

Advancing human lives.
It's in our blood.



Wolfgang Marguerre – Chairman & Chief Executive Officer

Revenue

€1.6bn

Employees

7,094

I am proud to introduce this special Annual Report that focuses on the patients whose lives are being transformed by our therapies. Profiling the stories of children, women and men in Argentina, Brazil, Canada, Europe and the US, this report reflects our company's vision: "Our passion drives us to provide new health solutions advancing human life." I have been moved by the passion and courage of all participants, including the families, patient advocates, nurses, physicians and scientists supporting patients with rare and complex diseases. Thanks to all interviewees for their openness in sharing their stories.

Since I founded Octapharma in 1983, the company has grown into a truly global group. At heart we remain a family business but we are now a much larger family, employing 7,094 people and serving patients in 113 countries. This year we achieved record-breaking revenue of €1.6 billion and pre-tax profits of €388 million.

We have been investing in the future to continue to grow in a sustainable way, including increasing our fractionation capacity to help even more people in need. Our five company values – Ownership, Integrity, Leadership, Sustainability and Entrepreneurship – will continue to guide all our decisions and actions.

Committed to meeting the increasing demand for Octapharma's plasma-derived therapies, we are expanding our fleet of plasma donation centres. A very important milestone was the US Food and Drug Administration (FDA) approval of our new state-of-the-art plasma testing laboratory in Charlotte, which will give us greater control and further strengthen our operations.

We are committed to developing novel solutions to address the unmet needs of patients with rare diseases. We are accelerating the development of new products in both our plasma and recombinant product pipelines. Our new third generation 10% intravenous immunoglobulin (IVIg), panzyga®, was launched in Canada, and is expected to reach other major markets in 2017 and beyond. We also submitted our new fibrinogen concentrate for registration in the EU, the US and Canada.

Many patients are making the switch to our fourth generation, human cell line derived recombinant factor VIII (FVIII) product, Nuwiq®. The development of inhibitors remains the biggest challenge for patients with haemophilia.



Our official interim results from the previously untreated patient (PUP) study, NuProtect, were presented at the World Federation of Hemophilia (WFH) World Congress in Orlando and vindicate our proof of concept.

Octapharma continues to invest heavily in clinical trials – both registration studies to support marketing authorisations for new products and studies to support new indications for existing products. Recognising the individuality of patients, we are continuing important clinical studies in "personalised prophylaxis" for haemophilia A and B patients with Nuwiq® (NuPreviq) and our factor IX (FIX) product octanine®F (ProNINE).

Access to medicine continues to be a persistent dilemma in many countries for a variety of reasons, from lack of diagnosis and knowledge to insufficient healthcare systems and conflicting priorities. Octapharma supported the WFH Humanitarian Aid Program with several million IUs of Nuwiq®.

In 2016 I celebrated both my 75th birthday and 33 years since I founded Octapharma. These anniversaries cause reflections on the progress we have made in terms of advancing science and treatment options. I want to thank all Octapharma staff for their commitment to the company and its well-being. My family is committed to leading this company into the future. We will continue with our efforts to provide patients worldwide with our lifesaving therapies.

Wolfgang Marguerre

Chairman & Chief Executive Officer

Investing in strong governance. It's in our blood.

From left to right, standing:

SIGURD KNAUB
RESEARCH AND DEVELOPMENT

FLEMMING NIELSEN
PRESIDENT, OCTAPHARMA USA, INC.

FREDERIC MARGUERRE
SHAREHOLDERS' REPRESENTATIVE
PRESIDENT, OCTAPHARMA PLASMA
INC. USA

WOLFGANG MARGUERRE
CHAIRMAN & CHIEF EXECUTIVE
OF THE OCTAPHARMA GROUP

TOBIAS MARGUERRE
MANAGING DIRECTOR,
OCTAPHARMA NORDIC AB

ROGER MÄCHLER
CHIEF FINANCIAL OFFICER

From left to right, seated:

MATT RIORDAN
BOARD MEMBER

JOSEF WEINBERGER
CORPORATE QUALITY AND
COMPLIANCE OFFICER

NORBERT MÜLLER
BOARD MEMBER

GEROLD REMPETERS
CORPORATE PRODUCTION OFFICER

OLAF WALTER
BOARD MEMBER



Our Board of Directors' decisions are guided by our five company values. **Ownership** means that we take responsibility and are fully accountable for our conduct. Our **integrity** guides us to live by high ethical standards and care less about being right than about doing the right thing.

