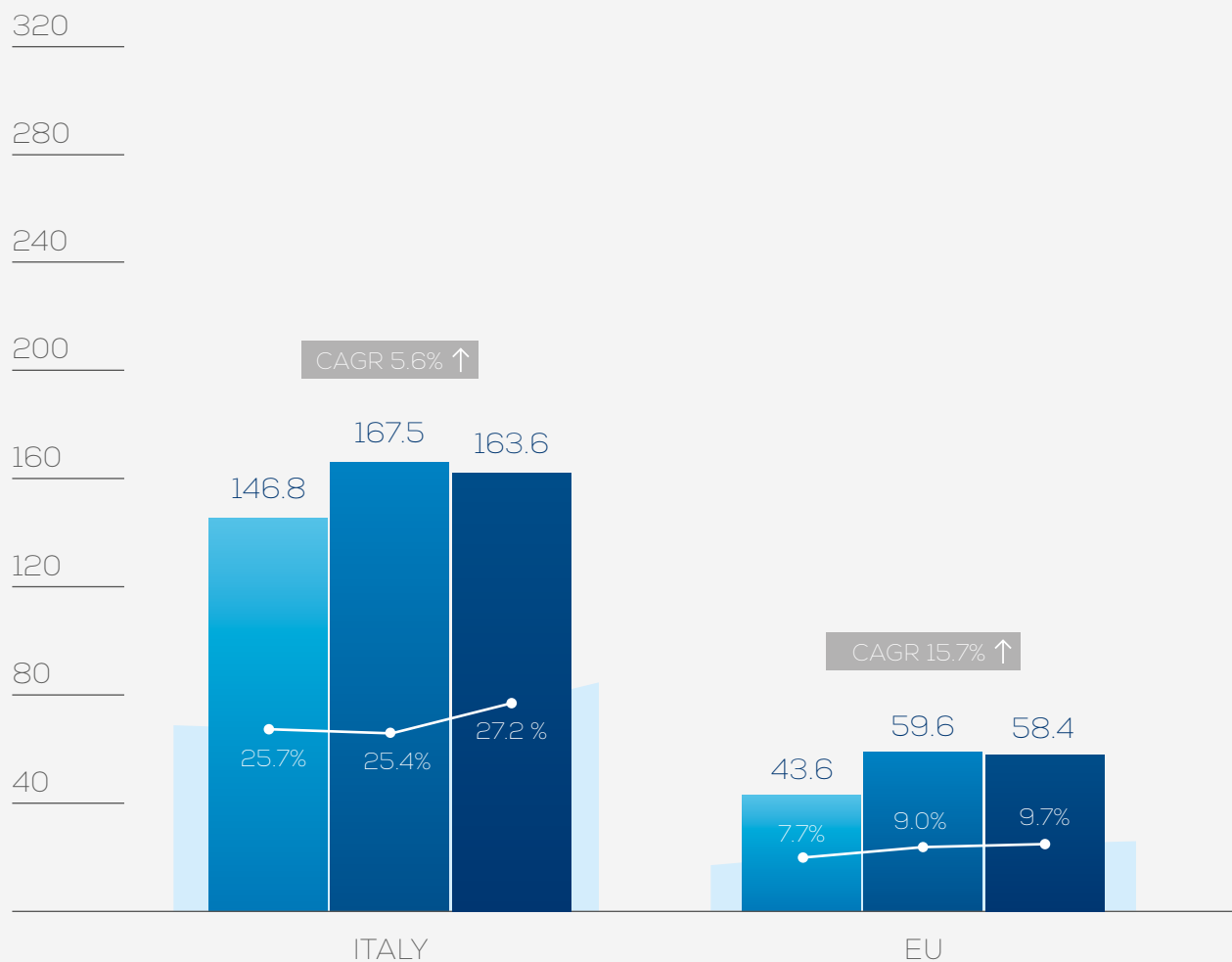
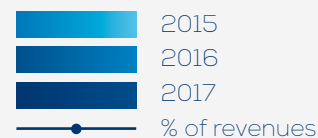
## REST OF THE WORLD

At 31 December 2017, the turnover for this geographic area amounted to Euro 136.1 million, up 0.9% from 2016 and accounting for 22.6% of total revenues. Turkey consolidated its position as the area's largest market in terms of turnover - thanks to, among other things, a comprehensive product portfolio - followed by Mexico. The weakness of the respective local currencies weighed on the performance in both countries. Along with Russia, Vietnam, Iran and Israel, Turkey and Mexico accounted for approximately 71% of the area's total revenues.

