octapharma

# Imagine a healthier, better world

Annual Report 2018

Since 1983, we have imagined a healthier, better world. Every day, we strive to help hundreds of thousands of patients around the world, believing that together we can invest to make a difference in people's lives. At the heart of our business is our vision – our passion drives us to provide new health solutions advancing human life.



**Cover Page:** Brandon (30) diagnosed with haemophilia A. Read more on page 11.

**Content double page:** From left: The siblings Robin (16), Mariliis (25) and Kristopher (18) spending time together in Toila (Estonia).

What guides us

# Our values are in our blood

Our values are the code that guide us in what we do and how we do it. They govern our decisions and actions, help us form our relationships and run right through our business.

Our values have remained consistently the same since we started. They're in our blood.

**Ownership**
We do amazing things. We create products that allow people to live healthy lives all around the world; products that everyone at Octapharma has played a part in.

We take pride in the work we do. And we are proud of the colleagues we work with.

We are **committed responsible focused**

When assigned a new project, I like to be hands-on and understand every aspect. When the project is done, everyone involved, myself included, is highly accountable for creating a life-saving product.

**Anthony Truong**
Project Lead, Operations, Charlotte, North Carolina, USA

**Integrity**
We are who we are. Nothing more, nothing less. And we're nothing at all without the trust of our patients, donors and partners. They depend on us to know what is right, and to do it. They look to us for honesty, transparency and respect.

We are **reliable trustworthy respectful**

Integrity is doing what is right and correct, even though no one sees it.

**Johan Ekvärn**
Project Manager, Quality Unit, Stockholm, Sweden

**Leadership**
Leadership is often said to start at the top. But at Octapharma, everyone can be a leader. We can all strive to be the best at what we do. We all put our minds together to get the better of challenges we face. And we give our support to colleagues, encouraging them to be the best they can be, too.

We are **innovative goal-oriented inspiring**

Leadership is the willingness to push one's own borders, to move out of their own comfort zone. As a company to be successful and sustainable we need the critical mass of the right leadership with the right leadership skills.

**Martin Pichler**
Head of IT Centre, Vienna, Austria

**Sustainability**
Day to day, we sustain life and the quality of life for hundreds of thousands of people worldwide. It's what we love doing. And it's what keeps us going.

We sustain our business by focusing on the future: maintaining our supply of plasma donations; developing long-term outcomes for our patients, and anticipating their needs for the years to come. We build relationships that last. We get things right today so that tomorrow, and the day after, will follow.

We are **forward-looking empathic persistent**

A company is sustainable when it puts people at the heart of its business. To reach this goal, HR recruits talented people, develops their skills and retains these people.

**Sophie Klein**
Head of Human Resources, Lingolsheim, France

**Entrepreneurship**
It's where we started: with the drive and ambition to develop innovative products that could help people lead normal lives. And it's where we are today. Awake to opportunities, and ready to act on them. Thinking creatively and keeping a can-do attitude. Placing our faith in innovation. And believing in the people around us.

We are **agile empowering proactive**

I'm always looking for new ideas and opportunities that will serve our staff and donors best and encourage my staff to share their best practices with others. I believe in myself and the team around me.

**Ronaver McDaniel**
Donor Centre Director, Petersburg, Virginia, USA

# The spark of a big idea

Our ability to develop and manufacture life-changing treatments is just one of the many reasons I am proud of our company.



**Wolfgang Marguerre**
Chairman and CEO, Octapharma Group

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

**In 2018, we continued to drive growth in many of our products, received important regulatory approvals, made advances in our clinical studies and further strengthened our patient-oriented corporate culture.**

Kristopher and Robin, two brothers from Toila in Estonia, were once little boys close to death. As babies, they were diagnosed with the rare immune disease X-linked agammaglobulinaemia (XLA), which means a complete lack of the antibodies needed to defend their body against infection. Kristopher is now 18 and Robin is 16 and they have been using our product octagam® ever since they were born. Our ability to develop and manufacture life-changing treatments is just one of the many reasons I am proud of our company.

The impact of our products over the last 35 years has been extraordinary. We have grown to become a world-class organisation in which decisions and actions are constantly guided by our strong company values – Ownership, Integrity, Leadership, Sustainability and Entrepreneurship. Around the clock, around the world, our 8,314 employees are unified by our vision – to provide new health solutions advancing human life.

In 2018, we achieved revenues of €1.8 billion and pre-tax profits of €346 million.

Even more important for the future is that our product pipeline has made very good advances. Our new fibrinogen concentrate, fibryga®, received regulatory approval in Switzerland to treat congenital and acquired fibrinogen deficiencies. Our new 10% IVIG product, panzyga®, received FDA approval for the USA market, whilst our new SCIG product, cutaquig®, was approved by both Health Canada and the FDA. These approvals are significant achievements for the company and, most importantly, represent major progress for patients and physicians.

We have continued with our clinical trials – we have 15 ongoing studies involving more than 750 patients.

2018 was also a significant year in terms of our pre-clinical developments. As respected healthcare partners in haematology, we approached the World Federation of Hemophilia World Congress in May 2018, where we shared promising data from our pre-clinical study for SubQ-8, our recombinant FVIII for subcutaneous administration.

Helping as many patients as possible with efficacious medicines that improve therapeutic outcomes is inextricably linked to our future growth potential. In 2018, we invested €87 million in R&D for development of life-changing treatments. While our medical and scientific capabilities continue to be a source of strength, much of our future success depends on how effectively we drive our operations by focusing on production efficiencies and increasing capacity and scale in both our plasma donation centres and manufacturing sites. We have therefore invested in our manufacturing and plasma facilities across Europe and the United States €153 million. In terms of the plasma collection part of our business, we continued to increase the number of our plasma donation centres in order to increase plasma supplies.

As this year's annual report shows, everyone at Octapharma has his or her own story to tell.

For example, Christoph Kannicht and his team set out to develop an easier route of administration for FVIII for haemophilia A patients; Angelika Hurtl, together with her team, ensures traceability of individual plasma donations throughout the production process to guarantee patient safety; and Balazs Toth and his team is tasked with making sure that our products are as safe as possible.

I am grateful for the commitment our employees have demonstrated in bringing our vision to life once again over the last 12 months. I extend my sincere thanks to all of them for their outstanding achievements.

**Wolfgang Marguerre**
Chairman and CEO,
Octapharma Group

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

**8,314**
employees (2017: 7,674)

**€1.8bn**
revenue (2017: €1.72bn)

> The impact of our products over the last 35 years has been extraordinary. We have grown to become a world-class organisation in which decisions and actions are constantly guided by our strong company values – Ownership, Integrity, Leadership, Sustainability and Entrepreneurship.

Our three therapeutic areas

# Free to imagine

# Real hope...

**Ida Norberg, Stockholm, Sweden**
Success at our manufacturing sites depends not only on high quality standards, precision and professional skills, but also on the connection colleagues feel to our company's vision of providing new health solutions that advance human life. "Almost every day is different. The ability to work in a team, solve complex challenges and strive for life-changing impact is what drives me day in and day out," says Ida Norberg, process engineer at the Nuwiq® manufacturing site in Stockholm. "It's rewarding to hear from patients about how our medicine helps them and invigorates their outlook on life."

Ida joined Octapharma in 2013. "In my team, we work on the first steps of Nuwiq® production, the cell cultivation. This means cells are grown to produce FVIII," Ida explains.

In her spare time, Ida loves to go trail running. "Trail running is about spirit and strength. I like the endurance you develop while doing it. It's something that I cultivate at work as well. I am always learning."



# ...for Brandon

**Brandon, Chicago, USA**
Brandon was born and raised in Chicago. Aged five, he was diagnosed with a brain bleed and fell into a coma. He recovered to become an optimistic 30-year-old who loves to explore new cultures and cuisines but, above all, loves automobiles. "I love cars! All kinds of cars. If it has a motor and I can go fast in it, then I like it!"

Over the years, Brandon has learned a lot about his haemophilia. His positive mindset gave him the courage to fight against it. "But I felt I would never be able to break away from three-times-a-week dosing until an old friend of mine from a haemophilia camp told me about Nuwiq®."

Brandon now takes Nuwiq®: "It not only helped me get control over my bleeds, but I was soon able to switch to twice-weekly dosing and maintain protection. For a haemophiliac, that's huge – it equates to 52 fewer infusions a year. I feel very hopeful for the way my treatment is progressing."

# Strong commitment...

**Camilla Haag, Stockholm, Sweden**
"Imagine the impact that we all have together. I say this to myself every single day and feel proud that what we do helps others so much. Together we give our patients the opportunity to experience everything that we too often take for granted. We save people's lives," says Camilla Haag, a 25-year-old process operator at the octagam® manufacturing site in Stockholm.

Camilla works night shifts and enjoys horse riding in her spare time. "Being with my horse puts me in contact with the simplest of qualities, such as grace, beauty and freedom," Camilla says, smiling at the thought.



# ...for the two brothers from Estonia

**Kristopher and Robin, Toila, Estonia**
Kristopher, Robin and their older sister, Mariliis, are siblings living in Estonia. As babies, the two brothers were diagnosed with the rare immune disease X-linked agammaglobulinaemia (XLA), which means a complete lack of the antibodies needed to defend their bodies against infections. But despite their illness they can handle everything in life and are an inspiration, as Mariliis describes.

"Kristopher and Robin make me a better person. When I get annoyed over the smallest things, Robin just says, "Pole vaja kuri!" ("There's no need to be angry"). That's his motto! And I gain courage from Kristopher's eyes. He seems the quiet one, but he shows me that you don't need to be extrovert to be confident," says the 25-year-old.