The cornerstones of great **leadership** are always leading by example and striving to be the best at what we do. **Sustainability** reminds all of us to focus on the long term and of meeting the needs of patients not only for today but also for tomorrow. Our **entrepreneurship** honours our roots while encouraging innovative thinking to inspire progress.





Vision: Our passion drives us to provide new health solutions advancing human life.

Values:

- Ownership
- Integrity
- Leadership
- Sustainability
- Entrepreneurship



PATSY
CORNWALL, UK
p45



JANNIK
HAMBURG, GERMANY
p29



LISA
MERSEA, UK
p49



TADEO
SALTA, ARGENTINA
p9



ED CARLOS
SAO PAULO, BRAZIL
p33



GABRIELA
SAO PAULO, BRAZIL
p37

We are passionate about making a difference to patients' lives around the world and **understand local healthcare challenges.**



IMAD ISSA
OCTAPHARMA REGIONAL SALES MANAGER, GULF COOPERATION COUNCIL FOR THE ARAB STATES (GCC)

When I joined Octapharma in 2002, our strategy in the region was to promote the concept of quality for plasma products and differentiation between the available brands for the benefit of patients in terms of efficacy, safety, commitment and availability. We launched an educational initiative for doctors and pharmacists throughout the region called the Plasma Quality Program. The objective of the program is to increase awareness of best practices in plasma products and the international guidelines for the selection of high quality products. The program is approved by the Council for Health Specialists and participants are credited with continuing medical education (CME) hours.

The major trend of the countries in the GCC region for plasma products is the tender market. There is a large tender which covers the demand for these products in Saudi Arabia, the United Arab Emirates, Kuwait, Oman, Qatar and Bahrain. We were successful in improving the guidelines of this tender by implementing international quality standards, which has had a very positive impact on patients.

The greatest challenge in the region is availability of plasma products to fulfil continuous increases in demand. In 2013, Saudi Arabia's Ministry of Health (MOH) added octaplas®, our pharmaceutically licensed, standardised solvent/detergent treated human plasma, to its Central Formulary of Pharmaceutical Products, allowing us to sell octaplas® to all MOH hospitals. This is of great value for patients because it provides them with a reliable and continuous supply of octaplas® with all the clinical advantages it has over single donor fresh frozen plasma (FFP). This is especially important in treating thrombotic thrombocytopenic purpura (TTP) and factor V deficiency patients.

I feel for the families and the people who require plasma products. Just like bread, food and water, these products are essentials for life. Imagine you are a parent and you give your son a home, you provide food and water for him. You give him all he needs to live and be healthy, but there is something essential which you cannot give him. Without plasma products lives can become very miserable.

Just before the Eid holiday, I received a call from a mother of a child with haemophilia B. The boy had returned from school with bleeding in his knee. The mother was crying. She was desperate – she needed factor IX for her son. As a human being, when you get a call like that there is nothing else you can do except drop everything and work hard to secure the medication. Understanding the urgency of this case, we immediately began coordinating a solution and instructed the mother how to acquire octanine®F for her son.

Later that night, the mother sent me a picture of her son and he was laughing. I felt so happy knowing that the patient was doing well. In this region haemophilia is treated on demand rather than prophylactically. I believe that introducing prophylactic and home therapy treatment will greatly contribute to a much higher quality of life for all haemophilia patients. When I look at that photo of the boy laughing, I feel that I really did something good. The mother was not in the picture, but I am sure that she was happy and smiling too.



