


# ANNUAL REPORT 2022

KEDRION  
B I O P H A R M A





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# LETTER FROM PAOLO MARCUCCI

2022 was a momentous year in the history of Kedrion. A year of growth and challenges met. The most significant development has been the integration of UK-based Bio Products Laboratory (BPL), which has been possible thanks to the investment of private equity firm Permira, now our majority shareholder. This move, completed in September, has resulted in a stronger Kedrion, with annual sales of more than Euro 1.1 billion and nearly 4,800 employees worldwide.

When 2022 began, the plasma-derived sector was still affected by the pandemic and a drop in plasma donations. We concentrated on efficiency, along with increased donor fees, so in 2022 we achieved a 54% increase in volume over 2021, collected from Kedrion and BPL centers in the US. To secure an increasing amount of high-quality plasma, in December 2022 we acquired five collection centers in the Czech Republic, thus becoming once again a player in the European plasma space.

In the year 2022, Kedrion Group (without BPL Group) generated revenues of Euro 719.8 million, a 9% increase over 2021, while BPL Group generated revenues of

Euro 458.2 million. The combined Group, that consolidates BPL in the last four months of the year, ended with revenues of Euro 886.7 million, up Euro 226.3 million (+34,3%) from 2021. Notable sales performances were realized in the US, in Turkey and Mexico. The US remains our most significant market, and it is expected to continue to be so.

Today's Kedrion has the crucial components to make a significant impact in the plasma derivative sector: an ample and reliable supply of plasma; critical fractionation capacity, including a network of manufacturing facilities with expansion potential; an impressive portfolio of products; and a global commercial team with a strong position in the US market - all leveraged by the resources and expertise of Permira together with the other shareholders in the pharmaceutical sphere.

Our future is promising. We can go forward on our historical path, offering traditional plasmaderivatives, while exploring the opportunity to establish ourselves in the orphan drug market with therapies for Factor X Deficiency and for Congenital Plasminogen Deficiency.

In December 2022, we welcomed Ugo Di Francesco, the new CEO of the combined company. Ugo is an extraordinary leader and comes to this role with an outstanding record in growing companies in the pharmaceutical sector. The Marcucci Family has promoted and supported these remarkable changes and remains as the Kedrion largest minority shareholder; CDP and FSI have chosen to remain as investors, which for us is a great news.

My family founded Kedrion more than 20 years ago. We are proud to have built something that has helped so many people and we are proud of the many people who have helped us make this happen.

The dedicated men and women of Kedrion and BPL will ensure that the name will continue to stand for the very best and most caring mission and traditions.

I look forward to carrying on in serving Kedrion as Chairman.

With gratitude and sincerity.

Paolo Marcucci,  
Chairman



# LETTER FROM UGO DI FRANCESCO

I am pleased and honored to introduce myself as the CEO of today's Kedrion. I came on board as the year ended, but, of course, I had followed Kedrion's path for some time before that. The company often invokes the metaphor of a bridge to describe its mission to connect donors to patients, bring plasma to therapies and transform health challenges to a hopeful future. This seems especially meaningful to me as I write this because I feel that we are now standing at the end of a bridge. And that bridge was 2022.

At the beginning of the year, Kedrion - what we might now call the "legacy Kedrion" - was still under the continuing threat of the Covid-19 pandemic. Plasma donations were depressed throughout the sector, which brought on financial challenges as well as the prospect of product shortages. The need to grow capacity, expand markets, and enhance our portfolio was becoming clear. BPL was struggling with some of the same challenges, of course. Thanks to the bold and visionary work of Paolo Marcucci and the Kedrion leadership and with the perceptive support of Permira, these challenges were met. With the joining of Kedrion and BPL, plasma supply was amplified,

markets expanded and portfolios enriched.

And this is yet another way that the metaphor of a bridge is especially applicable to our activities in 2022. The people of these two legacy companies, Kedrion and BPL, with the robust support of Permira, set out to build a bridge between them. This can be appreciated most clearly in the initiation of the integration of collection centers of BPL Plasma with those of KEDPLASMA under the umbrella of the latter, while maintaining the deep respect and appreciation each company has for its donors. But all of the assets and qualities of the two companies have begun and continue to be integrated - bridged, if you will: the portfolios, the markets, the operating procedures, the leadership, the workforce.

A notable feature of this transition and integration is the emphasis on providing therapies in the rare disease and disorder space. Kedrion had made a sharp and insightful move at the end of 2021, acquiring the Canadian company, Prometic, along with its newly developed therapy to treat Congenital Plasminogen Deficiency. BPL came with its own therapy for the rare Hereditary Factor X

Deficiency. Both companies have a long history with rare bleeding disorders, but these two "orphan drugs" help put today's Kedrion on a path to prominence in the rare and orphan drug sector.

A bridge, somewhat paradoxically, is a symbol of both continuity and change. For while it carries us from one place or one circumstance to another, sometimes over "troubled waters", we carry with us our most dear and important qualities and practices. To continue. While our "legacy" companies experienced notable transformations late in 2022, overcoming significant challenges, relinquishing historical autonomies and coming together to form a new entity, their basic and common missions, values, ethics, principled practices and commitment to their corporate families endure.

I want to emphasize just a few of these ethical principles that will carry us into the future: diversity, sustainability and a responsible commitment to the communities we serve. We have and will continue to seek the valuable input of people often poorly represented - especially in higher leadership positions - groups whose diverse perspectives will also broaden and enhance our talent pool. We

will continually seek ways to minimize our impact on the precious environment which is home to all living things. We will respect and support the people who are our shareholders - patients and their families, donors, healthcare workers and our employees - as well as the communities where we work and in which they live. These are not boasts; I believe any company should practice such principles, but for one such as ours, whose mission is to provide help and relief to people suffering serious challenges, it is foundational.

The name of Kedrion endures. The end of 2022 marked the closing of a chapter in the proud name of Kedrion. Thanks to the Marcucci Family and all the dedicated people who worked with them since they founded the company more than 20 years ago, the name is associated with the highest professional and ethical standards and an unrivaled commitment to helping people. That name has earned an enviable reputation in the plasma sector, and we are proud to continue under its banner. It is also important to understand that this is a different company. We retain the name of Kedrion, we retain its values and its dedication to patients, but this is a new company. That fact

affords all of us the tremendous opportunity to build something special. Together.

Of course, crossing a bridge does not mark the end of a journey, but the beginning. Before us lie new paths to new horizons. With profound appreciation of the past and bright anticipation for the future, we set out with the Kedrion of today. With the firm foundation offered by Permira, we are bound to become a truly global company. And while we are determined and committed to significant growth, we do not aspire to be the *biggest* in the plasma sector; we do strive to be the *best*.

I look forward to joining with all of you who understand what a privilege it is to be working in a business whose primary objective is to help other people live better lives.

Ugo Di Francesco  
CEO





# WHO WE ARE







# OUR COMPANY

Kedrion Biopharma is a biopharmaceutical company that collects and fractionates blood plasma to produce and distribute worldwide plasma-derived therapies for use in treating and preventing rare and debilitating conditions like Coagulation and Neurological Disorders, Primary and Secondary Immunodeficiencies, and Rh sensitization, which can lead to Hemolytic Disease of the Fetus and Newborn.

In 2022, Kedrion joined forces with BPL (Bio Products Laboratory). Based in the United Kingdom, BPL has over 60 years of experience in the supply of high-quality plasma-derived medicines to treat rare diseases.

With the combination of Kedrion and BPL, Kedrion becomes a global player in plasma derivatives and rare disease medicines employing more than 5,000 people worldwide. The company has a plasma collection footprint of 73 centers operated by KEDPLASMA in the United States, and of 5 centers operated by UNICAPlasma in the Czech Republic, and a portfolio of 37 products distributed in over 100 countries around the world. With these figures, Kedrion is the world's

5th top player in the field of plasma-derived products.

In 2021, Kedrion's acquisition of Prometic, and of its first-ever therapy for Congenital Plasminogen Deficiency, has confirmed our commitment to fighting rare, or even extremely rare, diseases.

# PEOPLE TO PEOPLE

We are dedicated to helping people, to building bridges from plasma to treatments, from donors to patients, from diagnosis to health and hope.

We take this mission as a privilege and a profound responsibility.

\*Including Castelveccchio Pascoli plant (Lucca, Italy) completion impending  
\*\*Source: Marketing Research Bureau "The Worldwide Plasma Protein Market 2021"

As of May 2023

HQs in Italy with subsidiaries in Europe, UK, North America, Latin America and Asia



7\* manufacturing plants in 5 countries for a total fractionation capacity of ~3.8mL



73 plasma collection centers in the USA and 5 in Czechia



37 products



600+ marketing authorizations



Commercial presence in 100+ countries



5<sup>TH</sup>

5th world player in the field of plasma-derived products\*\*



People worldwide: 5,000+



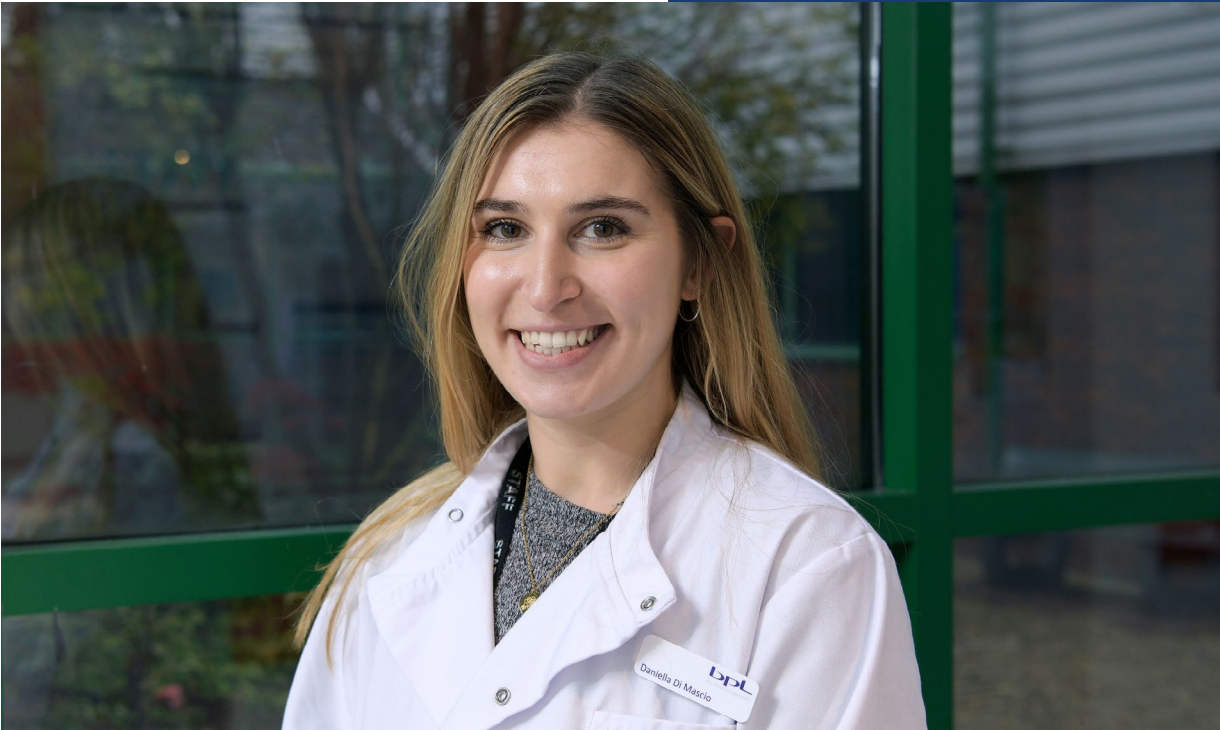
Partner in the self-sufficiency program in Italy and 1st player in the country in terms of production of plasma-derived therapies from Italian donor plasma



