octapharma

Annual Report 2019

From generation to generation

Octapharma has worked for a healthier world since 1983. Every day, we strive to help thousands of patients of all ages, on every continent, believing that together we can invest in a better future for generations to come. Guiding us in what we do and how we do it are our values – they're in our blood.

We would like to thank all interviewees for their openness in sharing their stories.

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Always on the go

Laurel was 49 years old before doctors finally confirmed her common variable immunodeficiency diagnosis. Like many other patients, she had spent many years since childhood under the care of multiple specialists without getting an accurate diagnosis to explain the root cause of her recurring illnesses.

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Trust and decision making

You might think that seeing dozens of patients every day would sap the mental energy needed for any sort of personal reflection. But, in his 30-year career, each experience seems to have taught Gennadiy Galstyan, MD, PhD, something new and motivated him further.

Continuing the impact of our products for generations to come

Wolfgang Marguerre
Chairman and CEO, Octapharma Group

“In 2019, we achieved good growth in all three therapeutic areas. We continued to invest significantly in R&D to fund the discovery and development of new life-changing treatments.”

From left to right:
Tobias Marguerre, Managing Director, Octapharma Nordic AB
Frederic Marguerre, Shareholders’ Representative, President Octapharma Plasma, Inc., USA
Wolfgang Marguerre, Chairman and CEO, Octapharma Group

Since I founded Octapharma in 1983, the company has grown into a truly global group. Today we have more than 9,300 employees serving patients in 118 countries. In 2019, we achieved revenues of €2.2 billion and pre-tax profits of €428 million, each representing a growth of more than 23% over 2018.

In this year's Annual Report, we speak to patients whose lives are being impacted by our products. The stories of young Sebaga from Botswana, Arne from Germany, and Nicholas and Laurel from the USA are incredibly inspiring for everyone at Octapharma. They remind us of the tremendous impact that we have on many thousands of patients all around the world.

Stories such as Sebaga's remind us of our vision, which is to provide new health solutions advancing human life. Our ability to deliver treatments in all three of our therapeutic areas – haematology, immunotherapy and critical care – is one of the many reasons I am proud of our company and our performance during the year.

In 2019, we achieved good growth in all three therapeutic areas. We continued to invest significantly in R&D to fund the discovery and development of new life-changing treatments. However, the journey of a new product to regulatory approval is one that requires incredible teamwork throughout our organisation. This teamwork is evident in the stories in this year's report highlighting the development of our fibrinogen concentrate, fibryga®, as well as the interview with our colleagues from Octapharma Plasma, Inc., explaining everything that goes into opening a new plasma donation centre in the USA.

9,307
employees (2018: 8,314)

€2.2bn
revenue (2018: €1.8bn)

€428m
pre-tax profit (2018: €346m)

In 2019, we received important regulatory approvals and label extensions. Our new subcutaneous immunoglobulin (SCIg), cutaquig®, received approval in Europe following approvals in 2018 in the USA and Canada. The European Medicines Agency (EMA) approved an updated label for our recombinant factor VIII (FVIII), Nuwiq®, that includes data on effective bleed protection with twice-weekly dosing using personalised prophylaxis. Fibryga® received European approval to treat acquired fibrinogen deficiencies, extending the earlier approval for use in patients with congenital fibrinogen deficiency. This represents a major milestone for bleeding management for patients in critical care settings.

During 2019, we invested heavily in our plasma collection capacities to ensure the future supplies of our life-saving products for patients. Now we operate more than 120 plasma donation centres across our fleet in Germany and the USA.

Beyond our core values – ownership, integrity, leadership, sustainability and entrepreneurship – we aspire to create a culture in which our employees feel inspired. We work today on what our patients need tomorrow, and I would like to thank everyone for their dedication and teamwork.

As I contemplate the year ahead, I believe that Octapharma is well positioned to master our future challenges. I look forward to another great year of advancing patients' lives together.

Wolfgang Marguerre
Chairman and CEO, Octapharma Group

Watch our corporate culture video to learn more about the passion behind Octapharma:
octapharma.com/about-us

“Beyond our core values – ownership, integrity, leadership, sustainability and entrepreneurship – we aspire to create a culture in which our employees feel inspired.”

Our shared company values are key to driving our culture and our performance

We asked five colleagues from around the globe what the Octapharma values mean to them – and their answers reveal some very personal and motivating responses.

Ownership

As a healthcare company, Octapharma fights for patients to improve and advance their lives. Helping people in this way is a noble and courageous endeavour in which taking ownership for each action is key.

For me, ownership means making sure that each of our actions brings a positive outcome on at least three levels: first, they must impact our patients, our main focus; second, they must create value for our partners: purchasing agents, regulatory bodies, physicians, etc.; and third, but no less important, they must have a positive impact on ourselves, in that the decisions we make must make us better people. If we are able to succeed on these three levels, we will create a virtuous circle of increasing trust that will better serve the needs of our patients.

Jorge Fernandez
Deputy General Manager,
Octapharma Mexico City, Mexico

Committed
Responsible
Focused

Integrity

Integrity is an important value for me. It is not just a normative ideal but a prerequisite for sustainable business. At Octapharma, integrity is integrated into our governance. We have created an environment where team members can develop their strengths and learn new skills – an environment in which integrity is fostered, supported and rewarded, consequently driving our performance.

For me personally, it means that I am reliable and trustworthy. I keep my word and fulfil my commitments, pay attention to the environment, stay focused, take responsibility and respect my colleagues.

Philipp Auf der Maur
Head of Finance,
Lachen, Switzerland

Reliable
Trustworthy
Respectful

Leadership

I link the tasks my team is responsible for to the bigger picture: meaning to our donors and, ultimately, to the patients who receive our medicines. No matter how trivial a task may seem, when it is tied to a loftier goal, the team is more likely to do a better job and feel better about their work in the process.

For me, leadership means standing up, sometimes even alone, to remove roadblocks and provide opportunities for team members and colleagues to be successful. Bottom line: a leader is only successful if his or her team is successful too.

Michael Savin
Director, Business Applications,
OPI, Charlotte, USA

Innovative
Goal-oriented
Inspiring

Sustainability

Sustainability has been a personal value of mine throughout my entire life. Since the age of 15, when I first arrived in a foreign country, I have learned to make decisions with a long-term perspective in mind.

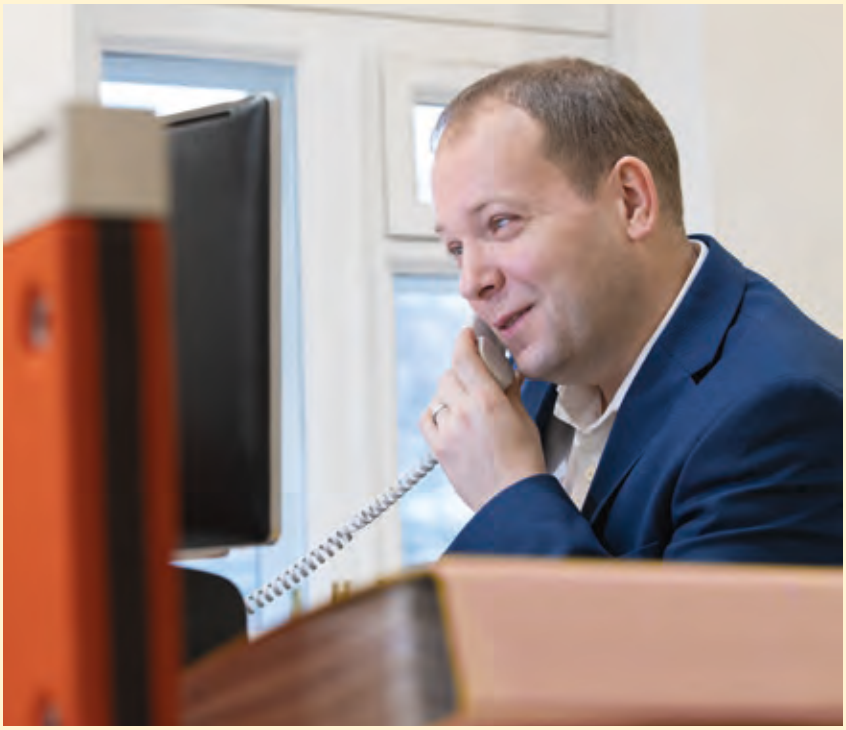
This approach is a vital component for achieving success in my daily work. For example, it is essential, for me, to create an inclusive work environment. Only in an inclusive environment, where all colleagues feel empowered and understand their roles, can everyone be their best self and fully thrive, and thus contribute to deliver high-quality products to our patients all around the world.

To me, sustainability is defined and achieved by the kind of clear-focus, long-term dedication and high level of competence required to provide a constant supply of top-quality products, now and in the future.

Parivash Gunnerfält
Head of Quality Unit,
Stockholm, Sweden

Forward-looking Empathic Persistent

Entrepreneurship



Entrepreneurship is the pursuit of opportunities. It is an engine for growth and a force for positive change. It is not something you can just tell people to do or to be. You have to provide an environment that encourages and supports an enterprise mindset. At Octapharma, everyone is part of the entire organism, and not just a small cog in the system.

For me, the ultimate goal every day is to do at least one thing better, faster, stronger than yesterday. It is important not only to achieve your own goals but also to collaborate with others and inspire them.

Often, the simplest way to a quick result is to give a direct task to a person, but that doesn't develop their self-sufficiency or their ability to think and work 'outside the box'. Self-sufficiency comes along with taking responsibility for results – and that is what I am trying to implement and encourage.

Sergey Gryaznov
Head of Financial Department,
Moscow Representative Office of Octapharma,
Moscow, Russia

Agile
Empowering
Proactive

Octapharma thrives as an organisation in which people take **ownership**, have **integrity**, demonstrate grounded and confident **leadership**, drive **sustainability**, and are inspired by and eager to embrace **entrepreneurship**.

Working together...

Our vision
Our passion drives us to provide new health solutions advancing human life

Our mission
For the safe and optimal use of human proteins

€2.2bn
revenue in 2019

€424m
operating income in 2019

>120
plasma donation centres

>6m
litres of plasma processed annually

71
nationalities

9,307
employees

5,509
female

3,798
male

...around the world

Family owned since being established in 1983, Octapharma is a global healthcare company headquartered in Lachen, Switzerland. Our products are available in 118 countries and reach hundreds of thousands of patients every year.