DR CHEN XUYU M.D.
OCTAPharma COUNTRY MANAGER, CHINA

Since 1986 Chinese government policy has forbidden all blood and plasma-derived products from being imported into China, with the exception of human albumin. This three-decades-long ban was a response to four cases of HIV infection caused by imported factor VIII (FVIII), detected in 1983. Today China has around 25 domestic plasma fractionators supplying plasma-derived products, such as immunoglobulin and coagulation factors, to its population of 1.4 billion people.

Despite its embargo on foreign imports, China is not self-sufficient in plasma products. In China plasma collection is forbidden in the big cities and takes place only in rural areas. There is some stigma attached to donating plasma. Recently Chinese domestic fractionators launched campaigns to educate the population and explain how plasma donations can help save many people's lives.

In China there is a huge demand for albumin with approximately 50% of that product being imported. Albumin is widely used in Chinese hospitals and is a critical component in saving lives. It is used mostly in critical care or emergency situations when people have traumatic injuries and burns. It is also used in the treatment of gastrointestinal conditions and liver disease.

Each year Octapharma supplies China with large volumes of its human albumin product albutorm®, the majority of which is produced in our Vienna production site. In 2016 we also started producing albutorm® for China in our Stockholm production facility.

The China Food and Drug Administration (CFDA) introduced a policy that every medical product requires serialisation. China is the first country to introduce the system, which aims to improve the traceability and classification of medical products. Each packaging level, from carton to pallet, is furnished with a unique serial number. Serialisation enhances patient safety and product traceability, making forgery of medicine and the illegal intermediary trade business more difficult. While China is the forerunner, more and more countries are enhancing protection against forgery. A multidisciplinary team, including experts in artwork, IT, packaging and production, collaborated to implement these track and trace systems in our Vienna and Stockholm production sites.

I hope that in future the Chinese government will lift its ban on importing plasma-derived products into China. Today Chinese patients with haemophilia experience shortages of plasma-derived coagulation products. Some patients have died as a result of not having access to treatment. The government eventually agreed to allow recombinant coagulation factor products to be imported to make up for the shortage. Octapharma is currently conducting a clinical trial in China for its human cell line recombinant FVIII Nuwiq®.

There are many challenges in the Chinese market, but there is a Chinese proverb: "Where there is a will there is a way." We will continue to work hard to advocate, educate and try to influence change in China and its approach to supplying patients with these lifesaving medicines.



ABEL FERNANDES
OCTAPHARMA VICE PRESIDENT, LATIN AMERICA

In 2012, Octapharma established the “Red Lapi Network”, which comprises 14 physicians each representing a different country. The network meets twice a year in different cities of Latin America (LATAM) to discuss challenges and best practices, and develop strategies to improve the situation for haemophilia patients.

LATAM is a diverse landscape when it comes to healthcare. Countries such as Argentina, Colombia, Chile and Uruguay have very sophisticated healthcare systems. They have very effective haemophilia treatment programmes with robust diagnostic infrastructure. In other LATAM countries, there is a lot of work to do in diagnosis and treatment programmes. Looking at the recent 2015 World Federation of Hemophilia (WFH) Global Survey report, there is a need for improvement in education and best practice. Several countries reported a very low consumption of factor VIII (FVIII) product, below 1 IU per capita. Furthermore, we can see very poor diagnostic programmes in the other countries.

Patient associations also have a key role to play in advocating on behalf of patients to convince the authorities that these diagnostics and treatments should be introduced. They will continue to raise awareness of new concepts of treatment and best practice based on WFH’s recommendations.

The LATAM division of Octapharma represents all countries of Latin America, including Central America and Caribbean countries, excluding Brazil and Mexico. Octapharma has been operating in LATAM for many years, initially managing activities from Europe. In July 2014, Octapharma established its representative office in Panama, which has allowed us to develop stronger ties with our distributors and key

stakeholders in the region. We have developed many workshops and “Octa Academy” meetings in the most relevant therapeutic areas, with many healthcare practitioners taking part in these scientific training courses.

Octapharma has been strengthening its business in the LATAM region, and in the last three years has achieved sales growth of over 20% per year. With a strong market share position in the coagulation products octanate® and octanine®F, we also have significant reinforcement in products such as alburnorm®, octagam® 5% and 10%, and the prothrombin complex concentrate octaplex®.