BioSC, the first GLP certified laboratory in Italy for pathogen safety



11 voluntary certifications in manufacturing, human resources, environment





# WORLDWIDE PRESENCE

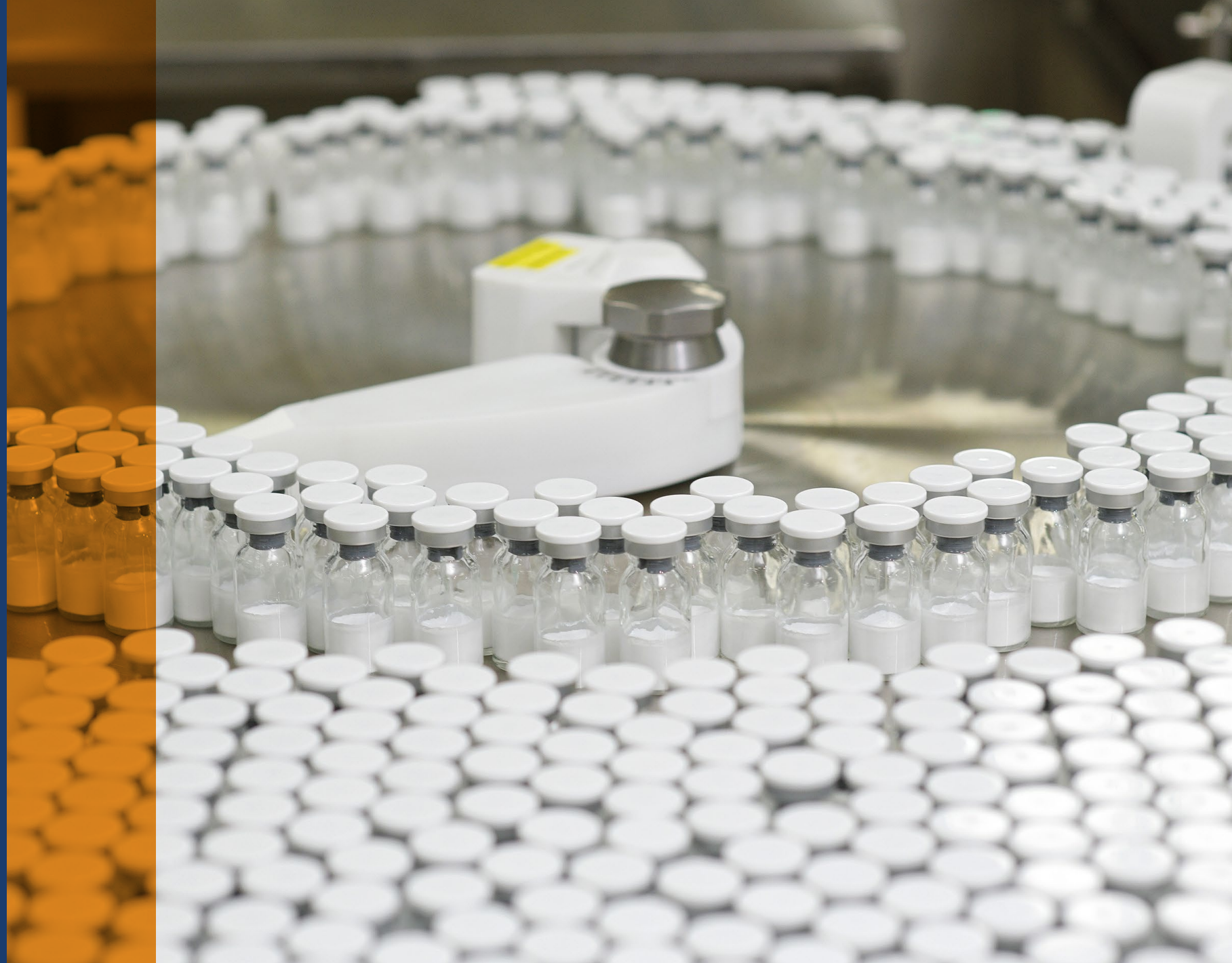


MAP LEGEND

- ◎ HEADQUARTERS
- 🏭 PRODUCTION
- 🧴 DISTRIBUTION
- 💧 PLASMA COLLECTION
- COMMERCIAL PRESENCE



# PORTFOLIO







# PRODUCTS

## 1 IMMUNOLOGY / NEUROLOGY

**GAMMAPLEX**  
Human normal i.v. Immunoglobulin 5%  
and 10%

**GAMMAKED\*\*\***  
Human normal i.v. Immunoglobulin  
10%

**Ig VENA / HUMAGLOBIN Liquid /  
KEDRIGAMMA / VENITAL\***  
Human normal i.v. Immunoglobulin 5%

**SUBGAM**  
Human normal s.c. Immunoglobulin  
16%

**OPTIGLOBIN\*\***  
Human normal i.v. Immunoglobulin  
10%

**NAXIGLO / KEYCUTE\***  
Human normal s.c. Immunoglobulin  
16%

## 2 RARE AND ULTRA-RARE DISEASES / COAGULATION DISORDERS

**RYPLAZIM\*\*\***  
Plasma-derived human Plasminogen

**COAGADEX**  
Human coagulation Factor X

## HEMATOLOGY / HEMOPHILIA

**EMOCLOT / HUMACLOT /  
PLASMACLOT / EMOWIL / KLOTT\* /  
KOÄTE\*\*\***  
Human coagulation Factor VIII

**8Y**  
Human coagulation Factor VIII with  
human Von Willebrand Factor (VWF)

**OPTIVATE**  
Human coagulation Factor VIII

**NUWIQ\*\***  
Human coagulation Factor VIII  
(rDNA), Simoctocog Alfa

**WILFACTIN\*\***  
Human Von Willebrand Factor

**AIMAFIX / KEDRIFIX /  
HUMAFactor-9 / IXED\***  
Human coagulation Factor IX

**REPLENINE-VF**  
High purity human coagulation Factor  
IX

**EMOSINT**  
I.m. Desmopressin

## 3 MOTHER AND CHILD HEALTH

**RhoGAM / IMMUNORHO / KeyRho /  
MICRhoGAM**  
Human Anti D Immunoglobulin

**D-GAM**  
Human Anti D Immunoglobulin

**IMMUNOHBs 180 IU**  
Human Hepatitis B i.m.  
Immunoglobulin

## 4 ACUTE / CRITICAL CARE AND TRANSPLANTATION

**UMAN ALBUMIN / UMAN SERUM /  
HUMAN ALBUMIN / KEDRIALB /  
ALBUPLEX / ALBITAL\* / KEDBUMIN /  
ALBUKED\*\*\* / ALBUMINA LFB\*\***  
Human Albumin solution

**ZENALB / ALBUMINEX**  
Human Albumin solution

**KEDRAB\*\*\***  
Human Rabies Immunoglobulin

**VENBIG / KEYVENB / VEBIKED**  
Human Hepatitis B i.v. Immunoglobulin

**IMMUNOHBs / UMAN BIG / KEDHBs\***  
Human Hepatitis B i.m.  
Immunoglobulin

**TETANUS GAMMA / TETIG**  
Human Tetanus Immunoglobulin

**UMAN COMPLEX / KEDCOM\* /  
PRONATIV\*\***  
Human Prothrombin complex

**AT III KEDRION / ATKED\***  
Human Antithrombin

**K FLEBO**  
Potassium aspartate

**PLASMASAFE / PLASMAGRADE\***  
Human plasma proteins /  
Pharmaceutical grade plasma

**MONOFERRIC\*\***  
i.m / i.v. Ferric Derisomaltose

# SERVICES

## 1 PLASMA PROCESSING FOR NATIONAL SELF-SUFFICIENCY PROGRAMS (ITALY AND ABROAD)

## 2 TECHNOLOGY TRANSFER

## 3 VIRUS AND PRION CLEARANCE STUDIES (BioSC)

\* Products for the Italian Self-Sufficiency Program  
\*\* Products in license  
\*\*\* Products only available for the US market

# OUR 2022







# 2022 TRANSFORMATION

2022 was a year of growth and transition. Indeed, it was a year of basic *transformation*. While the Kedrion that exited the year was fundamentally distinct from the one that entered, we have retained the essential values and commitments that the histories of all our constituents have established.

Already in January it was announced that private equity firm, Permira, would become the majority Kedrion shareholder. Partnering with the Marcucci family and other existing investors, the company's future would be charted together with that of the UK-based Bio-Products Laboratory (BPL).

It was immediately clear that the year would be devoted not only to maintaining our recovery from the effects of the still-threatening Covid-19 pandemic, but to consolidating and fashioning what in many fundamental ways would be a new Kedrion. Our skills and commitment to bridge building would now be turned inward as well: to scaffold this transition and to bring two successful companies, two legacies, two histories together.

Permira is a widely known and respected investment company, with a reputation for supporting successful enterprises with clear potential for growth in the middle and long term and focusing on the technology, consumer, services and healthcare sectors. The Permira private equity funds have made approximately 300 investments in these areas. In healthcare they have previously made some 18 finance commitments totaling €4.2bn, especially in innovative healthcare businesses in such areas as specialty pharma, medical devices, strategic outsourcing platforms and healthcare technology. Permira operates out of 15 offices in the US, Europe and Asia, employing more than 470 people.

The Marcucci family founded Kedrion more than twenty years ago and built it into a successful global enterprise through the leadership of Paolo as CEO, Maria Lina as Head of Global Communications and Andrea, Chair of the Plasma Business Unit. The Family remains as the largest minority shareholder along with existing investors including FSI and CDP Equity. While Maria Lina and Andrea Marcucci step down,

Paolo remains as Chairman and CEO until the end of 2022, when Ugo Di Francesco takes over as CEO and Paolo continues as Chairman.

The agreement was finalized in September. Kedrion and BPL officially combined to form a new and more robust Kedrion with a mission to serve even more patients worldwide with an augmented portfolio of therapies and the enhanced efficiency of size and expertise.

The combined company results in an impressive set of assets in operations, personnel and expertise including:

- 5000+ Employees
- 7 Production Plants
- 78 Plasma Collection Centers
- 37 Products

While Kedrion global headquarters will remain in Italy, it is expected that nearly 90% of our sales will be from markets outside the original home countries of Kedrion (Italy) and BPL (UK). The US will remain our leading market and the focus of greatest future growth, and potential new markets such as China will continue to expand our horizons.



“

This partnership with Permira has made it possible to make an exciting step forward in the history of Kedrion, allowing us to create a global player in the plasma derivatives sector that can successfully compete in a growing market that is increasingly critical in global healthcare. We are proud and grateful for Permira's support to integrate with BPL and thus significantly increase the global reach and competitiveness of the combined company.

**Paolo Marcucci, Chairman**



# BPL. A COMMITMENT FOR LIFE.

Before stepping on to the bridge leading to our “new” Kedrion, BPL has had its own journey during 2022, as well as a proud and rich history leading up to it.

In fact, its roots reach back nearly 60 years, to when it was founded as part of the Lister Institute of Preventative Medicine in Elstree, England. Still headquartered in Elstree, it has been a private corporation for more than a decade. The only plasma fractionator in the UK, it has become a leading global producer of plasma-derived therapies with robust markets in the US, Europe and around the world in more than 30 countries.

At the beginning of the year, BPL was organized in two operating divisions, BPL Plasma and BPL Therapeutics, the former collecting and providing plasma in the US for fractionation by the latter in England.

The company has shared the Kedrion emphasis on the patient as the core of its values and the center of its activities, producing a range of medicines for the treatment of immune deficiencies, bleeding disorders and infectious diseases as well

for critical care. It is especially recognized for its innovative product development in orphan drugs.

BPL Plasma has been headquartered in Austin Texas and has overseen the operation of 28 collection centers in the US until their joining the new KEDPLASMA.

## 2022 FOR BPL

Of course, the announcement in January by Permira and the Marcucci family to invest in BPL was clearly the most profound development in BPL’s year, the company observed many other notable milestones.

In that same month, the Chinese National Medical Products Administration (NMPA) granted a license to BPL for the marketing of its 25% Albumin solution in China, the world’s largest Albumin market.

“We are delighted to be able to provide our 25% Albumin to patients in China. Obtaining this important license and full distribution agreement

in China reflects strongly on our current plan for global expansion while highlighting our corporate mission of providing a continuous supply of high-quality plasma-derived products worldwide, supporting both healthcare professionals and patients every day.  
**Bob Rossilli, Chief Commercial Officer**

Shortly after this accomplishment, BPL made its first sale of its 20% Albumin solution to Mexico, the largest Albumin market in Latin America.

“

This first sale is a milestone for BPL, not just because it is the first product delivery, but also because of its importance for patients in Mexico. We have a steadfast commitment to enhance lives and serve more people who depend on our products.  
**Leonardo Torres, General Manager for BPL Mexico**

Also among its most significant marketing achievements during the year were the authorizations for the BPL treatment for Factor X Deficiency in Mexico and the Dominican Republic in the spring.

An important step in efforts to maximize the efficient use of our precious “natural resource”, human plasma, BPL developed an innovative process for extracting Immunoglobulin from what was considered “waste” precipitate from normal fractionation steps through an additional fractionation. Known as the “E+I” process, it was granted a patent by the US Patent Office in March. The inventive procedure had already been successfully implemented in the UK for two years achieving significant IgG yield improvement.





# FUTURE BRIDGES

The term “Rare Disease” is not universally defined. In the US, it refers to conditions that affect fewer than 200,000 people, or roughly 1 in 1,500, without regard to characteristic or severity. In the European Union the definition is 1 in 2000. A somewhat different, but parallel designation is “Orphan Disease”, denoting the unfortunate fact that so few people suffer from them that correspondingly few treatments are available or even researched. Therapies that do arise are termed “Orphan Drugs”.

Kedrion has a fundamental interest and long history in rare diseases and their treatments. Hemophilia and Immune Deficiency are two rare conditions our products ameliorate. Hemolytic Disease of the Fetus and Newborn (HDFN) is a rare condition our Anti-D prophylactic can prevent.

For many years we have been especially interested in one extremely rare condition called Congenital Plasminogen Deficiency (CPD) and have worked to develop an eye-drop therapy to address its dominant symptom, Ligneous Conjunctivitis. Since we acquired the Canadian pharmaceutical company Prometic in late 2021, we have been able to offer a breakthrough therapy that treats

all symptoms: Ryplazim. This is clearly an orphan drug for a

## THE NORD AWARD

In June, Kedrion Biopharma was presented with an Industry Innovation Award from the National Organization for Rare Disorders (NORD). The award paid tribute to Kedrion’s treatment for the ultra-rare disorder, Congenital Plasminogen Deficiency. The treatment was developed by our recently acquired subsidiary Prometic, based in Laval, Canada. Accepting the award, **Giorgio Masetti**, then VP, Regional Commercial Director US, and now VP, **Global & US Marketing Lead**, noted



Our mission at Kedrion is to provide patients with rare disease treatments that bring them hope. This treatment is especially important as it is the first available to people who have suffered for years with no relief. We are proud to deliver it to them.

condition affecting an estimated of 1.6 people per million in the general population. With the joining of BPL and Kedrion, we have added to our portfolio a treatment for another orphan disease, Factor X Deficiency, also a hereditary condition affecting approximately 1 in 1 million people.

Factor X (X for Roman numeral 10) is an enzyme protein in

the blood that is crucial in the clotting process. Hereditary Factor X Deficiency is inherited in an autosomal recessive pattern, i.e., both parents must have the gene variant associated with the condition and both must pass it on to their child for the child to experience symptoms. People who have this deficiency experience a wide range of symptoms, depending on the severity of the deficiency, but



common symptoms include easy bruising, nose and gums bleeds and excessive bleeding from injury or surgery. In more severe cases, symptoms, which can be present at birth, can include bleeding into the joints and muscles as well as in the stomach and intestines. Intracranial hemorrhage, a life-threatening event, is at high risk from birth.

Without treatment, symptoms can occur throughout life.

Coagadex (human coagulation factor X) is an FDA and EMA approved Factor X concentrate for the treatment and control of Hereditary Factor X Deficiency.

For people suffering from Factor X Deficiency, the development of this therapy by BPL in 2015, represented a monumental relief. From pain, fear... despair.

This is the story of one patient and her family. We have changed their names to protect their privacy.

When Kate gave birth to her second child, she knew a lot - too

much - about Hereditary Factor X Deficiency. She and her husband both carried the gene variant that can result in its expression. Her first child, Sean, was born with the condition. There was no screening for such a rare condition, but they learned early - after a bleed beneath his scalp at birth - that he had a deficiency of Factor X. Treatment options were limited and knowledge scant - again at least in part because of the extreme rarity of cases. The only available treatments were fresh frozen plasma (FFP) and prothrombin complex concentrate (PPC), both of which have a variety of factor proteins including Factor X, but at a low and variable concentration. At five weeks Sean experienced a brain bleed with profound consequences. Kate and her husband were looking forward to having another child, but more than anything, they needed more

information. She discovered a library in the basement of their hospital that was open to anyone. There she learned more about Factor X Deficiency and its consequences.



We also learned how rare it was, which also just put us in such a horrible category of feeling like we were completely alone in the world.

