octapharma

Annual Report 2022

It started with a belief

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I will be forever grateful to all the donors who have stepped up and ask everyone to seriously think about doing it. Your donation helps a child like mine live a normal and happy life.

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A belief that we can make a difference

For 40 years, we have imagined a healthier, better world, believing that together we can invest to make a difference in people's lives.

Today, Octapharma has 13 products in various formats and directly employs more than 11,000 people around the world, generating nearly €3 billion a year in sales. That success has been built on our vision to provide new health solutions advancing human life, our continuing commitment to financial discipline and customer service, and our corporate values of Ownership, Integrity, Leadership, Sustainability and Entrepreneurship.

"It started with a belief that we could provide haemophilia patients with a safer, higher-quality factor VIII (FVIII) concentrate. Today, driven by a vision to provide new health solutions advancing human life, we continue to find new ways in which to help people with life-changing medical conditions and to grow our business."

Wolfgang Marguerre
Chairman and CEO, Octapharma Group

Built on strength and stability

Number of employees

11,573

(2021: 9,977)

Sales

€2.85bn

(2021: €2.51bn)

Operating income

€522m

(2021: €459m)

In 2023, Octapharma celebrates 40 years of remarkable innovation and growth which has helped transform the lives of countless patients. What started in 1983 as two men with a shared vision to provide haemophilia patients with a safe and efficacious factor VIII (FVIII), has grown into a global company with more than 11,000 employees helping tens of thousands of patients every year live fuller, healthier lives.

In this year's report, we look back on the early origins of our company and explore the role Octapharma played in the development and introduction of the solvent/detergent (S/D) method for the inactivation of enveloped viruses. This technology played a crucial role in the war against viruses such as hepatitis and HIV, and it remains the gold standard for our industry today.

We also hear how our products continue to transform the lives of patients and their loved ones. Suzanne and Eva share their inspiring stories of living with and overcoming debilitating conditions, while Dr Victor Viersen provides his insights based on case studies into how lyophilised plasma can help stabilise and save the lives of trauma patients in a pre-hospital emergency setting.

We made excellent progress in several of our clinical trials. We successfully completed our LEX-209 phase III study into the efficacy and safety of octaplex®, our four-factor prothrombin complex concentrate, compared to a rival product in treating patients receiving vitamin K antagonist anticoagulant therapy who need urgent surgery with significant bleeding risk. We are hoping to receive FDA approval for octaplex® in the USA during 2023.

The first patients have also been treated in our LEX-210 study investigating the efficacy and safety of octaplex® in the treatment of major bleeding related to direct oral anticoagulant (DOAC) therapy.

The first patients were also treated in our ATN-106 study, a phase III study assessing the efficacy, safety and pharmacokinetics of atenativ®, our human antithrombin III concentrate, in patients with congenital antithrombin deficiency undergoing surgery or delivery.

Our research also continued to receive international recognition. Clinical data from the Progress in DERMatomyositis (ProDERM) study into the use of octagam® 10% as a treatment for dermatomyositis, a rare autoimmune disorder, was published in the October 6, 2022 issue of the *New England Journal of Medicine*.

In February 2023, European authorities approved octaplasLG® powder and solvent for solution for infusion, the line extension of our long-established octaplasLG®.