■
Octapharma Global HQ
Lachen, Switzerland

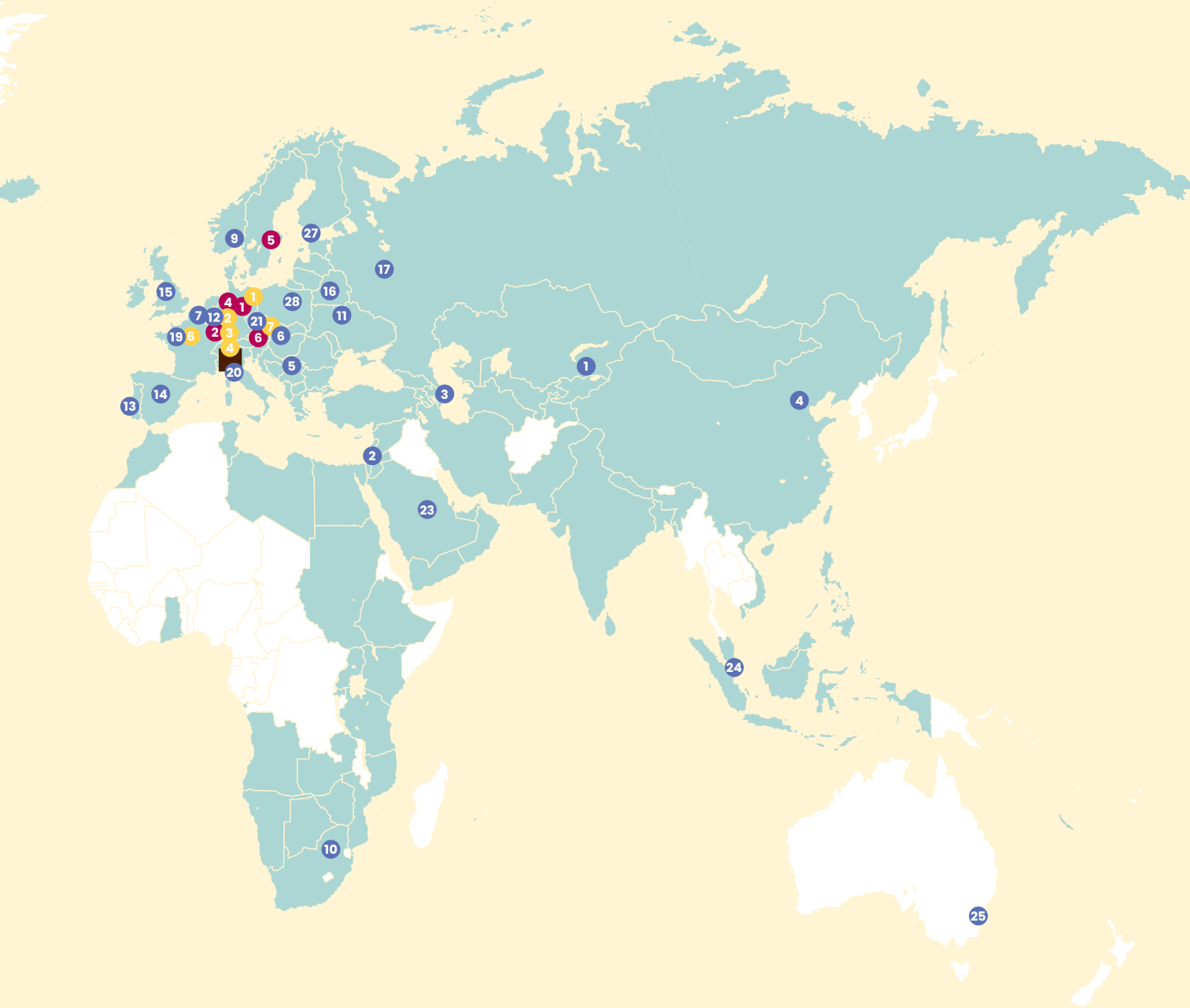
▲
Octapharma Plasma, Inc.
North Carolina, USA

●
Manufacturing sites
1. Dessau-Rosslau, Germany
2. Lingolsheim, France
3. Mexico City, Mexico
4. Springe, Germany
5. Stockholm, Sweden
6. Vienna, Austria

●
R&D sites
1. Berlin, Germany
2. Frankfurt, Germany
3. Heidelberg, Germany
4. Lachen, Switzerland
5. New Jersey, USA
6. Paris, France
7. Vienna, Austria

■
Countries where patients are treated with our products

●
Octapharma locations
1. Almaty, Kazakhstan
2. Amman, Jordan
3. Baku, Azerbaijan
4. Beijing, China
5. Belgrade, Serbia
6. Bratislava, Slovakia
7. Brussels, Belgium
8. Florida, USA
9. Jessheim, Norway
10. Johannesburg, South Africa
11. Kiev, Ukraine
12. Langenfeld, Germany
13. Lisbon, Portugal
14. Madrid, Spain
15. Manchester, UK
16. Minsk, Belarus
17. Moscow, Russia
18. New Jersey, USA
19. Paris, France
20. Pisa, Italy
21. Prague, Czech Republic
22. Rio de Janeiro, Brazil
23. Riyadh, Saudi Arabia
24. Singapore
25. Sydney, Australia
26. Toronto, Canada
27. Vantaa, Finland
28. Warsaw, Poland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Surviving the unknown

"Despite everything, Sebaga inspires me to do more in life. We've been through a lot together – we have hope and love!"

Nelly, Sebaga's mother
Gaborone City, Botswana

Nelly, the mother of three children living in Botswana in southern Africa, knows only too well what a lack of access to medicine and medical capabilities can mean. Sebaga, aged 11, her youngest daughter, was born with von Willebrand disease (VWD) but was only diagnosed seven years later.

Most people thinking of the Sub-Saharan nation of Botswana picture its diverse animal population or its breathtaking landscape, including the timeless expanse of the great Kalahari Desert and the crystal-clear waters of the Okavango Delta. Yet there is another Botswana, a vibrant nation which has transformed itself in recent years from one of the world's poorest countries to a middle-income one.

In Botswana, access to healthcare continues to be an enormous challenge. A lack of awareness, medical know-how and equipment to diagnose certain bleeding disorders, including VWD, represents a serious problem. This means that patients with bleeding disorders – like Sebaga – are very vulnerable. Currently, the number of patients diagnosed with VWD in Botswana is six, in a country of over two million people. Through its Continuing Medical Education (CME) initiatives, Octapharma is supporting doctors to improve their awareness of bleeding disorders, which helps more and more patients like Sebaga to be diagnosed.

A mother's intuition

When Sebaga was born and the nurse gave her an immunisation injection, the prick from the needle didn't stop bleeding for more than a day. Over the first months of Sebaga's life, her mother noticed other instances of prolonged bleeding that resulted from even small scrapes. Nelly was scared. She hadn't experienced this with either her elder son or daughter when they were babies. "Something was not OK, I told myself," she recalls.

In her early childhood, Sebaga had recurrent bleeds requiring hospitalisation, with some of the internal bleeds being life-threatening to the little girl. Exhausted, she often had severe headaches and could not even walk because of the pain.

Did you know?

1%

VWD is the most common inherited bleeding disorder. It is believed to affect 1% of the world's population.[1]

Lack of awareness

As most people experience very mild symptoms, it is estimated that 90% of individuals with the disease have not been diagnosed.[1]

Type 3 VWD

The most severe type of VWD is Type 3, characterised by a very little or a complete absence of von Willebrand factor.[2]

"Sebaga only got worse, and she fell into a coma twice," her mother recalls. She was given a blood transfusion five times and yet nobody knew the cause of her problems.

Desperately wanting an answer, Nelly ran from paediatrician to oncologist. "After so many results, we were finally sent to a haematologist, who told us about the possibility of von Willebrand disease," Nelly says.

Dealing with the diagnosis

Nelly now had an answer, but it wasn't one she fully understood yet. Worse still, following results from a blood test, it was confirmed that the little girl had Type 3 VWD – the rarest and most severe form of the disease. Sebaga was just seven and a half years old at that time.

Nelly felt overwhelmed and at a loss for information, remembering that "up until this point, I had heard about haemophilia but didn't have any other knowledge about other bleeding disorders".

VWD is the most common inherited bleeding disorder and affects the body's blood-clotting process. There are several forms of the disease, known as Types 1, 2 and 3. In patients with VWD, a genetic mutation results in the absence or defective production of the critical blood-clotting protein called von Willebrand factor (VWF). As treatment, patients receive intravenous infusions of VWF concentrate.

Often underdiagnosed, VWD is believed to affect 1% of the world population, but the prevalence of those who have symptoms and need treatment is believed to be about 1 in 5,000. It is estimated that 90% of those needing treatment are unaware they have the disease and are left untreated.

Nelly was shocked to hear from a local bleeding disorders specialist that her daughter was the only person diagnosed with Type 3 VWD in the country at that time.

But, as Nelly explains, Sebaga's diagnosis also brought other worries: "What kind of treatment would work? How would I pay for it, and how would I make up for missing time from work?" Nelly is a single parent supporting all three of her children. "I was dreaming up nightmarish scenarios, but I was also willing to fight for my little princess," Nelly says.

Adjusting to a new life

In the bustling capital Gaborone, three years after Sebaga's diagnosis, Nelly prepares dinner for her family. Tonight, she will serve homemade pasta, with a salad and baked tomatoes that she picked from her garden. "My little baby has been so weak," Nelly explains, looking at Sebaga playing with the pasta dough. Instantly, the child looks up at her mother, holding a piece of dough in the shape of a heart, and laughs. "She loves to help me with the cooking and be creative with the dough." Nelly smiles: "Life has become much better as we now know what we are dealing with."

At the end of 2017, Sebaga started treatment with wilate®. Now, she is on weekly prophylaxis and has regular follow-ups with a paediatric haematologist every three months. Like many kids her age, Sebaga is very inquisitive and always on the go.

Now 11, she is not only beautiful and adventurous – like her cartoon hero Princess Sophia – but she is clearly involved in managing her condition and is learning how to adjust to life with VWD. She has an interest in science and understands her disease, learning some of the disease terminology and actively engaging in conversations when she visits the clinic.

Sitting in the family's dining room, Nelly says, "Without access to her treatment, she would not be able to do the things she loves with the people she loves. Now, everything is much better! Gone are those long bleeds."