Thanks to octagam®, the "boys" are now young men of 18 and 16. Without their medication, the brothers wouldn't be with Mariliis and their family. "Though life seems to have played its cards the way it has, my brothers are the most unique people. I'm lucky to share my life with them."

# Timely help...

**Benjamin Kosch, Vienna, Austria**
Benjamin Kosch was drawn to helping people during his civilian service with the Arbeiter-Samariter-Bund (a German aid agency). "I was able to help many of the patients I met, even if only to bring a smile to their face," says the voluntary paramedic, whose outdoor pursuits include mountaineering and ice climbing.

Today, Benjamin is a shift supervisor in Purification 1 at the Vienna octaplex® manufacturing site. When asked what makes him proud about his work, he does not waver for even a second: "It's the team that works here. We all understand that we have to deliver on time. I feel lucky to have such dedicated colleagues who are so invigorated by helping others. Such spirit does not exist in many jobs."



# ...for critically ill patients

**Jeannie Callum, MD FRCPC, Toronto, Canada**
"Using fractionated plasma protein products is a core part of what we do every day in transfusion medicine," says Jeannie Callum, MD, FRCPC of Sunnybrook Health Sciences Centre, Toronto, Canada.

It is late afternoon when a patient is brought to Sunnybrook, Canada's largest trauma centre. The elderly man was hit by a car while crossing a road. He has severe injuries to his head, chest and pelvis. "To complicate matters, he has an irregular heart rhythm so he is on warfarin to help prevent him having a stroke. But warfarin prevents clotting during bleeding so it accelerates blood loss," she adds. Fortunately, the operating team administers prothrombin complex concentrates over five minutes and quickly normalises the patient's ability to clot.

"For octaplex® or prothrombin complex concentrates, we know that rapid reversal of anticoagulants for patients with serious bleeding (usually intracranial haemorrhage) improves their chance of survival and gives better neurological outcomes. Octaplex® is faster, safer, and logistically simpler than our only other option, plasma transfusion," Jeannie explains.

Procedures like this are done every day at Sunnybrook. "We deal with patients with postpartum bleeding, gunshot wounds, unstable cardiac problems and brain haemorrhages," says Jeannie. "There is no time to waste."

# Engaging with patients

Chris Bombardier on Mount Everest.

No one understands the impact of a disease and its treatment better than a patient. Patients know what their disease means to them and how it feels. Octapharma highly values and respects each patient's individual experience. We gain patient insights and collaborate closely with healthcare professionals on a daily basis. We take patient concerns and needs into account when we develop our life-saving medicines, as we continue towards our vision of providing new health solutions advancing human life.

When Octapharma decides to develop a new medicine, we are making a long-term commitment to focus on the lifelong journey of the patient. We are determined to help people in the bleeding disorder community enjoy their lives and achieve their dreams. For this reason, we are partnering with several healthcare and patient organisations to increase awareness and knowledge of the challenges facing patients, their families and care providers.

**Awe-inspiring patient journeys: from Mount Everest to the San Juan Islands**

In "Bombardier Blood", the Octapharma USA-sponsored documentary on Colorado mountain climber Chris Bombardier's quest to be the first person with haemophilia to climb the "Seven Summits" (consisting of the highest mountain on each of the world's seven continents), we show that people with bleeding disorders can enjoy a life without limits. In addition to Chris showing what can be achieved, the filmmaker, Patrick James Lynch, also has severe haemophilia.

Octapharma USA was also the exclusive sponsor of "Leading X San Juan Islands". Our grant to GutMonkey, an experiential educational organisation, provided a life-changing experience for 10 people with haemophilia during a week-long adventure in the San Juan Islands. The trip focused entirely on improving patients' confidence in managing their bleeding disorders.



**1%**

of the US population is affected by von Willebrand disease

**100**

Octapharma Academy courses have taken place to date

**10,000**

participants have attended Octapharma Academy courses

**Tapping into patient insights**

Von Willebrand disease (VWD), which affects up to 1% of the US population, is a genetic disorder caused by a missing or defective von Willebrand factor (VWF), a clotting protein in the blood. According to the US Centers for Disease Control and Prevention (CDC), despite the symptoms, many people, women in particular, are not aware of the disorder and therefore not diagnosed and treated. Octapharma is determined to change this.

Being a leading supporter of the VWD community, in 2018, Octapharma USA was the exclusive sponsor of three important educational programmes for the VWD community: the National Type 3/Severe VWD Conference, the Female Factor Retreat and the VWD Empowerment Weekend. In the words of Carl Trenz, Octapharma USA's Director of Therapy Development, "Octapharma USA is committed to working with the VWD community and fostering greater awareness of the many challenges faced by patients and caregivers."

**Partnering with healthcare organisations**

Octapharma USA has also been the sole sponsor of the Ig Academy at the Immunoglobulin National Society (IgNS) Annual Meeting for the past four years. In 2018, more than 200 nurses, pharmacists and physicians attended this very successful educational programme. IgNS is the only organisation dedicated to the field of immunoglobulin nursing and pharmacy practice. The Ig Academy is an annual one-day course that offers in-depth, evidence-based education on the most critical and relevant aspects of Ig therapy practice. It also teaches the foundational principles and practice parameters of Ig therapy to nurses and pharmacists.

**Facilitating wider access to medical information**

Keeping up to date with the latest medical information is always a challenge for patients and healthcare professionals, but even more so in low and middle-income countries. Octapharma has developed a range of initiatives in this area. We continue to launch partnerships with local healthcare professionals to support change, as well as the exchange of information and knowledge worldwide.

The Octapharma Academy is one such highly appreciated programme. Since its launch in 2009, the Octapharma Academy initiative has generated considerable interest, serving as a platform to provide high standards of education and tools for successful collaboration.

Following the motto, "Where science meets clinical practice", the Academy concept serves as an excellent forum in which healthcare professionals can interact, raise awareness and share their experiences.

The Academy combines education with interactive workshops within our three therapeutic areas: haematology, immunotherapy and critical care. To date, more than 100 Academy courses have taken place across Eastern Europe, the CIS region, Latin America and Mexico, attended by over 10,000 participants. Octapharma is determined to contribute to the ongoing quest of improving patients' lives – not only by offering our life-saving medicines, but also by facilitating the sharing of knowledge among healthcare professionals and patients across geographies.

> "Octapharma USA is committed to working with the VWD community and fostering greater awareness of the many challenges faced by patients and caregivers."

**Carl Trenz**
Director, Therapy Development, Marketing, Octapharma USA

Plasma donations

# Ensuring a good donor experience


1 **Handheld:** A pocket computer to document the several donation steps, scan materials and verify the donor.

2 **Samples:** Small volumes are extracted from the donation volume for pathogen testing.

3 **Set with filter:** For connecting the different objects of the donation process and to filter the blood (fat and cell residues).

4 **Needle:** To connect the plasmapheresis machine to the donor.

5 **Saline:** For compensating the fluid loss of the donor.

6 **Citrate:** An anticoagulant, so the blood does not coagulate during the donation process.

7 **Bowl:** The point in the donation process where the plasma gets separated from the cellular components.

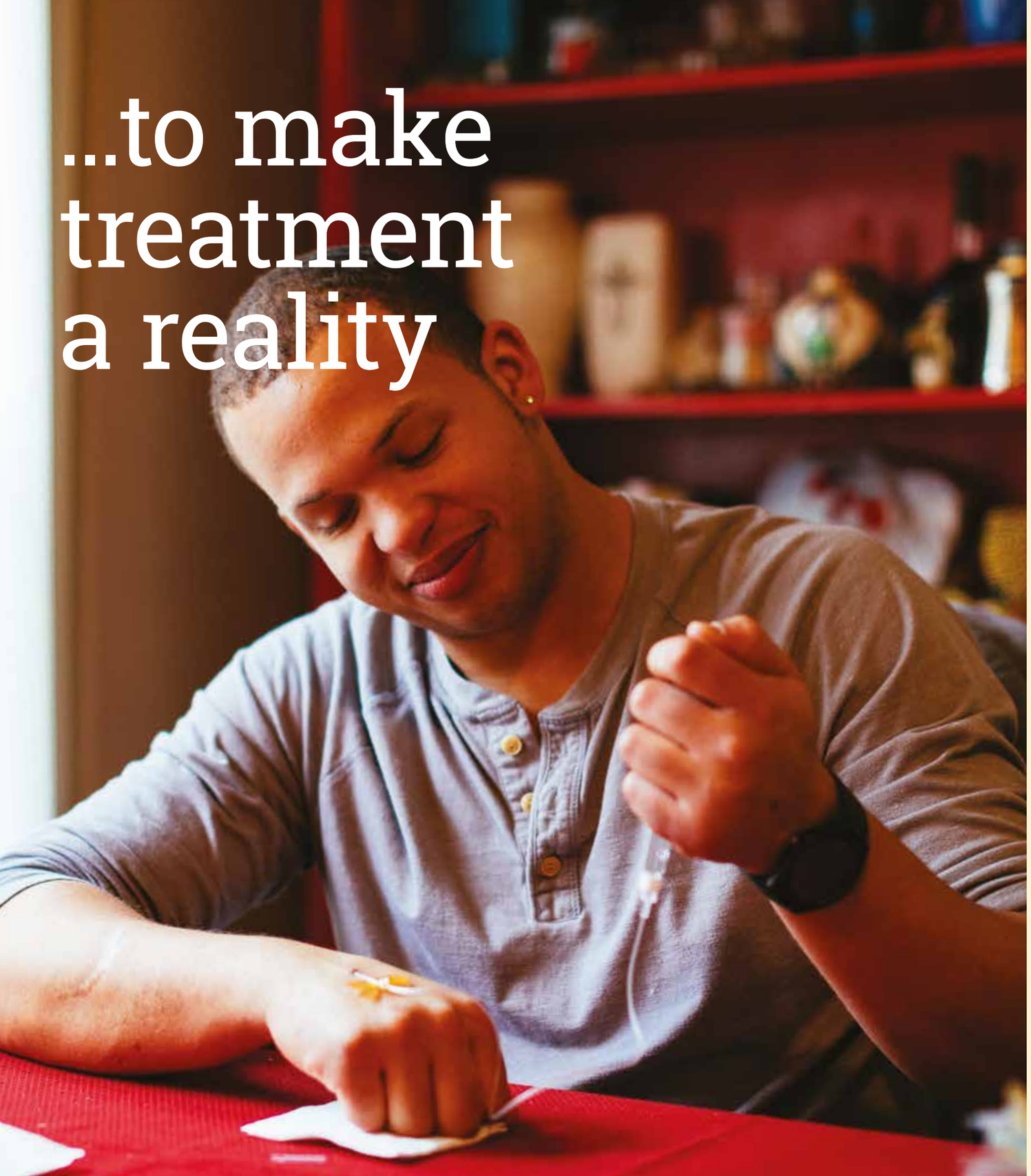
8 **Pumpball:** By pressing the pumpball the donor can support the blood flow.