During 2016, Octapharma launched its human cell line recombinant FVIII Nuwiq® in several countries: Colombia, Paraguay, Ecuador, Chile and Guatemala, with upcoming launches planned in Argentina and Peru. We expect to launch Nuwiq® in the remaining LATAM countries during 2017. Now we are working towards obtaining registration of Octapharma’s new intravenous immunoglobulin (IVIG) product panzyga®, and hope to launch this during 2018 in the most important markets in the region.

For me, working in a completely different pharmaceutical and sociocultural environment has been an enormous and exciting personal and professional challenge. The LATAM team is based in Panama but is supported by many people around the world. To sustain our leadership and continue to grow in this niche biopharmaceutical market, we must enhance support and collaboration with our local partners to implement and develop scientific meetings/workshops with key stakeholders in the region. There are many areas for future development and investment, including the introduction of new products and better product access contributing to an improvement of patients’ quality of life.

DR KATHARINA POCK
OCTAPharma SENIOR DIRECTOR, RESEARCH & DEVELOPMENT (R&D) PLASMA

Within R&D Plasma my group is responsible for the preclinical development of novel plasma-derived therapeutic protein products as well as the life cycle management of the established plasma product portfolio, focusing on regulatory, production and marketing topics. One of our key objectives is to ensure that Octapharma is optimally using every drop of its precious raw material – human plasma.

I completed my PhD thesis on factor VIII characterisation with Octapharma in 1998, and have been employed with the company since then. In the characterisation of plasma proteins one elucidates the structure of the protein. The goal in purification is to separate and protect the specific protein while optimising product yield. The integrity of the protein has to be maintained throughout the process because the resulting purified plasma component will, ultimately, reach our patients. The protein has to be pure, active and as close to its native state in plasma as possible. Using various analytical techniques, including chromogenic and potency assays, we analyse and profile the structure and properties of the purified plasma protein.

There are so many proteins found in plasma, with different concentrations, molecular weights, half-lives and stabilities. This is a fascinating field and I am proud to be in a position that combines science with the management of people. It is very rewarding to work together on scientifically challenging areas in order to develop products that save lives. We can make a real difference to quality of life, for example by developing new applications for existing products to improve convenience and allow patients to be more independent. This is especially important when it is considered that many of our patients need lifelong treatment.



One way of improving convenience for patients is by developing a product with a reduced volume for intravenous administration, or a subcutaneous application for an existing intravenous product. When embarking on such a project, there are various factors to consider. The formulation of a subcutaneous product must be more concentrated compared with the intravenous product because one cannot infuse a large volume subcutaneously. Therefore the protein must be stable in higher concentrations. We must also ensure that the active ingredient is not degraded when applied subcutaneously.

In March 2016 we held the ground-breaking ceremony for our new R&D centre in Vienna, which will be home to my R&D Plasma group and the Clinical Research & Development (CRD) department. The building has a net floor space of 4,500m² and consists of six floors with 13 laboratories (1,600 m²) and 39 offices (1,200 m²), accommodating around 100 people – 60 from R&D and 40 from CRD. We have been in our current location for 18 years, so the new building had to be planned with a long-term view considering what the future needs will be, especially as Octapharma continues to grow. The investment in our new home shows Octapharma's long-term commitment to R&D.

Our donors transform lives by giving their plasma so our patients can be treated with life-changing medicine.



SHERRY, 60
PINEVILLE, NORTH CAROLINA

Sherry is a great-grandmother, seamstress, tax professional and long-time Anti-D plasma donor. She runs her own tax company and for the past 40 years has donated plasma twice every week, even during the busy tax season. She spends the hour it takes to donate reading on her Kindle and relaxing.

Sherry first learned about donating plasma after her second son was born. As an Rh negative mother she was at risk from complications during pregnancy. She didn't know much about the Rh factor at the time, but learned that a plasma-based treatment during her pregnancy was necessary to prevent harm to her developing child. She says: "I am truly grateful for that treatment and for the health of both my babies."

