

ANNUAL REPORT 2020

KEDRION
B I O P H A R M A





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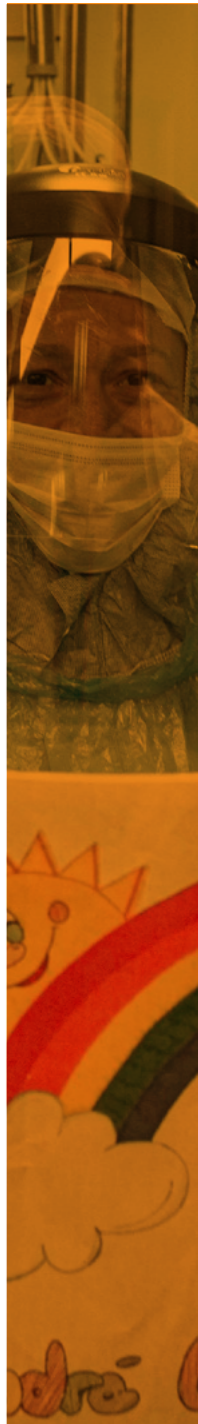
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LETTER FROM PAOLO MARCUCCI

Dear Friends,

First of all, I wish to extend my heartfelt sympathy and condolences to those who have been personally touched by the pandemic. Covid-19 has emerged with singular force in our home country in 2020, and eventually its consequences have known no borders.

Our business is protecting people from the pain and suffering of rare and serious conditions: we could not allow even a pandemic to prevent us from this mission. Already in early February we created a Covid-19 Global Response Team that met daily to assess the evolving situation across our activities in all the countries where we operate. Its primary and essential goals were to protect our employees and to maintain the supply of vital plasma-derived therapies to our patients. Many employees transitioned to working remotely from home. Extensive measures were put in place to protect workers who were essential to production and could not work from home. Thanks to their dedication and quick and nimble action, we accomplished our goals. I am proud of the ways in which our colleagues have responded. I also stand in awe of the patients and their caregivers who have courageously faced the special consequences of the pandemic.

One of the consequences of the pandemic was a significant reduction

in rates of plasma donation in the United States and to a lesser extent within the Italian National Health System and in our collection centers in Hungary.

The disruptions caused by the pandemic have made us even more aware of the importance of resilience in the global plasma collection flow. It is essential that regions like Europe become more self-sufficient in plasma collection and less dependent on US supply.

As the pandemic struck, we quickly realized that our special expertise might contribute to the quest for an effective Covid-19 treatment. We donated that expertise and exclusive technology, enabling Italian hospitals to infuse donated Covid-19 convalescent plasma. We also entered into agreements with Kamada, already a trusted partner, and with Columbia University Irving Medical Center, to research and develop a potential anti-SARS-CoV-2 Immune Globulin.

To be sure, although the pandemic commanded our full attention, our eyes were on the future as well preparing for eventual FDA approval of RhoGAM production at our Melville plant, while increasing market coverage of our other Anti-D prophylaxis, IMMUNORHO. The anticipated approval of our 10% Immunoglobulin for

treatment of adults with Primary Immunodeficiency, "Klg10", took a significant step forward in 2020, when the final subject in the phase III trial supporting an FDA Biologics License Application received treatment.

Perhaps most significant, as we looked forward, was the appointment of our new Chief Executive Officer, Val Romberg. Val comes to us with more than 30 years in the pharmaceutical business, much of it in the plasma derivatives sector. I remain as Chairman and will concentrate on strategy, M&A, business development, communications and public affairs.

Val came on board in October and, although that was at the beginning of the severe winter surge of the pandemic, he quickly embarked on a bold transformational program - dubbed NEXT - aimed at streamlining and increasing efficiency in our operations.

The NEXT program will be a major undertaking in 2021, which is somehow appropriate as we will be celebrating our 20th anniversary. The roots of our company go back much further - to when my father established a small pharmaceutical business in our native Tuscany some seventy years ago. Kedrion Biopharma began in Tuscany as well and we are still headquartered

there in Castelvevchio Pascoli, near Lucca. My family and I are proud of what we have become: a global company helping people in some 100 countries.

Notwithstanding the adversity we are still facing, I trust in Kedrion and its people and I am very confident we can look forward to much progress!

I wish you and your families and friends good health and continued safety.

Paolo Marcucci,
Kedrion Chairman



COMPANY OVERVIEW



THE BASICS

Kedrion Biopharma is headquartered in Tuscany, Italy, where it began as a family business nearly twenty years ago and quickly established a strong and enduring partnership with the Italian National Health System and its network of blood donors. It has grown to join the world's leaders in the production of plasma-derived products.

Kedrion is proud to serve and protect a wide community of patients who suffer from rare and serious diseases and conditions including Hemophilia, Primary Immunodeficiencies and Rh sensitization. Its products are distributed worldwide in some one hundred countries.

Kedrion's experience in supporting and promoting Italian national self-sufficiency in the production of essential plasma-derived medicines is an invaluable asset available to other countries pursuing this vital goal.

BEYOND THE BASICS

Kedrion Biopharma prides itself on its focus on people - from our employees to the generous donors who underpin our mission; from our partners in the healthcare community to the patients who are our ultimate focus and concern, we seek to help people and to help them help others.

In this sense we see our mission as providing a bridge: from donor to patient; from plasma to therapies; from despair to hope.

*Including Castelvécchio Pascoli plant (Lucca, Italy) completion impending
**Source: Marketing Research Bureau "The Worldwide Plasma Protein Market 2018"
As of December 31st, 2020

Headquarters in Italy with subsidiaries in Europe, USA, Latin America and Asia



5* manufacturing plants in 3 countries



27 plasma collection centers worldwide



5th world player in the field of plasma-derived products and 1st in Italy in terms of production from Italian donor plasma**



Partner in the self-sufficiency program in Italy



Commercial presence in approximately 100 countries



2020 turnover: 697.2 million Euro



Annual growth rate since 2013: 7.3%



People in the world: 2,658



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



11 voluntary standards and certifications in manufacturing, human resources, environment



OUR WORLD



MAP LEGEND

- 📍 HEADQUARTERS
- 🏭 PRODUCTION
- 📦 DISTRIBUTION
- 💧 PLASMA COLLECTION
- 🟠 COMMERCIAL PRESENCE

As of December 2020

In 2021 a project is currently underway to reorganize Kedrion's corporate structure involving a number of subsidiaries with headquarters in European Countries. Up-to-date information is available at this link www.kedrion.com/kedrion-world

WHAT WE OFFER



PRODUCTS

1 RARE DISEASES

IMMUNOLOGY / NEUROLOGY

Ig VENA / HUMAGLOBIN Liquid / KEDRIGAMMA / VENITAL*
Standard i.v. Immunoglobulin 5%

GAMMAKED***
Standard i.v. Immunoglobulin 10%

NAXIGLO / KEYCUTE*
Standard s.c. Immunoglobulin

HEMATOLOGY / HEMOPHILIA

EMOCLOT / HUMACLOT / PLASMACLOT / EMOWIL / KLOTT* / KOÄTE***
Factor VIII/Von Willebrand Factor concentrate

NUWIQ**
Recombinant Factor VIII

WILFACTIN**
Von Willebrand Factor concentrate

AIMAFIX / KEDRIFIX / IXED*
Factor IX concentrate

EMOSINT
DDAVP Desmopressin

2 MOTHER AND CHILD HEALTH

RhoGAM / IMMUNORHO / KeYrho / MICRhoGAM
Anti-D i.m. Immunoglobulin

IMMUNOHBs 180 IU
Anti-Hepatitis B i.m. Immunoglobulin

3 INTENSIVE CARE AND TRANSPLANTATION

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

KEDRAB***
Human Rabies Immunoglobulin

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

IMMUNOHBs / UMAN BIG / KEDHBs*
Anti-Hepatitis B i.m. Immunoglobulin

TETANUS GAMMA / TETIG
Anti-Tetanus i.m. Immunoglobulin

UMAN COMPLEX / KEDCOM* PRONATIV**
Prothrombin Complex concentrate

AT III KEDRION / ATKED*
Antithrombin concentrate

KOLFIB / SILKETAL*
Fibrin sealant

K FLEBO
Potassium aspartate

4 TRANSFUSION MEDICINE

CERUS INTERCEPT**
Plasma and platelets pathogen inactivation system

PLASMASAFE / PLASMAGRADE*
Pharmaceutical grade plasma

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
As of March 2021



OUR 2020



ON A HAPPY NOTE

Much of our Annual Report for 2020 focusses necessarily on the challenges of the Global Covid-19 Pandemic. But there is good news in any year, no matter the tests. For us, one significant, very good news story was the naming of our new CEO.



VAL ROMBERG

Welcome aboard, **Val Romberg**. Kedrion Biopharma greeted a new **Chief Executive Officer** in 2020. While Kedrion co-founder Paolo Marcucci, who had held that position, will continue to chart our course as Chairman, Mr. Romberg will take the helm, steering the company in its day-to-day operations.

Mr. Romberg arrived with an impressive record in the pharmaceutical industry and more than twenty years' experience in the plasma sector. Most recently, he was Executive Vice President of Operations for CSL Behring. His nearly forty years in pharmaceuticals have included significant responsibilities in Operations, R&D and Manufacturing with various leadership roles.

A graduate of the University of Michigan, where he studied Chemistry, Val spent a decade working as a chemist before moving into management. It was while working for a company that made packaging for pharmaceuticals that he saw his future path:



From there you could kind of see the pharmaceutical industry and I thought, I really liked that: it's science-based and I especially liked that it's patient focused. The nice thing about being in the pharmaceutical industry is that every day you're working to make people's lives better. It was meaningful. So I really wanted to move into the pharmaceutical industry and I got in and I've never left.

But why Kedrion?

I have to say that it started really with Paolo Marcucci. I knew Paolo before I retired from my previous role, and I was always impressed with his entrepreneurship. He's very, very broad thinking, very visionary. So, the idea of working with Paolo was attractive. And then as I looked into Kedrion, I thought, well, it's a very

interesting company: clearly has good people, has lots of opportunities. And I think that it was a good fit for me. I think I'm somebody who can help bring opportunities to fruition and help move the company further. So, I'm excited to be here.

And what did he find?

I was pleasantly surprised at the quality of the people. I think we have people who are smart, who are dedicated and engaged, who want to do good work for patients. I think Kedrion has the opportunity to increase our outputs, increase our yields, reduce our cycle times - all sorts of tools that you can use to bring more drugs to patients. So, the opportunities are definitely there. And I think they are opportunities that we, as a team can execute on.

It did not take him long to get to work on how he would like to see the company transform.

You can't flick a switch and have things change; it takes planning, it takes engaging people. To help in that process, we hired a consulting firm, BCG (Boston Consulting Group), who worked with us in terms of defining what a

transformed Kedrion would look like - what are the important levers we need to transform? We've completed that process at the end of January, and I think it lays out a lot of work to do over the next couple of years to really move the company from being an entrepreneurial, promising, I'm going to say 'young company', to being a much more efficient, and effective mid-sized company. The management team is clearly on board with the change - very "bought into" it.

And the future?