9 **Plasma bottle:** Collects the blood plasma after the separation.

10 **Blood pressure cuff:** The cuff supports the extraction process by building up pressure, so the blood has a better flow.

11 **Plasmapheresis machine:** The engine of the donation process, which runs the separation, extraction and returning process.

# The start of a long journey...



# ...to make treatment a reality

## The journey of plasma from the USA to Europe

The donor provides plasma via an apheresis machine. The donation is stored in a plastic bottle.

The plasma donation is frozen and stored below -25°C. It is recorded in a Donation Management System.

**45–90 mins**
Length of each donation process

**Days 1–3**
Collected samples are sent for pathogen testing in different labs, including Octapharma Plasma Inc.'s Charlotte, N.C. (USA) laboratory.

**300–880ml**
of plasma is taken each time

**61%**
of source plasma donors are male

**Days 7–10**
Plasma bottles of suitable donations are packed in cartons and stacked on pallets. They are then ready for pick-up.

**Days 10–13**
Pallets are transported by truck to a central warehouse in Kentucky (USA).

**Day 25**
After a documentation check, the plasma pallets are loaded into a container and sent by truck to a port on the East coast, Norfolk, Virginia, USA.

# 13,000 litres
The capacity of 18 pallets

18 pallets correspond to around 13,000 litres of plasma. Sea freight coordination involves many stakeholders in the USA and Europe to ensure timely plasma availability for fractionation. Third party logistics companies work to mitigate the risks for both storage and transport.

# –25°C
The temperature plasma has to be kept at throughout its journey

# 13 days
Length of sea journey from USA to Bremerhaven port in Germany

**Day 31**
Following customs clearance (which may take a day or two), the containerised pallets are placed in a ship's hold.

**Day 44**
The sea crossing to Bremerhaven (Germany) takes approximately 13 days.

# 6–9
containers are transferred every week

# 3,190kg
The plasma pool size in Vienna. Nine plasma pools are produced every week

**Days 47–50**
After customs clearance at Vienna (Austria), the truck arrives at the Octapharma Vienna plant or the external warehouse.

The pallets of plasma are labelled, registered and moved to the main freezer warehouse.

# 25 mins
This work is performed by just four or five staff within 25 minutes in a temperature controlled area. The plasma is separated and palletised on receipt to simplify further distribution.

Based on the production schedule, plasma is transferred in refrigerated (-30°C) trucks from the external warehouse to the Vienna plant's freezer storage facility.

Pallets and plasma documentation are prepared for the Single Donation Control (SDC) process. There are several transports between the external warehouse and the manufacturing plant every day.

**Days 45–46**
The container is transferred to a truck bound for the Vienna or Stockholm Octapharma sites.

# 70%
Vienna is the central plasma warehouse in Europe and receives 70% of the total plasma used by Octapharma.

# –30°C
Temperature that plasma is transferred under

# 60%
of received plasma is transferred every week

# 15–19 hours
The length of time for each pool rotation

**Days 54–58**
A large amount of received plasma (60%) is transferred every week in temperature monitored trucks to other fractionation sites, such as Lingolsheim (France) and Springe (Germany).

Throughout the entire process, the Corporate Quality Plasma Department processes the documentation, including testing certificates and bleeding lists, as well as assessing temperature controls to release the plasma for production.

The correct pallets of plasma, based on the pre-planned plasma pools, undergo SDC where the donations are scanned three times and put into blue plastic boxes. When the target weight is reached for each pool, it is returned to the freezer.

After the SDC process, the plasma pallets are stored below -30°C waiting for the plasma to be released.

Precise scheduling and communication between the Plasma Logistics teams and Production teams determine when each pool will be put into a pre-thawing freezer (below -5°C). The pools are rotated through this process. Each rotation lasts for 15–19 hours.

**Days 61–65**
In production, the plasma bottles are cut open and put into the thawing tank.

Once all donations are thawed together to form a plasma pool, samples are taken for additional virus testing at the pool level. Most of these tests are performed by our dedicated laboratory in Frankfurt (Germany).

More information on our production process can be viewed in the 2017 Annual Report: annualreport2017.octapharma.com

Distribution and supply chain

# Getting our medicines to patients

Getting medicines to patients requires a hugely complex supply chain, with lives possibly at stake if anything goes wrong. To protect patients from unsafe medicinal products, regulatory authorities agree it is critical that "no weak link exists in the supply chain". Octapharma places great emphasis on achieving and maintaining good distribution practice (GDP) to ensure that our patients receive Octapharma medicines of the highest quality.

**Transporting biologics is no easy task. Every shipping option and route is analysed and risk assessed.** We look for the most sustainable packaging and the most reliable mode of transport because each shipment of our products can be highly sensitive to potential temperature change.

Octapharma ensures that all plasma products complete their journey safely and maintain perfect quality whether in a small shipment of a few vials or a shipment of more than 10 pallets, specially packed and wrapped for the anticipated temperature range during their journey.

For example, if we ship our products during winter from Europe via the Middle East to the final destination, we know that the mode of transport has to withstand cold weather in Vienna, Austria, while the destination enjoys the summer season, in temperatures up to 40°C and more. For such instances, active and passive containers are available. These containers can stabilise the temperature. We also use various methods of applying thermofoil to insulate the goods. Most importantly, the transport chain has to be harmonised with the respective equipment. To achieve this, colleagues from several departments work closely together.

Octapharma also engages with an extensive network of third parties worldwide. While the contributions of our suppliers are crucial to our success, our internal guidelines and GDP regulations set out our expectations about quality standards.

**Coordination is key**
Managing the global supply chain for our products takes all the skill of a chess Grand Master. It requires strategic thinking at every move and the ability to anticipate the unexpected, coupled with the determination to get the products to their destination.

The success of logistics allowing a shipment to be released to the market has its roots in an extensive preparation phase, but ultimately the "green light" to release a shipment comes from the Customer Service team.

"Careful analysis, collaboration and timing are essential to guarantee delivery into patients' hands. It is crucial that all colleagues from departments such as the Corporate Business Planning and Allocation team, local Packaging, Material Management and Supply Chain teams, Assessment and Release, and Export teams are fully involved. It is a close and intense collaboration where everyone contributes specific skills," says Rute Martins, Customer Service Manager at Corporate Customer Service.

Based at the Octapharma headquarters in Lachen, Switzerland, the Corporate Customer Service team, which is part of the Corporate Supply Chain Unit, is the central contact point for customers represented by local sales teams. The team, which consists of eight people, is the interface between all departments involved in the ordering process and the customer. Rute and her team handle all the orders for finished products and other enquiries coming from 115 countries around the globe. While it is a demanding and complex process, the team must ensure that every requirement is met, from the beginning until the end of the process.

**Step by step**
The Corporate Customer Service team follows up on every step of the process, from the first order being sent, to the batch allocation, packaging, batch release, payment confirmation and then shipment to the customer.

Every step in the supply chain is linked to another, and everyone must play their part every day to ensure that our patients receive on time Octapharma medicines of the highest quality.

It is only after all the previous steps are concluded and confirmed that the Corporate Customer Service team gives the "Go!" to the Export department to organise the shipment to the customer. "Each individual member of each team understands that we have to deliver our medicines on time. We work together to contribute to a major and noble mission: to help hundreds of thousands of patients around the world change their lives," Rute adds.

A successful supply chain strategy is at the core of Octapharma.

While handling this global network, our priority is – and always will be – process reliability, safety and improvement of the service levels for those who are the focus of our daily work: our patients.

Rute and her team handle all the orders for finished products and other enquiries coming from 115 countries around the globe.



"Each individual member of each team understands that we have to deliver our medicines on time. We work together to contribute to a major and noble mission: to help hundreds of thousands of patients around the world change their lives."

**Rute Martins**
Customer Service Manager at Corporate Customer Service

Octapharma products reach hundreds of thousands of patients worldwide every year. Products are thoroughly tested before they are approved, with their efficacy and potential side effects properly recorded and documented. At Octapharma, patient safety is paramount.