As Sean’s condition improved somewhat, they decided to have another child. The elation that accompanied newborn Olivia was so intense that Kate did not at first understand what her doctor meant when she visited just after the birth: “Olivia does not have Factor X.”





“

I am holding her and I say, “Of course she doesn’t: she is absolutely beautiful!” But the doctor quickly explained: “No, she doesn’t have any Factor X in her body; she does have Factor X Deficiency.”; she does have Factor X Deficiency. It took me a few minutes to truly realize what that meant.

The healthcare team and the well-informed parents determined to begin preventative care before any kind of bleeding episode.

“

After everything that my son went through and knowing the severity (of the deficiency) that she actually did have, we just wanted to protect her. My daughter started having prophylactic care the day that they found out that she had Factor X Deficiency.

The narrow choice of available treatments which were only marginally effective, along with the limited knowledge about Factor X Deficiency meant that both Sean and Olivia would continue to experience symptoms. Although each produced less than 1% of normal levels of Factor X and Sean had suffered a profound early outcome,

Olivia’s symptoms tended to be the more challenging as they grew up.

For her, a lot of her life was a challenge. She and her brother were subject to the same precautions their parents imposed to keep them safe and both followed the same therapy regimen, so Olivia didn’t really think of her life as different. The padded corners and cushioned hard surfaces in her house, the constant bruising all over her body, the frequent treatments – they were all just the way things were. In fact, when she was still quite young, she asked her mother at the local pool where the other kids’ “ports” were. She was referring to the port installed in her chest to facilitate her twice-weekly infusions.

So, despite these prophylactic treatments with PCC, she experienced significant symptoms.

“

I started taking dance classes and after my dance class every week I would have like terrible, terrible ankle pains and that’s when I first started realizing, hey, I don’t think this is normal; other people don’t seem to be having this issue; it’s just me. So that was kind of my first major thinking about I have a bleeding disorder and it’s a bit indifferent. I ended up having

to quit taking dance lessons because I couldn’t really handle it with all of the joint pain that I was having. It was not uncommon for my legs to be all purple and blue. I also had a lot of nose bleeds that lasted for hours.

Sports were pretty much out of the question for Olivia, which made her feel left out and she missed the “camaraderie” of that experience. She was able to turn to music, where she was able to find that feeling of being part of a group. Factor X Deficiency – indeed, most bleeding disorders – can be especially challenging for girls and women during menstruation.

“

Menses were really, really difficult for me to deal with. I would bleed a lot, so much so that it was difficult for me to walk and get up a flight of stairs, because I had lost so much blood.

For people suffering from rare diseases and disorders, a special complication lies in the understandable widespread lack of knowledge and experience among healthcare professionals.

“

My doctor knew that periods were an issue for women with bleeding disorders, but he kind of just said, it’ll be fine, you’re just having a hard time right now. Even after six months, he just said, “You’ll grow out of it, it’ll be fine, we’ll deal with it later when it’s better.” But the most common thing that was discounted was the joint pain and swelling. When I was younger, if I had issues, especially with my joints, my pediatric hematologist would just say: “You’re fine. It’s growing pains. That’s not a bleeding disorder symptom. Your bleeding disorder is just mucosal bleeding.” So I was never really treated for my joints or believed that I was having any issues and that was difficult to deal with because it was some pretty intense pain that I would have with activity.



## FINALLY, A BREAKTHROUGH

“

Growing up we’d have to go to our annual visits with the hematologist and he would always tell us, “Hey, I’m hearing about a Factor X Deficiency drug that’s going to be coming out soon.” And we would say, yeah, that’s cool, but that’s never going to happen. No one’s going to do that. There’s too few people for that to make sense. Sounds great, but that’s probably not going to work out.

But it did.

“

I haven’t had a nose bleed in many years, which is awesome. I don’t look all bruised up all the time. I don’t really get random bruises anymore. I do get some joint pain, but it’s only with really intense activity. So my symptoms are a lot more controlled now.

Nearly as important as the relief from pain and bleeding is for Olivia, the independence.

“

I always had to rely on one of my parents to help me infuse my

medication. But now we knew exactly how much medicine we were getting and exactly what our peak and trough levels would be because of that. I also didn’t need to be infused over such a long period of time. Our volume was way less, which meant I could start learning how to do the infusions myself intravenously. So I did. Later I got my port taken out because I didn’t need it anymore. So that was a bit of a transition. But it was great for me because I could start doing the things myself. I didn’t need my parents to be there, which was a huge independence boost for me. When I was in high school and people were thinking about college and stuff, I was just thinking, you know, that’s not gonna work out for me. I can’t move away right now. I have to have my parents or a nurse or somebody come give me my medication twice a week. So college was not really on my radar at that point, but after the Factor X came out, I became a lot more independent and was like, “Hey, I don’t really need to rely on anybody anymore. I can go to college.”

And she did. She is still careful about big bumps and bruises – especially on days when her



Factor X is low just before her regular infusion, but all in all, she feels, as she puts it “pretty normal.”



I would say on days that are closer to when I’ve taken my factor, I can operate pretty well as normal. On days that I am lower, I tend to think a bit more about what I’m going to do. So maybe not plan a long hike on the day right before I need a treatment or the day I’m needing a treatment. So on higher days it’s pretty normal, but on days that I’m lower I think about it a bit. I have not taken an on-demand treatment in a very, very long time, and it’s going well.



For Olivia’s mom, it has also been transformative.



Today, all these amazing years later, my son is 25 years old. He’s doing very, very well. The neurologist had told us he would not walk or talk, but he is doing great. He does not stop talking. He loves to sing. He’s recently been in a play and he was the narrator so he talked very well throughout the whole play. He actually plays a lot of different sports. He’s in Special Olympics and he loves to play baseball. He’s going to be our “forever child” because he’s going to need to have that extra care. And my daughter: she’s phenomenal. It really changed her life.

Both Olivia and her mom have become advocates, educating both patients and the healthcare community.



We’ve been able to meet quite a few families that have people with Factor X Deficiency, which has been really cool. Very different, but a lot of us have had the same issues, the same issues with doctors with bleeding, what have you. So it’s been really cool being able to talk to other people and say, oh hey, yeah, that happened to me too, or what do you do about this situation? And my mom actually is running a Facebook group that is for Factor X Deficiency patients and families. We’re all able to communicate even from very different parts of the world.

Having an ultra-rare disease and finding a way to treat it has, of course, played a major role in shaping Olivia’s life and her future.



Growing up having a bleeding disorder, we sometimes had to understand it better than some doctors do. We would have to know this is what the bleeding disorder is, this is exactly how it works - in case we needed to go to a hospital that was

not our own. Because Factor X Deficiency is very rare; it’s not something that other doctors really know about. It really made me aware of science. So I graduated from undergrad with a degree in biology and chemistry. And now I am in a PhD program for pharmacology and neuroscience, and I’m studying drug development.

Olivia visited the BPL plant where the medication that changed her life was developed and is produced.



Visiting the plant and seeing Factor X being produced really made me realize this was a hugely important deal for me and for the people working there. That their life’s work is super important and that I want to do that with my life. So I am studying drug development to help give other people medications that are needed that they once did not have. Because I understand how important that is and how life

changing it can be. One last thing that I want to share; I hope it has been conveyed, but I would just like to repeat: I am very thankful for what you guys at BPL have done. My family is super thankful. It’s really been life changing for how we can handle our bleeding disorder and our activity level and for my independence. It’s been huge. So I just want to say Thank You.

We thank Olivia and her mother for the inspiration that makes our work so rewarding.





# DONORS AND DONATIONS

## GROWTH AT THE FOOT OF THE BRIDGE

We began the year under the significant pressure of the Covid-19 pandemic, which had depressed donor numbers and donations and had inflated plasma prices. We ended the year with very promising increases in donors and donations, but even higher plasma prices.

Regarding bridges, one of the most significant and

exciting challenges for this year of transition, has been the integration of KEDPLASMA and the KEDPLASMA centers with BPL Plasma and its centers, also based in the US. This process began with the Permira assumption of leadership and was completed - in terms of management - by the end of the year. Further integration of branding and operations is ongoing. All centers, other than

those in the Czech Republic, will be organized under the KEDPLASMA banner.

The acquisition in December of UNICAprasma s.r.o and UNICAprasma Morava s.r.o.\*, which operate five centers in the Czech Republic, marked a return to European plasma collection and will significantly enhance plasma availability for the company.

It all begins with plasma, and that means it all depends on donors. There would be no bridges, no therapies, no hope without the generosity of our donors. To them we give our highest respect and gratitude. The Covid-19 pandemic had a profound impact on donations, but the rebound has been remarkable, demonstrating the courage and determination of those who are so committed to helping others.

Like **Leslie**, who donates in one of our KEDPLASMA centers:



I donate because I have a few friends that had cancer and are now in remission because of the medications made from plasma. When they found out that I donate they cried because I was part of saving their life.

Or **James**, another KEDPLASMA donor:



I donate plasma to simply help someone. I may be offering a lifeline to a friend in my community or someone miles away from here. No matter who it is or where they are, I know that I'm making a difference by donating my life-saving plasma and to me, that is the most rewarding aspect.

**Alexandra** is a new donor in the Czech Republic:



I'm a student and this is my second donation of plasma. What I like about this is that I can help in some way. I wanted to, I don't know, help and I'm a little bit of an experimenter so I wanted to try how does it feel like to donate. I'm the first one. My family don't donate, and I didn't know anyone who was donating. It was from my own initiative. So, of course I said to my parents that I started to donate plasma and my mama asked if it's safe and okay. The personnel here is amazing and yeah, I feel safe here and I think that the everyone who comes here like, feels the same way as I do.



Winning this tender is one of the greatest accomplishments the Kedrion team has achieved in Portugal over the past few years, and it shows the important role our company plays as a national partner for the supply of plasma-derived products.”  
**Stephan Proske,**  
**Commercial Director**  
**Western Europe**

## CONTRACT MANUFACTURING

Procuring plasma from other countries in return for finished products is a good way to effectively enhance our plasma supply while helping these countries on a path to plasma self-sufficiency, a goal we have supported from our inception as part of our overall mission. Our historic relationship with the Italian National Blood System has provided a model for contract manufacturing - fractionating plasma collected by the various regions and deriving medicinal products for the nation.

During 2022, for example, we were fractionating some 230,000 liters of plasma from Poland, obtained as part of one of the largest plasma tenders in the world which Kedrion was awarded - for the third time - at the end of 2021. We successfully secured this tender again at the end of 2022 and will be fractionating the Polish plasma throughout 2023, producing essential products for that nation as well as others.

Another example is Portugal, where, after several years of unsuccessful attempts, we secured the contract manufacturing tender for that country's plasma. The agreement, signed in November, calls for Kedrion to fractionate some 60,000 liters of plasma collected from blood centers across Portugal, and deliver back three products - IVIg 5%, Human Albumin, and Factor VIII.



We are very proud to add these new companies to the Kedrion group and we welcome all new employees into our corporate family. A special welcome also goes to donors: their contribution is vital in helping to provide life-improving and life-saving therapies to the growing number of patients that we serve around the world.

**Paolo Marcucci, Chairman**

\*In 2023, UNICAprasma Morava s.r.o. has been merged into UNICAprasma s.r.o.



# PEOPLE HELPING PEOPLE... HELPING PEOPLE.

## AN INSPIRING STORY



We had the honor meeting two donors in one of our new collection centers in Prague that are inspirational examples of what we mean by bridges that help people help people. And the bridge they were on was being traveled in both directions. Jaina and Alina are from Ukraine. They are sisters. When the war began, they sought safety. Jaina was living in Kiev and as the city came under bombardment, she was especially worried

about protecting her two young sons. Alina was living in Sebastopol in Crimea and knew the war would soon be on her doorstep. Fortunately, her son was studying in Prague and the Czech Republic offered refuge. Jaina and her sons had to bid husband and father goodbye ("It's a really hard story", she says) and joined Alina in the Czech capital. They felt very fortunate. And they thought of a way to express their gratitude.

**Jaina:**



The Czech Republic is our escape place - the country that has helped us a lot. So, we started to donate our blood (plasma) because it is our way to help and to say thank you to the Czech Republic and to the people who live here.

In Kiev, Jaina was a screenwriter, and she continues to write in Prague. Alina is working as a teaching assistant, helping to educate both Czech children and refugee children from Ukraine.

**Alina** puts her hand to her heart and speaks to the Czech people:



We can say thank you... thanks... thank you for your support... and...

She struggles to find words.

**Jaina helps:**



Thanks for support, thanks for helping, and thanks for a safe and great place where we can live while in Ukraine is war. I think about my children and of course, Ukraine is not a safe place now.

We wish Jaina and Alina and their families safety and peace and offer our heartfelt thanks for their generosity toward the people they - and we - seek to help.



## Our new collection centers in the Czech Republic join the Kedrion family with a history of care.



**Milan Maly** directs and was the founder of the UNICAprasma collection centers. He was a lawyer looking for something that would



make more meaning in my life. I ended up in plasma collection and there I found a sense of life because what we do here at the end of the day, our jobs, save lives of patients around the world.

I sort of put the whole idea on paper, produced a business plan out of it, and July of 2008, we founded a company for plasma collection. We opened our first plasma collection center on May 7<sup>th</sup> of 2009.

UNICAprasma was the very first plasma center in the city of Prague. So, to some extent, we have been the pioneers of the industry in the Czech Republic.

The goal has always been providing the best quality, providing the best service, and building a long-term re-

lationship with our donors. There was not much awareness about plasma donation at all, but historically people knew that it's important to donate blood. We had a huge population of blood donors in this country, one of the best countries in Europe in terms of numbers of blood donors. So, when we first started, our goal was to actually build awareness of what plasma donation is, what it is good for.

Everybody can imagine, when they go to donate blood, you know, they fill up the bag with blood and they can imagine that a nurse is running across the hospital halls with a bag full of blood. Then it gets infused into someone. It is slightly different with plasma, but at the end of the day, plasma saves lives exactly as blood donation does.

So, one of the biggest advantages of being part of the Kedrion family is that there is a clear connection between the donor, the donation process, the manufacturing, the finished product and the patient.

I'm the kind of person that likes to talk about legacy. I think what we've built here, and the base of our success is that we have always treated our staff, our own workers, our colleagues as part of our family. And we've always had the same approach to our donors. And I think that Kedrion shares this vision. Kedrion still has sort of a firm family feel. It's more than a corporation. Kedrion feels more like a family.

It feels like a place where we care about each other and really care about our donors and our patients.