Our transformation project is a big piece of that, and when you look at the end of the transformation project, what you see is a company that is much more efficient... able to create and deliver products much more effectively for patients. I think we'll have a broader footprint. We're already in a hundred countries, but I think we'll be growing our sales teams in a lot of our important countries. What I would like to be in five years is a strong competitor to what we call the "three sisters", the three larger companies in the plasma industry who really dominate the plasma business. We're going to max out our

manufacturing capacity in the next few years, even with the kind of improvements in efficiency and yields that I've talked about, because demand is so strong. So we are dedicated to both growing our plasma collection and our plasma fractionation capacity.

And when he is not at work?

I am happily married, with six kids and six grandkids. Hobbies: woodworking; I enjoy traveling with my family. We lived for six years in Switzerland, where I learned to ski. I enjoy lots of different kinds of food, but especially Italian. One of my sons is a chef in NYC, but did his training in Florence. Two of my daughters work in the pharma industry, so the apple doesn't fall far...

He also took up the guitar last year. He admits his new responsibilities have taken a toll on his practice time, but he still has high aspirations. His inspiration?

Jimmy Hendrix, of course.

PANDEMIC

2020 was a year that challenged all of us around the world. The Covid-19 pandemic – still with us at this writing – will join in infamy the great trials of recent human history. Not for a century had the world been tested by such a global public health crisis. While the year was filled with fear and tragedy, striking with what seemed like random brutality in one family after another, one community after another, one country after another, it also brought out the best of us: extraordinary care, sacrifice, industry and determination. Heroes emerged from the depths of despair.

The threat crept in with the new year, as the first reports of a heretofore unseen and unknown virus arose from China. The first confirmed virus death occurred there on January 11th. The United States reported its first case on January 21st. As cases appeared in increasing numbers of countries, the World Health Organization (WHO) declared the virus a “public health emergency of international concern” on 30 January, 2020. A day later, the virus appeared in Italy, our home country, when two Chinese

tourists in Rome tested positive. The new virus was given a name by the WHO on 11 February: “Covid-19”, for Corona Virus Disease-2019, 2019 being the year it was first seen in China. It was found to be caused by severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2).

It seemed in the first months that the disaster unfolded in steps, each of which appeared to catch the world continually off-guard. By the end of February, Italy was emerging as a global center of concern with more than a thousand reported cases. The Italian government ordered a general “lockdown” on the 9th of March, but by the week of the 14th, Italy had surpassed China with the highest death toll in the world. In the next week, according to the Johns Hopkins Coronavirus Resource Center, the United States became the world epicenter of Covid-19, with more than 100,000 reported cases. In Hungary, the other country in which Kedrion has a significant operational presence, the virus first appeared in March with a state of emergency declared and restrictions imposed on 11 March.

As terrible as these numbers were, they were to be dwarfed by a surge in cases and deaths in the fall, affecting most regions of the world with notable exceptions including China and Australia.

The pandemic had a striking effect on the global economy within the first few months. GDP plunged to record lows in many countries and stock markets dived in February and March. Most markets recovered by the end of the year, but the International Monetary Fund reports the global economy shrank by 3.5% in 2020. Many consider the pandemic recession to be the worst global economic crisis since the Great Depression.

Government response to the rising and falling case load predictably varied from country to country. In the US, because of its federal government structure and fragmented healthcare system, personal and commercial restrictions were especially difficult to plan for. The plasma sector in general suffered: social distancing and other restrictions depressed donations.

THE KEDRION EXPERIENCE

At Kedrion Biopharma we marched – unsuspecting – into the new year with resolve and enthusiasm, having received

a major vote of confidence in the form of significant outside investment at the end of 2019, and looking forward to recruiting a new Chief Executive Officer. But even before the effects of the pandemic, the year began somewhat inauspiciously when the FDA flagged our initial

RhoGAM validation batches at our Melville plant. Our reaction was swift, and we expect to submit a new application to the FDA in early 2022, and commence production later in the year. Our commitment to patients has continued without disruption.



ANOTHER KIND OF BRIDGE

As a company that helps people across “troubled waters”, we know how to make bridges. In the US, the leading market for RhoGAM and where the brand is market leader, we have ensured adequate supply through a new contract with Ortho-Clinical Diagnostics, from whom we acquired the brand in 2011, until we take over production in 2022. In other countries, we are able to guarantee supply with our other Anti-D Immunoglobulin, IMMUNORHO, manufactured in our plant in Sant’Antimo, Naples, Italy.

As **Global Marketing Director, Roberto Tana** noted,



It was a necessary change of course and we reacted fast. A new plan is in place to guarantee broader access to Anti-D prophylaxis for mothers at risk in our current market and to have access to new ones.

As Covid-19 crept into our collective consciousness, we nonetheless had a positive outlook. Our new Quality and Control laboratories at the Sant’Antimo site, completed late in 2019, as part of a 10 million Euro investment plan for the plant, was given approval for operation by the Agenzia Italiana del Farmaco (AIFA), the Italian Medicines Agency. The same agency also announced it was including our Plasminogen concentrate, which treats the rare, sight-threatening disease, Ligneous Conjunctivitis, in the reimbursed drugs list of the Italian National Health System. The product, offered under compassionate use programs, is not yet approved by the FDA nor the EMA.

THE PANDEMIC WIDENS AND DEEPENS

But as February rolled on, so did the Coronavirus. By the end of the month, it was clear we had to focus on two objectives: *Protect our employees and ensure the supply of our vital products to the people who needed them.* A “Covid-19 Global Response Team” was formed to coordinate our reactions internally and externally. An evolving series of measures was taken, instituting practices and procedures that would address both of our essential objectives. Sub-teams were organized in the US and in Hungary, all meeting daily as circumstances changed relentlessly.



It was a Friday, April 17, 2020, around 5 p.m., when I received my first phone call from HR that there was a problem: a full shift was put in quarantine. They asked me to organize my team to replace the team affected by the quarantine for the weekend, as the plant cannot be left unattended and production must be maintained. The day before we had night shift, so we could have only a short rest. My team has such a good team spirit, I was sure that my

colleagues would take this extra challenge without hesitating. On Friday, by 10 p.m. we had the necessary number and we started to work next morning knowing that it would be hard but “Who else could do it if not we?”. I do think that performance of my team was extraordinary, able to control the processes without

any significant delay in the production. The difficult period we experienced together made our team spirit even stronger, and the term “together through thick and thin” made sense for us again.

Máté Karancsi - Production Supervisor (Gödöllő, Hungary)



Employees, whose work allowed, worked remotely. In Italy, Kedrion's efforts - already in place - to responsibly conserve energy and reduce greenhouse emissions by encouraging regular "smart working" from home, helped ease this transition.



THERE WERE "UP-SIDES"



We were able to share with our colleagues who were required to stay at home, the positive impact on our carbon footprint. During 2020, "smart working" in Italy reduced the kilometers driven in commuting by 2,000,000 - more than 51 times around the planet!

Marta Bonaldi, EHS Manager, Italy



When Covid-19 came on the scene, my department and I were completely immersed in the activities for the preparation of the fourth and last tender for the Italian Plasma Derivative Service, a long awaited project that required maximum concentration and teamwork involving all the Kedrion departments. For the second half of this project we had to switch to videoconference meetings. Each meeting



excited me because I was able to see that we had become "ONE KEDRION". We were also proud of our continuing support and solidarity with the National Health System, patients and Italian donors, and happy to note that plasma donation in Italy has - in the end - remained steady, despite the challenges of the pandemic.

Chiara Montingelli, Marketing Manager, Italian Contract Manufacturing



Our people have responded finding new ways of working (digital symposia, telephone, extensive tele-conference, chat apps, etc.). Great resilience, no need of "heroism". The pandemic has pushed the company to discover and appreciate the benefits of "smart working" and the value of digitalization.

Alessandro Gringeri, Chief Medical and R&D Officer

As is our duty, Kedrion continues to do its utmost to combine the need to safeguard the health of our workers and their families with production of our products. Our drugs are essential to the life of those who use them and who, in many cases, do not have adequate alternative therapies: now more than ever it is our duty and honor to guarantee supply to patients, who represent one of the most vulnerable and exposed groups in our society.

Paolo Marcucci, Chairman



WE JOIN THE FIGHT...

As a company dedicated to protecting and improving human health, we were determined from the first word of the gathering threat of pandemic to pitch in, however we could, to mitigate its effects. We have joined in a number of ways the campaign to develop an effective treatment based on “convalescent plasma”, that is, plasma collected from people who have recovered from Covid-19. This plasma

carries antibodies created by the immune system to fight the SARS-CoV-2 virus. Two basic methods using this plasma are in direct infusion into affected patients and in concentrating antibodies from many donors to produce a hyperimmune globulin. Our expertise allowed us to engage in both of these areas in hopes of eventually providing relief to people in Italy and around the world.

...AT HOME...

Kedrion Biopharma has a long and proud history of partnering with the Italian Health System in support of its mission to achieve self-sufficiency in plasma-derived medicines. The Health System quickly turned its attention to providing convalescent plasma for Covid-19 patients, but by law such plasma must undergo pathogen inactivation before transfusion. As sole distributor of the Intercept technology, produced by the American company, Cerus, for this inactivation of pathogens in blood components (plasma and platelets), we were in a position to provide the kind of immediate help that was required.

We quickly made the technology, along with the necessary consumables, available to hospitals requesting it. This was a donation we were happy to be in a position to make.

As **Italy Country Manager, Danilo Medica** put it,



One cannot imagine the sense of pride that has spread across Kedrion for this activity. It was the proof that our daily work could help save lives. It is the most honorable part of our job.

...AND ABROAD

For some years now we have partnered with an Israeli biopharmaceutical company to produce and market KEDRAB, our post-exposure prophylaxis Immunoglobulin against Rabies. In April - still early in the pandemic, which was nonetheless already raging in many parts of the world - we entered into another collaboration with Kamada Ltd. to develop a hyperimmune globulin that could fight the Coronavirus. We would provide convalescent plasma collected from generous,

Covid-19-recovered donors in the United States and Kamada would refine and test a polyclonal anti-SARS-CoV-2 Immunoglobulin therapy. Additionally, we established a research partnership with Columbia University Irving Medical Center to study and test anti-body titer in the convalescent plasma collected in the US. This exciting and promising project is ongoing with the hopes of providing the world an efficacious treatment for Covid-19.

Kit Linck was the first person to donate “convalescent plasma” to our collection center in **Mobile, Alabama (USA)**, as we were beginning our research into the possibilities of developing a treatment for Covid-19. He had recovered from the virus and wanted to help others.



When I first got it, I joked around with my friends, saying, well, the only way you can help anyone else is by getting it and beating it.

So despite the restrictions and fears caused by the pandemic, he decided visit the center and donate his Covid-19 antibody-rich plasma.

If it saves one person’s life, it’s worth everything I’m doing.





KEDPLASMA FACES THE PANDEMIC

Of all of Kedrion Biopharma’s operations, the collection of plasma is the most fundamental to our mission. Plasma is the scarce natural resource we transform into life enhancing, life protecting and life saving products. It is also the most vulnerable to disruptions like the Covid-19 pandemic. Collecting plasma requires close contact between donor and staff – especially the phlebotomists – with the constant and changing flow of the donor population. In addition, in the United States, which is where most of our collection centers are and is the source of the great bulk of our plasma, responses to and restrictions for the pandemic varied from state to state, city to city and over time.