Drug safety

# An eye for detail

**The Corporate Drug Safety Unit, headed by Balazs Toth, is tasked with making sure that our products are as safe as possible.** It is a responsibility that requires a detail-oriented approach and compliance with the strict rules and regulations regarding pharmacovigilance.

Regulatory authorities continuously revisit and amend their legislation. The development of drug safety legislation, also known as pharmacovigilance legislation, is based on the observation that adverse drug reactions (ADRs) could cause significant harm to patients.

"Our products have to prove themselves continuously, even after regulatory approval has been granted, as this is the only way to ensure that patients receive the treatment they need and deserve," says Balazs, who, as well as heading up the Corporate Drug Safety Unit is the European Qualified Person for Pharmacovigilance (EU-QPPV) at Octapharma in Vienna, Austria.

## Know the product

"We work here to ensure patient safety. We have patients in 115 countries who are treated with our products. Monitoring our products and ensuring patient safety is a huge responsibility for the Drug Safety team," adds Balazs. "We produce medicine that is compliant – nevertheless, we collect data on any reported side effects in a constant process of analysis to ensure our medications are as safe as possible."

Balazs' team also keeps relevant regulatory bodies and healthcare professionals up to date. "Our work is to inform health authorities, healthcare professionals and patients on how to administer our products and what can be expected," Balazs says.

The World Health Organization (WHO) defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problem.

"The main objective is to reduce patient safety risks by monitoring the risk-benefit ratio of the products based on incoming case reports."

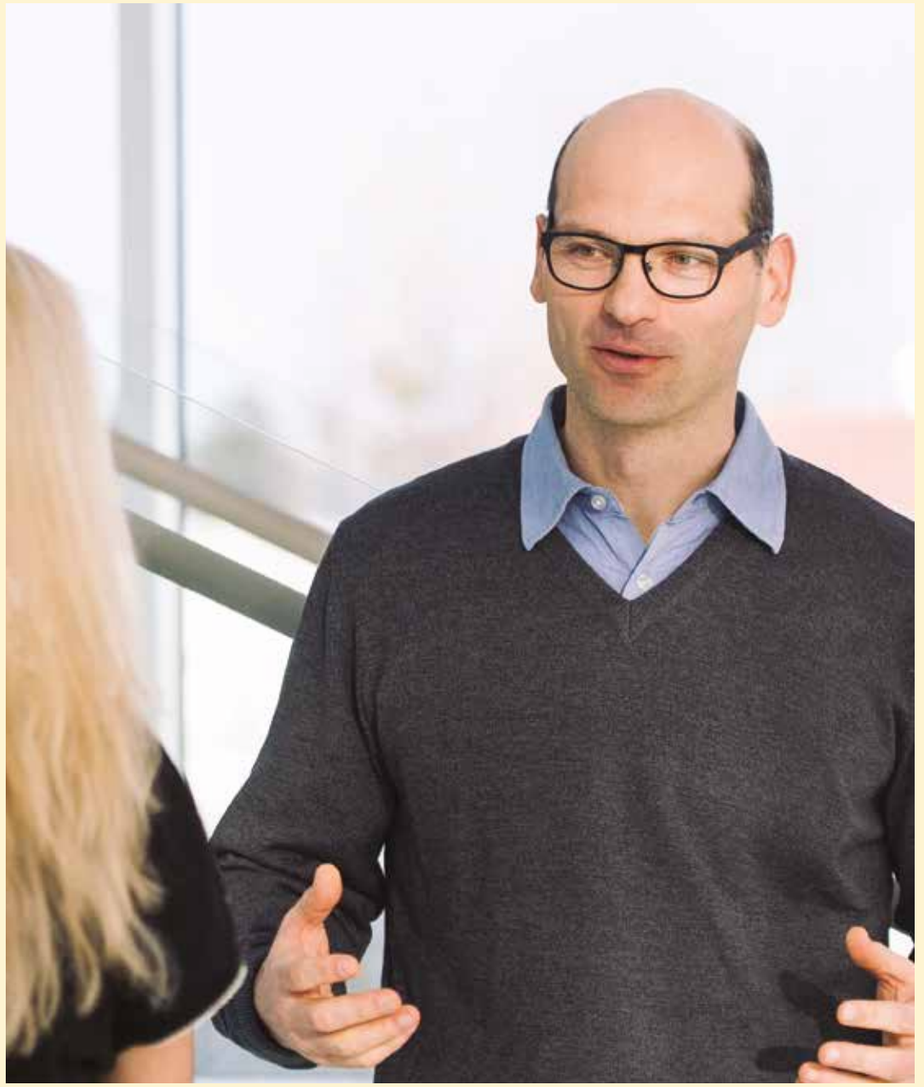
## An eye for detail

The Drug Safety team closely monitors the side effects of products, taking into consideration reports received from healthcare professionals, articles in scientific journals and information from health authorities. "We enter all information in our drug safety database. We review, assess and, if necessary, further investigate the cases and forward them to health authorities," explains Balazs. "We have a strong team of around 20 colleagues located in Vienna. However, the team of colleagues engaged in pharmacovigilance is significantly larger. Without the help of our local drug safety officers located in most of the countries where Octapharma products are marketed, we would not be able to fulfil our legal and ethical obligations."

Besides medical review of cases, Balazs and his team evaluate "safety signals" deriving from case reports. A safety signal is information on a new or known adverse event that may be caused by a medicine and requires further investigation. Safety signals, just like reports, can be detected from a wide range of sources, such as spontaneous reports, clinical studies and scientific literature. As Balazs explains, the evaluation process can lead to a follow-up or it can be decided that no further action other than updating the product information is required.

"The pharmaceutical industry is a truly significant one – we produce life-saving medicines. I always say to myself: when someone from my family takes medication, I want them and all other patients to get the best medicines and to be fully informed about what they are taking. That is my motivation! We have to do the right thing for our patients. We owe it to them and we owe it to our company," concludes Balazs.





> "Our products have to prove themselves continuously, even after regulatory approval has been granted, as this is the only way to ensure that patients receive the treatment they need and deserve."

**Balazs Toth**
Head, Corporate Drug Safety Unit & EU-QPPV

Octapharma has not only big ideas to improve the lives of patients, but also big data. Computational resources are capable of mining huge databases, ensuring traceability of individual plasma donations throughout the production process to guarantee patient safety.

Traceability

# Using big data to improve lives

**Traceability requires close collaboration across many functions.** The plasma donation centres are responsible for the collection of all relevant data for each plasma donation – including the donor's unique identification number, blood type, date of the donation, donor centre, plasma volume and type (source or recovered plasma).

Before any plasma can be released for use in production, each donation must be independently verified to confirm that the donation complies with all release criteria. This is the task of the Corporate Quality Plasma teams in our manufacturing sites in Vienna (Austria), Stockholm (Sweden), Springe (Germany) and Lingolsheim (France).

Octapharma processes annually over six million litres of plasma donated by hundreds of thousands of committed donors. This equates to more than ten million individual donations.

Each data set requires protocol management, coordination with local sites and, above all, accurate and precise collaboration of local and global team members. "The ability to collect and access vast data sets of plasma donations is the foundation of our team. Traceability is important for safe and efficient manufacturing of our medicines," explains Angelika Hurtl, who leads the Corporate Quality Plasma team in Vienna.

> "The ability to collect and access vast data sets of plasma donations is the foundation of our team. Traceability is important for safe and efficient manufacturing of our medicines."

Angelika and her team monitor all information from the donor centre to manufacturing.

## Capturing big data

Traceability is the ability to track all relevant information about a plasma donation throughout its lifecycle – from the time of the donation itself, throughout the manufacturing process to when the medicines are produced and Quality Control-released for patients around the world.

Angelika and her team monitor all information from the donor centre to manufacturing. “For instance, you may want to know what kind of plasma the end product has been produced from, or from which country or donation centre the plasma came from, even how many units were used – this is all traceability. It also includes information on specific donation dates, or potential deviations during transport.”

Besides the compliant aspect of traceability, Angelika says that the collected data has also transformed the way we look at efficient production. “We are a data company in healthcare, but also a data-driven organisation,” she explains.

> “We understand the story our data is telling us. We are used to generating and working with huge amounts of data, analysing it and using this knowledge for further development of streamlined planning and workflows.”

## A complex process

Human plasma is a precious resource for developing our novel plasma-derived therapeutic protein medicines. It is the clear, straw-coloured liquid portion of blood that remains after all cellular components are removed. Of the plasma which Octapharma processes, we collect the vast majority ourselves through more than 100 donation centres which we operate in the USA and Germany.

Each plasma donation is stored in a bottle or a bag. After the verification of all quality requirements, the respective individual data set is released and scanned during the process of physical acceptance. This process is called Single Donation Control (SDC). SDC is the proven foundation of traceability for all individual plasma donations in Octapharma. After the SDC step, Angelika’s team must approve the plasma for use in production. Every donation is cross-checked to confirm its compliance – for example, that it is really from the particular donor listed in the documentation, that the virus testing result was negative, that there were no temperature deviations during shipment to our manufacturing sites in Europe, that there are no look-back or post-donation notifications, and so on.