Sebaga knows the story but, as her mother speaks, she leans against her. "Despite everything," Nelly says firmly, "Sebaga inspires me to do more in life. We've been through a lot together – we have hope and love!"

A passion for living

"My goal is to get them outside and show them that haemophilia doesn't limit them but that they can limit haemophilia."

Nicholas (29)
California, USA

Did you know?

400,000

Today, approximately 400,000 people are living with haemophilia worldwide. Approximately 75% of them still have no access to adequate treatment.[3]

A or B?

Haemophilia A is the most common type of the disease, accounting for 80–85% of cases.[4]

Mainly inherited

Approximately 70% of patients have a family history of the condition, whilst the other 30% of cases (called sporadic haemophilia) are presumably caused by changes in the patient's genes.[5]

Nicholas likes to go for long-distance hikes and enjoys fishing with his buddies. That is when this young sales representative can relax and let his mind wander after a week of hard work. He has lived with haemophilia his entire life and experienced all aspects of this extremely painful disease. Now he devotes his working hours to raising awareness about the illness, and helping other haemophiliacs in the USA live their best lives through his work and his different non-profit organisations.

His story did not begin so positively. At birth, due to complications, Nicholas was forcibly delivered, a procedure which punctured several blood vessels in his head. "I was bleeding – and because of that bleeding, my head went from 22 to 44 cm," says Nicholas, adding after a long pause, "I had to have a double volume blood exchange through my umbilical cord." A neurosurgeon explained to his parents, Hema and Michael, that their newborn son was a haemophiliac. Completely exhausted, they tried hard to process this devastating news.

Inspiring support

Over the years, the family learned how to live with haemophilia and, just like other kids, Nicholas spent most of his childhood outdoors, having on-demand treatments to stop his spontaneous bleeds when needed. The family's life came to a near standstill again in 1998, this time when their son was diagnosed with cancer: non-Hodgkin's Burkitt's lymphoma.

Earlier that year, Nicholas had an inflammation of the appendix, which was removed in emergency surgery. His recovery was not going well and, some days after the surgery, a lymph node in his neck expanded to the size of a golf ball. Doctors at first suggested antibiotic treatment but the lymph node turned out to contain tumour cells. This was a hard situation to digest. "Within a week, I ended up having two surgeries and five tumours excised from my neck," recalls Nicholas. It was a difficult time for everyone in the family but, thankfully, Nicholas recovered.

Besides depending on the love and support of his parents, Nicholas also became close to his haematologist, Dr Diane Nugent. Over the course of many years, Nicholas and Dr Nugent bonded through his history with cancer, and through her attention and expertise: "Through the years of cancer I was able to connect and learn more about my haemophilia and about haematology in general." Nicholas adds, "There is a special bond built with your haematologist at a young age and that is what inspired me then and continues to do so now."

No limits

Nicholas is a very warm-hearted and curious person. He has a passion for exploring and trying out new things. As a child he wanted to do everything from rock climbing to riding a mountain bike – something so simple yet, for him as a haemophiliac, potentially very dangerous. But his parents fully supported him. "I've always been curious. And being curious for me means being adventurous, being able to continuously explore and be outdoors," says the 29-year-old.

He still recalls his first rock-climbing team. "I joined a mountaineering club at college and climbed outdoors. I was totally taken by this fascinating sport." Climbing is an endurance sport which needs physical and mental determination. Sadly, in the end, Nicholas had to give up active climbing when his joints and hands simply could not take the physical pressure any more.

However, despite his physical limitations and the damage caused to his joints, Nicholas has the same determination he always had whilst climbing. "No limits," smiles Nicholas, as he continues, borrowing a quote from the Native American, Tecumseh: "I live my life that the fear of death can never enter my heart."

"The drug changed my ability to do stuff in life"

His desire to take on a challenge drove Nicholas to study developmental biology, virology and chemical engineering. After graduation Nicholas launched an exciting career, but life was not always easy for this Californian. At a certain point he had to reduce any physical activities because his joints were so bad. "I was taking about 400,000 units of factor VIII per month, which is a lot of units for a person of 230 pounds (about 104 kilos)," explains the young man. "And I had 72 bleeds in a single year!"

Haemophilia poses a significant lifetime burden in terms of quality of life. It is a bleeding disorder, meaning that the blood-clotting process in the patient does not work properly. Recurrent bleeding into joints is one of the most severe consequences of this incurable disease, as it reduces movement and causes both chronic pain and stiffness.

Nicholas was losing hope. This active young man, who spent his entire childhood outdoors, was now living with almost unbearable pain – or at least he was until one afternoon when he mentioned his pain to Paul Wilk, his current boss. "I remember very vividly when Paul told me about Nuwiq®."

A short time later, after his next spontaneous bleed had lasted for about 45 days, Nicholas tried a single dose of the suggested medicine. "It resolved the bleed," remembers Nicholas. "Now, I am down to just 94,000 units of factor VIII a month and I haven't had a single spontaneous bleed since I started taking the recombinant clotting factor VIII concentrate, Nuwiq®."

Even better, Nicholas is now able to enjoy activities like white-water kayaking and has started hiking again, going to places he hasn't seen, just to fish. As he puts it, "The new drug has changed my ability to do stuff in life!"

Haemophilia 101

Today has been another hard but rewarding day for Nicholas, who now works as a coagulation sales specialist for Octapharma in California. All day he has had meetings with doctors, pharmacists and patients, educating them on the company's coagulation drugs.

Nicholas is happy and it goes without saying that he is well aware of the responsibilities he bears when interacting with his stakeholders. "Being open and transparent is essential to build trust," says Nicholas. "I help set up events where we talk to haemophilic patients, alongside nurses, and teach them haemophilia 101 – how to infuse in an outdoor environment."

Like his favourite animal, the wolf, Nicholas loves being out in the wild, enjoying the independence. "I always tell patients, 'Don't be afraid to go outside into the wild. Don't sit on your computer all the time – you can go outside and actually infuse in a non-sterile environment." With a wide smile he says, "My goal is to get them outside and show them that haemophilia doesn't limit them but that they can limit haemophilia." And that is a life lesson worth sharing.

Reaching new donors

Plasma collection is the foundation for our work and, in 2019, Octapharma further expanded its network of plasma donation centres in order to reach a growing number of donors. But what exactly does opening a new donor centre mean in practice?

We looked for answers to this question in conversations with USA-based Octapharma Plasma, Inc. (OPI) leaders Alice Stewart, Bill Griner, Carole Michelson and Jonathan Prater.

Did you know?

45–90 mins

A donation session takes between 45 and 90 minutes.

300–880ml

Between 300 and 880ml of plasma is taken for each donation.

61%

Males constitute 61% of Octapharma source plasma donors.

Donors are fundamental stakeholders

At Octapharma, patients are our ultimate stakeholders; but our donors are clearly also fundamental stakeholders in the business. Carole Michelson, Senior Director of Operations, Centre Development, notes that: "Donors are our fundamental stakeholders – plasma-based therapies are dependent on people being willing to donate. I always thank the donors for coming in."

Plasma is central to our business, with 80% of our supplies coming from company-owned donation centres. In 2019, continuing the significant investments of recent years, we invested heavily in our plasma collection facilities. In the past few years we have more than doubled our fleet of plasma donation centres.

Expanding our network

"It's important to remember that our business is built upon donors volunteering to help us," says Jonathan Prater, Senior Director of Operations. "In order to ensure the future supplies of our life-saving products for patients, we need donor volunteers. Therefore, we need to ensure the right places for our donation centres."

Jonathan and his team in North Carolina, USA, are responsible for the site selection process for new centres. They make a basic reconnaissance of a potential location by analysing several demographic data sets, always looking for sites which best fit the needs of the organisation and which – of course – offer easy access for new donors. But, as Carole adds: "Many times, new donation centre launches depend on myriad details determined by external factors, and coherence and efficiency are vital elements to succeed."

Bill Griner, who runs the Operations and Marketing team, also plays a vital role in the process from the outset. Bill and his team are heavily involved in market analysis, as well as creating ambitious marketing strategies, goals and objectives for new centres.

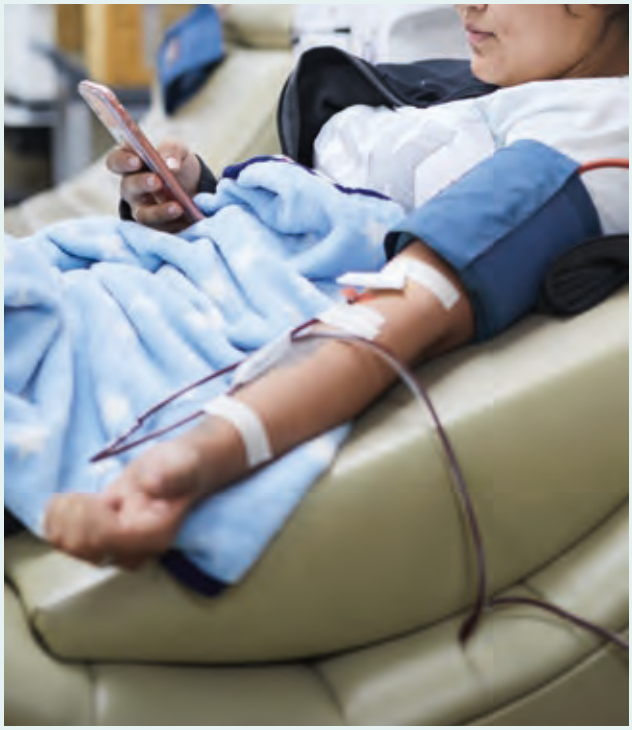
> For Bill, "Clarity and prioritisation of what will make a launch a success, as well as differentiating it from the competition, are paramount elements when carving out a market strategy for a new centre."

Bill's team knows that meeting ambitious goals requires everyone's continued commitment and strong collaboration across the organisation, as well as audacity and expertise. He explains that, beyond the core Octapharma values, OPI leaders aspire to create a culture in which teams feel inspired. "We work in a culture in which leaders serve their people from the bottom up by setting clear goals, removing obstacles and empowering their teams."

From left to right: Carole MIchelson; Jonathan Prater; Alice Stewart; Bill Griner.

"The new donor management system is the 'brain' of OPI from a system perspective. We know how much hard work and effort has gone into this."