She donates to help give mothers a better chance of having safe, full-term pregnancies and healthy babies. She encourages everyone in her family to donate plasma, even her son who is currently serving in the army. Sherry believes her plasma donations, and her personal story, are the most important things she can share with others.

MARK, 48
MILWAUKEE, WISCONSIN

Mark learned about the life-saving benefits of plasma donations when he served in the Marine Corps during the Gulf War. In May 2016 he read that an Octapharma Plasma donation centre had opened nearby. A single father, he began donating at the centre to help others while also earning money which he could put toward his daughter's confirmation.

To reach his donation centre Mark travels by bus on a two-hour round trip. Including time for the donation process, each trip takes him about three hours. Originally, since it was such a time commitment, Mark planned only to donate until after his daughter's confirmation. However, he decided to continue donating once he learned how many people could benefit from his regular donations. To this day Mark still makes the three-hour trip to donate twice every week.

Mark donates plasma because it helps give patients medicines that can change their lives. He says: "Plasma isn't made in a lab, and this is an easy way for me to help others. Donating plasma is one of my favourite ways of giving back."



OUR VIRUS INACTIVATION STEPS WERE PROVED TO BE SUCCESSFUL AGAINST ZIKA VIRUS.

DR DENIS KÜHNEL

OCTAPharma STUDY DIRECTOR, VIRUS & PRION VALIDATION, OCTAPharma, FRANKFURT, GERMANY

On February 1st 2016, the World Health Organization (WHO) declared Zika virus (ZIKV) a public health emergency of international concern. The scientific consensus is that Zika virus, a mosquito-borne flavivirus first identified in humans in 1952, causes neurological disorders including microcephaly and Guillain-Barré syndrome.

Octapharma's Virus & Prion Validation group in Frankfurt responded quickly by planning and executing studies to validate our existing viral inactivation/elimination processes against Zika. Octapharma uses a variety of dedicated viral inactivation and removal steps in our fractionation processes in order to ensure the viral safety of our plasma-derived products. For an enveloped virus, solvent detergent (SD) treatment is still, some three decades after introduction by Octapharma, the current gold standard in inactivation. For a virus larger than 20 nanometres, nanofiltration removes the virus.

As ZIKV is an enveloped virus SD treatment or pasteurisation are highly effective in inactivation, and as it is larger than 20 nanometres, nanofiltration is effective in eliminating it. Despite having the theoretical knowledge that our existing production processes will inactivate and remove the virus, it was important for us to demonstrate this scientifically and validate that our production techniques are successful in inactivating ZIKV.

Our whole scientific team was involved in the Zika studies. In a biosafety-level laboratory the safety measures were scaled down and the virus was added to intermediates of the respective production process. The viral inactivation techniques of SD treatment and pasteurisation (60°C) were applied, then we determined if the virus titre was below the detection limit and if the virus safety steps were sufficient to inactivate ZIKV. We completed studies for four Octapharma products, then analysed and collated the results from February until June 2016. The findings were very satisfying as our well-established virus inactivation steps were proved to be successful against ZIKV. The study results have been published in the "Transfusion" journal.



In our routine work we perform virus and prion validation studies for all Octapharma products, both plasma and recombinant, as well as new development products in the pipeline. We verify the efficacy of the viral inactivation or removal methods used in our production processes by performing Good Laboratory Practice compliant studies on a laboratory scale. In our studies we use samples of Octapharma products from the different production sites. In our labs we add to product intermediates various viruses, including human immunodeficiency virus (HIV), West Nile virus (WNV) or hepatitis A (HAV), in order to perform our validation studies.

I know many people who don't like to work in a biosafety-level laboratory but I enjoy it. I am fascinated to know that we are handling dangerous viruses which can cause fatal diseases. I am very proud to be part of a team which is responsible for the viral and prion safety of Octapharma's products. Viral safety was the idea upon which Octapharma was founded. Our viral safety steps mean that no patient has to fear being infected with viruses from our products. I am proud to see our products helping so many patients all around the world. Mark Twain said: "Give every day the chance to become the most beautiful day of your life," and I try to live up to this every day.