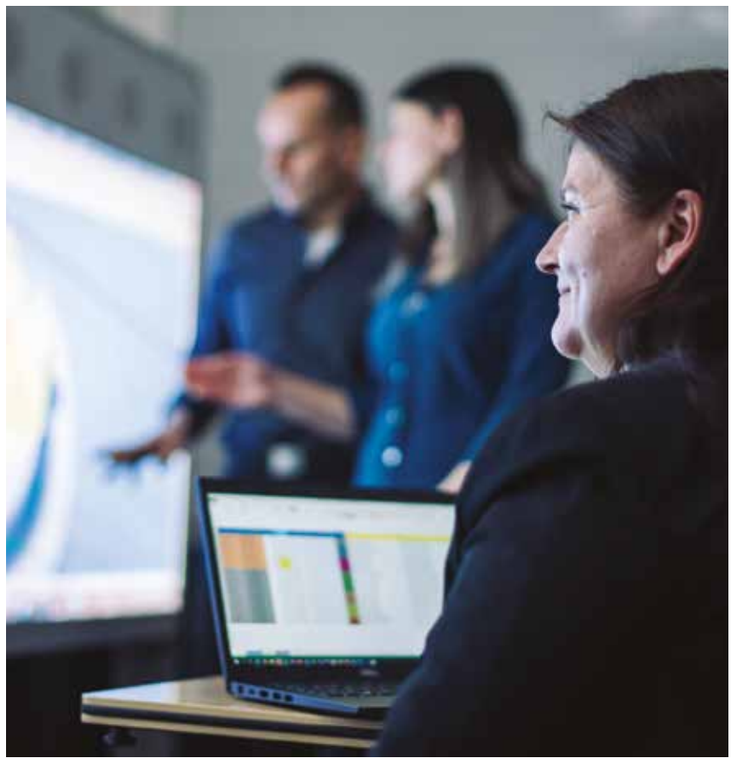
Individual plasma donations are released for production only if all relevant data is in compliance with many parameters. “It is a very complex process,” adds Angelika. “To have all plasma units in compliance with all required parameters also means, for instance, to analyse matching plasma units by their age, blood type or origin.

“After passing that final check, the plasma unit can be used for production in conjunction with the number of units which is needed to fulfil the needed plasma pool size,” she continues. “One plasma pool can be formed from many donations, anywhere from 700 up to 16,000



> “We are proud to say that we master our field and our plasma donations are fully compliant. All our local teams should also be more than proud of their achievements.”

The ability to collect and access vast data sets of plasma donations is the foundation of the team.



donations. We must ensure that we know exactly and at all times which plasma units have been used in the production of each batch of our medicines sold all around the world.”

After SDC, plasma is transferred to production by the logistics department. The basic fractionation department then begins the process of thawing the plasma donations and forming the plasma pools. Freezing and storage parameters follow defined standard operating procedures in which the plasma units are thawed for pooling and then production. Production involves separating out the relevant proteins from the plasma, firstly in an intermediate step via fractions or pastes, which are then purified and put into Octapharma finished products used by patients around the world.

## Tracking ahead

By maintaining this digital thread of information, Octapharma is able to trace each individual donation at all times.

“We are proud to say that we master our field and our plasma donations are fully compliant. All our local teams should also be more than proud of their achievements,” adds Angelika.

Traceability means delivering to the business requirements, where accurate teamwork is essential. Angelika considers team spirit to be the secret behind making traceability a reality. The team she leads is very diverse and this allows them to contribute their individual strengths.

> “What I appreciate best about the team is the cooperation among the experts and the willingness to step in if support is needed.”

Traceability is critical for quality in production and patient safety. “We are a partner in the production process and our colleagues really depend on us,” concludes Angelika.

# From vision...

€1.8 billion

revenue

€117 million

invested in our production facilities across Europe

€87 million

invested in R&D

>6 million

litres of plasma processed annually



67

nationalities

8,314

employees

4,790 female

3,524 male

...to innovation

Women in science

# Medicine as an art form

Medicine is often compared to art because of a physician's ability to devise the right therapy at the right time. Ruth Wagner, Group Manager R&D Cell Line Development at Octapharma, and her colleagues achieve something similar when they develop recombinant cell lines that fit perfectly well for further biopharmaceutical manufacturing. Ruth believes in pushing boundaries in order to live a fulfilling personal and professional life.

Ruth is Group Manager R&D Cell Line Development at the Octapharma Biopharmaceuticals centre in Heidelberg.

**Biology came easily to Ruth. Growing up with parents who were both biochemists, she credits her early interest in science to her pre-school age:** "My mother had a very rational, but at the same time playful and understandable way to explain nature, science and even chemistry. This just captured my imagination and I loved doing science projects for school and learning all about biology." As her broader passion for biology and science developed, she also found inspiration in the way the teachers pushed students to discover new things.

"Science was always a topic at home. It came naturally. Very soon I had the idea, what I could do with it."

Ruth holds a PhD degree in molecular biotechnology from the University of Heidelberg, Germany. She conducted her PhD research in the field of adeno-associated virus (AAV) mediated gene therapy at the German Cancer Research Centre also in Heidelberg. During her doctorate, she worked closely with her scientific mentor, Prof. Dr. Jürgen Kleinschmidt. "My mentor made a real impact on my scientific career. While working together, he took the time to explain every detail of how the viral system has evolved to make use of complex human biological systems for its own reproduction purposes and how we can translate that information into gene therapy products." Kleinschmidt gave Ruth his full support. He always gave her advice and encouraged her to discover new solutions. "Jürgen was a walking encyclopaedia. I would discuss my experiments and data with him. His feedback and inputs were very encouraging."

During her PhD studies, Ruth also focused her attention on publishing several papers on the biology of AAV. AAV is a viral vector tool used in many fields of gene therapy, including haemophilia.

## A scientific journey

Solving scientific problems requires time, stamina and focus, something Ruth cultivated as a horseback rider and now a trainee in horsemanship. "Being authentic, progressive and at the same time having a positive attitude is what makes you a great leader for your horse," she continues. "I like the feeling and focus you develop while working with the horse. In the past, I used to ride for competition. Now, I'm learning the language of the horse." Ruth does this for life, for her personal development and for her career. "Focus is one of the key elements for being a good horsewoman. You need to think ahead, have a clear picture in mind of what you would like to teach the horse, and stay consistent over the long term. The same applies to research."

Curiosity also drives her. A fascination for how nature has evolved biological pathways that work together in the human body remains a guiding theme for Ruth.

"I think the idea of using individual components of complex biological pathways as tools and turning them into medicines is extremely exciting."

"My mother had a very rational, but at the same time playful and understandable way to explain nature, science and even chemistry. This just captured my imagination and I loved doing science projects for school and learning all about biology."


Having the right balance of different talents in a team is a key contributing factor to innovation.

**Passion for work and moving forward**

Ruth joined Octapharma in 2012 as a scientist in the Quality Control team for analytical method development. In 2014, she became Group Manager R&D Cell Line Development. "It takes courage, self-confidence and focus for a young researcher to assert her or himself. It can be an ambitious goal. And in order to achieve that you have to keep pushing boundaries," explains the biologist.

With her team, she develops and optimises recombinant cell lines, which serve as production platforms for recombinant therapeutic proteins such as Nuwiq®. "We are responsible for developing and optimising these cell lines. For this we use state-of-the-art technologies such as CRISPR/Cas 9. These technologies allow us to engineer cells in a way to make them produce innovative recombinant therapeutic proteins that have quality attributes beneficial to our patients' needs."

By modifying the properties of the cells by genetic manipulation, Ruth and her team can learn about the dependencies within the biological system. They follow an approach known as "quality by design". This is a systematic approach translating information into generation of cell lines that produce therapeutic proteins with superior quality attributes, such as prolonged bioavailability for patients.

**Team balance promotes innovation**

Having broad diversity within her individual team is important to Ruth. She is convinced that having the right balance of different talents in a team is a key contributing factor to innovation.

"In research having a balanced team is very important for ensuring the ability to innovate. It is great working together with so many smart and motivated individuals who are filled with curiosity and have a thirst for knowledge."

For Ruth, great team balance provides room for thinking out of the box and a culture of learning in which researchers are not afraid to step out of their comfort zone, a culture in which they inspire and respect each other. "I greatly enjoy the spirit that arises when a challenging and time-critical task is successfully accomplished by the effort and scientific input of motivated individuals in my team."

Beyond her scientific achievements and work, Ruth also thinks that as an innovator, staying open-minded is the key to success and finding the courage to lead. "I enjoy reading literature from great German authors. I love the way the authors are able to speak their minds and express their convictions. Their writing even has the power to change your mind and you see something from their perspective."

Looking back, Ruth is proud of what she has achieved during her time in Octapharma with her teams and for our patients. As her friends would describe her, she is an empathic, endearing and easy-going person, but she has her parents' life story – they fled from Romania to Germany – to thank for her perseverance. "I am very happy at the moment. My journey has been one of self-discovery."

R&D innovation

# Persistence – and ingenuity – pays off

Long-term medical conditions often impact patients beyond their physiological effects. Time off work may be needed for treatment, for example, or the treatment itself may affect a patient's quality of life. Such is the case with haemophilia A, the treatment of which requires regular intravenous injections. But thanks to the determination of researchers at our Octapharma Biopharmaceuticals centres in Berlin and Heidelberg, Germany, a breakthrough is on the horizon that could lead to this debilitating condition being treated with a true FVIII product via a much more convenient subcutaneous route.

Christoph and his team relish a challenge.

From left to right: Tobias Stuwe, Barbara Solecka-Witulska, Christoph Kannicht.

**Things started back in 2014 when Christoph Kannicht and Barbara Solecka-Witulska, together with their teams, set out to develop an innovative and "easier" treatment.** As Barbara Solecka-Witulska, Senior Scientist, Molecular Biochemistry, in Berlin explains, "The treatment has been that recombinant factor FVIII is injected into a patient's veins. This can be extremely challenging with newborns, for example, where it is difficult to find a vein. So, having the treatment given subcutaneously would be an enormous advantage."