We do something that is irreplaceable. All jobs are important. Everybody who does something is important. But we are one of the few industries, one of few, very few workplaces where we can actually say that our job saves lives. It is at the end, the most satisfying thing about it; it is the most satisfying thing you can have in your life.



## AT HOME. PLASMA IN ITALY.

Plasma collection in Italy was challenging again in 2022, continuing a trend started with the pandemic. One contribution from our side has been the support to a campaign developed by *Donatori H24* called *#DaMeaTe* (meaning “from me to you”). The voices of patients and donors helped to raise public awareness of the importance of plasma donation for those affected by rare diseases and conditions. In short videos participants recount the

impact of donating from both perspectives.

For the eighth year we further continued our support of AVIS, *Associazione Volontari Italiani del Sangue* (the Association of Voluntary Italian Blood Donors), by partnering with the *Fondazione Campus of Lucca* to organize the “*Scuola Nazionale di Formazione AVIS*” (the AVIS National Training School) at the University of Milan. The program seeks to

increase the level of awareness among upcoming generations of the donor community about the management of non-profit organizations, the ethics of giving and the various models of blood systems in Europe. Students this year joined the *#DaMeaTe* campaign (see above) with personal individual video messages about the experience and the importance of donating plasma.





# PATIENTS. WHERE ALL BRIDGES LEAD.

In the end, of course, all of our endeavors are in the service of patients. Our commitment is to help people worldwide who are suffering from difficult, often rare, life-altering and life-threatening conditions.

Our growing portfolio can be considered in a range of broad therapeutic areas. For us, serving patients does not begin and end with supplying treatments. We strive to serve the patient community by collaborating with healthcare workers, medical research and patient advocacy groups. Here is a sampling of some of the patient-oriented activities we engaged in during the year.

## IMMUNOLOGY / NEUROLOGY

### Immunology

■ In Brescia, Italy, with the financial support of Kedrion, the Associazione Immunodeficienze Primitive (Italian Association for Primary Immunodeficiencies) (AIP) opened the House of "Lino Globulino". This facility, named after a cartoon superhero created for children suffering from Primary Immunodeficiency Disease (PID), was established to provide young patients and their parents a comforting place to stay during their hospital visits for treatment.



For an association like ours, having the Lino Globulino House means offering a warm and welcoming place to families that radiates that warmth of all of our members, friends, and supporters. We are aware that this is not always enough to relieve all stresses, but it certainly makes guests feel a little less alone.

**Alessandro Segato,**  
**President of the Italian**  
**Association for Primary**  
**Immunodeficiencies**



■ In the United States, we continued our collaboration with advocacy groups like American Immunodeficiency Foundation with which we participated in the "IDF Walk" in various locations around the country. We took part in various medical professional and educational functions as well, such as the annual Infusion Nurses Society (INS) Conference.

■ To support training for the medical-scientific community in Poland, Kedrion was the main sponsor of the two annual editions of the Young Immunologists Academy (YIA), an educational initiative Kedrion established to support young specialists.

■ In Germany, we collaborated with the Deutsche Selbsthilfe Angeborene Immundefekte (DSAI), a national patients' association for PID, by supporting communication activities and various training courses for clinicians.

■ We organized a scientific symposium focused on the screening of PIDs for the VIII Turkish Congress of Clinical Immunology held in Antalya, Turkey.

■ We also continued our long association with the International Organization of Patients with PIDs (IPOPI) by serving as a Platinum sponsor of the IPIC Congress organized by IPOPI in Vilamoura, Portugal. In addition

to taking part in the conference with a stand and a large delegation of international guests, we organized a scientific symposium entitled "Patients with IDP and medical needs of the scientific community".

### Neurology

■ In support of the ASNP - Associazione Italiana per lo studio sul Sistema Nervoso Periferico, the Italian Association for the Study of the Peripheral Nervous System, we were a Gold Sponsor of the XII ASNP Meetings held in Genoa, Italy, and co-sponsored the scientific workshop "Covid-19 and peripheral neuropathies".

■ In the United States, we lent our support for the GBS/CIPD International Foundation by participating in "Walk & Roll" events that took place throughout the year.

■ In Turkey, we supported a satellite symposium focusing on Immunotherapy in patients with Myasthenia Gravis at the 58th National Congress of Neurology held in Antalya.

■ Our commitment in the neurological field has expanded to the DACH countries (Germany, Austria and Switzerland), where we have participated in major national and international conferences such as the VIII Congress

of the European Academy of Neurology (EAN), which took place in Vienna, and the Deutsche Gesellschaft für Neurologie (DGN) Neurowoche 2022, held in Berlin.

■ In DACH countries, namely in Germany, we renewed our support for the Neuroimmunology Academy for the fourth consecutive year, which was held in autumn in Munich.

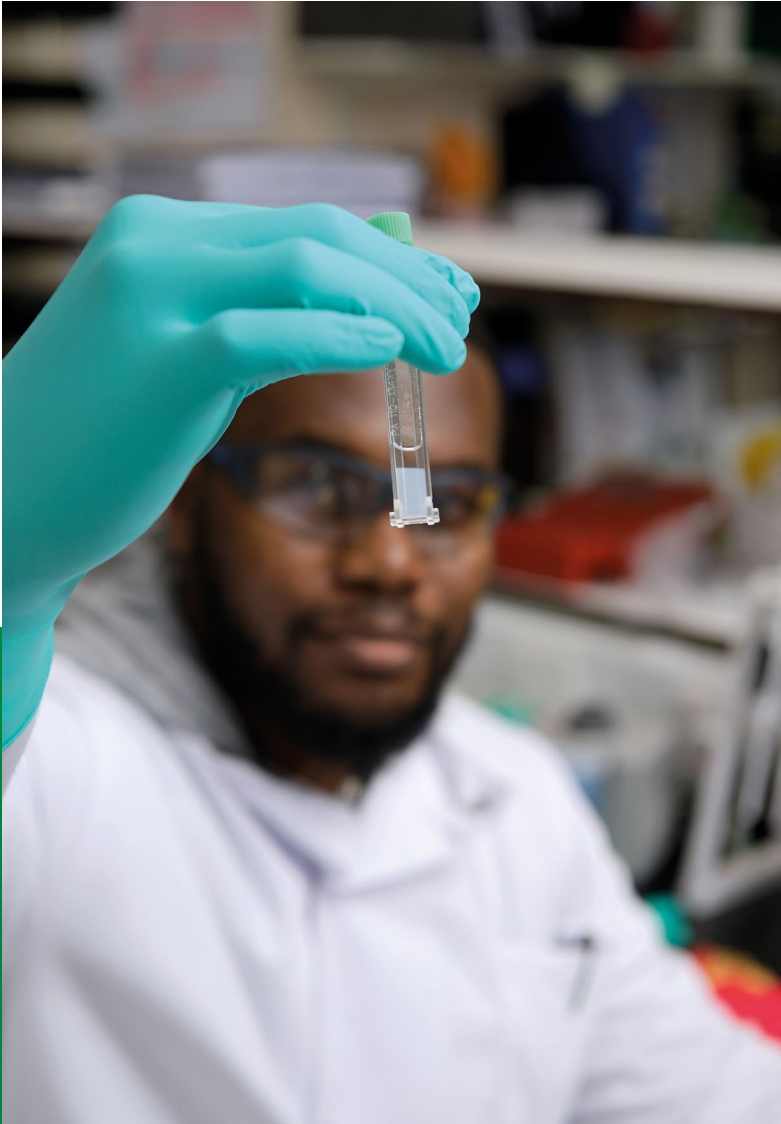


# RARE AND ULTRA-RARE DISEASES / COAGULATION DISORDERS

The world of Hemophilia and Congenital Hemorrhagic Diseases is experiencing a period of great transformation, marked by rapid and profound changes from a technical and scientific point of view. Given this landscape, we believe it is essential to encourage and collaborate with the medical community to continuously reflect on new research methodologies, available treatments, access to therapies and the most recent advances in the diagnostic and therapeutic fields. With this in mind, ■ In the United States, we took part in the annual Symposium of the Hemophilia Federation of America (HFA) in San Antonio, Texas and, subsequently, in the Thrombosis and Hemostasis Summit of North America held in Chicago.

■ In Turkey, we participated in the 19th International Hemophilia Congress held in Antalya, supporting a satellite symposium on the best therapeutic approach in previously untreated patients. ■ In Italy on the occasion of World Hemophilia Day, celebrated every year on April 17, we supported a round table entitled “Let’s bring prospectives to life” organized in Rome by the Feder-

ation of Hemophilic Associations (Fedemo). ■ On the same day, we supported various activities organized by the National Hemophilia Federation in Mexico to mark this special annual observance. ■ To learn more about our commitment to fighting rare and ultra-rare diseases, (see our special section on Rare and Ultra-Rare Diseases, pages 14-16.)



# MOTHER AND CHILD HEALTH

The vertical transmission of Hepatitis B (HBV) from mother to child is a serious concern in areas of high incidence of HBV such as the Western Pacific region and Africa. The preventative regimen includes administration of HBV vaccine along with Hepatitis B Immune Globulin at the time of, or shortly after, birth.

■ In Colombia, Kedrion de Colombia supported the “Congress for primary care for the treatment of Viral Hepatitis”, organized by the Colombian Association of Hepatology. Prof. Giuseppe Indolfi, Associate Professor of Paediatric and Liver Unit at Anna Meyer Children’s University-Hospital of Florence, Italy, chaired a special scientific session on the topic of Vertical Transmission (from mother to child) of Hepatitis B.

■ For World Hepatitis Day, celebrated every year on 28 July, Kedrion supported the World Hepatitis Alliance (WHA) with an unconditional educational grant used in the publication of a White Paper entitled “Mothers and babies can’t wait – A call for action to end mother-to-child transmission of Hepatitis B”. In addition to providing an overview of the current situation and potential future scenarios, the document contains a series of recommendations addressed to policymakers around the world for the prevention of vertical transmission of Hepatitis

B, especially in countries where access to therapies remains scarce or non-existent.

**Anita** lives in Ghana. She draws on her own experience to support expectant mothers living with Hepatitis B and she contributed with her testimony to the creation of the White Paper.

“

I found out I was living with Hepatitis B in 2012, aged 22. I used to fall sick a lot of times. I went to the hospital, and my brother, who is a lab technician, did tests on me and that’s how I found out. I felt that was the end of my life. I tried to trace back to how I got it. My brother keeps telling me a lot of people in my family have it, so I shouldn’t be so worried that I am the only one with the virus. I had heard of Hepatitis, but I didn’t know what it was, and I started researching it. I learned more when I joined the Hepatitis B Foundation of Ghana. I did a liver function test, the “LFT”. I was told I’m just a “carrier” and there’s no way I can transfer it to anybody. So, I just told myself “maybe I can get through this”. There isn’t any specific education

when they let you know you are Hepatitis positive. You are just left on your own to sort out treatment. Most people don’t talk about it because they are afraid to be stigmatized. In 2014, I was 24 years old, and I got pregnant and gave birth to my first child. I told the healthcare professionals of my status, that I’m a carrier, and they did the tests. Because it was my first pregnancy, I was scared and I kept asking questions. I was told that there’s no way I can transfer it to my child until at birth. Once my child was born, I still wasn’t given any information, however, my brother ensured my baby received the birth dose. He gave the vaccination to my newborn baby less than an hour after birth and before I breastfed my baby for the first time. After 3 months we ran a test and my baby was negative. It was the same for my second child. I wasn’t offered any treatment or prevention during my two pregnancies. I have decided to share my experience because I want to help young women like me who have little or no idea about Hepatitis B and its effects. And to help prevent mother-to-child transmission. The health professionals need more education, especially the

midwives and nurses. Most of them would advise that you use herbal medication, which is not the best option. In the village I come from there is lack of education. It has been one of my top priorities to help people get to know more about Hepatitis. It’s really killing a lot of people and there’s a lot of mother-to-child transmission. We also need help with equipment and materials. We need education to help people understand the problem.

Our preventive treatment for Hemolytic Disease of the Fetus and Newborn (HDFN) or Rh disease is administered to women with Rh negative blood who are pregnant with an Rh positive fetus. Awareness is vital. If such a pregnancy is not protected by a preventive treatment, the mother’s immune system can become “sensitized” to the Rh positive protein in the fetal red blood cells and prepared to fight it in the future. Should she become pregnant with another Rh positive fetus, her immune system can attack its Rh positive red blood cells and cause catastrophic damage or even death. This sensitization can last a lifetime, threatening all subsequent Rh positive pregnancies. The prophylactic must therefore be administered during the first such pregnancy, so the mother



and her healthcare provider must know her blood type, the fetus' blood type and – most important – that there exists a way to protect her and her pregnancies. Although the “Anti-D” therapy has been available for more than fifty years, millions of women around the world still do not have access. We are working to change this.

■ In Mexico, during the 70th Mexican Congress of Obstetrics and Gynecology, Kedrion Mexicana supported a symposium on Rh Disease chaired by Dr. Daniel Alatríste, Gynecologic Oncologist of Hospital Angeles Pedregal in Mexico City. The congress was organized by FEMECONG (the Federación Mexicana De Colegios Obstetricia Y Ginecología) in Guadalajara, Mexico.



Knowledge and awareness are two of the pillars on which our mission is based. In Latin America – especially in Mexico – we have continued to increase resources and energy devoted to raising awareness among pregnant women, as well as those who assist them in this journey and the general public about Hemolytic Disease of the Fetus and Newborn (HDFN) and the administration of proper prophylaxis. The number of registered cases in Mexico is still very high.

**Daniela** lives in Mexico City.



Before I got pregnant, I had never heard of Hemolytic Disease of the Fetus and Newborn. During my pregnancy, the doctors told me that my blood is Rh-negative and that this could cause problems for my baby if it was Rh-positive.

This was the first time she had heard of the potentially catastrophic consequences of Rh disease. Daniela was a lucky mother because she received prophylaxis for the prevention of Rh sensitization in a country where many women do not have access to this treatment or are unaware of its availability.



I decided to share my experience with the hope that it will help many other future mothers who have the same blood type as I do, and who too often, even today, are unaware of the risks this can pose to their children.

## The Fifth John Gorman Lectureship at the BIRTH 2022 Congress

In 2018, as part of the 50th Anniversary celebrations of the discovery of an Anti-D Immunoglobulin prophylaxis for preventing HDFN and in support of and collaboration with Columbia University Medical Center, Kedrion committed to underwriting the John Gorman Lectureship In Transfusion Medicine in perpetuity. The lectureship was established in 2016 and is named after one of the pioneers who developed the Anti-D prophylaxis at Columbia.