It is understandable under these circumstances that some donors are reluctant to risk possible added exposure to the Coronavirus. These kinds of

disruptions were experienced in the sector worldwide and they were reflected in our overall volume numbers, which tended to fluctuate with the local severity of Covid-19 caseload.

Plasma collection in the US suffered a peak decline of some 46% early in the crisis, but rebounded to finish the year 18% lower than the 2019 volume. Similarly, in Hungary, collection was affected substantially in the first half of the year (~15%), but recovered strongly in the second half so that annual volume was actually 14% higher than in 2019. This was also due in part to two of the centers were in a “growing phase”.

Fluctuations notwithstanding, KEDPLASMA was able to meet the needs of Kedrion Biopharma and avoid disruptions in the supply of medicines and treatments to our vulnerable patients.



As this team always does, it responded with fortitude, determination and agility to manage the situation as best as could be handled under the circumstances. The KEDPLASMA team led the industry in developing SOP’s for social distancing and Covid restrictions. Our head start – in part because the virus struck Italy very early – helped to mitigate the inevitable disruptions of the pandemic.

**Helen Nasser, KEDPLASMA
US Managing Director**



KEDPLASMA is now able to focus all its efforts on the collection of plasma in the US, with the current 27 centers set to become 30 by the end of 2021, ensuring the procurement of precious raw material for Kedrion’s production processes so that the needs of product distribution are met with the greatest possible efficiency.

**Paolo Melloni, Plasma
Business General Manager**

And, although pressure was felt on the daily volume of plasma collection, Kedrion kept its eye on the future. We made the determination that that future leaned in the direction of the US and with assertive optimism initiated the sale of our collection centers in Hungary, while opening two new centers in Pennsylvania and Alabama.

Plasma collection in Italy is done at the Region level in partnership with “donor associations”. The country has made progress toward national self-sufficiency in plasma, but it still must rely on foreign supply for about 30% of its needs. The system withstood the challenges of the pandemic rather impressively though with whole blood collection (from which a portion of the plasma supply is recovered) off by 5% and plasma collection down 2% for the year.

MAINTAINING ESSENTIAL OPERATIONS

While operations essential to the production of our line of plasma-derived medicines continued uninterrupted, thanks to the courageous determination of our plant employees, most of the day-to-day interactions that are also necessary to our business and our mission were accomplished with the help of remote technology. Training sessions, sales and marketing meetings, regulatory and health and safety initiatives and inspections, recruitment... all continued remotely with minimal disruption. A significant contributing factor to this accomplishment was the maturing use of a new internal communications tool called JAM. As **Chief Human Resources Officer, Gianpaolo Naef** recalls, it was originally thought of as "a collaborative platform for internal use in HR. The turning point was Covid. We realized that JAM could become quickly the place to share most of Kedrion information and we made a great job with Global Communication colleagues in

helping it become the employees portal for everything. Now we are live in Italy, US and Hungary with dedicated web pages. Great stuff!"



Working at Kedrion during the pandemic initially scared me (honestly I would have liked to work in a company that could close during the lockdown), then as time went by and with fewer fears I felt proud to be able to keep on working even in such a delicate moment. I think of the patients who need our life-saving medicines, but I also think of those who have lost a job and all those companies that have never reopened after the imposed closure. I thank Kedrion who "rewarded" those workers who, with their presence, have ensured that the work did not stop.

Sara Martinelli, Packaging Head (Bolognana plant, Italy)



Our way of socializing, our attitude, our habit of making plans have changed radically. We are living in a gray and very sad way, and it will take a long time, perhaps our children will have forgotten it. The doctor-patient relationship is the only social connection we have. In the end, paradoxically, the relationship with the patient is what still saves sociality, there is that minimum of "physicality" that is no longer possible with others. And when I make private visits, sometimes I spend an hour because we go on chatting...

Giovanni Antonini, MD, Neurologist (Rome, Italy)



This unfortunate situation has placed us in a position of privilege. The awareness of being lucky and being able to continue helping patients with our products is a source of pride and responsibility.

Massimiliano Ramelli, QC Manager (Sant'Antimo plant, Italy)



I thought about it (our mission) more than usual and I was happy to be able, together with the whole company, to guarantee the continuous supply of life-saving drugs.

Simona Nesi, QA Operations Supervisor and QP (Bolognana plant, Italy)



OUR PATIENTS AND THE BRIDGES WE OFFER THEM

Under the shadow of the pandemic, our intensified focus on protecting the needs of our patients within each of the therapeutic areas our products address, involves, as always, more than the ensured availability of medicines. It requires active dialogue with, not only patients, but researchers, healthcare providers, and patient associations. The limitations imposed by worldwide outbreaks of Covid-19 inspired us and our partners to creative use of digital technology. Some examples:

RARE DISEASES HEMATOLOGY / HEMOPHILIA

■ The pandemic has presented difficulties for all of us, but for people dealing with a condition like Hemophilia, the challenges are profound. They depend for their health on specific medicines. In the case of patients with Hemophilia A, this is a clotting factor that they must infuse either regularly as a prophylactic against bleeds, or “on demand” when experiencing a bleed. In either case, it is essential that the clotting factor be close at hand. “Popping in” to a local pharmacist is not an easy option during a pandemic.



■ For this reason, early on as Covid-19 spread in Italy, Kedrion supported a home delivery service of Hemophilia therapeutic products. The service, known as #KoalaACasaTua, is carried out by Domedica, a leader in support programs for patients, physicians, clinical centers and other constituencies in health care.

■ With the support of Kedrion, participating patients are delivered their medicinal requirements at no additional cost. This provides them not only necessary Hemophilia therapy, but added protection from unnecessary exposure to the Coronavirus.

■ In June we supported and participated in the Virtual

Summit of the World Federation of Hemophilia (WFH). As **WFH President, Alain Weill** observed, “We think it was really important to organize this Virtual Summit. On the one hand, because it’s crucial for us to keep the dialog alive with the whole global community and, at the same time, we know how essential it is for our Federation and for our partners - the pharmaceutical industry, scientists, researchers, healthcare and industry professionals - to meet with and engage one another. On the other hand, we’re witnessing a rapidly evolving landscape in the world of Hemophilia. The scenario is changing from a technical and scientific point of view and, therefore, it’s necessary to keep up to date with all the recent developments.”

■ Faced with profound and rapid changes, including the introduction of innovative therapies for the treatment of Hemophilia and congenital hemorrhagic diseases, Kedrion has continued to contribute to the medical-scientific debate on the present and future role of Factor VIII. We supported a symposium entitled “Why Do We Still Need Factor VIII Today?” at the International Hemophilia Congress of Turkey held remotely in December.

■ We renewed our support to the PARTNERS project promoted by the European Hemophilia Consortium (EHC) for improving access to treatment for coagulation disorders.

■ In Latin America - specifically, Mexico and Colombia - we organized medical-scientific webinars that attracted nearly one thousand clinicians. Presenters included **Dr. Miguel Escobar of the University of Texas** and **Dr. Carmen Escuriola Eittingshausen, Director of the Hemophilia Center Rhein Main in Frankfurt, Germany.**

■ In Italy, in alignment with our advocacy for the active inclusion of the patient in his or her own treatment regimen, Kedrion provided an unconditional grant to support “Words in Hemophilia: Towards Patient Engagement”, at the EngageMinds HUB, a research center at the Catholic University of the Sacred Heart in Milan, Italy.



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One more challenge to face. When I tested positive for Covid-19 I was a bit afraid of how my defenses work and the continuous challenge of my body to be healthy and fight my conditions. But like everything else in life, I faced it with courage and faith that I could overcome it and succeed. Fortunately I am doing well and stronger than before. Somehow I even feel happy to be part of history and to have defeated the virus.

René Montt (Monterrey, México)



The project is unique at the international level because it aims to give a voice to those who have experienced the disease and to those who are involved in the care of patients with Hemophilia. The project also aims to understand the conditions that encourage and motivate patients to adhere to therapy, as well as to support their engagement in the treatment process.

Prof. Guendalina Graffigna, Director of EngageMinds HUB (Milan, Italy)

IMMUNOLOGY / NEUROLOGY

In the field of Immunology and Neurology, our commitment has taken the form of support for a number of initiatives organized by patient associations in various countries around the world. Digitally, of course: lamentable but necessary. For example:

■ In Italy, we participated in the webinar entitled "Product Availability and Safety. Actions During the Covid-19 Emergency," promoted by the

Italian Association of Primary Immunodeficiencies (AIP).

■ In the United States, we confirmed our support for the Immune Deficiency Foundation by participating in the 2020 digital version of the IDF WALK event for Primary Immunodeficiencies.

■ Our collaboration with the International Patients Organization for Primary Immunodeficiencies (IPOPI), has been long-standing and consistent and we participated in IPOPI's Global Patient's Meeting as part of the 19th Biennial Conference of the European Society for Immunodeficiencies in October.

■ To promote scientific research and awareness of Peripheral Nervous System disorders, we participated in several charitable activities in the United States, including the Raise Well 30-Day Wellness Challenge and the Walk & Roll digital events promoted by the GBS/CIDP International Foundation.

■ In Italy, this effort took the form of supporting the joint congress of the Italian Association of Myology and the Italian Association for the Study of the Peripheral Nervous System.

MOTHER AND CHILD HEALTH

■ Kedrion took an innovative approach to wider awareness by hosting a live streaming discussion of the recently published "Good Blood: A Doctor, a Donor, and the Incredible Breakthrough that Saved Millions of Babies", written by American journalist, Julian Guthrie. The book recounts the story of the development of a prophylactic treatment, some fifty years ago, that essentially ended the threat of Hemolytic Disease of the Fetus and Newborn (HDFN). One of the pioneers of that development, Dr. John Gorman, joined the discussion along with the author and Dr. Steven Spitalnik of Columbia University Medical Center (New York, USA). Dr. Spitalnik is Executive Director of WIRhE, the Worldwide Initiative for Rh disease Eradication, an initiative that seeks to extend access to the prophylaxis to the millions of women around the world who still do not have access or who are unaware of its availability.

■ Kedrion provided an unconditional educational grant to support the development of a section dedicated to the eradication of HDFN within the Global Library of Women's Medicine - an online, open-access bibliographic database focused on women's health and aimed at specialists in the field.

■ The extent of the global inequality of access to treatments that prevent HDFN was analyzed and detailed in a scientific study supported through an unconditional contribution by Kedrion and published in the July issue of the journal, *PlosOne*, under the title "Hemolytic disease of the fetus and newborn due to Rh(D) incompatibility: a Preventable disease that still produces significant morbidity and mortality in children."

FOR A CLOSER LOOK AT HOW WE CONTINUED OUR MARKETING COMMITMENTS IN MOTHER AND CHILD HEALTH, INVOLVING TRAINING AND EDUCATION, EVEN WHEN WE COULD NOT SIT DOWN WITH OUR HEALTHCARE, RESEARCH AND ADVOCACY PARTNERS, SEE BELOW: "MARKETING IN THE VIRTUAL WORLD".



Kedrion is constantly working with us to increase the knowledge and training of patients and physicians. The company supports our IPIC International Congress and our webinars. Kedrion has also supported the initiatives of our national patient organizations during World PI Week and has supported our patients directly with the PID GENIUS App that helps them manage their health status and treatments. IPOPI is very grateful to Kedrion for all the support that it provides.