Alice Stewart
Senior Director of Operations & Supply Chain, OPI



Building a strong team

Opening and maintaining a new donation centre is not an easy task, demanding a coordinated effort which affects every department at OPI. As well as managing a dedicated team driving the process from the initial site selection to opening a donation centre, Carole also oversees training for employees. "My job is to create open and inclusive environments that are productive and where people come to work thinking they can be the best version of themselves," she notes, adding: "and with the right people on board, we can create a culture that can be our unique competitive advantage to drive business and innovation for patients."

Managing data: OPI's brain

Besides expanding its network of plasma donation centres, Octapharma has also invested in state-of-the-art collection devices and operating systems. The result for the organisation is that OPI is now equipped with a new donor management system which captures data for all collections in every centre. The project was begun just one year ago and was successfully completed in 2019. "It is the 'brain' of OPI from a system perspective," says Alice Stewart, Senior Director of Operations & Supply Chain, adding: "We know how much hard work and effort has gone into this."

Every donor is registered on the new system, which records their full name and other relevant information. The new system supports other donation centre systems also in place to manage quality, safety and traceability.

Delivering such a complex system in a short period of time, while maintaining existing systems, was a massive challenge. The completion of the project was only possible because of the outstanding collaboration of the various implementation teams, who achieved their success through sheer hard work whilst always focusing on the wider Octapharma vision of 'providing new health solutions advancing human life'. "This collaboration has been one of the critical success factors of OPI and is something we are proud of," says Bill.

Putting patients first

At the heart of every donation centre – whether long established or newly opened – there is an unwavering commitment to our patients. It is a powerful motivation for our more than 4,200 passionate and dedicated OPI employees who successfully navigate more than 20,000 donors across the USA every day.

> As Carole puts it: "If we believe in ourselves and do what is correct according to our conscience, taking ownership for our actions, success is more likely to follow. Patients are at the heart of everything we do."

And this message is a powerful motivation for our donors. "Donors express many different reasons for donating. Some give plasma to earn supplemental income, others donate to save a life, and still more donate because they have either been a patient, or know someone who has benefited from the medicines we help make," says Jonathan, adding: "And there are countless stories of patients who use our products and are able to live better lives. And all of those stories are incredibly inspirational!"

Every donor is registered on the new system, which records their full name and other relevant information.

Creating a positive impact is what Octapharma is all about

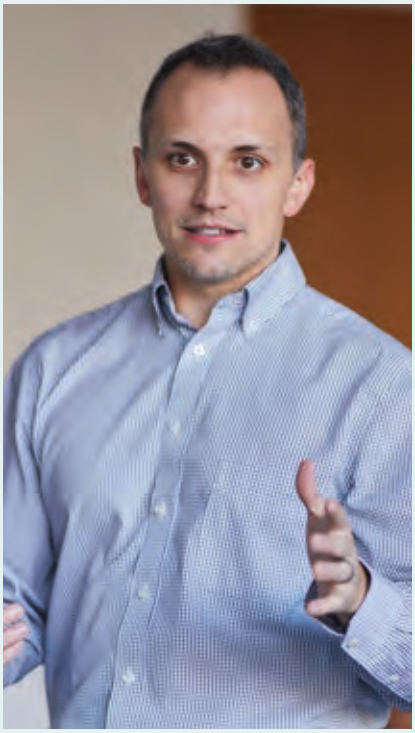
Our goal at Octapharma is to build an agile organisation that cherishes and celebrates each individual in order to produce a lasting, positive impact – on our patients and our donors, on healthcare professionals, on the wider community, on our fellow employees and, ultimately, on the business itself.

Claremont Moyo
Divisional Director of Operations, Octapharma Plasma, Inc., Charlotte, North Carolina, USA

As a Divisional Director of Operations, I work through the Regional Directors to ensure that donation centre compliance and performance objectives are met. My team is responsible for delivering a better donor experience. We set ambitious goals and, to live up to them, we take ownership for our actions. Within my team, I aspire to create a culture in which everyone feels inspired and empowered. I believe that when a high level of **ownership** is present in our team, it shows that you can be trusted to do the right thing, even when you're not being watched.

Anna Rowe
Senior Automated Systems Analyst, Genesys team, Omaha, Nebraska, USA

To me, the value of **integrity** means balancing your personal morals and work ethic with truthfulness and accuracy. Integrity is evident when opening a new donation centre because all the information that is entered into our systems is expected to be accurate right from the start. It all has a ripple effect and if my part of a centre set-up is inaccurate, anything that stems from it has the potential to be inaccurate as well. Knowing that my part in the process affects others doing theirs – and that they are trusting that my information is correct – keeps me motivated to double-check entries and verify that a centre set-up is 100% right.



Patrick McFall
Human Resources Recruiter, Corporate Office, Charlotte, North Carolina, USA

Leadership means putting your faith in someone. I believe we can only reach our full potential if we can create safe and stimulating work environments. That means that leaders should empower their teams to progress beyond where they thought they could originally take themselves – which, at the same time, also helps to encourage leaders to develop themselves. When done effectively and successfully, everyone wins and improves while accomplishing a shared goal.

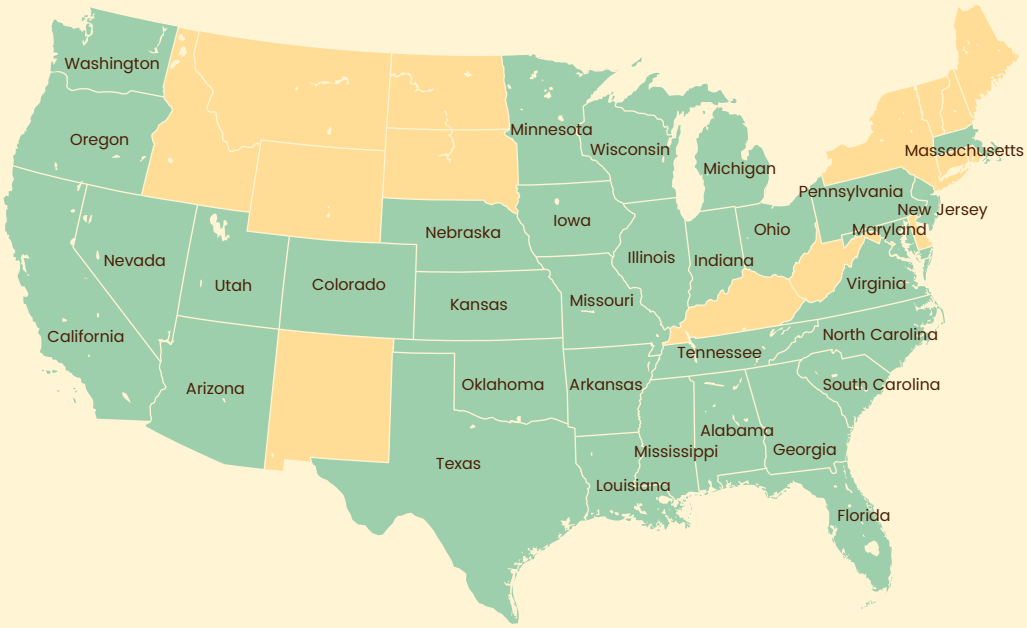
Amanda Keller
Manager of Automated Systems Support, Genesys team, Virginia Beach, Virginia, USA

As the Manager of Automated Systems Support responsible for leading initiatives to improve the efficiency of centre systems, **sustainability** for me means remaining relevant at all times. I operate with the understanding that the only constant is change. The key premise is thinking out of the box and looking at the big picture in order to anticipate future challenges and being more proactive instead of reactive. It does not mean getting things done, no matter what – it means staying efficient and effective.

Joel Arnold
Regional Director of Operations, Nashville, Tennessee, USA

The way we interact with each other and feel connected to the vision of Octapharma will determine our business success. Therefore, as a Regional Director, I focus on hiring and developing the right people to set a culture of growth, development and compliance, but also a culture in which we can be our best selves – personally and professionally – and help make Octapharma a great place to work. For me, **entrepreneurship** means that I hold myself and my team 100% accountable for hitting our goals and inspiring every employee with our vision for growth and success.

From coast to coast



>20,000
donors a day

>4,200
employees

States with Octapharma donation centres

During 2019, we invested heavily in our plasma collection capacities to ensure the future supplies of our life-saving products for patients.

Expanding across Germany

>1,800
donors a day

>540
employees

Regions with Octapharma donation centres

Plasma is central to our business, with 80% of our supplies coming from company-owned donation centres.

Why worry?

"Stick to your medication plan and keep your antibody level high. There are definitely more 'annoying' diseases than these."

Arne (21)
Germany

Did you know?

400

PIDDs are a group of more than 400 rare, chronic disorders in which part of the immune system is missing or functions improperly.[6]

1 in 200,000

XLA occurs in 1 in 200,000 newborns. The basic defect in XLA is an inability to produce antibodies.[7]

1–2 months

Children born with XLA are usually healthy for 1–2 months, being protected by antibodies acquired before birth from their mother.[7]

Arne is a typical 21-year-old who enjoys having fun and spending time with his friends and his girlfriend. But he is also living with a rare disease – diagnosed when Arne was just two years old.

A few days before Christmas 2001, Arne's mother, Kerstin, noticed that her toddler was not feeling well. He was not acting like his usual curious, energetic self but instead was lethargic and cranky. And he did not want to be touched, which was not like him; usually Arne was very cuddly.

The family was preparing for the festivities in their home town in northern Germany. Christmas dinner was going to be at Arne's grandparents' house, but Kerstin insisted they have it at home instead because she felt Arne would be more comfortable in his own bed. Immediately after Christmas, she was going to take him to the doctor but, two days before Christmas Eve, Arne's fever seemed to break and Kerstin was hopeful that things might be getting better.

However, he remained lethargic and, at noon that day, Kerstin was sitting on the sofa with Arne when he was suddenly sick. She noticed blood in the vomit, and immediately she and her husband drove Arne straight to the nearest hospital. The short journey seemed to take forever.

From pneumonia to XLA

Arne had pneumonia. The normally playful boy, just short of his second birthday, was missing his usual sunny demeanour and having great difficulty breathing. For the next few months, his condition would improve and then worsen again, a cycle that was very difficult for his parents to witness. During this time, Arne seemed to have intense pain throughout his whole body, as well as dry coughs, fever and joint pain with inflammation in his wrists and hips. "Because of this, I just sat down, even though I had already learned to walk," recalls Arne. The once bouncy toddler had lost the ability to run, walk or even crawl.