Developing a subcutaneous treatment is more difficult than it may sound. Despite haemophilia A being a well-studied genetic disorder, characterised by abnormalities in a single gene, it is challenging to treat. Recombinant factor FVIII administered intravenously remains the therapeutic cornerstone.

## The search begins

When Octapharma launched its SubQ-8 study, there was no product on the market which could achieve subcutaneous administration of FVIII. But Christoph Kannicht and his team relish a challenge. "We've learned that if you administer FVIII without any protection subcutaneously, it will not reach the bloodstream. So, the goal was to identify a fragment of the von Willebrand factor (VWF) with the best affinity to FVIII and use that as a "protective wrapping"," explains Christoph.

FVIII and VWF are two distinct but related glycoproteins that circulate in plasma as a tightly bound complex. Their deficiencies or structural defects are responsible for the most common inherited bleeding disorders, namely haemophilia A and von Willebrand disease. By adding a certain fragment of the VWF to FVIII, the compound safely carries FVIII into the bloodstream and protects it from degradation.

The team had to analyse numerous fragments of VWF. "We knew that we could not take the entire VWF," says Tobias Stuwe, Head of Recombinant R&D in Heidelberg. A FVIII complexed with full-length VWF multimers would likely be trapped in connective tissues and not enter the veins. "The challenge was to find the right size and type of VWF fragment. Was a monomeric or dimeric molecule the best choice?" Tobias asks.

Eventually one molecule, later named OCTA12, turned out to be a promising candidate. The team had to test the bioavailability, efficacy and many other key aspects of the fragment relating to its function to bind FVIII with high affinity. The hypothesis was confirmed in subsequent experiments in animal models, and at the World Federation of Hemophilia (WFH) 2018 World Congress in Glasgow, a team of scientists led by Christoph Kannicht presented for the first time this promising data from the pre-clinical study for SubQ-8. A successful Investigational New Drug (IND) approval followed, and now researchers can plan the clinical phase of SubQ-8's development.

## Team spirit

Looking back, Christoph, Barbara and Tobias believed in the idea. After three years, their resilience paid off. "It was certainly a difficult and challenging time," recalls Barbara.

"We hope that the data from our pre-clinical studies of the new subcutaneous FVIII product, SubQ-8, will ensure an easier route of administration for haemophilia A patients."

"Ever since this project started, I have always reminded my team members how important it is to understand the patients before they start working on a study or product," Christoph adds. "We have to understand what patients' daily lives look like, what their environments are like, what are they missing, and what they need. With this information in hand, and the incredible efforts of the team, we can then start looking for solutions hopefully with as much success as our SubQ-8 work!"

Octapharma invested into the project, trying to approach the challenge from various angles and leveraging its scientific talent base. "It is gratifying to see what we have achieved. Much of this is owed to our belief that we have to innovate to help patients. But it was the courage and incredible teamwork of many different people from very different backgrounds that brought us here in the first place," says Tobias.

> "Ever since this project started, I have always reminded my team members how important it is to understand the patients before they start working on a study or product."

**Christoph Kannicht**
General Manager, Senior Vice President Recombinant R&D, Octapharma Biopharmaceuticals

Women in science

# From childhood dream to research team

Accurate, ambitious and reliable – these are three words which Andrea Heger, a senior scientist and Team Leader for Plasma R&D, uses to describe herself. Even as a child, Andrea liked to research things and dreamed of working as a scientist. Now she leads a research team of 14 technicians at Octapharma Plasma R&D in Vienna, Austria.

Andrea is Team Leader for Plasma R&D in Vienna.

**When Andrea was in elementary school, she discovered her passion for biology and her fascination for new things.** But she also enjoyed the clarity of mathematics. Being inspired by her mother, who was a teacher, Andrea excelled in maths since as long ago as she can remember. Andrea grew up in Subotica, a town on the Hungarian-Serbian border, speaking Hungarian at home and learning Serbian-Croatian, and later German and English, at school.

## From hometown to Zagreb

After completing college, Andrea immediately set about pursuing her plans, going abroad for her scientific studies. Like the protagonist in her favourite film, Erin Brockovich, she had an innate sense of curiosity. Andrea also received the decisive push for her studies from her mother.

"My mother inspired me on my journey into healthcare medicine. She fully supported and motivated me during my education."

Andrea was equally motivated to study medical biochemistry at university by famous scientists such as Marie Curie.

Andrea completed her master's degree in medical biochemistry at the University of Pharmacy in Zagreb, Croatia. At this time she was still a novice in the field and therefore spent one year at the University Hospital in Zagreb rotating between the biochemistry, haematology and microbiology departments. As a trainee, she had to learn a lot. "I learned from my research experiences that it is important to be diligent and to have endurance. This can lead to success. If you don't keep developing, you'll become obsolete."

"I learned from my research experiences that it is important to be diligent and to have endurance. This can lead to success. If you don't keep developing, you'll become obsolete."

In order to expand her knowledge, she decided to pursue a doctorate in pharmacy at the Karl-Franzens University of Graz in Austria. "After completing my PhD, I worked as a postdoctoral student at the Biochemical department of the Technical University in Graz, Austria where I collected significant laboratory experience," she recalls.

## Finding the courage to keep going

Today, Andrea lives and works in Vienna and does not regret any of her decisions. "It was that special "can-do" attitude that I have inside of me. I am rather a calm and pleasant person, but at the same time I like a proper challenge," explains the lover of winter sports and passionate traveller.

Thanks to her hard work, persistence and above all her confidence in herself and her knowledge, Andrea managed to overcome any hurdles. "I moved to different countries. Learning new languages and adapting to new cultures as well as being far from my parents, family and school friends – well, at times it was hard, but at the same time it challenged me to keep going," she adds.

## Start in the pharmaceutical industry

After some years working at the Biochemical department of the Technical University in Graz, Andrea realised she wanted to move into the scientific field in the pharmaceutical industry.

"In the scientific area one has more challenges. I have learned that through science you really can make a difference in the world and benefit other people."

In 2000, Andrea was appointed as a scientist at Octapharma R&D in Vienna. "During this time I partly worked in the lab myself," she recalls. "Later I became a senior scientist for solvent/detergent-treated pooled plasma octaplas®, and gained more and more responsibilities." As her responsibilities increased, Andrea found more and more questions directed to her. "For particular projects, there were a lot of reviews. So, I always had to explain why we did certain things. It was a good experience because I learned a lot more quickly this way."

Andrea leads a team of 14 technicians.

Recently, Andrea was promoted to Team Leader. Now leading a team of 14 technicians, she believes in team balance, reliability and hard work. Beyond her scientific skills, Andrea also believes that as a scientist, staying open-minded, being precise and being a good listener are key to success. “While I am very precise and exact at work, I can listen to people and I am glad if I can help someone,” she continues.

**Driven to help**

“I enjoy my work. It is very versatile and varied,” she says, reflecting on her career at Octapharma. “It is great to enjoy what you are doing, be a good scientist and help people. As senior scientist, together with my team within the R&D department, we are developing new products and processes and optimising existing processes, which leads to new applications and improvements required for product safety and patient treatment.”

Andrea has successfully worked on the development of a second generation octaplas® product, octaplasLG®, by introducing a new dedicated prion removal step. OctaplasLG® contains more than 1,000 proteins that all have important roles in plasma and must be protected during production. For Andrea this was a challenging project, but at the same time one of the proudest moments in her career.

“In research, we always have to think several steps ahead. So, I was very proud when the FDA approved octaplasLG®, for both the Vienna and Stockholm sites.”

Andrea enjoys taking on a heavy workload, including working on several scientific studies and publications on octaplasLG®. She also presents her work at major scientific congresses.

Her latest challenges focus on designing two new developments for octaplasLG®. Both are high-priority projects in the pre-clinical stage, with the aim being to improve treatment in intensive care and emergency situations. “My job can be very challenging, but what’s especially important is that, at the end of the day, it’s for the benefit of the patient – and that’s the highest reward.”

Andrea and her team’s latest challenges focus on designing two new developments for octaplasLG®.

# From a living room...

Wolfgang Marguerre established Octapharma from his home in Paris in 1983. Founded on the desire to provide new health solutions that advance human life, Octapharma has grown into a truly global company providing life-enhancing therapies to patients in 115 countries.


- Octapharma Global HQ
- Octapharma Plasma, Inc. HQ
- Octapharma locations
- Manufacturing sites
- R&D sites
- Countries where patients are treated with our products

...to 115 countries

**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.

### Who we are

Family-owned since being established in 1983, Octapharma is a global healthcare company headquartered in Lachen, Switzerland. Our products are available in 115 countries and reach hundreds of thousands of patients every year. We focus on three therapeutic areas: haematology, immunotherapy and critical care.

Octapharma is one of the largest human protein product manufacturers. We develop and produce medicines based on human proteins from human cell lines and human plasma, sourced by our own plasma donation centres and external sources.

### Working at Octapharma

Octapharma focuses on long-term success and recognises the value of teamwork. We have a multicultural working environment filled with highly engaged people of diverse backgrounds and talents. Our five company values are Ownership, Integrity, Leadership, Sustainability and Entrepreneurship. We aspire to embody these values in everything we do, every day.