Martine Pergent, Chair of IPOPI



INTENSIVE CARE AND TRANSPLANTATION

In addition to renewing our commitment to EPATEAM, the Italian health networking project dedicated to liver transplantation - by supporting several digital events, we provided an unconditional contribution in support of the educational initiative "The management of complex clinical cases in liver transplant patients: comparing experiences," consisting of five webinars aimed at Italian specialists in this field.

In the field of Intensive Care, on the occasion of the Smart Congress (Smart Meeting Anesthesia Resuscitation Intensive Care), Kedrion added its support to a scientific symposium dedicated to the present role and future prospects of the clinical use of Albumin.

TRANSFUSION MEDICINE

In Italy, we supported a scientific symposium entitled "Challenging the unpredictable: what we have learned and how to prepare for the future," held during the virtual conference organized by the Italian Society of Transfusion Medicine and Hematology (SIMTI).

PLASMINOGEN: AN EXAMPLE OF OUR COMMITMENT IN THE FIELD OF "ULTRA-RARE" DISEASES

Many of the conditions Kedrion products address are defined as "rare" diseases. Dealing with these in normal times is difficult enough, but, as we have noted, the pandemic can present special challenges. There is a sub-class of disease that is even more uncommon than "rare", and that is "ultra-rare". These diseases are often generally defined as affecting fewer than 20 people in one million.*

One condition that falls in this category is congenital Plasminogen deficiency and its sentinel manifestation, Ligneous Conjunctivitis, which can result in blindness. Kedrion is developing a Plasminogen replacement treatment for this condition, which is awaiting regulatory approval.

In the fall, the Italian Society for the Study of Hemostasis and Thrombosis (SISSET) organized a webinar entitled "Congenital Plasminogen Deficiency and Ligneous Conjunctivitis". The initiative, in collaboration with the Italian Association of Ophthalmologists (AIMO) and the Italian Federation of Rare Diseases (UNIAMO), was supported by an unconditional contribution from Kedrion.

Armando Tripodi, the President of SISSET, addressed a virtual audience of some ninety university professors and clinicians, who discussed the need to improve the diagnosis of Ligneous Conjunctivitis and to promote the inclusion of this disease among the rare diseases being researched by scientific institutions.

The Honorable Fabiola Bologna, a member of the Social Affairs Commission of the Chamber of Deputies and sponsor of a bill on rare and orphan diseases introduced in Parliament, emphasized the important role of patient and doctor associations as well as researchers and relevant companies.

*There are no universally accepted definitions for these terms. For example, in the United States a rare disease is defined as one which affects fewer than 200,000 people in the country (about 1 in 1,600). In Europe, a rare disease is one that affects fewer than 1 in 2,000 people.



The attention being given to this ultra-rare disease is still very low; a multidisciplinary commitment is needed to promote its diagnosis and to prevent and treat eye injuries which, in a third of patients, can lead to irreversible damage. This is essential considering the fact that a specific replacement therapy which has proven to be safe and effective in preventing relapses of the disease exists and is available.

Dr. Maria Teresa Sartori, University Hospital of Padua (Italy)

LOCKED DOWN. BUT STILL REACHING OUT

A pandemic exacerbates many problems; it rarely eases them. In 2020, Kedrion Biopharma continued to support programs and organizations benefitting diverse populations. For example:

For the sixth year, Kedrion supported the *Scuola Nazionale di Formazione AVIS*. AVIS is the *Associazione Volontari Italiani del Sangue*, the Association of Voluntary Italian Blood Donors, a charitable organization bringing together more than a million volunteer blood donors across Italy. The *Scuola Nazionale di Formazione* is a course for young members of the association who aspire to be tomorrow's leaders. Held virtually for 2020, it was designed in cooperation with *Fondazione Campus of Lucca*.

The need for Factor VIII, the plasma component used to treat Hemophilia, is not diminished in a pandemic and many countries have inadequate access to this life-saving treatment. Despite the complications of Covid-19, Kedrion continued its cooperation with the Italian National Blood Centre (*Centro Nazionale Sangue - CNS*) and

with several Italian Regions (Tuscany, Emilia-Romagna, Calabria and Sicily) to provide Factor VIII to stressed regions. This year Factor VII from the Region of Sicily was sent to Palestine and from Tuscany to the Mother Teresa University Hospital Center in Tirana, Albania for treatment of hemophilic children. Kedrion provided logistical support for these shipments. This donation was especially meaningful in light of the recent arrival of thirty doctors and nurses from Albania volunteering to help the Lombardy Region fight the Coronavirus.

Our social responsibility program in the US, "Kedrion Cares", continued its activities with even greater urgency under the pandemic, organizing food drives, collecting clothes, volunteering with local charitable organizations, etc.

- In a direct response to the pandemic in our own home region of Tuscany (Italy), Kedrion donated personal protective equipment (PPE's) to the Department of Civil Protection for distribution in the city of Lucca.

- The pandemic stops many activities, but climate change remains a threat. Kedrion Biopharma continued its support for "Treedom", a program planting trees in Guatemala, Honduras, Colombia and Kenya.

Although focused on the present and our obligation to protect both our employees and our patients, we did not neglect the future, supporting education and training opportunities in our sector, including:

- PharmaMark, the Master's Degree in Pharmaceutical Marketing at the "PIN - University Center, City of Prato (Italy). This course trains professionals in the field of ethical medicines and over-the-counter (OTC) medicines. Kedrion is supporting the course for the third consecutive year.

- Second Cycle Master's Degree in Sustainable Industrial Pharmaceutical Biotechnology offered by the Department of Excellence of Biotechnology Chemistry and Pharmacy of Siena University (UNISI), in Italy. The curriculum provides access to a unique educational program that combines biochemical

knowledge with management skills and focuses on crucial socio-environmental-economic sustainability as well as the deep digital transformation of 4.0 Health and Industry.

- With the Plasma Protein Therapeutics Association (PPTA), in collaboration with the Carlo Erba Foundation, two awards in memory of the late plasma researcher, Dr. Fabrizio Fabbrizzi.

- Also with the Carlo Erba Foundation, we continued to support two scholarships in honor of Kedrion founder, Guelfo Marcucci, for promising scientists in the field of non-oncological hematology.



It goes without saying that this experience has touched us all psychologically. We found ourselves having to maintain balance between the people we manage and our worries about ourselves and our loved ones. I think this was one of the most complicated things we had to face. After a year I can say that, both for family and professional responsibilities, the choice to make was only one: to react and give your best.

Giovanni Mazzone, Filling Supervisor (Sant'Antimo plant, Italy)



REACHING OUT - AT A DISTANCE. MARKETING IN THE VIRTUAL WORLD



Of course, our commitment to taking care of our patients and their medicinal needs involves more than production and distribution. Perhaps equally important, it requires communication and education as well. Two way communication and two way education - with the medical, healthcare and research communities; with those patients; and with patient associations. In more “normal” years, this involves meetings, conferences, symposia, marketing meetings, ... - a range of in-person gatherings in which we can stay current with latest developments in research, practice and the evolving needs

and characteristics of the people suffering from the (often rare) conditions we address.

One major example of these kinds of projects was already in the planning stages in 2019 and is scheduled to extend into 2022. The Mother & Child Health Campaign addresses two health threats to developing and newborn babies. Hemolytic Disease of the Fetus and Newborn (HDFN) or Rh disease is caused by a mismatch in blood types between mother and her fetus. It can result in death or life-long disabilities. Hepatitis B is a liver disease that is likewise life-threatening, especially if chronic.

Without intervention, a mother with Hepatitis B will pass the disease on to her child and this “vertical transmission” is likely to result in life-long, incurable Hepatitis B.

These two dangerous complications share a number of common characteristics: they are both potentially very serious and they are both rather easily preventable. Most important, prevention depends on awareness and access. So the Mother & Child Health Campaign is directed at pregnant women and their caregivers and is designed to raise awareness and educate. Its initial focus is on

Asia, the Middle East and Africa where incidence is especially high and awareness low. The campaign kick-off, postponed because of restrictions imposed by the Coronavirus pandemic, was a major part of an innovative, TV format, virtual meeting of Kedrion regional distributors for Asia and the Middle East and Africa. In the first months, outreach has included distribution of brochures and videos; preparation and delivery of educational materials to doctors’ offices and hospitals; and remote medical/scientific initiatives with Iran, Morocco and Bangladesh.



We welcome very much the campaign of a company like Kedrion, the Mother and Child Initiative, which is looking to the awareness and the diffusion - as much as possible around the word - our capabilities to overcome two major diseases.

Prof. Gian Carlo Di Renzo, Chair, Department of Obstetrics and Gynecology, University of Perugia (Italy)



The WHO has set an ambitious target to tackle Hepatitis B and chronic viral Hepatitis by 2030, reducing the number of new infections by 95%. If we want to achieve this target, every stakeholder that is involved in the fight against Hepatitis B should contribute. And when I talk about stakeholders, of course, I talk about academia that is doing its job, and I’m talking about governments that should put everybody and every child in the position of getting the best treatment to prevent infection. And I’m talking about industries, and Kedrion is doing this job by addressing and improving the knowledge of both doctors and families with regard to prevention of these infections that could have a very bad outcome for those who get infected in childhood.

Dr. Giuseppe Indolfi, Pediatric Hepatologist, Meyer Children’s Hospital (Florence, Italy)

BITS AND PIECES. IN THE NEWS... AND INTO THE FUTURE



The pandemic has revealed the importance of sound scientific communication and the dangers of quick and wide dissemination of misinformation. As Kedrion's **Head of Research & Innovation, Andrea Caricasole**, observed, "In recent months, we've had frequent opportunities to see how communication about research can be confusing and how it can sometimes even be contradictory." Consistent with our commitment to research, transparency and the value of collaboration in sharing knowledge and expertise, Kedrion Biopharma is proud to support the inauguration of the online magazine, "Nature Italy", reporting "on Italian research and the Italian science community", a project of the prestigious scientific journal, "Nature".

Research and Development cannot be stopped by a pandemic. Our mission to protect patients now extends into the future. In addition to the ongoing development of the aforementioned Ligneous Conjunctivitis treatment, Plasminogen, we continued to improve other parts of our portfolio. For example, at the end of 2020, we could report the final subject to receive treatment in the phase III trial of our 10% Immunoglobulin for treatment of adults with Primary Immunodeficiency, "Klg10". The trial will support a Biologics License Application (BLA) submission to

the US Food and Drug Administration (FDA). KEDRAB, our post-exposure Rabies prophylaxis is poised to become the only such treatment officially approved for pediatric use. Clinical trials supporting our application to the FDA were successfully completed and described in an article submitted to the peer-reviewed journal of Human Vaccines & Immunotherapeutics in September. The article was accepted for publication in November to be published in early 2021. FDA approval of the pediatric indication is expected in the spring.

In October, the Plasma Protein Therapeutics Association (PPTA) held a special, virtual Global Plasma Summit especially to address "the industry's unique ability to respond to the current Covid-19 pandemic" along with "ongoing conversations regarding the imperative for plasma donation and plasma-derived therapies relied upon by people with rare diseases." Kedrion's **Alessandro Gringeri, Chief Medical and R&D Officer**, described how the company reacted promptly and efficiently in the face of the Covid-19 pandemic through its efforts to protect the health and safety of all its employees, while also guaranteeing continuity of the company's activities, and its commitment on the front line to developing an anti-Covid-19

plasma-derived hyperimmune Immunoglobulin. Most noteworthy was the presentation of the Otto Schwarz Award to our **Chairman, Paolo Marcucci**. The award is a prestigious international recognition of those who have distinguished themselves with their contributions to the industry. Paolo was noted for "having understood and embraced the multiple challenges that the world of industry and patient communities have to face" and "proving himself to be a global leader committed to advancing the plasma-derivatives sector in order to satisfy the demands of a population which, in the 21st century, has an increased need for lifesaving therapies produced by the members of the PPTA".