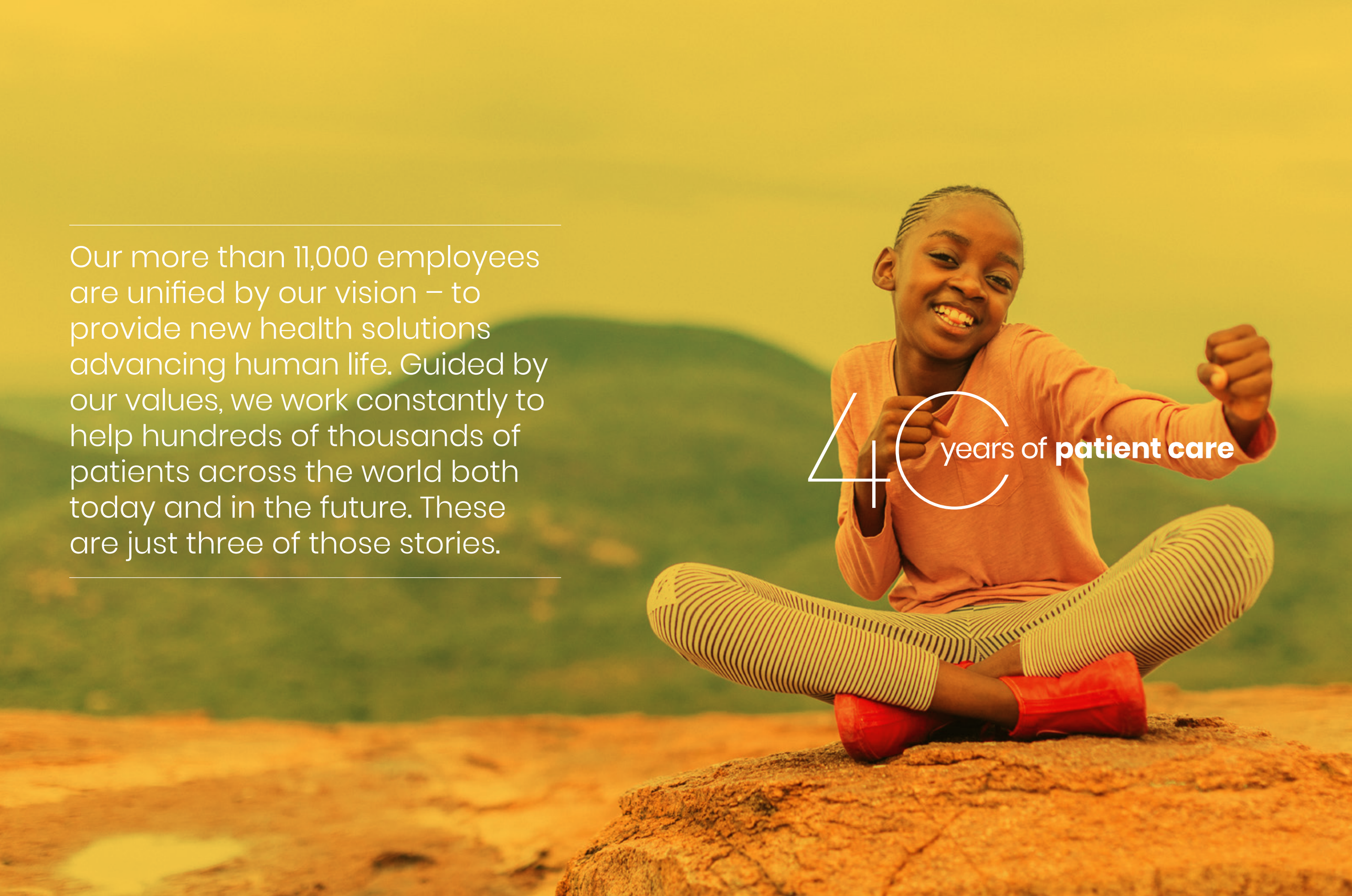
This new lyophilised presentation maintains the efficacy and safety of the frozen format – however, due to its dried form, it can be stored at room temperature (below 25°C), representing a life-saving treatment option in both civilian and military prehospital emergency settings, and in locations with limited frozen storage facilities and cold chain infrastructure needed for fresh-frozen plasma (FFP).

We continue to invest heavily in new plasma donation centres in the USA, and we now operate more than 190 donation centres across our fleet in the USA and Germany.

These and many other successes contributed in 2022 to sales of €2.854 billion and an operating income of €522 million, representing growth of 13.7% over 2021 in both cases. I would like to thank all Octapharma employees whose hard work and commitment have made these strong results possible, and the many healthcare professionals and patients around the world who continue to put their faith in us.

Wolfgang Marguerre
Chairman and CEO, Octapharma Group

Our more than 11,000 employees are unified by our vision – to provide new health solutions advancing human life. Guided by our values, we work constantly to help hundreds of thousands of patients across the world both today and in the future. These are just three of those stories.