DONATING PLASMA HELPS ME PURCHASE BOOKS FOR ALL MY CLASSES.



JAMIE, 23
MILWAUKEE, WISCONSIN

For years, Jamie's grandmother relied on the life-saving donations of strangers to maintain her health. Jamie started donating in her late grandmother's honour to help others in similar situations. Jamie says: "If plasma donations weren't used for a good cause, I probably wouldn't donate. I enjoy helping people, even if I don't know them."

Currently a student at the local university, donating plasma helps Jamie purchase books for all her classes. She works full time in a retail chain store corporate office, and is studying Supply Chain Management and Marketing to help further her career.

Jamie donates plasma after work at least once a week. While donating she listens to music, scrolls through Pinterest, and plans her photography, scrapbooking and other craft projects. Jamie says: "Donating isn't a big time commitment, it's easy and it's not painful. Every time I donate I'm impressed by Octapharma's clean facilities and friendly staff."



AMBER, 31
MILWAUKEE, WISCONSIN

Amber is a single mother who has donated with Octapharma Plasma for about eight months. She started donating because she wanted a way to fund vacations with her daughter, and liked the idea of being able to make money while making a difference.

Amber researched several plasma companies before she started donating. Once she found Octapharma Plasma's website, she became comfortable with the donation process, confident that donating was safe and positive she'd found her donation centre. Amber donates during her lunch break once or twice every week. She finds the overall donation experience very relaxing because the staff are always extremely conscious of both her time and health. Donating plasma fits easily around Amber's full-time job, and also lets her focus on family time with her daughter. In 2016 she used the money she made from donating to take her daughter to Walt Disney World.

As part of her job Amber works on a health and wellness committee. She constantly educates and encourages her colleagues to donate, saying: "Don't be scared to donate, because it's great to be directly helping patients in need of plasma products, and at the same time earning some extra money."

DONATING PLASMA EASILY FITS AROUND MY FULL-TIME JOB, AND ALSO LETS ME FOCUS ON FAMILY TIME WITH MY DAUGHTER.

WE PERFORM TESTS ON EACH AND EVERY PLASMA DONATION COLLECTED IN OUR CENTRES.

MONICA BYRD
OCTAPharma PLASMA INC. (OPI),
SENIOR DIRECTOR REGULATORY AFFAIRS
& QUALITY ASSURANCE

At OPI in the US we collect, test and supply human blood plasma for the manufacture of Octapharma's lifesaving medicines. All OPI plasma collection centres are licensed by the relevant national health authority, and are operated in compliance with EU and/or US Food and Drug Administration (FDA) Good Manufacturing Practice (GMP) and the quality and safety standards of the Plasma Protein Therapeutics Association (PPTA).

My team is responsible for regulatory affairs and quality assurance for OPI. In partnership with the operations teams in our plasma collection centres, we ensure that our business and products are compliant with the regulations and that we are operating in the most efficient and compliant way. Looking at the business in totality and working together with different functions to find solutions is the fun part of my job.

The quality systems and best practice templates in place guarantee a consistent level of information and integrity of our processes for our existing and newly opening plasma centres. We believe that quality should be a habit, not an act. And we are even more conservative when it comes to safety because we have a responsibility to our business, to our reputation and, ultimately, to our patients.

To ensure the product quality and safety, we perform tests on each and every plasma donation collected in our centres. We screen for the presence of specific blood-borne viruses, such as human immunodeficiency virus (HIV), hepatitis B (HBV) and hepatitis C (HCV). The plasma is physically held and electronically quarantined until successful test results are confirmed. Only then will the plasma be shipped to our European production sites to be manufactured into medicines.



OPI is in a growth phase. We have 73 plasma donation centres as of the end of 2016, and plan for 82 by the end of 2017. In August 2016 we received approval from the US FDA for our new state-of-the-art viral testing laboratory in Charlotte, North Carolina. Bringing our plasma viral testing in-house gives us more control over our processes, and will also enhance our ability to expand operations.