Last year, the lecture, titled “Maternal fetal hemorrhage at the time of labor and its implications for alloimmunization”, was delivered by the American physician-scientist Kenneth J. Moise Jr., Professor of Gynecology and Obstetrics at Dell Medical School at the University of Texas at Austin, and Director of the Center for Prenatal Diagnosis and Fetal Medicine at Dell Children’s Hospital. The occasion was the 7th BIRTH Congress, held in Milan in December, which we supported. The overall symposium focus was on “Advances and challenges in preventing alloimmunization in pregnancy and labor.”

Chief Business Development & Strategy Officer, Gioacchino De Giorgi, represented Kedrion at this important gathering.

Out of these occasions, the Worldwide Initiative for Rh disease Eradication (WIRhE) was launched and Kedrion continues to work alongside this important organization for this worthy cause.

## ACUTE/CRITICAL CARE AND TRANSPLANTATION

■ In March, Kedrion Biopharma entered into an agreement with Pharmacosmos, a Danish pharmaceutical company specializing in the treatment of Iron Deficiency Anemia, to distribute their treatment for the disorder, in Italy. Iron Deficiency Anemia is a condition in which the blood lacks healthy red blood cells due to insufficient iron. Without enough iron, red blood cells do not carry adequate hemoglobin (oxygen), which can lead to fatigue and shortness of breath. Left untreated, Iron Deficiency Anemia can cause more serious health problems like irregular heartbeat, enlarged heart or even heart failure. It can lead to growth problems in children. Women are at increased risk of developing Iron Deficiency Anemia because of increased blood loss during menstruation. Pregnancy is also a risk factor.

The World Health Organization estimates that more than one billion people worldwide suffer from Iron Deficiency Anemia. It is estimated that 5% of the female population in Italy is affected.



Pharmacosmos is deeply committed to improving the treatment of patients suffering from Iron Deficiency Anemia. We are very pleased to partner with Kedrion to make this therapy available to the many patients suffering from Iron Deficiency Anemia in Italy.

**Lars Christensen, MD,**  
Deputy Chairman of the Board, Pharmacosmos



This agreement will allow us to expand our commitment beyond that of rare diseases, redefining and consolidating our efforts to support a new community of patients affected by a disease that is very common amongst the population on a global scale.

**Paolo Marcucci,**  
Kedrion Chairman

The distribution of this therapy marks a new and important frontier for Kedrion. First, it is a product that is not plasma-derived and second, it serves a wider population than many of our therapies addressing rare diseases.

■ In Denmark, we supported a multidisciplinary delegation of 18 Italian clinicians participating in the “2022 Anemia Day” organized by Pharmacosmos, an international event that brought together experts to discuss best standards in the management of Iron Deficiency Anemia, from emerging therapeutic areas to safeguarding patient wellbeing throughout their course of treatment.

■ In Italy, Kedrion has supported numerous events and initiatives to gain more information on the different aspects of the physiopathology of iron, with the aim of

making the experience and skills gained in recent decades in hospital specialties and hematology available to Italian healthcare professionals involved in its treatment. In addition to promoting training for the Italian medical-scientific community, we aim to contribute to the dissemination of a multidisciplinary approach, considering that Anemia and iron deficiency are associated pathological disorders and lead to an increased risk of cardiological, obstetrical-gynecological, gastroenterological and other conditions. In Rimini, the Italian Society of Transfusion Medicine and Hematology (SIMITI) held the 44th Conference of Transfusion Medicine Studies, its first in-person meeting in three years. In keeping with its deep association with the world of blood transfusion in Italy, Kedrion



sent a delegation of more than twenty participants and organized a workshop on a new iron-based formulation for the management of patients suffering from Iron Deficiency Anemia.

The meeting was chaired by Dr. Ivo Beverina from Milan and Dr. Patrizia Di Gregorio from Chieti (also Vice President of SIMTI), with Dr. Di Gregorio and Dr. Marco Marietta from Modena as guest speakers.

In Rome, we attended a symposium on Sideropenic Anemia during the 123rd National Congress of the Italian Society of Internal Medicine (SIMI). Kedrion supported a Speakers' Corner with two lectures on new therapeutic approaches to patients with Sideropenic Anemia, moderated by Prof. Elena Corradini (Modena) and featuring Prof. Eleonora Gaetani (Rome) and Dr. Marco Marietta (Modena).

Kedrion also participated in the XXVII National Congress of Siset in Perugia, Italy, supporting a session on "Women and Congenital Hemorrhagic Diseases". This was moderated by Siset President Prof. Paolo Gresele and included Prof. Mariasanta Napolitano (Palermo) and Prof. Elvira Grandone (Foggia - San G. Rotondo) as speakers. We also supported a session chaired by Prof. Raimondo

De Cristofaro (Rome), with Prof. Antonia Follenzi (Novara) as a speaker, focused on research in biological and molecular processes of endothelial cells.

“

It is so important today to draw the attention of the entire medical and scientific community - including hemostasis and thrombosis experts, who are often called upon to globally manage women's health issues, including hemorrhagic issues - to the consequences of excessive bleeding, including Sideropenic Anemia.

**Paolo Gresele, Siset Past President**

Kedrion supported the 97th National Congress of the Italian Society of Gynecology and Obstetrics (SIGO), held in Milan. It was an opportunity to address current clinical issues and challenges which Italian gynecology will be called upon to face in the coming years. We held a symposium entitled "Iron Deficiency Anemia (IDA) and Women's Health."

The symposium was moderated by Prof. Nicola Colacurci (SIGO President) and featured Prof. Giuseppe Rizzo (Rome), Prof. Giuseppe Ettore (Catania) and Prof. Irene Cetin (Milan) as speakers. The symposium provided an overview on the topic of Iron Deficiency and Sideropenic Anemia in women in pregnancy and in cases of metrorrhagic phenomena, such as profuse or prolonged menstrual bleeding, including various therapeutic approaches available.

“

Iron Deficiency Anemia is the main cause of various forms of anemia in Western countries, where iron deficiency is a clinically relevant and extremely widespread pathological condition, especially in women of childbearing age. As regards transfusions, we are very busy in carrying out Patient Blood Management in Italy; it is a multidisciplinary patient-candidate approach for major surgery that uses methods and tools capable of optimizing patient blood management, thus improving clinical outcomes. One of the pillars of this path is the correction of pre-operative anemia. It is for this reason that our transfusion center now has a clinic entirely dedicated to the management of the various types of deficiency anemias.

**Giovanni Inghilleri, Director of the Immunotransfusion Service Operating Unit (SIT) - ASST Bergamo Est**

■ In Italy, we supported a training webinar entitled "Multidisciplinary approach to hepatocellular carcinoma and recurrent ascites" for specialists in the field of liver transplantation. We also participated in the 54th Annual Meeting of the Italian Association for the Study of the Liver (AISF) held in Rome, a two-day annual event that brings together top national and international experts to discuss current hepatological issues.





# OUR COMMITMENT TO COMMUNITIES

Our commitment to people naturally extends to the communities in which they live - locally, regionally, nationally, globally. This might mean supporting local food drives or regional healthcare initiatives. It also includes special care for their - our - environment. Again, locally as well as globally. In short, we aspire as a corporation to be a good citizen as a local neighbor and as a global actor.

In our home base of Italy, we have centered our actions on these principles, working with relevant organizations such as:

- The Luigi Villa Foundation, by sponsoring a scholarship aimed at supporting research within the project “Cardiovascular risk and endothelial damage in the hemophilic patient” and by contributing to the purchase of equipment, reagents and other materials.
- The Paracelsus Foundation, supporting the organization’s activities.
- Alessandria’s section of the Italian Association against leukemia, lymphoma and myeloma (AIL), guaranteeing our support for awareness activities.
- The Umberto Veronesi Foundation, supporting the 14th Science for Peace and Health World Conference held on November in Milan.

In the spring, in response to the grave and extensive needs brought on by the war in Ukraine, and in alliance with Robert F. Kennedy Human Rights Italia, Kedrion donated 29 laptop computers for use by children rescued from an orphanage in Ukraine and welcomed by Misericordia di Fosciandora in Garfagnana, in the Province of Lucca (Italy). The computers had been requested to allow children to study online and avoid losing a school year, and to help them learn Italian.



We are happy to make this small gesture to improve the situation of Ukrainian children hosted in our area. This is consistent with our values of respect and support for the local communities in which we operate.

**Paolo Marcucci, Chairman**

Kedrion has a long and consistent record of supporting the medical-scientific community, especially for research and continuing education. We have paid special attention to fostering the diffusion of excellence and the development of innovation, with particular attention to younger generations. In line with these interests, we have each year provided, among the research prizes awarded by the Carlo Erba

Foundation in Italy, two scholarships dedicated to the memory of Kedrion founder, Guelfo Marcucci. These prizes are aimed at Italian graduates under the age of thirty-five for original research in the non-oncology hematology field. The two awards, each worth €10,000, were presented in October to Sara Arcudi from the University of Milan and to Gaia Spadarella from the University Federico II of Naples.



These awards intend to support Italian biomedical research and, at the same time, offer Kedrion a privileged window on the most innovative trends in the field of medical-biological studies.

**Paolo Marcucci, Chairman**

The “Fabrizio Fabbri” research prize was awarded in November. This scholarship is given to young graduates who have distinguished themselves for original research in the field of plasma-derived drugs. The recognition was established by the Carlo Erba Foundation with the support of Kedrion. This second edition was presented to Aida Cavallo from the Scuola Superiore Sant’Anna of Pisa (Italy). For the fifth year, we also renewed our support for Phar-

maMark, the Master in Pharmaceutical Marketing offered at the PIN - Polo Universitario Città di Prato, Italy. The program is aimed at training professionals with a broad view of the ethical drug sector.

We have been involved in a range of humanitarian projects around the world. In 2022, we supported the shipment of various medicines made available by the Marche and Emilia-Romagna Italian Regions to Palestine. This donation is part of the HAEMO-PAL project, an initiative of the National Institute of Health and coordinated by the National Blood Center to support the Palestinian Ministry of health in strengthening local clinical centers for the diagnosis and treatment of congenital hematological diseases. We have also provided logistical and financial support to enable a humanitarian donation of Factor VIII to Albania, made available by the Tuscany Region.

In the United States, motivated by a compelling sense of social responsibility, Kedrion employees in our Fort Lee, New Jersey offices and our Melville, New York production plant supported various volunteer initiatives, including:

- “The Seasons of Giving” of Feeding America campaign.
- Two fundraising events promoted by “Breast Cancer Awareness Month”.

- The “Athletic Shoe Recycling Campaign”.
- The “Adopt a Family” campaign.

In Hungary, we have continued our support of various organizations including:

- The hospital of the city of Siófok, by donating surface-sanitizing.
- The “Csontvelő Transzplantáció Alapítvány” Foundation to support a sterile room to welcome children during their post-transplant convalescence.
- The “Mosoly Egyesület” Association in Gödöllő, supporting the purchase of a defibrillator.
- The “Hemofíliások Baráti Köre” Association, supporting a camp for education and rehabilitation activities for hemophilic patients.

Promoting the environment and biodiversity are an integral part of our mission to protect and enhance the health of people. For some years we have supported the work of Treedom, an online platform organizing the planting of trees in support of rural communities in developing countries.



# OUR BRIDGE BUILDERS

## THE PEOPLE OF KEDRION: MEETING THE CHALLENGE OF CHANGE

Bridges don't get built by themselves. The people of the new Kedrion - from our legacy company, from BPL, from Prometic, from every office and lab, every plant and warehouse, every collections center - are responsible for all the vital connections we make. Working in the shadow of the global pandemic, through the change of corporate transformation, our people have maintained their focus and energies on the one most important function of the bridges they build: helping people.

### MAXWELL HUNTER

Sr. Director, US Plasma Quality for KEDPLASMA

"I was excited by the huge potential for growth and innovation: two companies with strong track records coming together. Combined experience and expertise leading to more achievements."

"Team executed at an amazing speed. Getting to meet the patients is tremendous. Good days, rough days, keep in perspective why we do what we do. I always wanted a role that made a positive impact on someone's life. Enhanced their quality of life and makes it better."

### WES HAULBROOKS

Regional Operations Manager for KEDPLASMA

As the pandemic eased, "Donors started to come back, and we received an influx of applications from people ready to get back to work. The centers got busier, and staff had to get used to that again, or for the first time if they were new and never experienced a full center. Nice to see donors come back. The new donor population came in because it was in the news that plasma was being used to cure Covid-19".

"The integration with BPL was "a nervous time, mixed with excite-

ment. It's the biggest thing I have ever been involved in. But people were warm and welcoming. And we have doubled our knowledge! Kedrion has always cared about donors and staff. We will never say goodbye to that."

### AMANDA JARVIS

Center Manager for BPL Plasma Legacy, Texas

She is now overseeing two centers. She is proud of how her team met the lingering challenges of the Covid-19 pandemic.

"We are doing very well. We met our goals and are expanding hours. We got involved and did canned food drives for the community. Donors noticed this, and return donors have made comments about this support in the community. Being transparent is important to me, so having plans in place to let the team know what was going on was crucial."

"The ongoing integration with KEDPLASMA involves change at

many levels. The Nexus Plasma Collection System (PCS) conversion was also big. We told people what to expect and working as a team and sending frequent communications helped keep things moving.

I was excited to get different programs, and we got to meet the executives which makes people feel included.

Communication is good. When questions are asked there is cooperation, not silence. That can help with growth.

In the end, whether under the banner of BPL Plasma or KED-PLASMA, the work that is most rewarding is similar: working with the team and hearing donors make positive comments, since we are there to serve the donors."

### ROB ELMORE

Sr. Manager - Facilities, New Center Development and EHS

"The biggest challenge we faced during 2022 was Covid-19 supply chain issues in the construction sector. We have been experiencing supply chain delays since the end of 2020, but 2022 was extremely difficult to meet construction timelines due to material shortages. Now we are slowly getting back to normal, but we were able to overcome these obstacles by planning in advance for equipment we knew was running into lead time constraints, keeping some inventory on hand for other items

such as key equipment weight scale, refractometers and vital sign machines."

"My initial thoughts about the integration of BPL and Kedrion were excitement and nervousness. But it is very exciting to see Kedrion and BPL come together to create a global leader in the industry. And there are great opportunities for career advancement and to learn new skill sets that you might not otherwise have been able to learn.