“I remember thinking how wonderful it was to feel that good. I joked that I felt better at eight months pregnant than I did for decades because of the prophylactic factor infusing care.”

Suzanne
California

Building a dream family despite VWD

“Suzanne almost died going through the birth of our first daughter, Miriam,” recalls Suzanne’s husband, Dan. “It was a very tough, traumatic time for all of us.”

A little over nine years later, Suzanne and Dan welcomed their fourth child, a son, into the family. This time, Suzanne’s experience during pregnancy could not have been more different to her first, largely thanks to prophylactic treatment with wilate®, Octapharma’s von Willebrand factor (VWF) concentrate.

Suzanne has type 3 von Willebrand disease (VWD), the most severe form of the hereditary bleeding disorder. People with VWD either have a low level of the clotting protein VWF in their blood, or it doesn’t work as it’s supposed to. According to the Centers for Disease Control and Prevention (CDC), 3.2 million people in the USA have VWD. It occurs equally in men and women. However, women may be more symptomatic due to heavy menstrual bleeding (periods).

There is currently no cure for VWD, but patients like Suzanne can replace or supplement the missing clotting factor by infusing wilate®, which is manufactured from donated blood plasma.

Struggling with difficult moments during pregnancy

“I always wanted a big family, but Suzanne was not certain at first because of her VWD,” says Dan.

Trying to get pregnant with Miriam, their first child, was very difficult, primarily because of the bleeding issues Suzanne faced. “Finally, joyfully, I fell pregnant but almost immediately started bleeding,” remembers Suzanne. “We assumed it was a miscarriage, but the doctors assured us that it was not.”

The pregnancy was extremely stressful. As Suzanne recalls: “Each morning, we didn’t know what we were going to face that day.” She was in and out of hospital due to bleeding complications and, at that time, she had no access to factor concentrates. “I was 26 weeks pregnant, and we had no other option but to go into hospital to deliver Miriam early,” she recalls.

There were life-or-death moments during Miriam’s birth. “There was a point where I had to make medical decisions on behalf of Suzanne since she was incapable of making them herself because of some of the treatments they were giving her,” says Dan.

Eventually, baby Miriam was safely delivered but she needed to spend seven weeks in a neonatal intensive care unit. Suzanne spent a week and a half in hospital recovering from the birth.

How VWD is inherited

If one parent has a genetic change that causes VWD, there is a

50%

chance of a child having VWD.

It is estimated that

90%

of people with VWD have not yet been diagnosed.

Sources: https://www.nhs.uk/conditions/von-willebrand-disease/ https://www.wfh.org/en/our-work-global/vwd-initiative-program

Living with a chronic bleeding disorder
Over the next seven years, Suzanne had six miscarriages, all due to bleeding. "If you're bleeding that much, you can't support another life," she explains. It was a difficult time, but Suzanne and Dan were still able to expand their family: "Wonderfully, we adopted two children, Josiah and Rachel, and our kids are the light of our lives," says Suzanne.

"Living with a chronic bleeding disorder is not easy, but Suzanne has an excellent attitude to daily life with VWD," says Dan. That positive outlook is helped to a great extent by Dan and their children, and by her upbringing. "I was diagnosed at birth and have a family history of VWD, so my parents knew to look out for it when I was a baby and we shared experiences as I grew up," explains Suzanne. That positivity perhaps explains how the couple decided to explore the idea of one more pregnancy despite all the hardships they had experienced.

It's wonderful to feel this good
In planning this latest pregnancy, they began to explore how prophylactic care and factor infusing prior to becoming pregnant could help Suzanne during pregnancy.

Suzanne was not aware that prophylaxis for VWD patients existed. In fact, it was only after attending a patient conference and speaking to other women with VWD that Suzanne heard about the possibilities that prophylaxis could offer her. At the time, she went to her physician but was told that it wasn't for VWD patients, and she didn't need it.