It was six months before he was eventually diagnosed with X-linked agammaglobulinemia (XLA) – a primary immunodeficiency disease (PIDD). The diagnosis was a very difficult moment for the entire family.

PIDDs are a group of more than 400 rare, chronic disorders in which part of the body's immune system is missing or functions improperly. XLA is the most common PIDD, characterised by a low concentration of antibodies in the blood due to the lack of particular lymphocytes in the blood and lymphatic system.

After diagnosis and treatment, Arne learned how to sit, crawl and walk again, and his affectionate nature and his smile returned. To begin with, he was on intravenous immunoglobulin therapy but then, aged nine, he was switched to gammanorm®.

Designs on life

Witty, smart and a little bit chaotic – these are the three attributes Arne uses to describe himself today. As he rides the bus to his first class of the week at the Bochum University of Applied Sciences where he studies mechatronics, Arne's mind is already racing. "It's as if my brain has arrived in class before my body. I'm already thinking about how to engineer the next assignment I'm working on," says Arne with a smile, before continuing:

> "We don't realise it, but we use something created by mechatronics engineers every day."

When Arne was a child, he discovered his passion for science and technology. Watching his father fix a microwave oven or a moped, he would study the principles of motion, energy and force involved. "I've always been interested in technology and how it works. I'm amazed by its uses in everyday life – from something as simple as just turning on your TV or heating your food in the microwave," says Arne, adding: "For instance, look at the iPhone. It symbolises the pinnacle of design, a device that's one of the greatest technological advancements of the 21st century."

“I’m able to do everything I imagined”

Although he has a PIDD, Arne has been able to lead a relatively normal life without any special restrictions. “I’m able to do everything I imagined,” says the 21-year-old lover of football and the rock band Linkin Park. “Thanks to gammanorm® I can travel, study, do sports or just hang out with my friends.”

Arne has an easy-going attitude. But that doesn’t mean he’s careless; he’s just a fun guy to be around. “When I visited Brazil three months after my graduation, I lived with a host family,” he explains. “It looked a bit challenging to organise my medication abroad, but in the end it worked out perfectly. So, why worry?”

While Arne has his health back, he continues to think about other people also diagnosed with a rare disease. Sometimes he wonders how differently things would have been if he had been diagnosed later in life. And he also wonders what he would say to someone else with XLA. “I’d probably tell them that despite the disease you can lead a relatively normal life,” he says, thinking out loud. “Stick to your medication plan and keep your antibody level high. There are definitely more ‘annoying’ diseases than these,” he adds with a smile.

Always on the go

"You have to maintain a positive mind-set and decide if you are going to live your life being sick or do everything you can to be well."

Laurel (55)
Chicago, USA

Did you know?

1 in 25,000

CVID is a relatively common form of primary immunodeficiency, found in about 1 in 25,000 people.[8]

A later diagnosis

Around 80% of CVID sufferers are diagnosed in their 30s or later in life.[8]

Zebras

When you hear the sound of hooves, you most likely think of a horse, not a zebra. PI patients identify with zebras, as their diagnosis is often difficult due to a focus on more likely diseases.[9]

Clinical nurse educator (CNE) Laurel has little time to rest when she is travelling the country to meet healthcare professionals and educate them about subcutaneous immunoglobulin therapy and primary immunodeficiency diseases (PIDDs). Whether in New York, Los Angeles or Chicago, Laurel keeps going, as she knows first-hand how important education and advocacy can be for each and every patient.

Sitting in an airport, waiting for a flight is a weekly experience for Laurel. This vibrant and energetic CNE is accustomed to the congested highways and airports of the USA's largest cities. Late into the night, Laurel combs the primary immunodeficiency (PI) social media support groups, answering questions and providing encouragement to patients. Driven by passion and purpose, she is determined to make an impact on the PI community or to simply help a single person cope or understand their diagnosis, treatment and management.

Spreading the word

"I am used to the hectic rhythm," says Laurel, who was born and raised in Chicago, and lived in South Florida for 20 years. She joined Octapharma in April 2019. As part of her job, she regularly meets with medical staff, pharmacies and patients, helping to advance knowledge and understanding of PIDDs and immunoglobulin therapy. "As a CNE I spend most of my time in the field," Laurel says. "The immunologists and other healthcare professionals that I meet are knowledgeable about PI, but often lack awareness and insight of the impact that PI has on the individual – how personal lives are impacted, the challenges and what it takes living with this diagnosis."

Her interactions and education bring a unique perspective, as Laurel herself was diagnosed with the rare disease known as common variable immunodeficiency (CVID) only a few years ago.

Years of not knowing

Laurel was 49 years old before doctors finally confirmed her CVID diagnosis. Like many other patients, she had spent many years of her life since childhood under the care of multiple specialists without getting an accurate diagnosis to explain the root cause of her recurring illnesses. Unfortunately, a common thread prior to a PI diagnosis is shaming: "My physician and multiple specialists accused me of malingering and attributed my health status to lifestyle issues: work, sleep, diet, exercise and stress," remembers Laurel.

All the time, her doctors were distracted, only treating individual symptoms. Laurel experienced hallmark symptoms of PI: recurrent ear, sinus, respiratory, skin and urinary tract infections, and systemic inflammation, yet no one thought to look at her immune system. But, most significantly, she developed recurring inflammatory breast disease. Her surgeons were perplexed and giving up hope. In one year, Laurel underwent three surgeries and two hospitalisations. Although she did not have cancer, she required a mastectomy and, as a result, she had to stop working because her body was so taxed. "It was exceptionally challenging to cope with being so sick, forced to abandon my career and imagine what my future will hold," she says today.

"But I always had a strong will and was determined to put the puzzle pieces together, turn it around, so that I could live my best life."

Looking back at her medical records, Laurel now knows what was not obvious at the time: somebody should have said, "Why don't we look at her immune system?"

Life-changing diagnosis

The explanation for her infection and fatigue finally came when she was working as a clinical director of operations for a home care company that subcontracted intravenous immunoglobulin (IVIg) nurses for specialty pharmacies in South Florida. Laurel realised that the clinical paths of many of the patients she encountered had a similar history to her own. She immediately contacted a prominent clinical immunologist who, after seeing her, initiated the three-month diagnostic process which confirmed the primary immunodeficiency: CVID. "Confirmation of my suspicion was still a shock, but I was relieved, because finally there was validation of the root cause and available treatment for all that stuff that was going on in my body," recalls the 55-year-old.

Laurel now dedicates much of her time to reading scientific abstracts and attending immunology conferences to fully understand current research trends in the diagnosis, treatment and management of PIDDs. PIDDs are a group of more than 400 rare, chronic disorders in which part of the body's immune system is missing or functions improperly. Some patients are more prone to recurrent infections while others have a deregulated inflammatory process which


octapharma


I AM A
ZEBRA!

makes them prone to auto-inflammation and auto-immune diseases. The treatment for PIDDs is life-long intravenous or subcutaneous immunoglobulin infusions to replace the missing or defective antibodies.

For the first two years after being diagnosed, Laurel received IVIg infusion therapy. But things got complicated. "I had adverse reactions. I couldn't go to work for days following my infusions. It was depressing," she remembers. Her doctors advised her to apply for disability support and referred her to the National Institutes of Health for genetic testing and consideration of a stem cell transplant. Laurel was strong and told herself: "You have to maintain a positive mind-set and decide if you are going to live your life being sick or do everything you can to be well." She decided to put in the effort and reclaim her life.

Facing life's challenges

Although it took some time for Laurel to bounce back, she was not willing to give up. Now she takes cutaquig®, a subcutaneous immunoglobulin (SCIg infusion. She administers the infusions independently, at home or on her travels. "SCIg was a life changer for me," she says. "I have no systemic side effects and I no longer require steroids and IV fluids pre/post infusions to mitigate adverse reactions, and very rarely have site reactions. Finally, I am able to plan the infusions around my life and schedule, instead of needing to plan my life around the scheduled infusions."

She feels invigorated and satisfied when, in the discussions she holds with patients, she hears stories about how doctors have been able to help them. Her positive attitude has helped her to pursue a career with purpose, and maintain good relationships with her family and all of her friends and colleagues over the many difficult years of the disease.

Before closing her suitcase, she sits for a short time at the edge of her bed and tells herself: "I will not let PI steal my life; I am not my diagnosis. I'm flying over the country to help my PI folks. I'm going to make the most out of all my challenges and experiences. No whining, Laurel!"

Testing boundaries

For Octapharma, viral safety and viral clearance evaluation have always been high-profile areas for product safety. So, more than two decades ago, finding the best possible way to ensure viral safety was a clear goal for the company. It was in this context that Octapharma introduced PCR testing.


ATG CAA
Control material

Did you know?

1993

The PCR testing method was recognised with a Nobel Prize in Chemistry in 1993.[10]

1994

Octapharma was a pioneer in performing viral safety tests using PCR testing tools to check for HAV, HCV and HIV viruses.

1997

Octapharma established its first PCR testing laboratory in Frankfurt am Main in 1997.

Polymerase chain reaction (PCR) is a complex yet effective method to copy or "amplify" small segments of DNA or RNA. Recognised with a Nobel Prize in 1993, PCR testing is still the most relevant nucleic acid amplification technology (NAT) test used for the diagnosis of pathogenic viruses or bacteria.

The office of Thomas Gärtner, Head of Corporate NAT Operations, looks almost like an inventor's laboratory. The walls are plastered with sketches of diagrams and DNA sequence figures, and his desk is covered with piles of technical manuals, reports and regulatory files which he frequently consults. But Thomas, who is also a passionate badminton player and nature lover, has anything but a chaotic mind. As a biologist who wrote his doctoral thesis on the expression of oncogenes in insect cells and the characterisation of proteins, he enjoys immersing himself in detail, without losing the wider perspective. He aims to achieve his goals with precision, efficiency, accuracy and elegance. And he also expects this from his team.

Ensuring viral safety

When Thomas joined Octapharma in 1994, the company was faced with a challenge that had kept plasma fractionators and the pharmaceutical industry busy since the 1980s: how to find the best methods and procedures to reduce the risk of virus transmission through plasma proteins and ensure the highest level of viral safety.