Patients are always in our mind and I believe that quality is everyone's responsibility, regardless of whether or not the word is in your job title. I experienced a big eye opener when I met someone in my personal life who told me she was a recipient of plasma therapy. I had advertised for a babysitter and one of the candidates told me that she has a chronic illness and has immunoglobulin infusions on a weekly basis. Meeting a person who relies on plasma products touched me very deeply. It brought home the importance of what we are doing every day, supplying safe plasma which is manufactured into lifesaving medicines for our patients all around the world.



TJ, 24
BROOKFIELD, WISCONSIN

Three years ago TJ attended art school for photography and advertising. He recently began attending a local technical college for a degree in IT. After several years of schooling, he has built up some student debt. Two years ago a friend recommended TJ start donating plasma as a resource for extra money.

He says: "Donating plasma does more than you think it will to help others, and at the same time you have a little extra cash in your pocket. I've donated with several plasma companies, and Octapharma Plasma is the cleanest, most smoothly run, and highest calibre facility I've seen." During one of TJ's donations at Octapharma Plasma an employee talked to him about applying for a job. He put in an application that day and was later interviewed and hired. He has been a floor technician with Octapharma Plasma for seven months, and plans to continue working and donating there.

TJ believes Octapharma Plasma employees treat donors like a community. His favourite part about donating plasma and working at a donation centre is the opportunity he gets to meet new people and talk to them, learning about each person's individual experiences.

OCTAPHARMA PLASMA EMPLOYEES TREAT DONORS LIKE A COMMUNITY.

LIKE MANY PLASMA DONORS, MY LIFE HAS BEEN PERSONALLY IMPACTED BY PLASMA DONATIONS.



ANGIE, 41
KIRKSVILLE, MISSOURI

Angie is a wife and mother of four children, and her days are extremely full. She donates plasma because it is flexible, like a part-time job. The money she makes through plasma donations covers her family's travel, date nights, and a variety of other "needs and wants". Donating lets Angie contribute to her family's budget while still focusing on her children.

Angie likes the atmosphere of Octapharma Plasma because she gets to visit with employees as well as take "personal time". Donating gives her time to check emails, read, and enjoy a peaceful respite from an otherwise busy day. She tells her friends and family: "Don't be afraid to donate, even if you're nervous around needles. The staff care and the donating process is so smooth, I don't even realise I'm doing it half the time. It's just not that big a deal."

Like many plasma donors, Angie's life has been personally impacted by plasma donations. She is Rh negative and received treatment with each of her pregnancies, and her cousin receives plasma-derived medicines for a lung disease. Knowing real patients makes donating plasma extremely meaningful for Angie.

OUR PATIENTS DEPEND ON US DOING OUR JOB IN THE BEST POSSIBLE AND COMPLIANT WAY.

MICHAEL SZKUTTA OCTAPharma, HEAD OF CORPORATE QUALITY PLASMA (CQP)

Most of our medicines are derived from a human-sourced raw material – human plasma – and it is essential that we have robust, compliant and fully traceable processes throughout the entire production. Each year Octapharma handles 5.6 million litres of plasma collected by 300 plasma suppliers.

Our goal in CQP is to ensure regulatory compliance of all our external and internal processes, from the point of collection at our plasma suppliers until the plasma is released for production. My group's responsibilities include auditing and qualifying Octapharma's plasma-related suppliers and maintaining our Plasma Master File (PMF), which is the compilation of all the required scientific and regulatory data on the quality and safety of human plasma.

In 2016 we established Octapharma's CQP function, which is responsible for all plasma-related quality activities. Previously the function was set up with local quality assurance plasma departments reporting into the local quality units. The corporate approach now allows possibilities for more harmonisation of our internal processes across all sites.

We have a clear understanding of the requirements dictated by regulations as well as our business needs, and we must communicate these effectively to our suppliers, which include plasma donation centres, blood banks, testing laboratories, transport companies and warehouses as well as our internal partners.

We conduct regular audits of about 500 suppliers to ensure they are working according to the mandated procedures and regulations. When we are auditing a plasma supplier we always try to include the processes for a completely new first time donor. We follow the entire donor flow from the moment the donor first registers, right through to when they leave the centre. We also look at the relationship between the staff and donors by observing how the donor centre staff behave towards the donor.