Kedrion's support to Nature Italy is a clear demonstration of the value that our company places on quality scientific communication and is a testimony of Kedrion's ethics in this regard.

Andrea Caricasole, Head of Research & Innovation



Receiving this distinguished recognition, in this delicate historical moment we are all experiencing, is a source of great pride for me. I am pleased to share this prize with all the women and men who work in Kedrion and with my family, recalling the contribution that our father Guelfo Marcucci made, since 1992, to the establishment and development of PPTA.

Paolo Marcucci, Chairman

STRENGTH. HEROISM. PERSEVERANCE

STORIES FROM THE PANDEMIC

TAYLOR'S STORY

Taylor Major has worked as a phlebotomist at KEDPLASMA (USA) since the fall of 2019. She became interested when she learned from a friend, who already worked at a collection center, that some of the plasma collected there was used to make drugs that treated Hemophilia. Taylor's 8-year old son, has severe Type A Hemophilia.

"So I decided to apply because I'm like, this plasma helps a lot of people; not just my child."

Taylor completed the course in phlebotomy and went to work. It wasn't long before the pandemic arrived and the world changed.

"It scared me a lot. Especially with my son having what he has. I refused to let him go to school because I felt like it is a danger to him. So even today we do virtual because I feel that that's the safest."

But Taylor has not escaped the impacts of the virus:

"Almost every member of my family, except my sister, has gotten the virus, except me. It's kind of interesting, since I do work with a lot of people during the day."

How does she keep safe?

"I wear my mask; I wash my hands as much as I can. I sanitize."

But what about the donors?

"We wear masks to keep us safe and them safe, and they do the same. Sometimes they don't remember that they need to wear a mask, but we have masks available if they don't have one."

On top of the pandemic and seeing to the needs of her son, Taylor has just returned from a leave of absence after a serious car accident.

"So right now, my schedule for work is from 12:30 to 8:30 to close, and the reason that is because, like I said, I'm doing virtual learning for my son and the teacher's

meeting is from 9 to 11."

How has she managed?

"Well, first, my son, he's very strong. And I will say, I do have a huge support system. I have my KED family - I call them 'my KED family', even though they're just my co-workers. I have my KED family and I have my actual family. So I have a huge, huge support system when it comes to me and my son."

Needless to say, we can all appreciate Taylor, especially during this challenging time. She is herself part of a support system for KEDPLASMA, for Kedrion Biopharma, for her son, for her donors and for all the patients our plasma helps. Thank you, Taylor!

SASHA PORTES' STORY

Her first concern was for her kids. Daycare had resumed,

"so I put the kids back in daycare, because I trusted where they were going. They (had been) here for three months. Putting them back in - I think it was one of the best decisions I've made with them, and - knock on wood - their health has been good. At that point, I decided it's a good idea to go back (to the office). So they were going to daycare and I was going to work and it made such a big difference."

Sasha Portes' 2020 was a story of fear, determination, tragedy and perseverance. It is personal and distinctive and yet we know - unfortunately - that it is not unique. As a member of the Kedrion family, we embrace her for it.

Sasha works in Finance in Fort Lee, New Jersey, USA, where she is Accounting Manager. She has worked at Kedrion since 2010.

When the pandemic began, Sasha and her husband Luis, who is a diesel mechanic, were both working, and their two children, aged 2 and 5, were in daycare. Suddenly, Sasha was sent home to work remotely for her safety. Her husband continued to work, but the daycare closed as well, so Sasha found herself at home, working and taking care of two small children.

Somehow, she made it work. In June, the company determined it would be safe to go back to work, if she chose to.

Sasha decided to go back two days a week. It was completely voluntary. (By the end of the year, with a new surge in cases, employees were notified to come in only if necessary).*

Darker days were yet to come.

"So we make it through the summer. My son starts school in September and then in October, that's when my husband gets Covid. So at that point in time, I just took the kids out of school. and

I also stayed put with them here as well as my husband."

"Luckily, we had renovated the basement recently. He was able to quarantine downstairs and the kids and I stayed upstairs. So I was quarantining, taking care of the two kids again and also my husband."

But things were about to get even worse. When Luis contracted the disease, his sisters and parents, who were visiting from Ecuador, also came down with Covid-19. Luis and the others recovered and Luis went back to work, but his mother's condition eventually worsened and she was soon hospitalized. After two weeks, she passed away. Luis had to take his devastated father back to Ecuador. He had to be away for six weeks.

"Yeah, it was... it was tough, because at that point I still working and was dealing with the kids on my own. But Kedrion was very supportive. I tried to keep them updated as much as I could."

(As this is written in early 2021, Luis is back home and back to work, the kids are in school or daycare and Sasha continues to work, mostly from home.)



When I first started with Kedrion, I wasn't even married yet and I didn't have any kids, so I've had my kids at Kedrion; I've gotten married at Kedrion; and we experienced this at Kedrion, and everyone was just super supportive. So I'm really grateful for that. And not only here, but overall: in KEDPLASMA,... whoever I interacted or worked with, everyone was just super supportive and I really appreciated that.

*As of this writing, this is still the policy at Kedrion's US corporate headquarters.

ELENA LABINI'S STORY

Elena Labini works in the Global Pharmacovigilance Department at Kedrion in Italy. During the pandemic, she has been working mostly from home.

"I go to the office twice a week at most, wearing the mask all the time and avoiding the canteen and the coffee area. Many of my activities are done well in so-called "smart working". Remote work, however, has introduced a new dimension: the absence of physicality; body language is lost, and that is an important vehicle of information. There is also no possibility of quickly sharing work updates; before, you could simply go to the next room."

"But the creation of a dedicated Covid-19 Response Team has been crucial. We have managed to maintain all our production lines."

"Personally, I experience conflicting emotions and feel the same in the people around me. The psychological resilience of each of us determines the way we face this particular historical moment. Flexibility often increases performance."

Working in Pharmacovigilance, Elena has noted how the pandemic has resulted in increased awareness of her field.

"Finally, many people realized how important this discipline is - the impact it has on the individual, and on the community."

The pandemic complicated a pregnancy for Elena that was already complicated enough.

"I have a condition that makes it difficult for me to carry on with a pregnancy. Paradoxically, the pandemic in such a delicate state of health with a small 3-year-old volcano around the house, because my husband worked remotely too." She smiles. "In that sense, I think it was harder for him!"

The experience left her even more confident about the future.

"When you have such strong experiences and struggle to accomplish the greatest thing you can create, nothing scares you anymore. Me, my husband and our two little ones make up a team, sometimes organized, sometimes ramshackle, but we are a team, and this allows us to do much more than we could imagine."

So for Elena, there is hope when she looks to the future.

"From a professional point of view, I expect smart working to remain the way we'll work; the pandemic has made it possible to bring this modality to a point of no return. Personally, I would like to travel again; to be free to reach my family and my hometown whenever I want; to hang out with old friends and new ones cultivated during the pandemic. I imagine doing all this with great enthusiasm and gratitude."



RODNEY'S STORY. HEMOPHILIA IN THE TIME OF COVID

Rodney Dalrymple speaks in the colorful dialect of the American South.

"I like to tell people, man, long as I'm still on this side of the dirt, I'm blessed. Or more than blessed. You know, it could be a whole lot worse."

That is an admirable attitude, especially given the challenges that Rodney has faced. Since birth, he has suffered from Hemophilia A. As a result of the many damaging bleeds in his joints over the years, he has had numerous surgeries, including replacements of one hip and both knees.

"Back in 2000, I had a total hip replacement and they damaged my sciatic nerve, so that kind of gave me like a 'drop foot'. And so I've been having trouble with that ankle and, man, it is shot to hell and back."

In 2013, he had his first knee replacement, but now,

"I can't catch a break, man: I gotta go back. I gotta go back

to New Orleans, because they want to do a revision surgery on my right knee."

His left knee was replaced in 2019.

"That's going pretty good now. I mean, they had me doing (physical) therapy three times a week while I still had staples or stitches in my leg. I guess they pushed me a little too hard in therapy, but my knee had busted open, back open. So they had to rush me to new Orleans. They did two more surgeries. I got an ugly scar on the inside of my leg."

And then... Pandemic. Rodney was working for a home health specialty pharmacy as a sales representative and patient mentor. He helped parents and kids deal with Hemophilia and stressed the importance of prophylactic infusions to the kids so they might avoid the kinds of complications that have plagued his journey. Despite the fact that he had worked at the company for fourteen years, the economic downturn forced them to let him go.

Losing his job was terrible. Losing the insurance that went along with the job was catastrophic. Hemophilia medication - Factor VIII - is expensive. His wife's insurance would not cover him

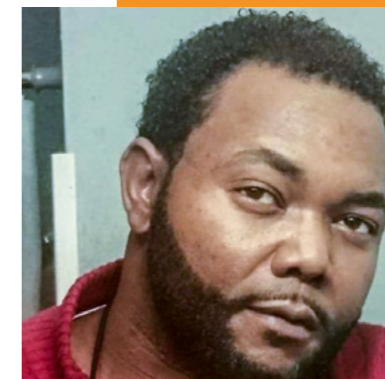
and her income was insufficient. They also had a 4-year old child to support.

Kedrion stepped in. Coordinating with the local Hemophilia Treatment Center, Kedrion agreed to supply Rodney with his vital treatments free of charge, until an adequate insurance coverage - government or private - could be arranged. We also endeavored to help in securing this coverage. It took nearly six months. Without these treatments of Factor VIII, Rodney could have suffered extremely painful, dangerous and damaging bleeds.

"I mean, that was a miserable five months, but hey, I made it. Thanks to Kedrion."

For all of Rodney's trials, he remains indomitable.

"Hey, I be tryin'."



A THANKFUL REFLECTION IN A WIDER CONTEXT

2020 was the 20th year of operations since the establishment of Kedrion Biopharma in 2001.

20 years, reaching out, supporting patients. We are very proud to celebrate this anniversary. And our journey.

Kedrion has deep roots. In fact, it could be said that, before it emerged, Kedrion began growing in the soils of Tuscany much earlier, when Guelfo Marcucci established a small pharmaceutical laboratory in Pisa in the early 1950s.

But as a tree grows and spreads, so has Kedrion. In 2004, we acquired our first collection center in the US. In 2008, we established our presence in Hungary, when we acquired the Gödöllő fractionation and production plant along with a plasma collection center. A major step was taken in 2011, with the acquisition of the Melville plant in Melville, New York, in what has become our major and fastest growing market, the United States. All of the increasing number of collection centers were gathered under a newly formed subsidiary, KEDPLASMA, in 2012.

plasma-derived medicines, with five manufacturing plants and 2500 employees. By the end of this year, we anticipate having some 30 collection centers, and our products can be found in 100 countries around the world.