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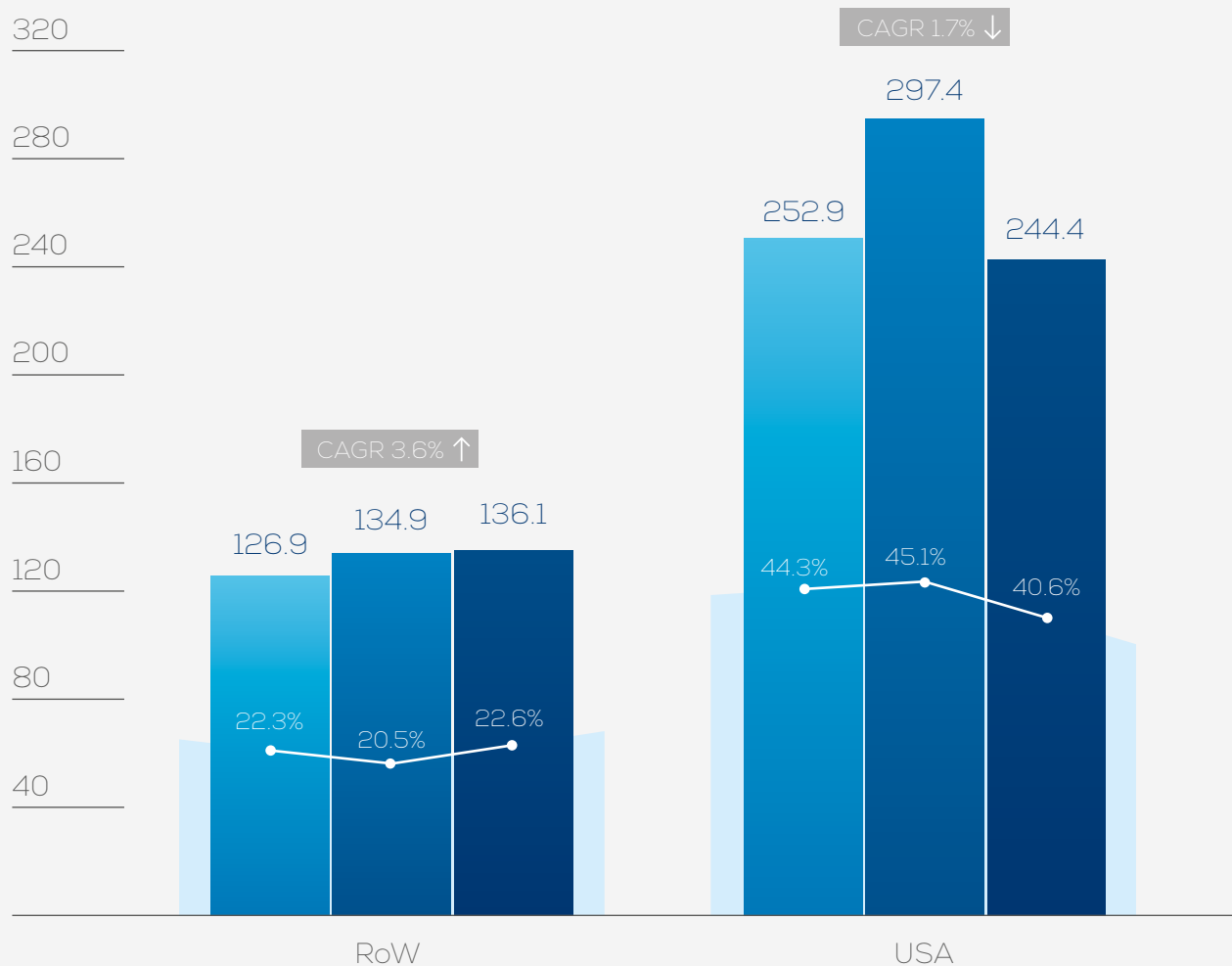
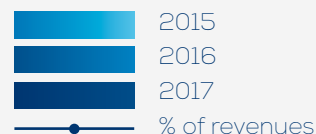
# ECONOMIC & FINANCIAL INDICATORS

DISTRIBUTION OF SALES  
BY GEOGRAPHIC AREAS (€ MLN)



# ECONOMIC & FINANCIAL INDICATORS

DISTRIBUTION OF SALES  
BY GEOGRAPHIC AREAS (€ MLN)



# CONSOLIDATED FINANCIAL STATEMENTS

## CONSOLIDATED INCOME STATEMENT (IN THOUSANDS OF EURO)

YEAR ENDED AT 31 DECEMBER 2017

Revenues from sales and services	602,501
Cost of sales	427,831
<b>GROSS OPERATING MARGIN</b>	<b>174,670</b>
Other income	52,887
General and administrative expense	80,757
Sales and marketing expense	51,785
Research and development expense	35,045
Other operating costs	8,325
<b>OPERATING RESULT</b>	<b>51,645</b>
Financial charges	43,750
Financial income	1,953
<b>RESULT BEFORE TAX</b>	<b>9,848</b>
Income taxes	3,657
<b>NET RESULT FOR THE PERIOD</b>	<b>6,191</b>
OF WHICH:	
GROUP RESULT	5,188
MINORITIES RESULT	1,003