For Octapharma, viral safety and viral clearance evaluation have always been high-profile areas for product safety. So, more than two decades ago, finding the best possible way to ensure viral safety was a clear goal for the company. It was in this context that Octapharma introduced PCR testing.

Top left: Ulrike, Christiane and Thomas, together with their teams, ensure viral safety at Octapharma.

The techniques and methods used in the 1990s for PCR testing were very time-consuming. "Often two consecutive runs were used, known as nested PCR," remembers Thomas. "Nested PCR is a modification of PCR that was designed to improve sensitivity and specificity, involving the use of two primer sets and two successive PCR reactions."

The other challenge that many industry players were facing was that there were no common regulations for PCR validation. In addition, companies had to define their own in-house standards. "With no standardisation of PCR tests and methodologies, there was a risk you didn't get acceptance from the authorities," explains Thomas. "Fortunately for Octapharma, we were working with our own state-of-the-art standards and materials."

Courage in our blood

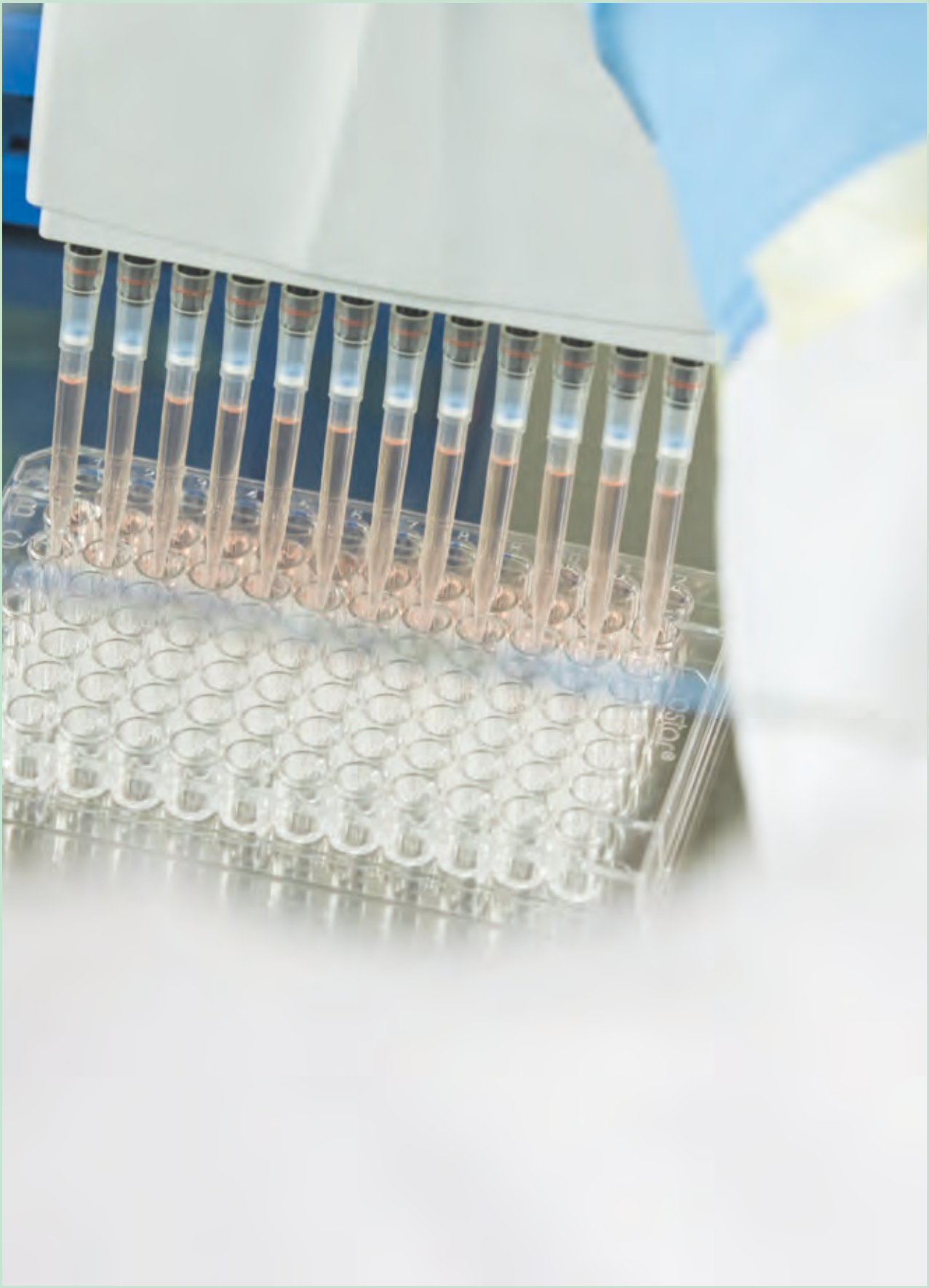
Back in 1994, Octapharma was a pioneer in performing viral safety tests using PCR testing tools to check for the hepatitis A and C viruses (HAV and HCV) as well as for HIV. "In the beginning, I shared the laboratory space with my former PhD colleagues and other staff members from Georg-Speyer Haus (GSH)," he recalls. "Later on, in 1997, Octapharma launched its first PCR testing laboratory in the GSH building in Frankfurt am Main."

In that same year, the company made significant strategic investments to develop in-house testing applications using the Nobel Prize-winning technology and the next step for Octapharma was to assemble a strong team of technicians. With the technicians on board, the team was now able to develop and validate in-house PCR systems. "This was a huge success for all of us," says Thomas. "Octapharma demonstrated that entrepreneurship, ownership and courage are in our blood."

Meeting the challenge

In 1999, PCR testing of plasma pools for HCV became a regulatory requirement. In close partnership with Thomas, the company's PCR testing methods were validated and approved by all major regulatory authorities around the world. Indeed, PCR testing became a standard tool for testing for the presence of bloodborne viruses in human plasma and the PCR laboratory performed the first analyses for batch releases of Octapharma products.

By the late 1990s, new advanced PCR techniques were also introduced, such as the TaqMan method, "an elegant and reliable real-time technique," explains Thomas. Overall, the TaqMan method was much faster and evaluation was more sensitive, precise and less laborious.




-82°C

As Octapharma expanded, so did the work of the PCR testing team. In addition to the Vienna site, the company acquired production sites in Lingolsheim, France, Stockholm, Sweden and Springe, Germany, and plasma samples from all sites were sent to Frankfurt for PCR testing. Due to the increasing number of analyses, by 2005 it was time for the PCR team to relocate to larger facilities in the Frankfurt Biotechnology Innovation Center (FiZ). Since that time, the portfolio of work undertaken using the PCR method has continued to grow.

Today, Octapharma routinely performs PCR testing on all plasma pools for HIV, HAV, HBV and parvo B19 viruses, as well as for HCV. In addition to these tests at the plasma pool level, every individual donation is also tested.

Taking pride in their work

Occupying the spacious facilities of FiZ, Thomas and his team have managed to install a full range of equipment, from automated extraction robots to real-time thermal cyclers and other modern lab equipment. But it is here that the dedicated Octapharma PCR team works vigorously to provide the best viral safety for our medicines at the beginning of the drug production process.

Ulrike Brandt, who joined the team in 2014, is responsible for the PCR lab support team. "Our job is extremely versatile. We focus very much on viral safety and expect high-quality controls. Clear and targeted communication, persistence and a strong understanding of Good Manufacturing Practice rules are the keys to our success," explains Ulrike.

Christiane Beckort, Research Specialist, Method Development & Validation, who joined the team more than 20 years ago, considers attention to detail and team spirit to be the secret behind the success of the PCR team.

For the past two decades, the PCR team has always delivered on time, whilst implementing sustainable PCR methods and achieving very good results in all proficiency studies. "Today, more than 20 years after the launch of the first Octapharma PCR laboratory, we can safely say that the team has taken up the challenge of viral safety and mastered it. Everyone involved can be more than proud of their work," concludes Christiane.

Octapharma routinely performs PCR testing on all plasma pools for HIV, HAV, HBV and parvo B19 viruses, as well as for HCV.

The story of fibryga®

"If you ever needed proof that Octapharma is a company with the courage to take a calculated risk and invest in science to develop new medicines that could save the lives of patients with bleeding abnormalities, then this AFD project is it."

Dr Sigurd Knaub
Senior Vice-President of Clinical
Research & Development Haematology

Did you know?

400 BC

Physicians first noted the presence of fibres in blood more than 400 years BC.[11]

Phase 3 trial

A phase 3 clinical trial is the final confirmation of the safety and efficacy of a new treatment for approval in a particular clinical indication.[12]

The 2011 launch of the clinical trial to investigate the use of fibryga® in congenital fibrinogen deficiency was the start of a clinical development programme in a very rare disease. But it also became an early step in one of the most audacious clinical programmes which Octapharma has conducted, targeting acquired fibrinogen deficiency (AFD).

AFD is caused by high blood loss due to, for example, major surgery or trauma. With no other alternatives, AFD is treated with cryoprecipitate in many countries around the world and thus there is a high medical need for a fibrinogen concentrate approved in this indication. The ambitious goal of this programme was to show that fibryga® is at least as effective as cryoprecipitate for AFD – and is a more practical and reliable alternative to it. Eight years on, and after the detailed design, planning and conduct of clinical trials by a dedicated Octapharma team, fibryga® has now been approved for use in AFD in 15 countries of the EU.

This approval extends the original 2017 marketing authorisation for fibryga® for use in congenital fibrinogen deficiency. Other major markets are planned to follow.

"If you ever needed proof that Octapharma is a company with the courage to take a calculated risk and invest in science to develop new medicines that could save the lives of patients with bleeding abnormalities, then this AFD project is it," says Sigurd Knaub, Senior Vice-President of Clinical Research & Development Haematology.

Members of the dedicated Octapharma fibryga® team.

The appliance of sound science

Fibrinogen, also known as factor I, is a naturally occurring blood plasma glycoprotein. It is essential for blood clot formation and stops excessive bleeding resulting from various injuries and traumas, or during surgery. Reduced or dysfunctional fibrinogen occurs in various congenital fibrinogen-related disorders. However, unlike in congenital fibrinogen deficiencies, AFD arises due to consumption of fibrinogen reserves after excessive blood loss.