After moving across the country for Dan's work, her new consulting physician immediately offered her prophylaxis and explained that she needed to begin treatment before becoming pregnant. "Factor infusing is something you deal with before, not after, getting pregnant so that you can have all the support you need to sustain a little life," explains Suzanne. "I was already using wilate® on demand but I switched to infusing factor prophylactically and started infusing it three times a week, one month before I got pregnant."

The difference between her life-threatening first pregnancy and her second was enormous: Suzanne got to do what many "normal" pregnant women do. "I was able to think about nurseries and baby names," she says. "I really didn't worry about my health or my child because I had the support that I needed – the support that I deserved and the support my baby deserved."

"I remember thinking how wonderful it was to feel that good," she admits. "I joked that I felt better at eight months pregnant than I did for decades because of the prophylactic factor infusing care. I can't speak enough about that feeling, of being strong and healthy in a way that I had never known was available to me."

Suzanne safely gave birth at full term to Samuel in June 2021 and the whole family have now settled into their new life together. Like his mother, Samuel has VWD, but Dan and Suzanne are reassured that Samuel will not have to go through the sort of bleeding that she endured, as they will ensure he has access to wilate® prophylaxis.

Did you know?

VWD occurs
equally
across all races and ethnicities.

VWD is named after the Finnish physician Erik von Willebrand, who first described it in the 1920s.

Source: https://www.wfh.org/en/our-work-global/vwd-initiative-program

“In a way, dermatomyositis forced me to re-define who I am and how I see myself. I now live much more in the here and now.”

Eva
Czech Republic

Living with the mystery of dermatomyositis

"I first noticed that my nail folds were reddish and shiny in summer 2014 but I didn't really think much of it," recalls Eva, 39, from the Czech Republic. When a rash appeared on her thighs a few months later, she was too busy to take much notice.

When Eva started feeling extreme fatigue and muscle weakness, however, her symptoms became impossible to ignore.

"The pain was intense. After a slight movement, I felt as if I'd run a marathon," she remembers. "I had trouble swallowing and real problems raising my arms above my shoulders or even standing up."

Despite the pain and weakness, she kept going. "I was starting my dream job in Prague and just had to get on with it. I told myself I didn't have time to think about the pain."

"I was starting my dream job in Prague and just had to get on with it. I told myself I didn't have time to think about the pain."

Eva

The pain will pass

Initially, Eva was not so much misdiagnosed as not diagnosed at all. Everyone saw her as a generally healthy woman and whatever the pain was, they were sure it would pass.

As a doctor herself, her intuition told her otherwise. After looking at the results of a blood test she'd had as part of a health assessment for her new job in a fertility clinic, she noticed higher liver enzyme levels and started searching for answers.

"I remember wondering whether it could be dermatomyositis but I didn't have anyone around to check with, so I put that thought to the back of my mind," she recalls.

Finally, Eva went to see a fellow doctor in her new hospital and was sent directly to the rheumatology clinic, where she was to learn much, much more about dermatomyositis.

Who does dermatomyositis affect?

Dermatomyositis affects

60–190

people per million in the USA.

Females are

2–3x

more likely to be affected by dermatomyositis than males.

In children, approximately

3

in every million are affected by juvenile dermatomyositis.

Sources: https://rarediseases.org/rare-diseases/dermatomyositis/
https://jamanetwork.com/journals/jamadermatology/article-abstract/2796168

Trapped in her own body
As a child, Eva had sometimes dreamed of being trapped and unable to move her body. Now, the feeling was the same. Once an independent person used to helping people, she was very quickly reliant on others for practically everything. "I lay in hospital, unable to move my body and just waiting for something to change," remembers Eva.

"Dermatomyositis can be difficult to diagnose, particularly if the typical rash is lacking," explains Professor Jiří Vencovský from First Faculty of Medicine, Charles University in Prague, who also treated Eva. "When patients present with classical signs and symptoms, making the diagnosis is relatively easy. The difficult part comes after that – the treatment."