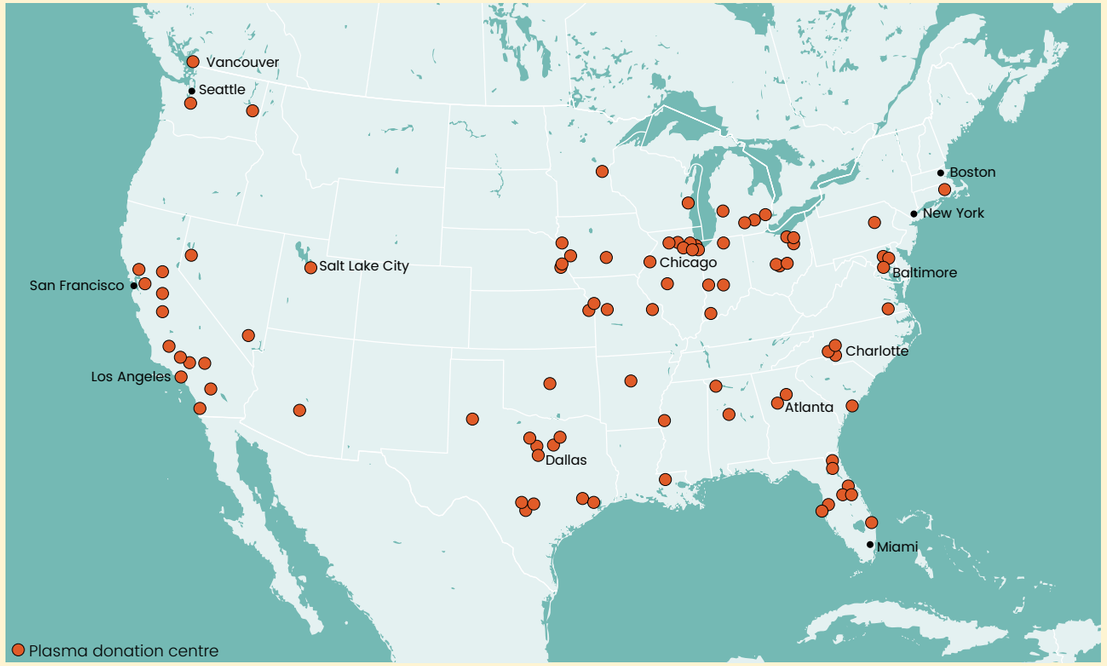
### Excellence in manufacturing

In 2018, we were working to enhance our manufacturing network and optimise our efficiency and growth. We have invested €117 million in our production facilities across Europe.

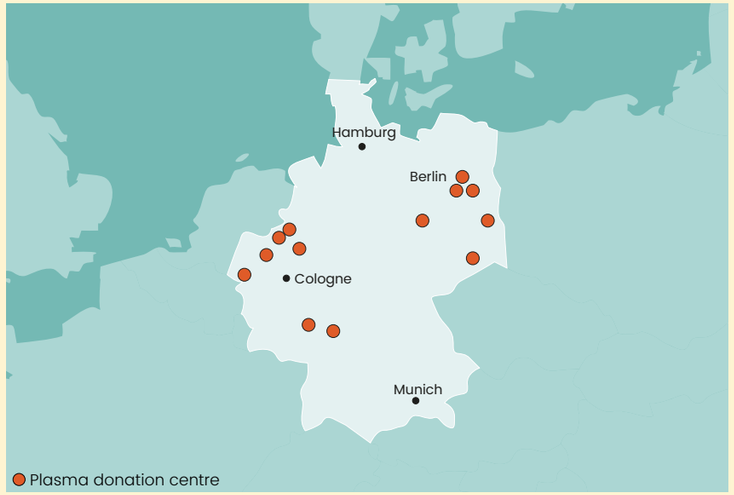
The €38 million invested in our Springe plant in Germany will significantly expand the manufacturing capacity for our plasma-derived products. This new fractionation plant will have an annual capacity of 1.8 million litres of plasma.

In Vienna, we have completed construction work on a €30 million pilot plant and thus strengthened Vienna's status as a group-wide centre for our R&D activities. This pilot plant is designed for the implementation of multiple products at various production scales and comprises the link between research work and routine production.

We have continued to improve our manufacturing operations. State-of-the-art technology for aseptic processing will help us improve efficiency and effectiveness. Our strategic aim is to implement new and standardised filling lines and freeze-dryers in our production plants to increase filling and freeze-drying capacities and to cover future products and format sizes.






**13**
plasma donation centres across Germany

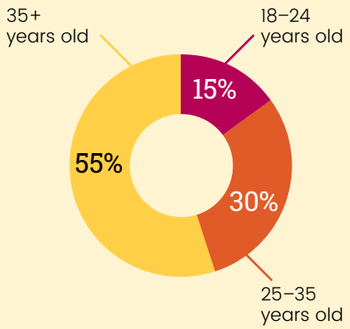
**80%**
of our plasma comes from company-owned donation centres

**6**
manufacturing sites

**7**
R&D sites

**86**
plasma donation centres across the US

**Breakdown of donors by age**




### Increase plasma collection

Plasma is the foundation of our business. As we rely on our plasma donors for this scarce raw material, we promise to use every drop optimally. Committed to meeting the increasing demand for our plasma-derived therapies, we have continued to increase the number of our plasma donation centres. In the US, Octapharma Plasma, Inc. (OPI) operates 86 centres in 26 states and serves over 120,000 donors per month. In Germany, our 13 donation centres operated by Octapharma Plasma GmbH (OPLG) have over 16,000 active donors.

### Research and development

We focus our R&D efforts on disease areas where there is still significant need for better treatment options and where we believe our skills will help us achieve our vision of providing new health solutions advancing human life. In 2018, we have continued with our major trials. Currently, we run over 15 clinical studies. 2018 was also a significant year in terms of our pre-clinical developments. For the first time, we have presented our promising data of the pre-clinical study for SubQ-8, a novel subcutaneous recombinant factor VIII (FVIII), at the World Federation of Hemophilia (WFH) Congress in Glasgow, UK.

### Doing business responsibly

We aim to be a good corporate citizen in the jurisdictions in which we operate. We ensure that all our actions and business activities are conducted in an economically, socially and environmentally sustainable way.

One of our goals is to achieve a significant reduction in our greenhouse gas emissions. In our sites in Stockholm, Springe, Dessau and Heidelberg we are switching to 100% renewable electricity. Since 2017, we have been using green electricity at our production plant in Vienna. In addition, we aim to reduce the volume of refrigerant loss in our cooling systems.

Our timeline

# Celebrating 35 years

## Since 1983, we have imagined a healthier, better world, believing that together we can invest to make a difference in people's lives.

**1983**
Wolfgang Marguerre establishes Octapharma with a single idea: people with haemophilia deserve access to better products.

**1985**
First factor VIII medicine launched, octavi®.

**1990**
Opens first state-of-the-art manufacturing site, acquired from Schwab in Vienna, Austria.

**1992**
Establishes laboratory in Frankfurt, Germany, for validation and documentation of virus inactivation methods.

**1999**
Acquires second manufacturing site from Aventis in Lingolsheim, France, to increase capacity.

**2002**
Acquires third manufacturing site from Biovitrum in Stockholm, Sweden, to increase product portfolio.

**2003**
Expands into USA market with FDA registration of octagam®.

**2006**
Acquires five plasma donation centres in Germany from Deutsche Gesellschaft für Humanplasma.

**2007**
Octapharma Plasma, Inc. founded in the USA to operate our own plasma donation centres.

**2008**
Acquires fourth state-of-the-art manufacturing site from German Red Cross in Springe, Hanover, Germany.

**2012**
Opens Institute for Recombinant Protein Research & Development in Heidelberg, Germany, to further invest in innovative therapies.

**2014**
European Medicines Agency (EMA) approves our first recombinant product, Nuwiq®, for haemophilia A patients.

**2015**
FDA approves Nuwiq® for haemophilia A patients in the USA.

**2016**
panzyga® receives regulatory approval in Canada and the EU for primary immunodeficiency syndromes and primary immune thrombocytopaenia.

**2017**
fibryga® receives regulatory approval in the USA, Canada and the EU.

**2018**

Octapharma announces promising data from the pre-clinical study for SubQ-8, our recombinant FVIII for subcutaneous administration.

Succeeding together – Octapharma welcomes its 8,000th employee on board.

Successful FDA inspections of our manufacturing sites in Lingolsheim, France and Stockholm, Sweden.

fibryga® receives regulatory approval in Switzerland to treat congenital and acquired fibrinogen deficiencies.

## In 2018, we celebrate 35 years of commitment to discovering innovative solutions to treat rare diseases, improving the lives of patients globally.

# From team...

Standing from left to right

**Gerold Rempeters,** Corporate Production Officer

**Josef Weinberger,** Corporate Quality and Compliance Officer

**Wolfgang Frenzel,** Research and Development

**Norbert Müller,** Board Member

**Matt Riordan,** Board Member

Round the table clockwise

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

**Olaf Walter,** Board Member

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

**Wolfgang Marguerre,** Chairman and CEO, Octapharma Group

**Tobias Marguerre,** Managing Director, Octapharma Nordic AB

**Flemming Nielsen,** President, Octapharma USA, Inc.

**Roger Mächler,** Chief Financial Officer

...to spirit

# Delivering remarkable growth year on year

Strong performance and continued investments in R&D and the extension of our production capacity and infrastructure to provide more medicines to patients in need.

**Roger Mächler**
Chief Financial Officer

**Over the last seven years, the Octapharma Group has accomplished a remarkable compound annual growth rate of 14% and for 2018 reports sales of €1.8 billion – €77 million (4.5%) more than 2017's figure (on a constant currency basis, the growth rate is 6.6%).**

All our products performed well, but to be highlighted are the year-on-year growth of our immunoglobulin product portfolio, as well as Nuwiq® and fibryga®. The company's continued strong and balanced sales growth would not be possible without effective collaboration across all divisions and regions, and the focus and commitment of all its employees and business partners.