I was involved in combining the new center process and the creation of a hybrid model to open two new centers at the beginning of 2023. These centers were intended to be opened as BPL centers and we were able to shift very quickly and open them as KEDPLASMA centers.

I was surprised with the short time frame it took for me to feel like part of the Kedrion team. Since the beginning of the merger, I have felt welcomed and included. I have been through multiple integrations/mergers in the past and have never experienced the warm welcome and sense of fitting in as much as I have with the Kedrion team."

### BRAD JENNINGS

Global & US Marketing, Therapeutic Area Lead - Hyperimmunes and Critical Care

"My reaction to learning about the integration with BPL was reserved. I guess that is human nature when you are joining together with a major competitor. But I was pleasantly surprised when they (they meaning the commercial and marketing teams) got together for the first time. From Day 1, we got along well, and have formed to become an epic team, with epic collaboration, that has led to just epic performance and results. We blew away goals: incredible year. It has been a stellar process."

"We went to the table as strangers and went away as family. Everyone has the same ambition, to improve the lives of patients, and to achieve more. We are a passionate team that is respectful, hungry and feisty, and driven by a common purpose."





## SOPHIE GUERINET

Senior Manager, Global Market Access, Rare Disease

"I'm originally from France, but I've been in the UK for 12 years now. I'm leading the activity and the expansion strategy to make sure that we can bring our therapy for Hereditary Factor X Deficiency to more patients across the globe. It's great because we know that with Kedrion being on board now we have access to more plasma and hopefully it will mean that we can bring our therapy to more patients; by the end of next year we'll have this therapy in 15 markets that will have much more ambition for the project in the future."

"It's very international here. You have so many different nationalities, and we are really rolling up the sleeves when we need, be-

cause we are all working to make sure that we are bringing the medicine for the patient. So obviously I've heard about Kedrion a lot and we met our colleagues in Italy. What is great about the merger is that we are going to have access to more, more products. And what is really important is to make sure that we can serve more patients."

## TIM SANDLE

Pharmaceutical Microbiologist for BPL Legacy, Head of GXP Compliance

"The great thing about working at Elstree is the sense of community. It's like a small village and everyone knows everyone and it's a very supporting culture, very interactive, very helpful, very enabling and such a committed group of people who are focused on

people's mission and values, which at the end of the day is getting high quality products to patients on time."

"I know that Kedrion is a large biopharmaceutical manufacturer making similar products to BPL and the coming together of the two organizations makes sense. Allows us to do a lot more on scale, improve our products and to meet the global demand. And there may be some cultural differences that we need to overcome, but it's a great opportunity. And the dealings I've had with people at Kedrion so far have been overwhelmingly positive, and there's already been a lot of sharing of ideas and processes and we are looking forward to the future."

## SARAH PASCIUTI

Organisational Development Director

"As always, change brought with it opportunities and possibilities: to get to know new realities and people, as well as to transform what we do or to do the same things with new people."

"I believe that the process of change we are going through is fundamental to building a larger company, and I am equally convinced that it will also contribute to the growth of each of us. Because it pushes us to get out of our comfort zone and to confront novelty and colleagues, ways of working and places that are different. I don't like predictions, because they can create an expectation that doesn't allow you to enjoy the journey, but I am sure that this period, the confrontation, and the desire to learn and open up to novelty, will be the winning mix to face this adventure."

## MARCO TINACCI

Group Administration, Treasury & Taxes Senior Director

"The year 2022 was - literally! - an endless race for the whole Finance team, who faced it with great commitment and dedication. We had not yet completed the integration with Prometic, which took place in the second half of 2021, when we found ourselves facing and managing a much bigger and extraordinary operation, which led to the integration of BPL with the entry of Permira as a majority shareholder. On a personal level, 2022 was a challenge within a challenge as I had recently taken up the position I currently hold. In addition, following the closing of the operation, our Function has experienced a profound reorganisation which has, inevitably, brought with it a certain degree of uncertainty."

"As in any process of change, as the new structure took shape, the uncertainty was replaced by an unprecedented and growing pride for the result achieved and enthusiasm for the challenge ahead with the integration of BPL. Today, we are a global player, able

to compete with more confidence and awareness in the market, and we owe this to the work done in previous years: we were already running in the right direction back then."

"With this in mind, 2022 has enabled us to make that long-awaited change of pace, which was necessary to continue providing patients with the best possible care in an increasingly dynamic environment."

## MANUELA SCARPELLINI

Medical Affairs Lead Italy/ICON

"For the Medical Affairs Team, 2022 has been a year of transition, marked by profound changes that have had a significant impact on the organisation of the entire Function. There have been moments of uncertainty, always accompanied by an awareness of the centrality of our role and the added value that Medical Affairs represents for the patient communities that benefit from our products. In my opinion, a full understanding of one's own identity and role - in the company, as in life - is a pre-

requisite for managing major moments of transition, and I must say that our team has shown character in the field!"

"In our case, in line with what Kedrion is going through, it was actually an evolutionary process. The arrival of BPL, in addition to broadening the therapeutic options and literally expanding the company's horizons, has brought new talents to the Medical Affairs team, enriching it in terms of knowledge and experience. In my opinion, these prerequisites are the best basis for optimising the quality and effectiveness of our contribution to the definition and implementation of corporate strategies and, at the same time, help to position Medical Affairs as a point of reference for our internal and external stakeholders."





# SAFETY FIRST.

Our people build bridges to protect and enhance the health of other people who are suffering and at risk. But bridge builders need protection as well, as do all the processes and activities carried out to produce our products.

“ONE TEAM. ZERO ACCIDENTS.” is a campaign introduced midyear in 2022 to achieve the goal of accident-free operations by working together as a team at all levels. It is a commitment made across all functions in all facilities in all the countries where we operate. It emphasizes the power and responsibility of individual team members to contribute to a culture of safety. The campaign encourages not just individual

behavior, but regard for and collaboration with fellow Kedrion “family” members in identifying and offering solutions for potential safety issues.

As the campaign puts it, “ZERO Vision is based on the assumption that all accidents and incidents are preventable; all injuries to people avoidable; and harm to the environment irresponsible and intolerable. ZERO ACCIDENTS is not just a goal or a slogan; it is a journey, and every step on that journey represents a triumph. Every precaution taken; every extra attention paid; every accident avoided marks a success. Working toward ZERO ACCIDENTS requires 100% commitment. And 100% teamwork.”

GEMBA Walks. Gemba, or Genba, is a Japanese term for “the real place”. In the context of business operations to increase efficiency or improve practices (in this case, workplace safety), it refers to the actual place where work gets done, where value is created. As part of ZERO ACCIDENTS, management teams make periodic visits to plant floors, talking with workers, eliciting suggestions for improvements and observations about processes, with an eye to safety. These encounters not only enhance safety, but also reinforce the commitment of EHS and management to listen to and team up

with plant workers. Referring to a checklist for uniformity, JSO’s are performed by supervisors on a regular basis. Focusing on specific tasks with their teams they seek to identify potentially unsafe practices as well as to highlight good practices with the goal of generating suggestions for improving work safety.

SOR’s encourage pro-active participation and a sense of team or “family” solidarity by eliciting observations of potentially unsafe practices (as well as environmental threats) in a “See Something – Say Something” framework.

The campaign includes periodic GEMBA Walks, Job Safety Observations (JSO’s) and Safety Observation Reports (SOR’s).

It is still far too early to know the full impact of ONE TEAM. ZERO ACCIDENTS., but the experience of our HUMAN BioPlazma Kft. (HBP) plant in Gödöllő, Hungary, where some of the basic features of the program (e.g., GEMBA Walks) were first applied, refined and expanded, is promising. Sixty inspections were completed in 2022, involving 20 leaders. Not only has the campaign been

enthusiastically embraced, the preliminary numbers look good.

Thanks to the team-building communication among employees, the number of safety observations increased significantly to 330. (Beginning in 2023, observation target numbers are included in employee personal goals). The number of reportable injuries dropped 60% from 5 to 2 for the year, and the international health and safety certification, ISO 45001 was confirmed with zero non-conformities.



Zero Accident is an ambitious goal. We can only achieve it if we all believe in it and work for it.  
**László Siadik, Managing Director, Hungary**



I’m glad that I can come to work safely every day and go home in the same condition I came in!  
**Gergely Plaier, Maintenance Technician, Hungary**





# ECONOMIC AND FINANCIAL INDICATORS





# INTRODUCTION

On August 31, 2022, Kedrion Group integrated BPL Group as part of the acquisition by Permira. Therefore, the economic data represented and commented on in the financial statements consolidates BPL Group for the last four months of the year. Moreover, at the balance sheet level, the effects of the acquisition of the Kedrion Group resulting from the Purchase Price Allocation process, which are recorded at the consolidated level in the parent company Kevlar SpA, are not included.

In the year ended December 31, 2022, sales for the Kedrion Group amounted to €886.7 million (€660.4 million in 2021), an increase of 34.3% (+ €226.3 million) compared to the previous year, due mainly to the contribution of BPL Group of €183.2 million in September-December 2022. Net of BPL Group's contribution, it was nonetheless a year of significant growth for the Group, which completely overcame the negative impacts caused by the Covid-19 pandemic, recording growth in sales of plasma-derived products (+9.1%) and plasma (+8.9%), mainly due to the price increase generated by demand. The Group's

internationalization continues, accelerated by the integration of BPL Group, with an export share of 89.4% in 2022. The United States consolidated its position as the Group's top market with a 48.6% share of sales, followed by countries in the Rest of the World with 27% (including the United Kingdom with 3.6%), the European Union with 13.8% and Italy with 10.6%.

EBITDA amounted to €213.6 million with a growth in profitability from 15.0% in the previous year to 24.0% in 2022, boosted by the extraordinary income from the BPL deal, recorded on the basis of business combination accounting, which offset the decline in profitability related to the persistently high costs of the plasma raw material, not fully offset by price increases, transaction costs, and the general increase in costs due to inflationary dynamics and energy costs.

In fact, adjusted EBITDA (calculated excluding the impact of non-recurring items, including the business combination income) amounted to €145.6 million, reaching 16.4% as a percentage of sales compared to 21.0% in 2021, due to the

decrease in profitability and the cost dynamics described above.

Finally, net income for the year amounted to €123.4 million, up from €11.6 million in 2021, as a result of the extraordinary income from the business combination and the improvement in financial management, with exchange rate differences having a positive impact on the result for the period of €62.2 million (€10.8 million recorded in 2021), net of non-recurring financial expenses related to the refinancing associated with the Permira transaction (€23.2 million).

At the economic level, summing the economic data of the two Kedrion and BPL Groups, total revenues over the full year (pro forma) would have been €1,146 million (€1,095 million in 2021 on a like-for-like basis), and adjusted EBITDA over the full year (pro forma), calculated excluding the impact of non-recurring items, including transaction costs and other effects of the business combination that took place in 2022, and the extraordinary income recorded from the BPL deal, would have been €187.3 million (€157.0 million in 2021 on a like-for-like basis).

# SIGNIFICANT EVENTS DURING THE YEAR

## THE PERMIRA DEAL AND INTEGRATION WITH BPL

In January 2022, funds managed by the private equity firm Permira, supported by its co-investor Abu Dhabi Investment Authority (ADIA), entered into a partnership with the former shareholders of Kedrion S.p.A. to acquire control of the company and, at the same time, of the UK plasma-derivatives company Bio Products Laboratory (BPL). The combination of the two companies has created a global player in the field of plasma-derived medicines, with estimated annual revenues of €1.1 billion and over 4,000 employees worldwide. Permira, in partnership with the Marcucci family, made the deal to support the new unified entity in organic growth through the internationalization of the existing portfolio and the development of new products, while also supporting the search for growth opportunities through external lines, with the ultimate goal of creating a diversified entity specializing in rare diseases.

The closing of the transaction took place on August 31, 2022, after obtaining approvals from the regulatory and antitrust authorities. The transaction was carried out through two corpo-

rate vehicles owned by Permira, Kevlar S.p.A. in Italy and Sevenplatform VI Ltd in the United Kingdom, combining the entire group under a holding company called Kedrion Holding S.p.A..

Following the closing of the deal, the Group launched a major reorganization of its top management, starting with the new CEO Ugo Di Francesco, in line with the strategic objectives of the renewed shareholding structure and the changed dimensional and competitive profile of the combined Group. The new leadership is tasked with completing the integration of Kedrion and BPL, aiming for increased plasma collection capacity, increased production capacity and improved cost efficiency, in terms of lower cost per liter and lower costs of indirect operations.

Moreover, immediately after this transaction, an integration program was launched, entrusted to an Integration Management Office and supported by qualified external consultants, aimed at utilizing the synergies expected from the combination of the two groups, to be achieved through:

- Integration of the plasma business into a single entity;
- Saturation of the capacity of BPL's Elstree plant and reduction

of production costs through increased absorption of fixed facility costs;

- Increased fractionation of the plasma collected at company-owned centers compared to plasma acquired from third parties;

- Increased competitiveness and market share of Immunoglobulins in the United States;

- Optimal use of the integrated commercial infrastructure between Kedrion and BPL in order to improve market presence and sales conditions, and the launch of new products in markets where the Group is already active;

- Other initiatives aimed at optimizing the organization and increasing efficiency, strengthening the procurement department, optimizing logistics at the Group level, and harmonizing and digitizing business processes to take advantage of the best practices of the two groups.

Finally, simultaneously with the closing on August 31, 2022, a refinancing process was implemented to reconfigure the entire financial structure of the Group resulting from the Permira transaction, through the signing of a bridge loan at the parent company level, with a total nominal value of \$865 million and a revolving credit facility ("RCF")



agreement up to a maximum amount of €175 million (which was unused as of December 31, 2022). With the funds from the bridge loan, the parent company Kedrion S.p.A. closed the pre-existing debt, including the bond loan in the amount of €410 million and the RCF facilities totaling €230 million.



## THE “PRODUCTION AND MARKETING OF PLASMA-DERIVED DRUGS” SEGMENT

### STRATEGIC PROJECTS

At the end of December 2022, the FDA approved the regulatory filing (PAS) authorizing the Melville facility to produce bulk of our Anti-D Immunoglobulin.

With this regulatory milestone, the strategic plan to fully internalize the production of Anti-D Immunoglobulin from the third-party supplier OCD to Kedrion Biopharma Inc. at its Melville, NY facility (which was already authorized to perform the inflating and packaging of the product) has been concluded. With the completion of this project, the US plant in Melville will be able to increase its activity levels and production efficiency, thus reducing unabsorbed costs. Non-recurring costs for the year amounted to €9.7 million.