# CONSOLIDATED FINANCIAL STATEMENTS

OTHER COMPREHENSIVE INCOME  
(IN THOUSANDS OF EURO)

YEAR ENDED AT 31 DECEMBER 2017

PROFIT FOR THE PERIOD	6,191
OTHER COMPREHENSIVE INCOME TO BE RECLASSIFIED TO PROFIT OR LOSS IN SUBSEQUENT PERIODS:	
Net movement on cash flow hedges	554
Income tax effect	(133)
	421
Exchange differences on translation of foreign operations	(26,050)
Income tax effect	(26,050)
NET OTHER COMPREHENSIVE INCOME TO BE RECLASSIFIED TO PROFIT OR LOSS IN SUBSEQUENT PERIODS	(25,629)
OTHER COMPREHENSIVE INCOME NOT TO BE RECLASSIFIED TO PROFIT OR LOSS IN SUBSEQUENT PERIODS:	
Re-measurement gains (losses) on defined benefit plans	9
Income tax effect	(2)
	7
NET OTHER COMPREHENSIVE INCOME NOT TO BE RECLASSIFIED TO PROFIT OR LOSS IN SUBSEQUENT PERIODS	7
OTHER COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX	(25,622)
<b>TOTAL COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX</b>	<b>(19,431)</b>
ATTRIBUTABLE TO:	
EQUITY HOLDERS OF THE PARENT	(20,118)
NON-CONTROLLING INTERESTS	687



# CONSOLIDATED FINANCIAL STATEMENTS

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION (IN THOUSANDS OF EURO)

YEAR ENDED AT 31 DECEMBER 2017

### NON CURRENT ASSETS

Property, plant and equipment	251,215
Investment property	2,386
Goodwill	219,318
Fixed term intangible assets	62,034
Investments in associated companies	331
Investments in other companies	2,095
Other non current financial assets	10,856
Deferred tax assets	6,089
Other non current assets	655

**TOTAL NON CURRENT ASSETS** 554,979

### CURRENT ASSETS

Inventories	280,180
Trade receivables	127,969
Current tax credits	7,237
Other current assets	36,829
Other financial current assets	564
Cash and cash equivalents	104,522

**TOTAL CURRENT ASSETS** 557,301

**TOTAL ASSETS** 1,112,280

# CONSOLIDATED FINANCIAL STATEMENTS

CONSOLIDATED STATEMENT OF FINANCIAL POSITION  
(IN THOUSANDS OF EURO)

YEAR ENDED AT 31 DECEMBER 2017

<b>GROUP SHAREHOLDERS' EQUITY</b>	
Share capital	55,186
Reserves	307,784
Group net income	5,188
<b>TOTAL GROUP SHAREHOLDERS' EQUITY</b>	<b>368,158</b>
<b>MINORITIES SHAREHOLDERS' EQUITY</b>	
Minorities capital and reserves	(153)
Minorities net income	1,003
<b>TOTAL MINORITIES SHAREHOLDERS' EQUITY</b>	<b>850</b>
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<b>369,008</b>
<b>NON CURRENT LIABILITIES</b>	
Medium-/long-term debt	511,932
Financial liabilities	346
Provisions for risks and charges	959
Payables for employee benefits	6,738
Other non current liabilities	7,834
<b>TOTAL NON CURRENT LIABILITIES</b>	<b>527,809</b>
<b>CURRENT LIABILITIES</b>	
Financial liabilities	41,248
Current portion of medium-/long-term debt	7,036
Provisions for risks and charges	598
Trade payables	122,522
Current tax payables	2,787
Other current liabilities	41,272
<b>TOTAL CURRENT LIABILITIES</b>	<b>215,463</b>
<b>TOTAL LIABILITIES</b>	<b>743,272</b>
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>	<b>1,112,280</b>

# CONSOLIDATED FINANCIAL STATEMENTS

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

YEAR ENDED AT 31 DECEMBER 2017

Net cash flow generated by operating activities (A)	35,536
Net cash flow absorbed by investment activities (B)	(91,350)
Net cash flow absorbed by financing activities (C)	93,766
<b>TOTAL NET CASH GENERATED/(ABSORBED) FLOW D=(A+B+C)</b>	<b>37,952</b>
Cash and cash equivalents opening balance (E)	66,508
Net effect of conversion of foreign currencies on cash and cash equivalents (F)	62
<b>CASH AND CASH EQUIVALENTS CLOSING BALANCE G=(D+E+F)</b>	<b>104,522</b>

# KEDRION IN THE WORLD

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## KEDRION SPA CORPORATE HEADQUARTERS

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**North America**  
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**Asia, Africa & Middle East**  
**Europe**  
**Italy**  
**Russia & CIS**

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# KEDRION IN THE WORLD

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KEDRION  
B I O P H A R M A

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