Our patients depend on us doing our job in the best possible and compliant way. Good manufacturing practice (GMP) is the world my team and I live in. These are the regulations that we follow to be compliant. As employees, we all have a responsibility to raise our hands if we recognise that something is not done in the right way. We have a duty to our patients.

Some countries have restrictions on plasma origin for their final products; therefore we must ensure that these products are made from the correct plasma source. This is ensured through robust traceability systems. If a plasma supplier is located outside of Europe and we want to use that plasma for European products, we need to ensure the supplier is approved by a European authority. For that reason we work very closely with the Austrian Agency for Health and Food Safety (AGES), which carries out the inspections in our US plasma donation centres.

Our objective in CQP is to sustain the high level of quality we have built up in correlation with our plasma suppliers in our internal processes, to ensure safety and tolerability for products and patients. Our patients cannot visit our manufacturing sites or our donor centres personally, so they rely on us. I am proud to know that my group and I are playing this important part in fulfilling our responsibility to our patients.

A strong performance keeps us
on track **for advancing human lives.**



Roger Mächler – Chief Financial Officer

Revenue

€1.6bn

Operating income

€383m

Capital expenditures

€166m

For the sixth consecutive year, the Octapharma Group can report a record-breaking result with sales of €1.6 billion, which represents an increase of €87 million or 5.8% compared with 2015. This outstanding performance is the result of enhanced collaboration and improved efficiencies across all functions and regions throughout the group. It would not have been possible without the focus, efforts and perseverance of all our employees and business partners.

Octapharma achieved sales growth of 18.8% in North America, 14% in Eastern Europe and 6% in our well-established markets of Western Europe. The main contributors of the growth were our immunoglobulin products octagam® and gammanorm®, and our factor VIII products octanate®, wilate® and Nuwiq®.

Gross profit in 2016 was €590 million, €8 million higher than in 2015. The 36.9% gross margin of net sales is slightly lower than last year due to our continued investment in the expansion of our plasma donation centres and production capacity. Our cost per litre of plasma is affected by both the industry-wide trend of increasing donor fees in the US and the opening of our new plasma donation centres. Expanding our fleet of centres is a high value investment for the future; however, time is required before the new centres are running to full capacity.

In 2016 Octapharma increased its investments in our future product portfolio and important markets; however, our total operating expenses decreased by €24 million to €207 million, due to an extraordinary income from a financial settlement. In addition to the €84 million investment in research and development (R&D), €166 million was spent on the extension of both our plasma collection and production divisions.

We achieved an unprecedented operating income of €383 million. Net cash from operating activities was €288 million or 18% of revenue. Trade receivables increased after a very strong fourth quarter and our net inventory rose due to welcomed greater volumes of collected plasma raw material.

Over the last five years Octapharma has experienced tremendous growth with a compound annual growth rate of 15%. Our development initiative, Program 2019, was launched in 2014 to double production capacity and significantly increase the overall efficiency of our manufacturing operations. We have been heavily investing in people, equipment and property to prepare for the increase in production capacity and volumes. While the technical infrastructure is largely in place, our focus is now on securing the necessary regulatory approvals to transform our investments into increased product availability for patients.

During a strategic workshop the Board focused on where we want the company to be by 2026. Our new strategic goals are: increase market penetration and expand into new geographies; expand the plasma and recombinant product portfolios and optimise R&D timelines; optimise production efficiency; increase plasma collection and fractionation capacity; proud and talented employees in a healthy organisation; and open and transparent communication. These pillars are at the forefront of planning and help to guide all the decision making and priorities of the Octapharma Group.

Our target for 2017 is sales growth of more than 10% and absolute profit results which are comparable to 2016. This year is expected to be the final transitional period before we finally start harvesting the real benefits of the profound investments made in plasma collection and production.

I am optimistic that Octapharma will continue to be in a strong position to deliver new health solutions advancing human life.

Roger Mächler
Chief Financial Officer