During the year, the validation procedure for the production process continued at the new plant in Castelvechio Pascoli (Lucca, Italy), for the purification of Immunoglobulin 10% (Klg10) using the chromatographic method, as did preparation for clinical trials for the commercial authorization of the new product. During the previous year, activities related to the clinical trial for the PID (Primary Immunodeficiencies) indication on the adult population in the United States (the so-called “CARES10” clinical trail) was completed and the final study report was obtained. In addition, as of April 2021, enrollment and treatment of pediatric patients began for the Pediatric PID study in Italy, Hungary, Slovakia, Russia and Portugal (the so-called “KIDCARES10” study) for the purpose of registering this indication in the United States and Europe. Due to the Russian-Ukrainian conflict, the enrollment of patients in Russia was discontinued in 2022, and the study is being reconfigured with some of the patients to be enrolled in the United States, also to meet FDA requirements. By the end of 2022, 13 out of 20 patients had been enrolled. Currently, production for clinical trials is being carried out at the Gödöllő plant (the purification phase) and the technology transfer is being completed at the Castelvechio industrial facility. Validation activities have continued as planned, and batches of PPQ will be produced in Castelvechio Pascoli in the coming months, in anticipation of the regulatory approval expected in the United States in 2025. Project costs charged to the year that have not yet been balanced in production and related revenues amounted to €4.2 million, while total investments in 2022 amounted to €14.6 million. The extension of the timeline for completing the Anti-D Immuno-

globulin project (regulatory approval was granted in late 2022) and the “Klg10” project have so far prevented full saturation of the US plant in Melville. Management is strongly committed to the search for efficiencies to increase commercial yields and reduce production costs, to compensate for the plant’s failure to fully absorb fixed costs. The “Global Albumin 25%” project, which will reduce lead time and increase yields of the product, i.e. Albumin purified in Bolognana from the Melville intermediate, is intended to be a step in this direction. The regulatory filing (PAS) was submitted in November 2022 and approval is expected by May 2023.

**PRICE TRENDS**

Sales prices of plasma derivatives in this year confirmed the historical upward trend for immunoglobulin, supported by the steady increase in demand in excess of supply increases by fractionators, which was heavily impacted by the reduction in plasma collection caused by COVID-19 in the previous two years. The structural imbalance between supply and demand, especially in the European and the Rest of the World markets, generated areas of opportunity that the Group was able to seize through its distribution network, implementing product allocation in markets with the highest growth rates.

### BPL ALBUMIN APPROVAL IN CHINA

After the first regulatory approval by the Chinese authority CDE (Center for Drug Evaluation) during 2022, the first batches of Albumin produced at Elstree were released by the National Institute for Food and Drug Control (NIFDC), and now, regular shipments of the product to China (the world’s largest market for Albumin in terms of volume and value) are planned.

## THE “PLASMA COLLECTION AND MARKETING” SEGMENT

### COVID-19 AND PLASMA AVAILABILITY

The plasma segment was characterized during the year by an increase in the volumes available to the Group, reflecting the gradual overcoming of the effects of the COVID-19 pandemic. By the end of 2022, the 62 company-owned centers (including 33 centers owned by KEDPLASMA LLC and 29 centers owned by BPL Plasma Inc) together had collected about 54% more plasma than they did in 2021 (Kedrion plus BPL on a like-for-like basis), reaching the level of 2.1 million liters compared to 1.4

million liters in 2021. As a result of careful inventory management, purchases of plasma from third parties were reduced, while supplying KEDPLASMA’s excess plasma to Elstree’s production needs and avoiding production downtime, while sales to third parties remained unchanged, generating segment sales of €46.8 million compared to €47.0 million in 2021.

### DISPOSALS AND PURCHASES / START-UPS OF COMPANY-OWNED COLLECTION CENTERS

In late November 2022, Kedrion SpA acquired two companies in the Czech Republic, UNICAPlasma s.r.o. and UNICAPlasma Morava s.r.o., which own and operate five plasma collection centers in that country. These five

centers currently have an annual collection capacity of about 70 thousand liters. This acquisition marks Kedrion’s return to the plasma collection business in Europe, in keeping with its strategic goal of expanding its network of centers, diversifying supply flows and lowering overall collection costs.

On the U.S. plasma center front: ■ Four in-house developed centers were opened, thus continuing the program to open and start up independent plasma collection centers; ■ A center was purchased in Rocky Mountain, North Carolina; ■ A center located in Westmoreland, Texas was sold on August 31, 2022 to Proesis Bio for €7.3 million, generating an income of approximately €4.0 million (last year, the sale of seven centers led to the recognition of an income of approximately €24.7 million).

At the end of 2022, the combined Kedrion and BPL Group had 62 company-owned centers, compared to 57 such centers at the end of the previous year (on a like-for-like basis).

### PRICE TRENDS

During the year, plasma sales prices were characterized by significant growth, which averaged 15% (in USD currency) for standard plasma.





FINANCIAL  
MANAGEMENT

EXCHANGE RATE TRENDS

Exchange rate trends (particularly of the US dollar, which went from 1.1326 as of December 31, 2021 to 1.0666 as of December 31, 2022 after reaching parity around the end of August 2022) and the Group’s financial exposure in US dollars as a result of the debt refinancing within the Permira transaction, generated a positive impact on the income statement for realized and unrealized exchange rate differences amounting to €62.2 million (€10.8 million in 2021), while the Group’s and third-party equity decreased by €27.1 million as a result of the change in the translation reserve due to the relative weakening of the dollar as of August 31, 2022, the date of consolidation of the BPL Group, whose assets are denominated in USD.

OPERATING PERFORMANCE

REVENUES

Revenues from the production and marketing of plasma-derived drugs segment as of December 31, 2022 amounted to €821.6 million (92.7% of the total), an increase of 37.9% compared to the previous year. The increase in the relative weight of this segment from 90.2% to 92.7% of the total was due both to endogenous growth factors of the existing structure (+9.1% on a like-for-like basis) and to the inclusion of BPL in the scope of consolidation, for the last four months of the year, which originated the rest.

First among all products confirmed by order of importance were Standard Immunoglobulin, which grew by 55% (14% on a like-for-like basis) due to the inclusion of BPL human normal Immunoglobulin in the portfolio and the significant increase in the average price (determined in the United States by excess demand over supply, and in the rest of the world by focusing on the most profitable sales markets through appropriate product allocation logics), and Albumin due to the price-volume-geographic mix, followed by Anti-Rabies Immunoglobulin, which in the US market grew by 64% (due to the gradual exit of a competing product from the market).

2022 was also the launch year for a plasma-derived human Plasminogen, the latest product acquired in the Kedrion Group’s plasma-derived products portfolio. Sales began in January and the product has been very well received by operators and patients. In addition to the plasma-derived human Plasminogen, it is worth noting the growing market penetration of another orphan drug, human coagulation Factor X, which was developed and approved by BPL in previous years, whose sales in the last four months of 2022 amounted to €22,100 thousand.

Within this segment, with the acquisition of BPL, the US plasma-derivatives market further increased its strategic importance from 41% to 56% of total sales, with a growth of 70% (the BPL Group is very focused on the US market, however, despite this, like-for-like growth without BPL still recorded a remarkable 15%). The Rest of the World, with 34% growth, ranked second in terms of importance, reaching 28% of total sales (27% on a like-for-like bases) due to both the Group’s growing engagement in emerging markets (such as Turkey) which are considered to have high potential and the development of the plasma processing account services business outside of Italy.

This was followed by Europe with 15% of global revenues, where the traditional markets (Germany, Austria and Poland) confirmed their importance for the Group. And finally Italy, which, as better specified in the geographical breakdown of revenues, confirmed the downward trend due to the lower volumes of plasma processed for the Italian National Health System.

As mentioned above, in 2022, the plasma processing account service segment for foreign customers confirmed the growth trend which started in 2021 by tripling its turnover to €19.9 million, while the traditional plasma processing account service for the Italian Health System, while confirming its relevance with 7% of the segment’s revenues, confirmed the continued decline.

Revenues from the plasma collection and marketing segment as of December 31, 2022 amounted to €46.8 million, which was essentially in line with 2021. The plasma surpluses made available by the resumption of post-COVID collection were used within the group to supply the Elstree plant, thereby avoiding the need to purchase plasma from third parties.

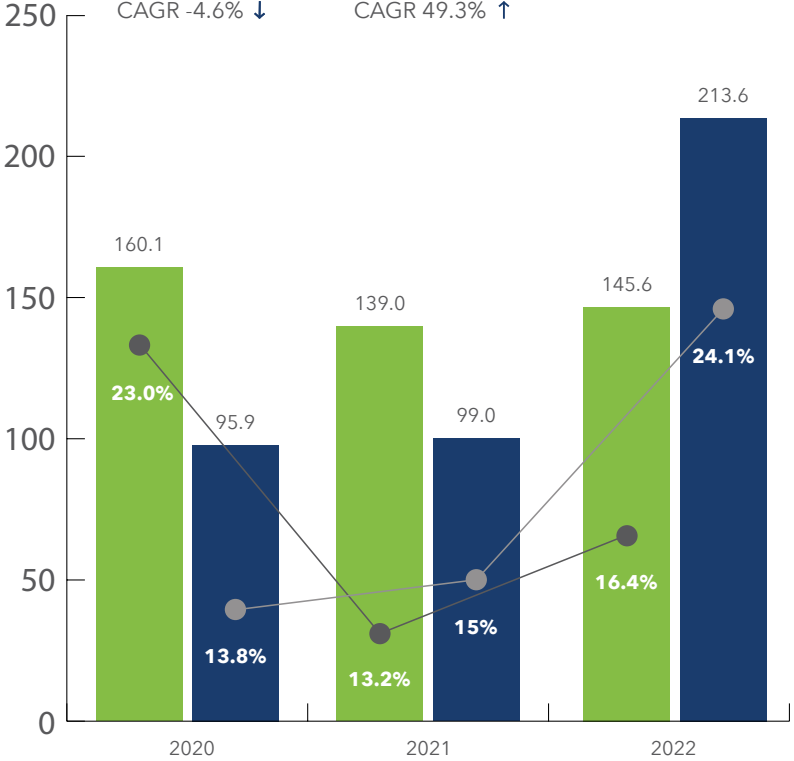
REVENUES (€ MLN)





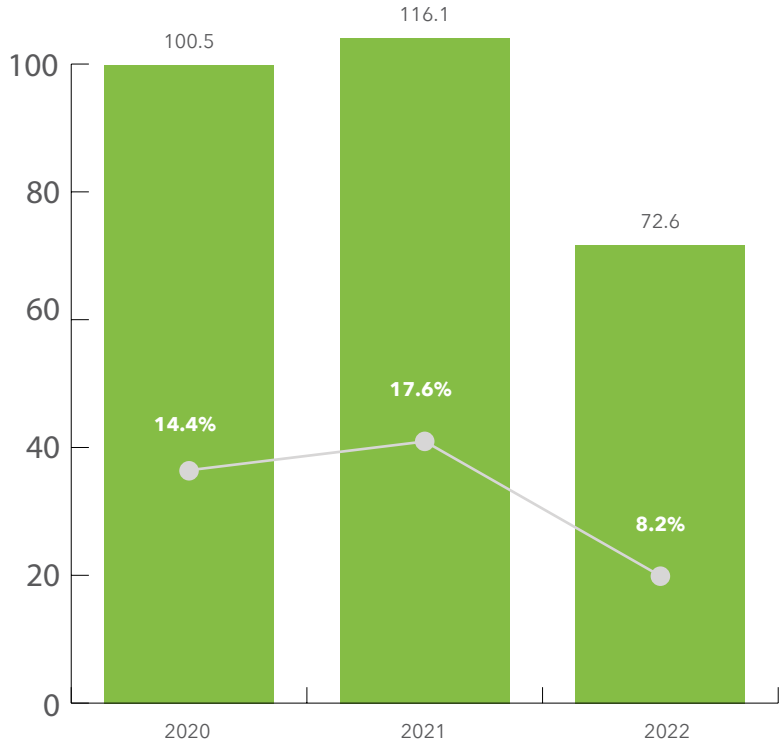
**ADJUSTED EBITDA (€ MLN)  
AND  
REPORTED EBITDA (€ MLN)**