Today, Kedrion Biopharma remains rooted in the strong family values of the Tuscan countryside, where it is still headquartered. And now it is a truly global company; always putting our patients first, while committed to innovation; still paying respect to our local communities, with our eye on the future of the planet.

These roots grow through a series of ever larger companies focusing on blood and plasma products until 2001, when the Marcucci family consolidates them to establish Kedrion. The foundation for Kedrion was its partnership with the Italian Health System, providing plasma-derived medicines fractionated and produced from plasma collected by the Italian Regions.

While Kedrion Biopharma has attracted significant outside investment and stakeholders, the Marcucci family remains in a central role. We are now 5th among the major producers of

Twenty years. The arc of our story is like a bridge - from Italy to the world. And so too is our mission: providing a bridge from donors to patients, from plasma to therapies, from despair to hope.



20 KEDRION

YEARS B I O P H A R M A

A FINAL WORD



So when this *annus horribilis* came to an end (though not the pandemic), we realized we still had much to be thankful for: our patients were secure, our employees safe and our business sound. While the path forward is still fraught with uncertainty, we are optimistic. With a new CEO leading an ambitious and fundamental program of transformation in both organization and operational practices, and with vaccines against Covid-19 now available, there is light on the horizon.



For sure the changes that the Covid-19 crisis has brought will outlast the pandemic and the capability of our company to adapt to those changes will determine our success.

Danilo Medica,
Italy Country
Manager

ECONOMIC AND FINANCIAL INDICATORS



SIGNIFICANT EVENTS OF THE FINANCIAL YEAR

Kedrion closed the 2020 financial year with a turnover of Euro 697.2 million, down 13.7% compared to the previous year due to the reduction in hospital treatments and plasma availability as a result of the Covid-19 pandemic.

The US market represents the Group's top market with 37.3% of turnover, followed by Europe with 35.7% (of which Italy accounts for 21.5%) and the Rest of the World with 27% of turnover. Revenues from the plasma-derivatives sector amounted to Euro 579.8 million, up 0.4% compared to 2019 due to the positive performance of the Immunoglobulin product in terms of volume and price. The US plasma-derivatives market increased by approximately 5% compared to the previous year along with other strategic markets, particularly in Europe (Poland, Austria, Portugal) and Turkey.

During the financial year the plasma sector was marked by a reduction in available volumes throughout the industry, which for the Group resulted in a substantial reduction in sales to third parties, generating sector

turnover of Euro 94.3 million compared to Euro 209.6 million in 2019.

EBITDA reached Euro 95.9 million or 13.8% of turnover, improving the previous year's value by 12.5%, despite the negative impact on both turnover and non-recurring costs related to the Covid-19 pandemic: the latter amounting to Euro 64.3 million, which, in the absence of the pandemic, would have been Euro 23.7 million, a sharp reduction (-65% compared to 2019), bringing EBITDA to Euro 136.5 million.

Adjusted EBITDA in 2020 was Euro 160.1 million, down slightly from Euro 166.1 million in 2019, but improving from 20.6% to 23% as a percentage of turnover.

COVID-19

Covid-19 has significantly impacted the global economy. Many countries have imposed travel restrictions on millions of people and many areas in different countries have been subject to quarantine measures. Companies continue to experience reductions in revenues and difficulties in obtaining supplies. Although

some countries have begun to lift lockdown measures, the lifting has been gradual, and as a result of the impacts on business, millions of workers have lost their jobs. The Covid-19 pandemic has caused significant volatility in financial and commodity markets around the world. Many governments have announced measures to provide financial and non-financial assistance to companies and institutions. The pandemic has also had significant and ongoing effects on the global plasma-derivatives market and on Kedrion's performance. In particular, the greatest effects have been on the collection of plasma in the United States, due to the combined effect of lockdown measures (stay-at-home orders) and the financial assistance program on the number and frequency of donations. This is especially the case for certain groups of regular donors, such as students, and has contributed to an increase in the cost per liter of collected plasma, due to the increase in donor fees paid to donors and due to the effect of higher proportions of fixed costs of the donation centers, compared to the lower volumes collected. There was

also an increase in the cost per liter of plasma purchased from third parties, in some cases, under contracts with previously determined prices, but for which the supplier invoked the force majeure clause to apply an adjustment. To a lesser extent, a decline in donations was also recorded in Italy. On the other hand, the pandemic has reduced the spending capacity for healthcare of some countries and, in general, has put a strain on the organization of healthcare systems, reducing access to diagnosis and treatment of chronic diseases managed at hospital facilities. As far as Kedrion's products are concerned, there was a significant impact on sales of Anti-Rabies Hyperimmune Immunoglobulins (KEDRAB) on the US market, as a result of lower exposure to infection due to the travel ban. Sales of Factor VIII were also impacted because the effects of the pandemic have led to more home-based treatment. Finally, it should be noted that higher costs were incurred for safety and prevention measures (sanitization, protective devices, etc.) implemented to ensure production continuity at the plants.

PERFORMANCE OF THE MELVILLE PLANT

With regards to the plasma-derivatives sector, the ramp-up process continued on the fractionation line at the US plant in Melville, following the completion of the refitting project with the inspection in August 2018 and final FDA approval in February 2019, consolidating the positive impact on the Group's performance already witnessed in the previous year. From an industrial perspective, the project had been completed in 2018 with the operational restart of fractionation in the second half of the year, with approximately 80,000 liters fractionated. During the 2019 financial year, the plant had fractionated approximately 480,000 liters, and during the 2020 financial year, it fractionated approximately 593,000 liters, in line with the projected plan of progressive growth towards the full utilization of production capacity. The plant met delivery schedules for Fraction II+III intermediate for production of Gammaked finished product at Grifols and for production of the clinical product for Klg10 (10% Immunoglobulin)



at Gödöllő. The plant also produced Cryo and Fraction V intermediates for production of Koate and Albuked finished products, respectively, at Grifols and is on its way to full integration with the Bolognana plant for the production of Factor VIII and Albumin.

The increase in production at the Melville plant, for both the fractionation plant and the new RhoGAM filling and packaging line, has led to a further significant improvement in the profit and loss statement for the year, primarily due to a reduction in non-absorbed plant costs, and has also resulted in an increase in margins on sales of products for the American market.

PROJECT FOR THE DEVELOPMENT OF 10% IMMUNOGLOBULIN (KIG10) AND THE DEDICATED PLANT AT CASTELVECCHIO PASCOLI (LUCCA, ITALY)

Validation of the production process continued at the new 10% Immunoglobulin (Klg10) purification plant in Castelvecchio Pascoli (Lucca, Italy), using the chromatographic method. Clinical trials also continued in view of the marketing authorization of the new product. After completion of the enrollment phase in 2019, the last patient enrolled in the clinical trial (so-called "CARES10") performed in the

United States for PID treatment (Primary Immunodeficiencies) on an adult population was treated in December 2020. No significant adverse reactions have been reported to date with respect to the treatment of enrolled patients and the final study report is expected by April 2021. In the second and third quarters of 2020, the company initiated a clinical study on pediatric patients with PID, with the aim of registering this indication in the US and Europe, by applying for regulatory approval in Italy, Hungary, Slovakia, Russia and Portugal. The first patient was enrolled in March 2021.

Currently, production for clinical studies is carried out in the Gödöllő plant (purification phase) and the completion of technology transfer to the Castelvecchio Pascoli plant is underway. Project costs charged to the financial year that have not yet been included in the balance of production and related revenues amount to Euro 2.9 million, while total investments for 2020 amount to Euro 22.8 million.

THE "NEXT" TRANSFORMATION PROGRAM

In order to improve its financial balance and competitive position, Kedrion has launched a transformation program, known as the "NEXT" program, following the appointment of the new CEO, Val Romberg in October

2020. The program, which follows the initiatives for performance improvement, efficiency and procurement excellence that have already been in place since 2019-20, focuses on the Operations, Commercial and G&A areas of the plasma-derivatives sector. It will draw on the support of qualified external consultants and will enable the Group to achieve the strategic and financial goals set out in the plan over the next three years. The NEXT program also includes a review of organization and governance, which was implemented in February 2021.

SALES AND PURCHASES/START-UPS OF COMPANY-OWNED COLLECTION CENTERS

During the year, this segment witnessed the early sale of most of the assets of the seven plasma collection centers in Hungary to HAEMA AG, as well as the purchase/start-up during the year of five centers in the United States, for a total of 27 company-owned centers at the end of the year. Early sale of the assets of the seven Hungarian collection centers to HAEMA AG, and the consequent transfer of all associated risks and benefits, contributed significantly to the result for the period, recording approximately Euro 15.5 million under other income (last year the sale of the German centers led to an income of around Euro 18.9 million).

REVENUES

Revenues from the production and marketing of plasma-derived drugs sector as of December 31, 2020 amounted to Euro 579.8 million (83.2% of total revenues) with a growth of 0.4% mainly due to the increase in sales of Standard Immunoglobulin and Albumin, as well as the increase in price for Standard Immunoglobulin. The US plasma-derivatives market increased by around 5% compared to the previous year thanks to the development of Standard Immunoglobulin, and other important markets continue to grow, especially in Europe (Poland, Austria, Portugal). During the 2020 financial year, the share of this sector increased by approximately 83.2%, due to a decline in the plasma sector caused by lower plasma availability as a result of Covid-19.

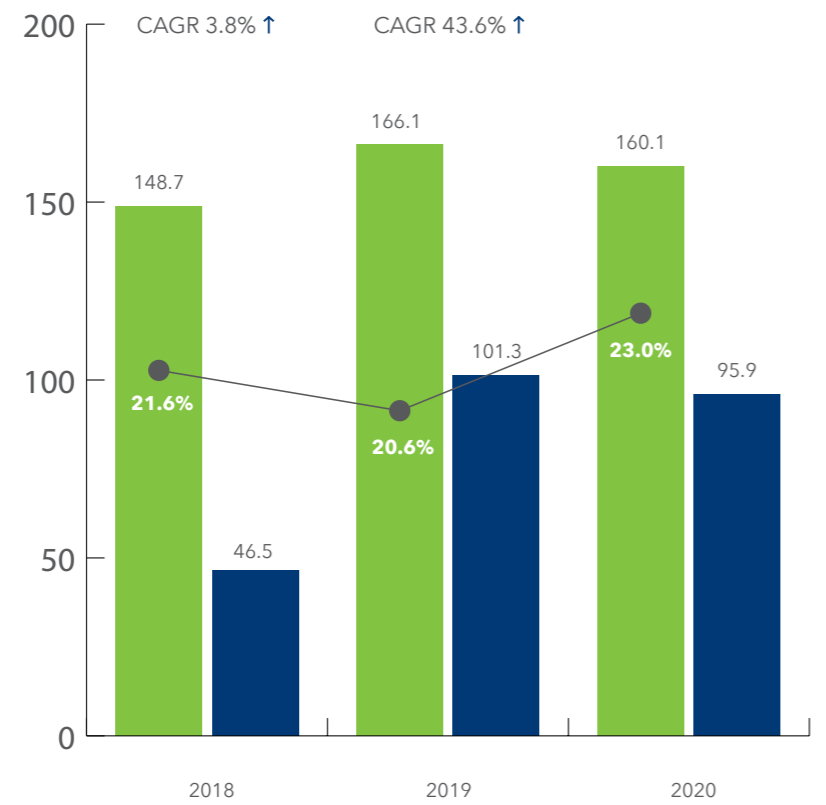
Revenues from the plasma collection and marketing sector as of December 31, 2020 amounted to Euro 94.3 million, down 55% from the previous year. This sharp decline is linked to the decrease in plasma collection on a worldwide scale (estimated to be between 20-25% less than in 2019) due to the pandemic and, in particular, the strong impact of the pandemic in the United States, where the 27 Group-owned centers are located.