Gross profit in 2018 was €631 million, which is €39 million higher than achieved in 2017. Despite continued investments in production capacity to fulfil the growing global need for plasma-derived products, the relative margin increased by 0.7 percentage points to 35.1%.

Operating income was €346 million. Net cash from operating activities was €261 million (14.5% of revenue). Trade receivables have slightly increased after strong sales in the last quarter of 2018 and our net inventory has increased by €172 million.

Our total operating expenses were €285 million. Significant investments were made for our future prosperity – €87 million for our R&D efforts and €153 million into the extension of our production capacity and infrastructure. Important milestones in the expansion of our plasma and recombinant product portfolio were reached in the last 12 months. To ensure each litre of plasma is used to best effect, the company will continue to expand its product portfolio with innovative new products and services, and enter new markets.

Major projects within Program 2019, the development initiative we launched in 2014 to double production capacity and significantly increase the overall efficiency of our manufacturing operations, were completed and contributed to the company's growth. Our investments in talent, equipment and property prepare the company for the demands of the future.

In 2019, our target is to further turn these successfully implemented capacity extension projects into sales growth of more than 10% and an absolute operating profit result comparable to previous years. This will allow us to continue investing in the future prosperity of Octapharma.

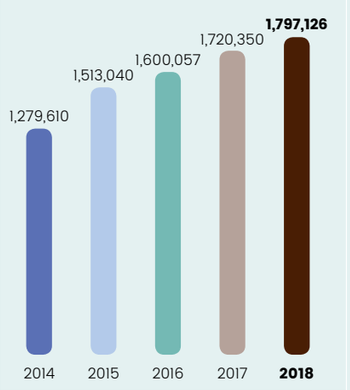
Our significant investments in research and infrastructure strongly position the company to fulfil the needs of more healthcare professionals and patients around the world.

**Roger Mächler**
Chief Financial Officer

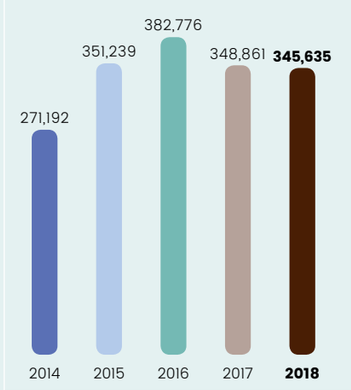
**€346m**
operating income

**€1.8bn**
revenue

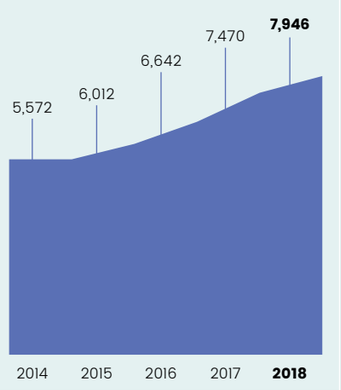
**Revenue in 1,000 EUR**




**Operating income in 1,000 EUR**




**Average headcount**






# Key figures of the Octapharma Group

| (Monetary figures are in 1,000 EUR) | 2018 | 2017 | 2016 | 2015 | 2014 |
|---|---|---|---|---|---|
| Operating income | **345,635** | 348,861 | 382,776 | 351,239 | 271,192 |
| Net profit of the year | **303,480** | 252,116 | 345,450 | 330,267 | 236,136 |
| Year-end headcount | **8,314** | 7,674 | 7,094 | 6,213 | 5,683 |
| Return on investment | **11.5%** | 10.2% | 15.3% | 17.0% | 14.2% |
| Profit from operations per employee | **43** | 47 | 58 | 58 | 49 |
| Cash ratio | **174%** | 187% | 180% | 174% | 122% |
| Days of sales in receivables | **126** | 126 | 137 | 123 | 135 |
| Days of inventory range | **250** | 217 | 218 | 227 | 249 |
| Cash flow from operations | **261,393** | 350,837 | 287,966 | 382,437 | 274,541 |
| Expenditures to ensure future prosperity | **240,183** | 287,197 | 249,611 | 242,383 | 168,265 |
| Research and development | **87,291** | 86,508 | 83,500 | 72,825 | 41,792 |
| Capital expenditures and investments in activities | **152,892** | 200,689 | 166,111 | 169,558 | 126,473 |

“Over the last seven years, the Octapharma Group has accomplished a remarkable compound annual growth rate of 14% and for 2018 reports sales of €1.8 billion – €77 million (4.5%) more than 2017's figure.”

# Financial statements of the Octapharma Group*

## Consolidated income statement of the Octapharma Group

| (All figures in 1,000 EUR) | 2018 | 2017 |
|---|---|---|
| **Revenue** | **1,797,126** | 1,720,350 |
| Cost of sales | **-1,166,158** | -1,128,068 |
| **Gross profit** | **630,968** | 592,282 |
| Research and development | **-87,291** | -86,508 |
| Selling and marketing | **-135,643** | -99,151 |
| Regulatory affairs | **-18,405** | -15,640 |
| General and administration | **-60,845** | -49,959 |
| Other income | **17,626** | 11,073 |
| Other expenses | **-775** | -3,236 |
| **Total operating expenses** | **-285,333** | -243,421 |
| **Operating income** | **345,635** | 348,861 |
| Non-operating income and expenses | **229** | -35,028 |
| **Profit before taxes** | **345,864** | 313,833 |
| Income tax | **-42,384** | -61,717 |
| **Net profit of the year** | **303,480** | 252,116 |

* 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 2018, 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) | 2018 | 2017 |
|---|---|---|
| **Assets** | | |
| Cash and cash equivalents | **502,153** | 485,600 |
| Trade receivables | **622,372** | 595,865 |
| Other receivables and current assets | **55,585** | 54,527 |
| Loans granted | **71** | 30,353 |
| Derivative financial instruments | **92** | 477 |
| Inventories | **827,276** | 655,048 |
| **Total current assets** | **2,007,549** | 1,821,870 |
| Financial investments | **1,370** | 2,559 |
| Deferred tax assets | **52,293** | 53,156 |
| Loans granted | **723** | 691 |
| Investments in associates | **0** | 8,270 |
| Property, plant and equipment | **693,611** | 655,311 |
| Intangible assets | **0** | 4,729 |
| **Total non-current assets** | **747,997** | 724,716 |
| **Total assets** | **2,755,546** | 2,546,586 |

| **Liabilities and equity** | | |
|---|---|---|
| Trade payables and other payables | **105,264** | 98,739 |
| Derivative financial instruments | **1,620** | 1,222 |
| Income tax payables | **19,952** | 24,292 |
| Accruals | **127,831** | 93,273 |
| Current provisions | **33,389** | 42,198 |
| **Total current liabilities** | **288,056** | 259,724 |
| Deferred income | **2,214** | 2,312 |
| Provisions | **87,321** | 82,489 |
| Deferred tax liabilities | **33,780** | 28,929 |
| Other non-current liabilities | **3,783** | 542 |
| **Total non-current liabilities** | **127,098** | 114,272 |
| **Total liabilities** | **415,154** | 373,996 |
| Share capital | **100** | 100 |
| Retained earnings | **2,340,969** | 2,180,532 |
| Currency translation adjustments | **-677** | -8,042 |
| **Total equity** | **2,340,392** | 2,172,590 |
| **Total liabilities and equity** | **2,755,546** | 2,546,586 |

## Consolidated statement of cash flows of the Octapharma Group

| (All figures in 1,000 EUR) | 2018 | 2017 |
|---|---|---|
| **Net profit for the year** | **303,480** | 252,116 |
| Depreciation of property, plant and equipment | **104,834** | 88,180 |
| Impairment of fixed assets | **12,379** | 10,000 |
| Change in fair value of non-current assets | **1,400** | -881 |
| (Profit) loss on sale of property, plant and equipment and equity investment | **-7,160** | 1,775 |
| Changes in long-term liabilities and provisions | **5,971** | 3,438 |
| Tax expense | **42,384** | 61,717 |
| Unrealised foreign exchange (gain) loss | **-3,013** | 22,472 |
| **Cash flow before changes in working capital** | **460,275** | 438,817 |
| (Increase) decrease of working capital | **-198,882** | -87,980 |
| **Net cash from operating activities** | **261,393** | 350,837 |
| Acquisition of property, plant and equipment | **-152,892** | -200,689 |
| Change of financial and equity investments | **16,759** | 1,579 |
| Proceeds from sales of property, plant and equipment | **718** | 563 |
| Interest received | **2,283** | 2,253 |
| **Net cash used in investing activities** | **-133,132** | -196,294 |
| Financing activities | **-112,241** | -110,000 |
| **Net cash used for financing activities** | **-112,241** | -110,000 |
| **Net change in cash and cash equivalents** | **16,020** | 44,543 |
| Cash and cash equivalents beginning of period | **485,600** | 445,467 |
| Effect of exchange fluctuation on cash held | **533** | -4,410 |
| **Cash and cash equivalents end of period** | **502,153** | 485,600 |



# 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 68 to 70, which comprise the summary balance sheet as at December 31, 2018, 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, 2018.

In our opinion, the accompanying summary financial statements are a fair summary of the audited financial statements, on the basis described on page 68 of the annual report 2018.

**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 22, 2019.

**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 68 of the annual report 2018.

**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

Hanspeter Stocker
Zurich, 22 February 2019

Anna Pohle

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