After fibryga® obtained regulatory approval in the USA, Canada and the EU in 2017 for the treatment of very rare congenital fibrinogen deficiencies (with further approval obtained in Switzerland in 2018 for both acquired and congenital fibrinogen deficiencies), clinical initiatives continued with FORMA-05, the first new clinical study in AFD.

The rationale for the FORMA-05 study was to investigate whether a fibrinogen concentrate is an effective alternative to cryoprecipitate in a model indication of AFD. "We wanted to develop a practical and safe alternative to cryoprecipitate," explains Sigurd. "In many parts of the world, patients are still treated with cryoprecipitate, as a fibrinogen concentrate is not licensed for AFD. Cryoprecipitate is less pure, contains several coagulation factors, and a higher volume is required than for fibrinogen concentrate. Furthermore, cryoprecipitate is not virus inactivated with a higher risk of virus transmission."

The FORMA-05 clinical study was a prospective, randomised, single-blind, controlled, non-inferiority study which compared the efficacy of fibryga® to that of cryoprecipitate during cytoreductive surgery to treat pseudomyxoma peritonei, a rare cancer that usually starts in the appendix. This major and complex surgical procedure is associated with extensive blood loss and patients are at high risk of developing AFD.

The trial process was arduous but "where others experienced setbacks and gave up, we had the courage to continue with an excellent and experienced team at the study centre," remembers Sigurd. The results of FORMA-05 were encouraging, indicating non-inferiority against existing therapies, with several advantages.

Patient benefits in multiple surgical indications

Meanwhile, for Sigurd and the team involved, work continued at a fast pace. In 2017, Octapharma started discussing another study using fibryga® in cardiac surgery with a group of Canadian physicians led by Dr Keyvan Karkouti in Toronto, Canada. Further discussions of the final study design with Health Canada led to the launch of the investigator-initiated FIBRES trial, a multi-centre, single-blind, randomised, comparator-controlled confirmative trial conducted to assess the non-inferiority of fibryga® compared to cryoprecipitate in patients undergoing cardiac surgery. In fact, this study was stopped early at a pre-planned interim analysis as the primary endpoint was already met.

Werner Gehringer and Petra Schulz, senior scientists.

"It was the largest study ever made with a fibrinogen concentrate comparing cryoprecipitate against our product. And again, the endpoint was non-inferiority," explains Sigurd, adding: "This confirmative phase 3 study has basically achieved what no other trials in patients with an acquired coagulation disorder has achieved with a single product, showing efficacy in a complex indication."

An eventful development journey

Clearly, the entire development and approval process was an eventful journey. "I think with every development journey there are challenges, but probably even more so with a unique project like this one," remembers Petra Schulz, a senior scientist. "But," adds Petra, "looking back, the rewards and satisfaction are great if you have been willing to pioneer something you really believe in and it pays off."

"Finally we succeeded in providing a product of very high purity, safety and efficacy with important and attractive properties," says Werner Gehringer, senior scientist, who was a member of the team from the outset.

So what got the team through these challenges?

The entire team – including research teams in Vienna, Austria, Frankfurt and Berlin, Germany, and production, quality, pre-clinical, clinical, marketing and regulatory affairs teams – has always had a very good identity and a feeling that they are doing something really worthwhile. "Many people have commented what a great team this is. We trust each other, we stick together. I believe that has been fundamental to keeping the programme on track and it is something everyone can feel very proud of," says Sigurd.

Although they experienced a few sleepless nights, with endless discussions internally and externally, and with inevitable resourcing and project management pressures, no one gave up.

"After so many years, it is gratifying to see that we have reached the point where we are today," says Werner. "I'm very excited. We all are! Our ultimate goal is to improve the lives of patients.

Dr Sigurd Knaub, Senior Vice-President of Clinical Research & Development Haematology.

Trust and decision making

"I think it is a great honour to be a doctor and see the lives of our patients years later."

Gennadiy (59)
Moscow, Russia

Did you know?

Critical care

Critical care is the management of patients in a critical state of health.

Interdisciplinary usage

Plasma and plasma-derived products are used by a range of medical specialists treating critically ill patients, including anaesthesiologists, intensivists and emergency physicians.

Reversal of anticoagulation

Rodenticides are pesticides that kill rodents. Many of them e.g. bromadiolone, chlorophacinone, difethialone and warfarin are anticoagulants, meaning that they stop normal blood clotting by restricting the availability of vitamin K, essential for coagulation. PCCs, like octaplex®, help doctors to revert the action of vitamin K antagonists and restore haemostasis.[13]

Trust, swift decision making and excellent medical skills are a priority for intensive care.

Every day, throughout the world, mass casualty situations happen due to both natural and man-made events, and severely injured casualties often end up in hospital intensive care units (ICUs). At the same time, every day, there are also patients in life-threatening condition being treated in ICUs. There is precious little time to waste. Mutual trust, swift decision making under pressure and excellent medical skills are essential for specialists and other medical staff in ICU departments.

Gennadiy Galstyan, MD, PhD, who heads the Department of Intensive Care at the National Research Center for Hematology in Russia, tells us about his working day and about his personal challenges and successes in improving patient care.

Driven to help

You might think that seeing dozens of patients every day would sap the mental and psychological energy needed for any sort of personal reflection. But, in his 30-year career, each experience seems to have taught Gennadiy Galstyan something new and motivated him yet further, and he never seems to have tired of caring for patients.

> Every morning he tells himself: "I can make a difference to somebody's life." In practice, for the Professor this means always giving his best, so that "at the end of the day I can say, 'Yes, you did well.'"

As head of the Intensive Care Department, his skills are constantly tested. "There was this one boy, almost 30 years ago. At that time, he was four years old and he had acute leukaemia. I transferred him to the ICU," Professor Galstyan remembers vividly. "It was a very difficult moment for the entire family. The boy was in a serious condition", he adds. The entire team did everything to stabilise the child and provide the best treatment for him. Leukaemia needs continuous treatment for up to three years, or it can come back. He recalls that "we weren't sure if he would survive". But he did – and Gennadiy adds that he has now grown to become a young man with an impressive career as a renowned lawyer in Russia. It makes him proud when a patient whom he once treated is now living a fulfilling life: "I think it is a great honour to be a doctor and see the lives of our patients years later."

ICUs of the future

Professor Galstyan can look back on great improvements that have been made in the number and quality of ICUs in the country during the past three decades, from improvements in life-sustaining technologies to therapeutic treatments. As a result of broad discoveries in critical care treatments, the curve of life has been extended. As Gennadiy remembers, 30 years ago septic shock in neutropenic patients was not a diagnosis, it was a death sentence. "It was the same situation with mechanical ventilation. Nowadays, we successfully treat half of the patients," he says. He hopes that medical and scientific advancements will continue to increase and doctors will be able to treat most of their patients.

Gennadiy also believes innovation can change the paradigm of disease treatment, whether that be from cryoprecipitate to FVIII treatment, or from plasma to prothrombin complex concentrates. "Thirty years ago we used only blood components, such as cryoprecipitate, fresh frozen plasma or native plasma concentrate," he recalls. This has all changed now. "For instance, in our ICU for oncohaematology, in the past two years we have been using octaplex®, a prothrombin complex concentrate (PCC) which contains clotting factors II, VII, IX and X for patients with haemorrhagic disorders," he explains. "Octaplex® is faster, safer and logistically simpler than our only other option: plasma transfusion. Recently, we had a case of rodenticide poisoning where, thanks to octaplex®, we saved several patients' lives."

Reflection and learning have become my working habits

The more of an expert you become, the more your expertise is sought, and it is perhaps no surprise that many doctors – including Professor Galstyan – are also teachers helping to improve medical education in Russia. In addition to seeing patients, he is academically active at the Institute of Post Diploma Education for Anesthesiology and Intensive Care, Burnasyan State Research Medical Center, Federal Medical-Biological Agency of Russia. "I do scientific research, such as verifying resources and writing publications, as well as presenting at conferences," says Gennadiy. "It is gratifying to help train the next generation of doctors, just as my mentors did when passing knowledge to me, and sharing knowledge with my peers," he adds. "If you ask me who inspired me most in life, I would say my teachers in medicine."

Dozens of patients are treated in the ICU department every day.

United to advance human life

Standing, from left to right:

Josef Weinberger, Corporate Quality and Compliance Officer

Gerold Rempeters, Corporate Production Officer

Wolfgang Frenzel, Research and Development

Norbert Müller, Board Member

Flemming Nielsen, President, Octapharma USA, Inc.

Tobias Marguerre, Managing Director, Octapharma Nordic AB

Roger Mächler, Chief Financial Officer

Matt Riordan, Board Member

Seated, from left to right:

Olaf Walter, Board Member

Frederic Marguerre, Shareholders' Representative, President Octapharma Plasma, Inc., USA

Wolfgang Marguerre, Chairman and CEO, Octapharma Group

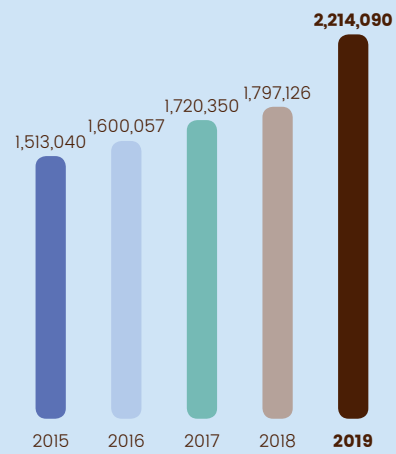
Judy Smith, Chief Operating Officer (Octapharma Plasma Inc.) & Board Member (Octapharma Group)

Continuing to invest in the future prosperity of Octapharma

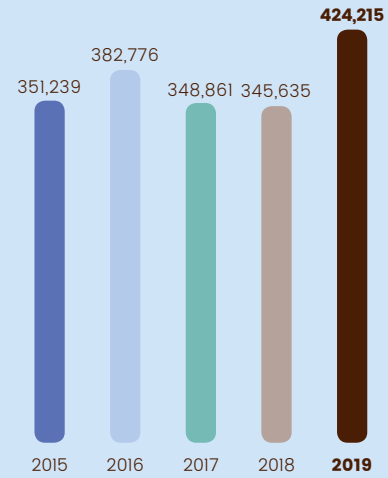
Roger Mächler
Chief Financial Officer

“Our significant investments in research and infrastructure strongly position the company to fulfil the future needs of even more healthcare professionals and patients around the world.”