REVENUES (€ MLN)



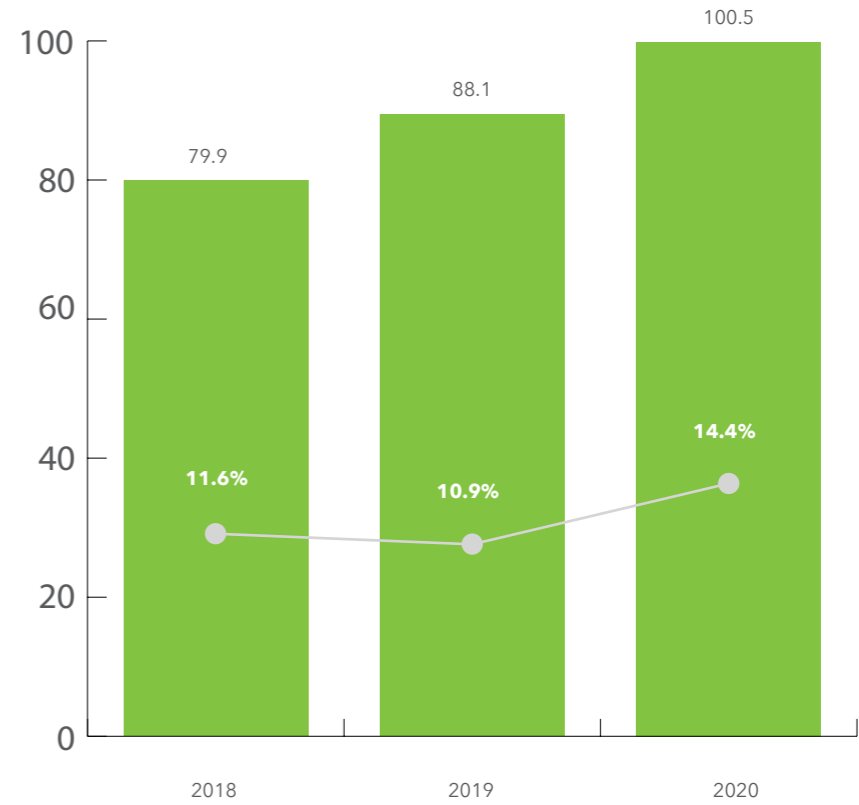
**ADJUSTED EBITDA (€ MLN)
AND
REPORTED EBITDA (€ MLN)**

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



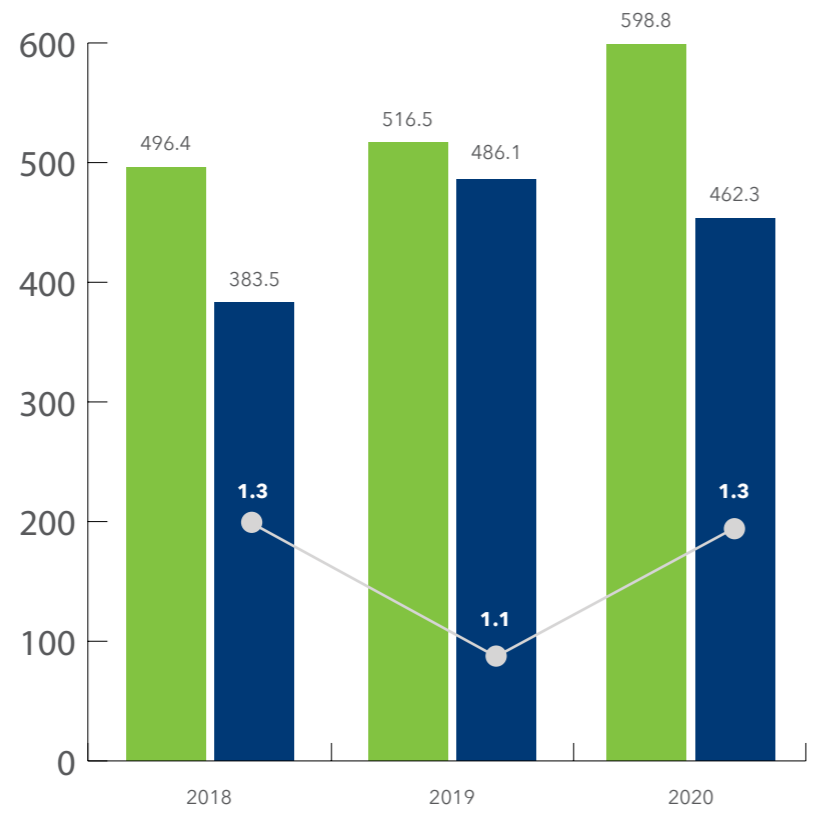
GROSS CAPEX INVESTMENTS (€ MLN)

- % OF REVENUES



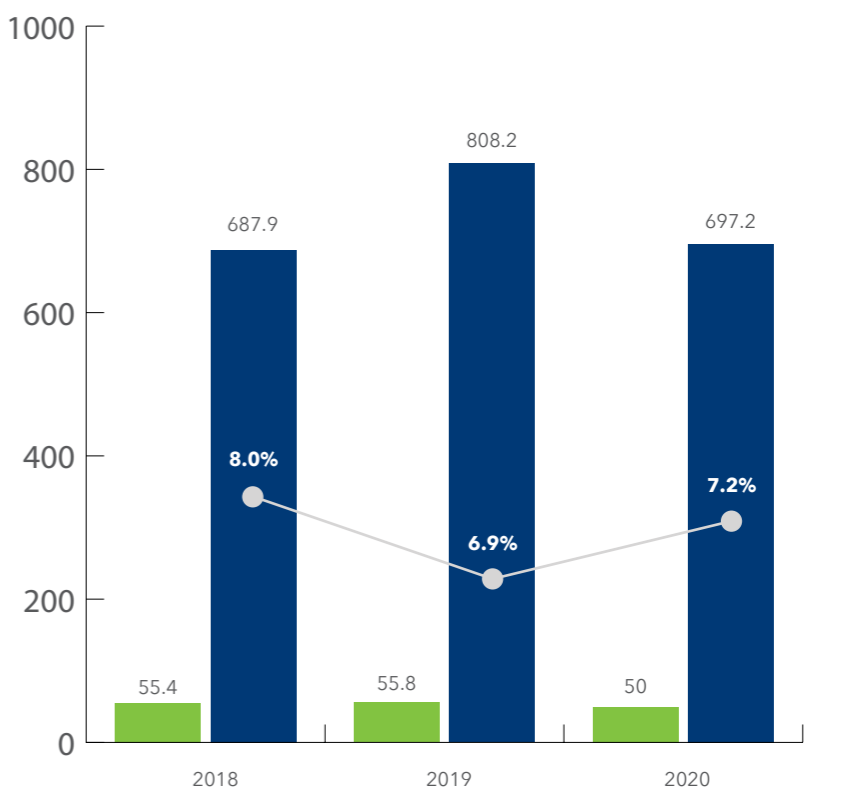
**NET FINANCIAL POSITION (NFP*)
AND NET EQUITY (€ MLN)**

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



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

- R&D
- SALES
- %



*NFP included the impact of IFRS16 of about 91.7 MLN

UNITED STATES

Turnover in this area reached Euro 260.4 million in 2020, reconfirming the United States as Kedrion’s leading market with 37.3% of total revenues, despite a 26% decrease compared to the previous year. The reduction is entirely due to the decrease in plasma availability as a result of Covid-19 with a negative impact on plasma sales to third parties while safeguarding intercompany supplies to production plants. For this reason, plasma sales in the United States decreased from Euro 139.4 million in 2019 to Euro 37.8 million in 2020. On the other hand, sales of plasma-derivatives in the US market grew by 5% compared to the previous year, with Standard Immunoglobulin leading growth in sales, followed by Albumin. However, there was a reduction in Anti-Rabies Immunoglobulin and Factor VIII sales linked to lockdown and the decrease in hospital treatments as a result of Covid-19, as well as the gradual introduction of Hemlibra. In addition to the sales of plasma-derivatives, activities carried out for third party operators in the Melville plant also produced turnover.

ITALY

The Italian market as of December 31, 2020 decreased by 6.1% compared to the previous year, with a turnover of Euro 150.1 million, corresponding to 21.5% of total revenues, as a result of sales of finished products on the commercial market and the contract manufacturing service for the Italian National Health System. Compared to the previous year the decrease was due mainly to the fall in the volume of contract manufacturing processed for the Italian National Health System.