- ADJUSTED EBITDA
- REPORTED EBITDA
- % ADJUSTED EBITDA/  
REVENUES
- % REPORTED EBITDA/  
REVENUES



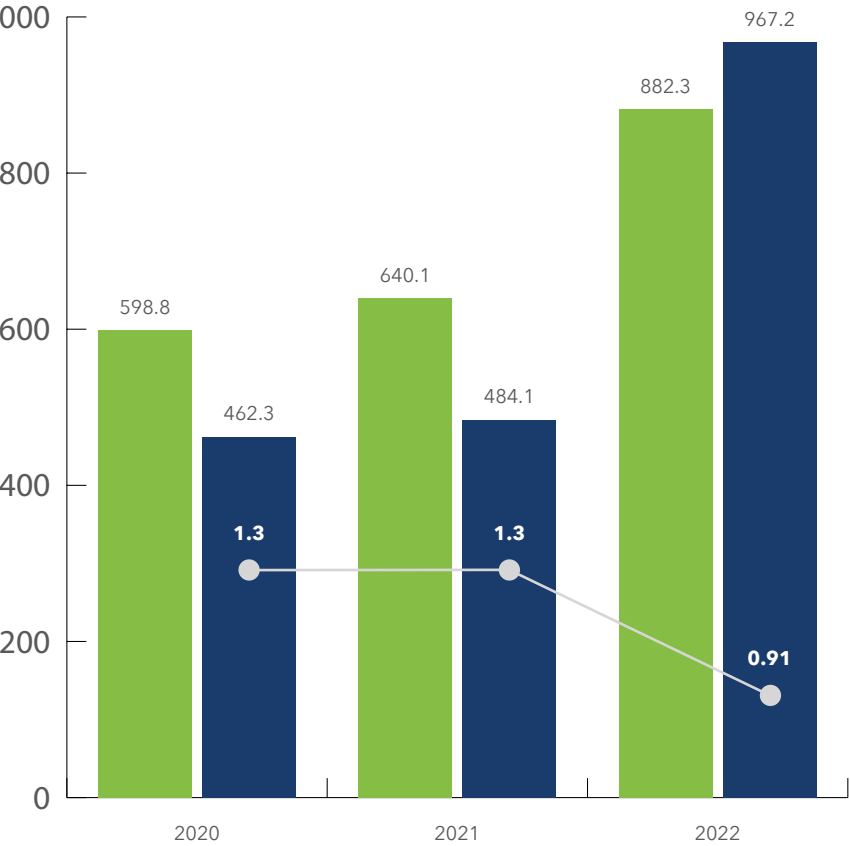
**GROSS CAPEX INVESTMENTS (€ MLN)**

- % OF REVENUES



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

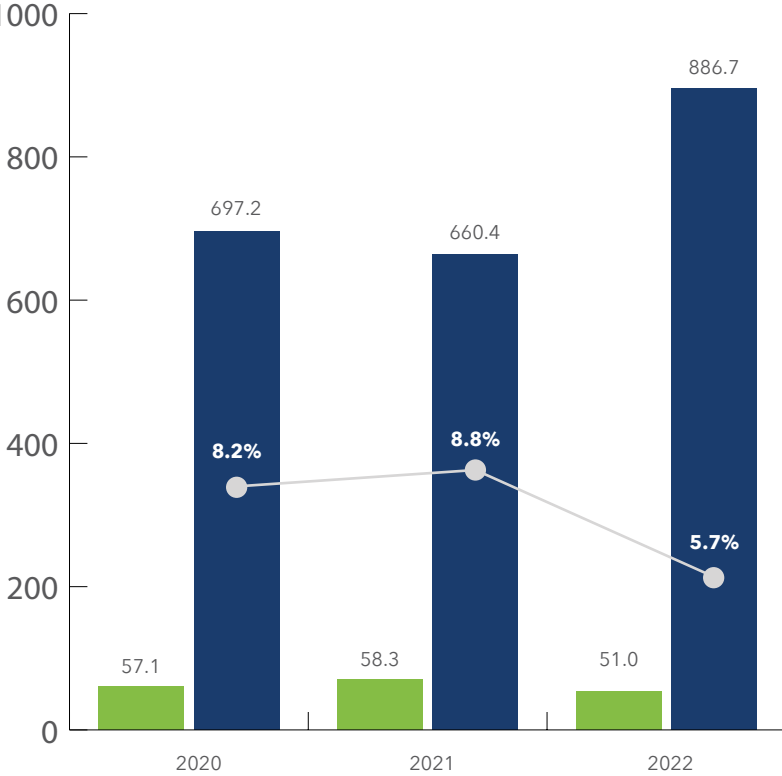
- NET FINANCIAL POSITION (NFP)
- NET EQUITY (€ MLN)
- NFP/NET EQUITY



\*NFP included the impact of IFRS16 of about 112.2 MLN

**R&D TOTAL EXPENDITURE  
AND INVESTMENTS (€ MLN)**

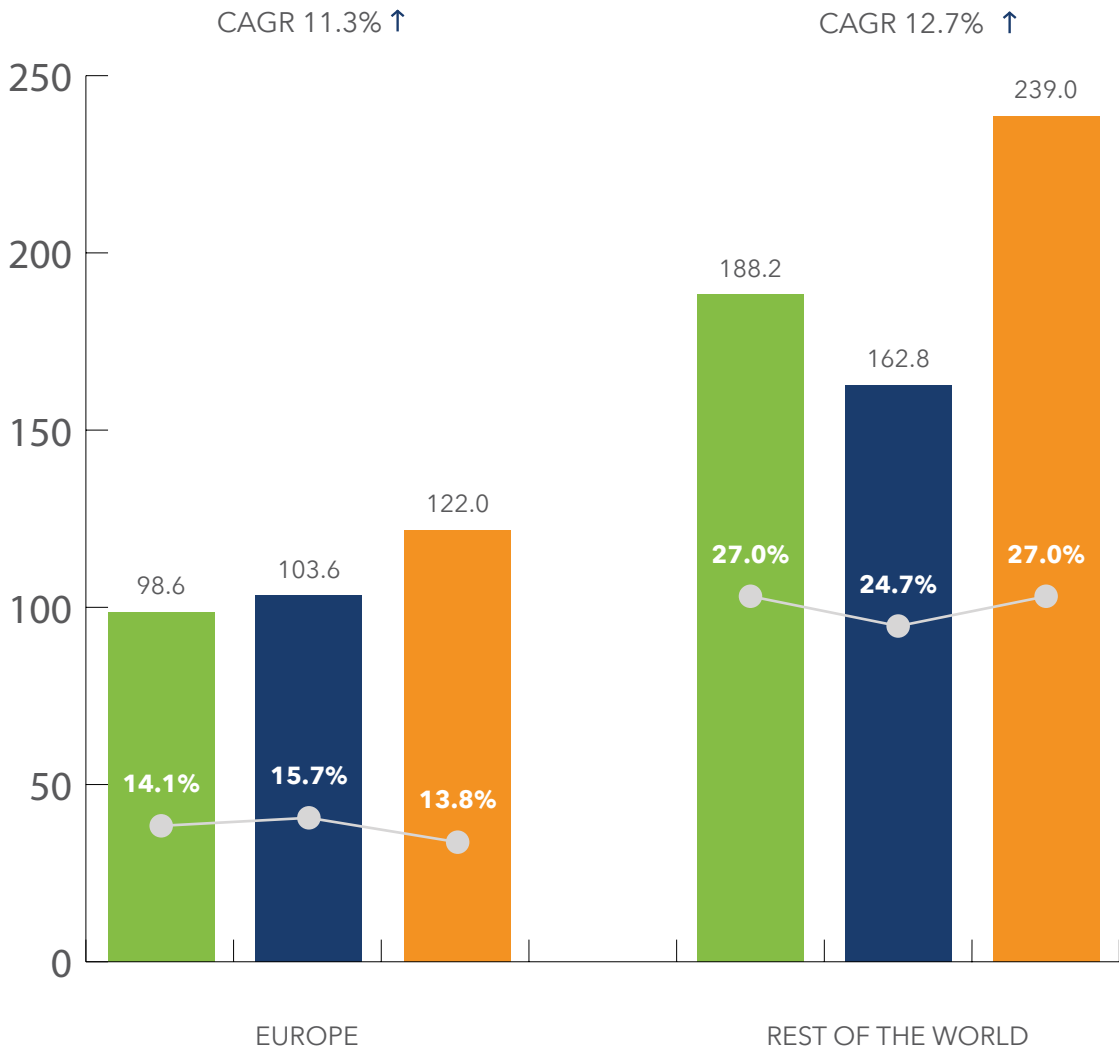
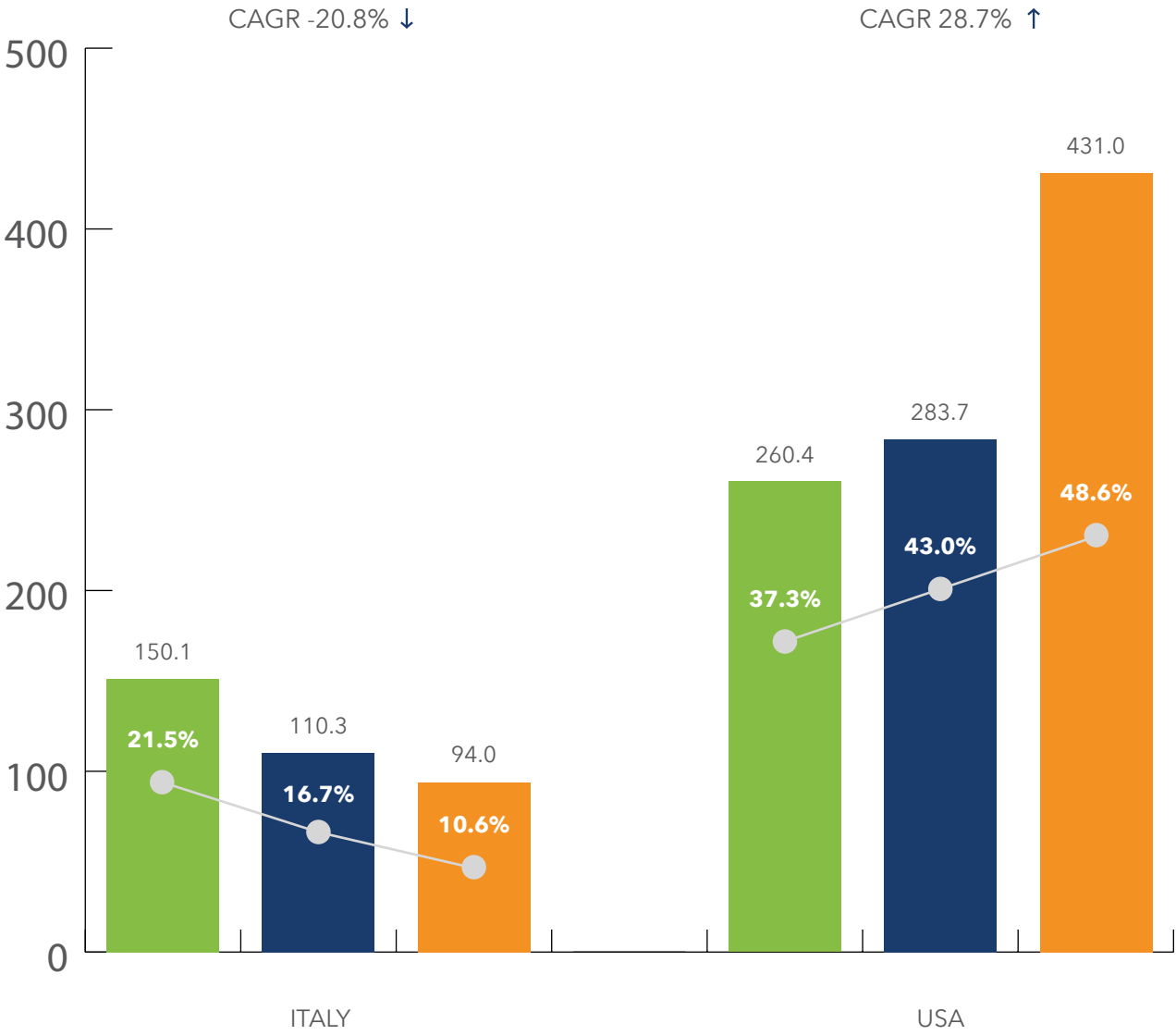
- R&D
- REVENUES
- %





**DISTRIBUTION OF SALES  
BY GEOGRAPHIC AREAS (€ MLN)**

2020 ■  
2021 ■  
2022 ■  
% ●





# FINANCIAL STATEMENTS

CONSOLIDATED STATEMENT OF FINANCIAL POSITION (In thousands of Euro)	12/31/22
<strong>NON CURRENT ASSETS</strong>	
Property, plant and equipment	559,624
Investment property	2,338
Goodwill	289,692
Right of use	153,789
Intangible fixed assets with a finite useful life	403,725
Other non current financial assets	6,877
Income tax receivables	4,546
Other non-current assets	1,114
<strong>TOTAL NON CURRENT ASSETS</strong>	<strong>1,421,705</strong>
<strong>CURRENT ASSETS</strong>	
Inventories	538,539
Trade receivables	156,535
Contractual assets	36,789
Income tax receivables	21,795
Other current assets	38,398
Other financial current assets	4,389
Cash and cash equivalents	123,037
<strong>TOTAL CURRENT ASSETS</strong>	<strong>919,482</strong>
<strong>TOTAL ASSETS</strong>	<strong>2,341,187</strong>

CONSOLIDATED STATEMENT OF FINANCIAL POSITION (In thousands of Euro)	12/31/22
<strong>SHAREHOLDERS' EQUITY</strong>	
<strong>GROUP SHAREHOLDERS' EQUITY</strong>	
Share capital	60,454
Reserves	782,170
Net profit attributable to the Group	118,161
<strong>TOTAL GROUP SHAREHOLDERS' EQUITY</strong>	<strong>960,785</strong>
<strong>SHAREHOLDERS' EQUITY ATTRIBUTABLE TO NON-CONTROLLING INTERESTS</strong>	
Capital and reserves of non-controlling interests	1,106
Net profit attributable to non-controlling interests	5,270
<strong>TOTAL SHAREHOLDERS' EQUITY ATTRIBUTABLE TO NON-CONTROLLING INTERESTS</strong>	<strong>6,376</strong>
<strong>TOTAL SHAREHOLDERS' EQUITY</strong>	<strong>967,161</strong>
<strong>NON CURRENT LIABILITIES</strong>	
Medium-/long-term loans	918,697
Provisions for risks and charges	3,703
Employee benefit liabilities	3,587
Deferred tax liabilities	31,623
Other non current liabilities	3,141
<strong>TOTAL NON CURRENT LIABILITIES</strong>	<strong>960,751</strong>
<strong>CURRENT LIABILITIES</strong>	
Payables to banks and other lenders	79,504
Current portion of medium/long-term loans	18,357
Provisions for risks and charges	32,251
Trade payables	210,924
Income tax payables	9,310
Other current liabilities	62,929
<strong>TOTAL CURRENT LIABILITIES</strong>	<strong>413,275</strong>
<strong>TOTAL LIABILITIES</strong>	<strong>1,374,026</strong>
<strong>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</strong>	<strong>2,341,187</strong>



STATEMENT OF PROFIT OR LOSS FOR THE YEAR (in thousands of Euro)	12/31/22
Revenue	886,669
Cost of sales	688,887
<b>Gross margin</b>	<b>197,782</b>
Other income	23,086
Gain on bargain purchase	188,075
General and administrative expenses	176,930
Sales and marketing expenses	66,450
Research and development expenses	25,819
Other operating costs	10,753
<b>Operating Profit</b>	<b>128,991</b>
Financial expenses	44,130
Financial income	2,966
Financial expenses from refinancing	23,166
Net foreign exchange gain	62,244
<b>Profit before taxes</b>	<b>126,905</b>
Income taxes	3,474
<b>Net profit for the period</b>	<b>123,431</b>
<b>of which:</b>	
<b>Net profit attributable to the Group</b>	<b>118,161</b>
<b>Net profit attributable to non-controlling interests</b>	<b>5,270</b>

CONSOLIDATED CASH FLOW STATEMENT (In thousands of Euro)	12/31/22
Net cash flow generated/(absorbed) by operating activities	-64,334
Net cash flow generated/(absorbed) by investing activities	-39,852
Net cash flow generated/(absorbed) by financing activities	93,464
<b>TOTAL NET CASH FLOW</b>	<b>-10,722</b>
Cash and cash equivalents at the beginning of the financial year	134,186
Net effect of foreign currency translation on cash and cash equivalents	-427
<b>CASH AND CASH EQUIVALENTS AT END OF YEAR</b>	<b>123,037</b>



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