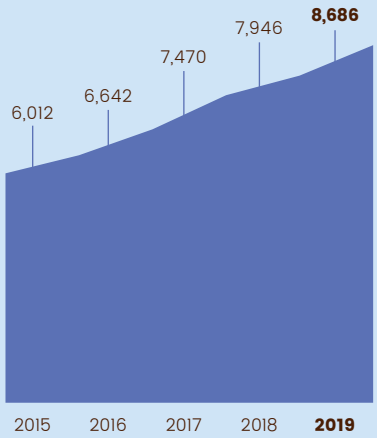
Revenue in 1,000 EUR



Operating income in 1,000 EUR



Average headcount



€424m
operating income

€2.2bn
revenue

23%
increase in revenue and operating income

The Octapharma Group has delivered a strong performance in 2019. Sales of €2.2 billion represent a significant achievement – and an increase of €417 million (23.2%) compared with 2018. Furthermore, our operating income has grown by 22.7% compared with 2018 to a record of €424 million.

Last year our products touched hundreds of thousands of patients globally. We have recorded a very strong year-on-year growth of our immunoglobulin product portfolio, as well as for albunorm®, Nuwiq® and fibryga®. Our continued strong sales growth would not be possible without effective collaboration across all divisions and regions, and the focus and commitment of all our employees and stakeholders.

Gross profit in 2019 was €783 million, which is €152 million more than achieved in 2018. Despite continued investments in production capacity to fulfil the growing global need for plasma-derived products, our gross margin increased by 0.3 percentage points to 35.4%.

Operating income was €424 million and profit before taxes €428 million. In the context of the corporate tax reform in Switzerland a deferred tax asset was created, which significantly reduced the Group's effective tax rate but did not impact actual income tax paid for 2019. Net profit for the year 2019 can be reported at a record of €403 million.

Net cash from operating activities was €257 million. The strong sales growth comes along with investment into working capital: trade receivables increased by €233 million after strong sales in the last months of 2019 and our net inventory increased by €96 million.

Our total operating expenses were €359 million. Significant investments were made both for our future prosperity in R&D and into the extension of our production capacity and infrastructure. Important milestones in the expansion and utilisation of our plasma and recombinant product portfolio became a reality in the last 12 months. To ensure each litre of plasma is optimally used, the company will continue to enter new markets and expand its portfolio with innovative new products and services.

Our investments in talent, equipment and property prepare the company for the demands of the future.

In 2020, our target is to continue turning these successfully implemented capacity extension projects into sales and operating profit growth of more than 10% while focusing on working capital management. This will allow us to continue investing independently in the future prosperity of Octapharma.

Our significant investments in research and infrastructure strongly position the company to fulfil the future needs of even more healthcare professionals and patients around the world.

Roger Mächler
Chief Financial Officer

Key figures of the Octapharma Group

(Monetary figures are in 1,000 EUR)	2019	2018	2017	2016	2015
Operating income	**424,215**	345,635	348,861	382,776	351,239
Operating profit margin*	**19.2%**	19.2%	20.3%	23.9%	23.2%
Net profit of the year	**403,445**	303,480	252,116	345,450	330,267
Return on investment*	**13.5%**	11.5%	10.2%	15.3%	17.0%
Year-end headcount	**9,307**	8,314	7,674	7,094	6,213
Profit from operations per employee*	**49**	43	47	58	58
Cash ratio	**120%**	174%	187%	180%	174%
Days of sales in receivables*	**141**	126	126	137	123
Days of inventory range*	**239**	250	217	218	227
Cash flow from operations	**257,180**	261,393	350,837	287,966	382,437
Expenditures to ensure future prosperity	**307,804**	240,183	287,197	249,611	242,383
Research and development	**75,748**	87,291	86,508	83,500	72,825
Capital expenditures and investments in activities	**232,056**	152,892	200,689	166,111	169,558

* Key figures are determined as follows:
Operating profit margin: Operating income/revenue
Return on investment: (Net profit of the year + interest expense)/average total assets
Profit from operations per employee: Operating income/average headcount
Days of sales in receivables: Trade receivables/revenue * 365
Days of inventory range: Average inventories/material - and production cost (part of cost of sales) * 365

Financial statements of the Octapharma Group*

Consolidated income statement of the Octapharma Group

(All figures in 1,000 EUR)	2019	2018
Revenue	**2,214,090**	1,797,126
Cost of sales	**-1,431,275**	-1,166,158
Gross profit	**782,815**	630,968
Research and development	**-75,748**	-87,291
Selling and marketing	**-202,357**	-135,643
Regulatory affairs	**-19,494**	-18,405
General and administration	**-63,812**	-60,845
Other income	**3,840**	17,626
Other expenses	**-1,029**	-775
Total operating expenses	**-358,600**	-285,333
Operating income	**424,215**	345,635
Non-operating income and expenses	**3,727**	229
Profit before taxes	**427,942**	345,864
Income tax	**-24,497**	-42,384
Net profit of the year	**403,445**	303,480

* The following summary financial statements are derived from the consolidated financial statements of Octapharma Nordic AB, Stockholm and comprise the summary income statement for the period from 1 January to 31 December 2019, the summary balance sheet and the summary cash flow statement for the year then ended, aggregating non-material financial statement captions.

Consolidated statement of financial position of the Octapharma Group

(All figures in 1,000 EUR)	2019	2018
Assets		
Cash and cash equivalents	**434,845**	502,153
Trade receivables	**854,992**	622,372
Other receivables and current assets	**67,590**	55,585
Loans granted	**96**	71
Derivative financial instruments	**1,129**	92
Inventories	**923,342**	827,276
Total current assets	**2,281,994**	2,007,549
Financial investments	**1,411**	1,370
Deferred tax assets	**103,798**	52,293
Loans granted	**738**	723
Property, plant and equipment	**973,890**	693,611
Intangible assets	**7,197**	0
Total non-current assets	**1,087,034**	747,997
Total assets	**3,369,028**	2,755,546

(All figures in 1,000 EUR)	2019	2018
Liabilities and equity		
Trade payables and other payables	**119,602**	103,616
Derivative financial instruments	**0**	1,620
Income tax payables	**44,236**	19,952
Short-term lease liabilities	**11,614**	1,648
Accruals	**151,049**	127,831
Current provisions	**36,279**	33,389
Total current liabilities	**362,780**	288,056
Deferred income	**2,008**	2,214
Provisions	**111,437**	87,321
Long-term lease liabilities	**177,787**	3,611
Deferred tax liabilities	**45,492**	33,780
Other non-current liabilities	**378**	172
Total non-current liabilities	**337,102**	127,098
Total liabilities	**699,882**	415,154
Share capital	**100**	100
Retained earnings	**2,665,738**	2,340,969
Currency translation adjustments	**3,308**	-677
Total equity	**2,669,146**	2,340,392
Total liabilities and equity	**3,369,028**	2,755,546

Consolidated statement of cash flows of the Octapharma Group

(All figures in 1,000 EUR)	2019	2018
Net profit for the year	**403,445**	303,480
Depreciation of property, plant and equipment and intangibles	**140,697**	104,834
Impairment of fixed assets	**3,233**	12,379
Change in fair value of non-current assets	**-55**	1,400
(Profit) loss on sale of property, plant and equipment and equity investment	**367**	-7,160
Changes in long-term liabilities and provisions	**13,684**	5,971
Finance costs	**9,520**	0
Tax expense	**24,497**	42,384
Unrealised foreign exchange (gain) loss	**-3,279**	-3,013
Cash flow before changes in working capital	**592,109**	460,275
(Increase) decrease of working capital	**-334,929**	-198,882
Net cash from operating activities	**257,180**	261,393
Acquisition of property, plant and equipment	**-213,629**	-152,892
Acquisition of subsidiary, net of cash acquired	**-18,427**	0
Change of financial and equity investments	**415**	16,759
Proceeds from sales of property, plant and equipment	**1,035**	718
Interest received	**1,012**	2,283
Net cash used in investing activities	**-229,594**	-133,132
Financing activities	**-78,450**	-112,241
Payment of lease liabilities	**-17,665**	0
Net cash used for financing activities	**-96,115**	-112,241
Net change in cash and cash equivalents	**-68,529**	16,020
Cash and cash equivalents beginning of period	**502,153**	485,600
Effect of exchange fluctuation on cash held	**1,221**	533
Cash and cash equivalents end of period	**434,845**	502,153

Report of the Independent Auditor on the summary financial statements

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REPORT OF THE INDEPENDENT AUDITOR ON THE SUMMARY FINANCIAL STATEMENTS

Octapharma Nordic AB, Stockholm

Opinion

The accompanying summary financial statements on pages 87 to 90, which comprise the summary balance sheet as at December 31, 2019, the summary income statement and summary cash flow statement for the year then ended, and related notes, are derived from the audited financial statements of Octapharma Nordic AB, Stockholm, for the year ended December 31, 2019.

In our opinion, the accompanying summary financial statements are a fair summary of the audited financial statements, on the basis described on page 87 of the annual report 2019.

Summary Financial Statements

The summary financial statements do not contain all the disclosures required by International Financial Reporting Standards (IFRS). Reading the summary financial statements and the auditor`s report thereon, therefore, is not a substitute for reading the audited financial statements and the auditor`s report thereon.

The Audited Financial Statements and Our Report Thereon

We expressed an unmodified audit opinion on the audited financial statements in our report dated February 14, 2020.

Management`s Responsibility for the Summary Financial Statements

Management is responsible for the preparation of the summary financial statements on the basis described on page 87 of the annual report 2019.

Auditor's Responsibility

Our responsibility is to express an opinion on whether the summary financial statements are a fair summary of the audited financial statements based on our procedures, which were conducted in accordance with International Standard on Auditing (ISA) 810 (Revised), *Engagements to Report on Summary Financial Statements*.

KPMG AG

Toni Wattenhofer Anna Pohle

Zurich, 14 February 2020

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1 https://www.wfh.org/en/our-work-global/vwd-initiative-program
2 https://elearning.wfh.org/elearning-centres/vwd/#what_is_von_willebrand_disease
3 https://elearning.wfh.org/elearning-centres/introduction-to-hemophilia/#hemophilia_treatment
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11 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4741261/
12 https://www.healthline.com/health/clinical-trial-phases#phase-iii
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