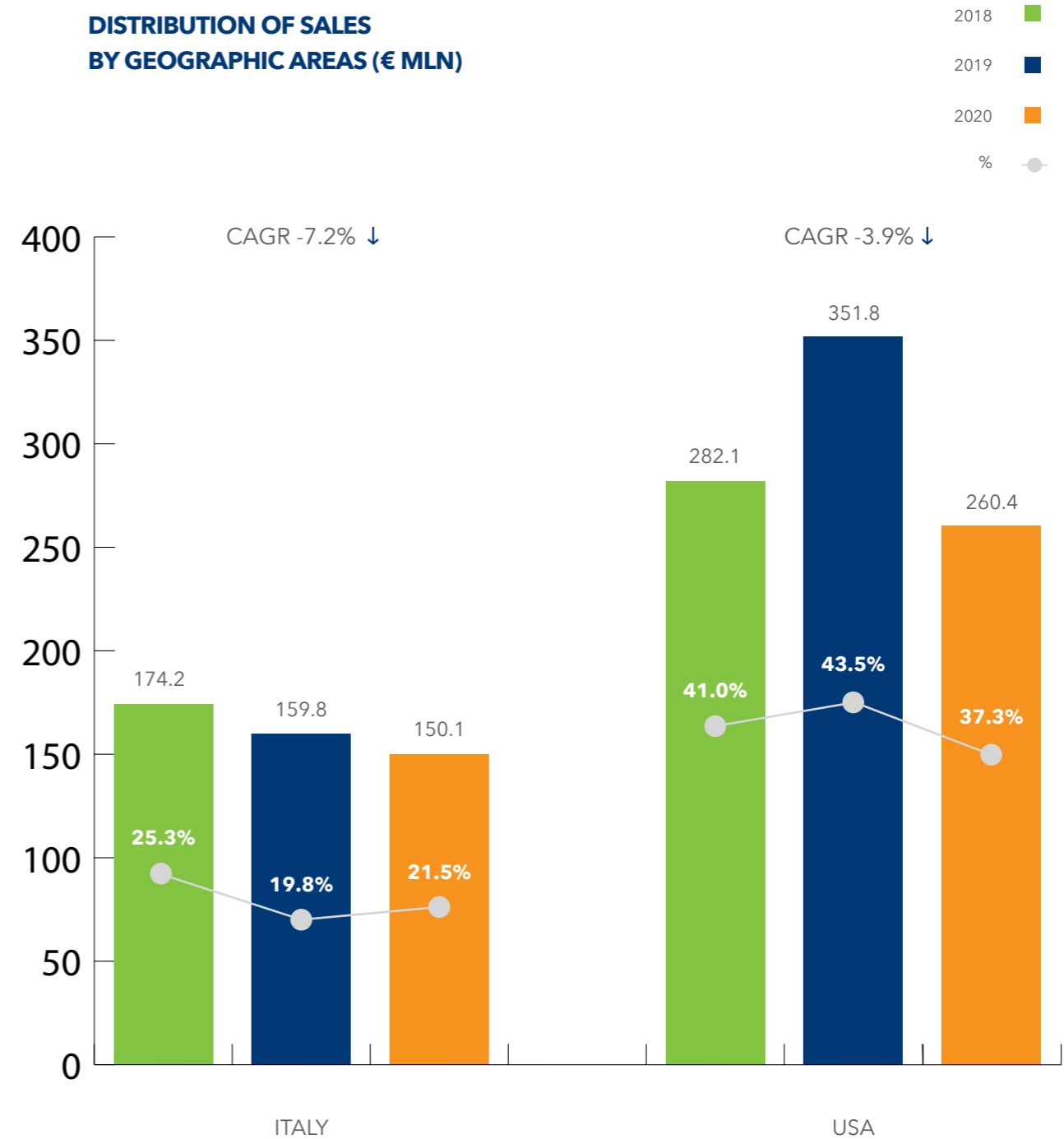
EUROPEAN UNION

Revenues in the other countries of the European Union amounted to Euro 98.6 million as of December 31, 2020, representing 14.2% of total revenues; an increase of 4.1% compared to 2019, despite a reduction in plasma sales to European customers, amounting to Euro 28.9 million, due to larger volumes of Standard Immunoglobulin placed at increasing prices in Poland, Austria and Portugal. Germany, Poland, Austria, Portugal and Romania were the main European markets in 2020.

THE REST OF THE WORLD

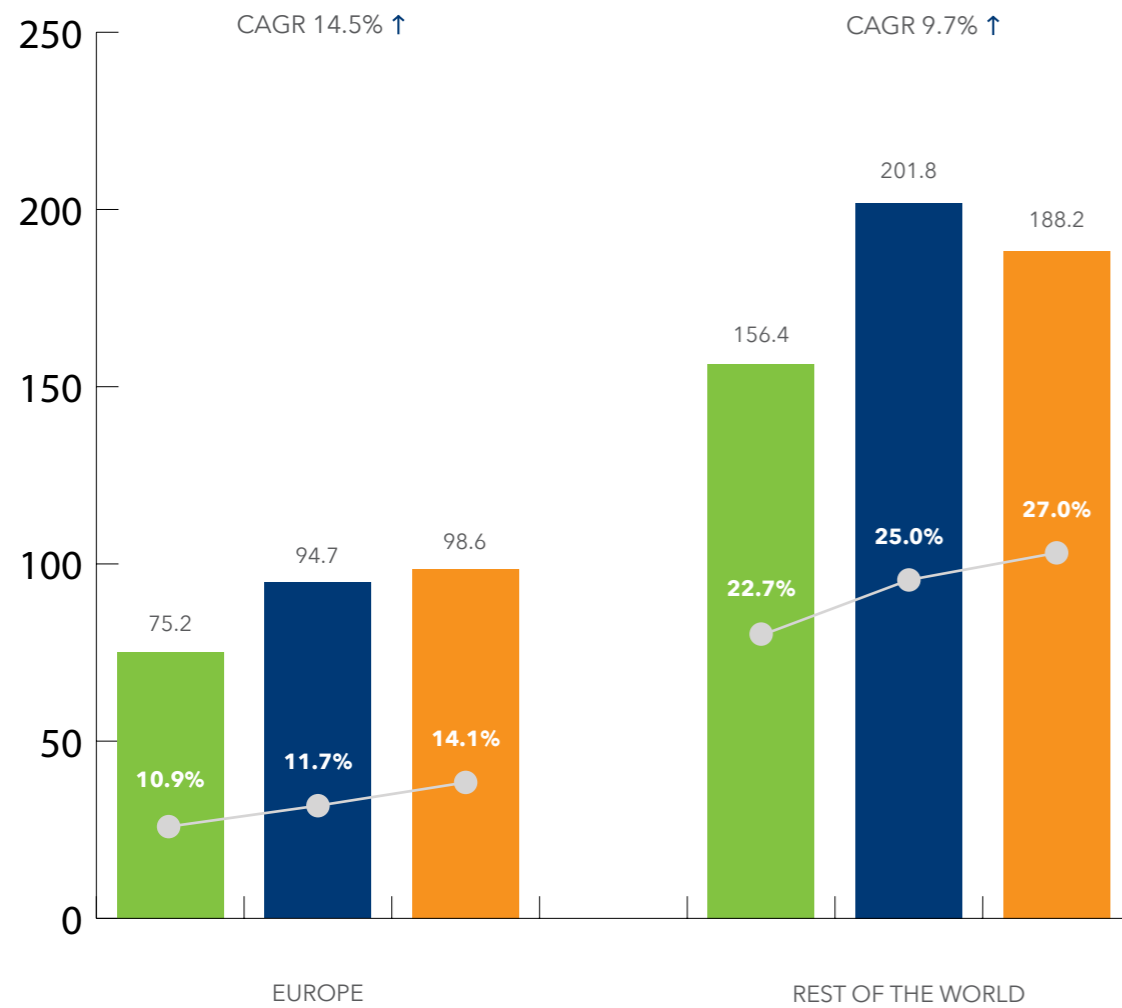
Revenues for this geographic area as of December 31, 2020 amounted to Euro 188.2 million, down 6.7% compared to 2019 and representing 27% of total revenues. Turkey remains the leading market in this area in terms of revenues reaching Euro 40.9 million, followed by Switzerland (mainly for plasma sales) and Mexico; together with Russia, India, Israel and Yemen, they account for approximately 70% of total revenues in this area.

DISTRIBUTION OF SALES BY GEOGRAPHIC AREAS (€ MLN)



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

2018 ■
2019 ■
2020 ■
% ●



CONSOLIDATED FINANCIAL STATEMENT

CONSOLIDATED INCOME STATEMENT (in thousands of Euro)

12/31/20

Revenues from sales and services	697,234
Cost of sales	533,505
Gross operating margin	163,729
Other income	50,278
General and administrative expenses	80,760
Sales and marketing expenses	45,677
Research and development expenses	29,165
Other operating costs	7,943
Operating result	50,462
Financial charges	67,814
Financial income	13,991
Result before tax	(3,361)
Income taxes	(9,399)
Net result for the period	6,038
of which:	
Group result	5,222
Minorities result	816

OTHER COMPREHENSIVE INCOME (In thousands of Euro)	12/31/20
Profit for the period	6,038
Other comprehensive income	
Other comprehensive income to be reclassified to profit or loss in subsequent periods:	
Net movement on cash flow hedges	191
Income tax effect	(46)
Exchange differences on translation of foreign operations	(21,407)
Net other comprehensive income to be reclassified to profit or loss in subsequent periods	(21,262)
Other comprehensive income not to be reclassified to profit or loss in subsequent periods:	
Re-measurement gains (losses) on defined benefit plans	(51)
Income tax effect	5
Net other comprehensive income not to be reclassified to profit or loss in subsequent periods	(46)
Other comprehensive income for the year, net of tax	(21,308)
Total comprehensive income for the year, net of tax	(15,270)
Attributable to:	
Equity holders of the parent	(14,997)
Non-controlling interests	(273)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION (In thousands of Euro)	12/31/20
NON CURRENT ASSETS	
Property, plant and equipment	298,592
Investment property	1,468
Goodwill	253,057
Right of use	88,377
Fixed term intangible assets	122,543
Investments in other companies	20
Other non current financial assets	8,565
Deferred tax assets	10,413
Other non current assets	1,048
TOTAL NON CURRENT ASSETS	784,083
CURRENT ASSETS	
Inventories	283,832
Trade receivables	138,308
Contractual activities	34,025
Current tax credits	6,578
Other current assets	30,681
Other financial current assets	6,636
Cash and cash equivalents	100,592
TOTAL CURRENT ASSETS	600,652
Assets available for sale	0
TOTAL ASSETS	1,384,735

CONSOLIDATED STATEMENT OF FINANCIAL POSITION (In thousands of Euro)	12/31/20
SHAREHOLDERS' EQUITY	
GROUP SHAREHOLDERS' EQUITY	
Share capital	60,454
Reserves	392,176
Group net income	5,222
TOTAL GROUP SHAREHOLDERS' EQUITY	457,852
MINORITIES SHAREHOLDERS' EQUITY	
Minorities capital and reserves	3,643
Minorities net income	816
TOTAL MINORITIES SHAREHOLDERS' EQUITY	4,459
TOTAL SHAREHOLDERS' EQUITY	462,311
NON CURRENT LIABILITIES	
Medium/long-term debt	592,412
Financial liabilities	109
Provisions for risks and charges	692
Payables for employee benefits	3,915
Other non current liabilities	1,610
TOTAL NON CURRENT LIABILITIES	598,738
CURRENT LIABILITIES	
Financial liabilities	103,271
Current portion of medium/long-term debt	18,801
Provisions for risks and charges	1,910
Trade payables	141,927
Contractual liabilities	7,649
Current tax payables	8,413
Other current liabilities	41,715
TOTAL CURRENT LIABILITIES	323,686
TOTAL LIABILITIES	922,424
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES	1,384,735

CONSOLIDATED CASH FLOW STATEMENT (In thousands of Euro)	12/31/20
Net cash flow generated by operating activities (A)	95,936
Net cash flow absorbed by investment activities (B)	(100,613)
Net cash flow absorbed by financing activities (C)	(15,547)
Total net cash generated/(absorbed) flow D=(A+B+C)	(20,224)
Cash and cash equivalents opening balance (E)	121,451
Net effect of conversion of foreign currencies on cash and cash equivalents (F)	(643)
Cash and cash equivalents closing balance G=(D+E+F)	100,584

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Teamwork means coming together to achieve common goals.

This has never been more clear, more important, nor more difficult than during the pandemic, when we have been reminded daily that only together might we defeat the virus and continue to fulfill our mission.

This was no less true when it came to creating this document. It took the contribution of many members of the global Kedrion community to convey not just the facts of 2020, but a sense of the personal experience through their collected words and images. It is a collective work, reflecting unity - even while distanced.

The cover photo of this edition of the Kedrion Annual Report is illustrative of this effort. With travel constricted by the pandemic, our regular photographer, Christian Sinibaldi, directed the shoot via a video call from his home in London. You might say he took the photograph with our hands,

guiding Elisabetta Gianasi from Kedrion's Global Communications team, operating the camera, and the subject, our colleague Veronica Gianotti from our BioSC Biological Safety Center. It was a novel creative experience and a touching human one as well, in which teamwork and a sense of belonging have made the difference. This helps us to look forward to a new beginning with renewed confidence and enthusiasm.

The photos on pages 3, 4, 8, 11, 12 (left), 14 (left), 17, 18, 20, 21, 25, 26 and 37 were all taken by Christian Sinibaldi before the pandemic.

Other shots of Kedrion people were either submitted by them or collected by Federica Piacentini and Elisabetta Gianasi from our Global Communication team.

The graphic layout of this Annual Report was created by the Genau agency and the Leo Burnett agency.





KEDRION
B I O P H A R M A

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