Autoimmune disorders cause the body's immune system to attack its own cells and tissue. Affecting 60-190 people per million in the USA alone,[1] dermatomyositis is an inflammatory disease marked by muscle weakness and a distinctive skin rash. More common in females than males, the condition usually occurs in adults in their late 40s to early 60s, or in children between the ages of five and 15 years. There is no cure for dermatomyositis and, until recently, patients were typically treated with corticosteroids, which can have serious side-effects with prolonged use.

Gradually, Eva responded to her medication. By the summer of 2015, almost a year after she entered the rheumatology clinic, she was able to eat on her own again, and speak and move. "Every single day, I told myself: this disease will NOT control me, I will control this disease."

Eva did just that. She did everything the medical team asked her to do, and more. She worked hard under the supervision of her physiotherapists and then continued to work at home. "I re-learned everything from scratch – to walk, to talk, to articulate."

Back to a kind of normal
By the autumn of 2015, Eva was finally able to properly start her new job as a gynaecologist. "In a way, dermatomyositis forced me to re-define who I am and how I see myself," admits Eva. "I now live much more in the here and now."

As well as being able to enjoy her rewarding job at the clinic, Eva also became pregnant in 2018. "I was extremely happy, and I never imagined that dermatomyositis would come back into my life." But it did.

Relapse and despair before new hope
After giving birth to her daughter Marta in late 2018, Eva's myoglobin levels rose again. The disease was back. "I immediately reached out to Professor Vencovský, the doctor who had looked after me during my first attack, and we increased my medication dose, which thankfully helped," recalls Eva.

Almost 18 months later, she had another relapse. This time, the muscle weakness and pain were intense and unfortunately Eva also suffered a miscarriage. "I couldn't pick up my daughter: I had no strength at all," remembers Eva. "I lived in constant fear that something would happen to me, and that Marta would grow up without a mother. I recorded myself singing songs to her, just in case I didn't make it."

However, new hope finally came with an invitation from Professor Vencovský to try Octapharma's intravenous immunoglobulin (IVIg) therapy octagam® 10%, which in 2021 became the first treatment to be approved for dermatomyositis in the EU, the USA and Canada.

Eva was immediately on board with this novel treatment modality. Under this therapy, she quickly regained her strength. "After starting IVIg therapy, I had no more muscle pain, and I could hug my little girl very tightly again." IVIg therapy has restored Eva's sense of wellbeing. "I see myself as a healthy woman – no more, no less – and that is all I could wish for."

1 https://onlinelibrary.wiley.com/doi/10.1002/acr.24786

Elisabeth Clodi, Senior Global Medical Advisor, Global Medical and Scientific Affairs

A long and rigorous process

In a first for Octapharma, clinical data from the Progress in DERMatomyositis (ProDERM) study was published in the October 6, 2022, issue of the *New England Journal of Medicine* (NEJM).

ProDERM was the first pivotal randomised placebo-controlled clinical trial to evaluate intravenous immunoglobulin (IVIg) (octagam® 10%) as a treatment for dermatomyositis.

The study clearly demonstrated that significantly more patients responded to IVIg than to a placebo, which in turn led to approval of dermatomyositis in adults as an indication for octagam® 10% in the USA, Canada and Europe.

"It was a long and rigorous process from first draft to first submission and finally publication, but the result is that more practitioners will become aware that octagam® 10% is a viable treatment option for dermatomyositis that will ultimately benefit patients," says Elisabeth Clodi, Senior Global Medical Advisor, Global Medical and Scientific Affairs, who led the effort to publish the data in the NEJM.

"Pre-hospital transfusion could be beneficial, but not when given to any patients with hypotension and suspected bleeding. We are just not that good at predicting who needs transfusion."

Dr Victor Viersen
Department of Anaesthesiology at the University of Amsterdam,
The Netherlands

To transfuse or not to transfuse: A challenging question in pre-hospital critical care

Healthcare professionals have a wide range of treatment options when a patient suffers significant blood loss in a hospital setting, but the situation becomes a lot more complicated in the outside world. One of the key decisions to make is whether or not to transfuse blood and blood products.

Dr Victor Viersen of the Department of Anaesthesiology at the University of Amsterdam, The Netherlands, shares the example of a motorcyclist who was involved in a head-on collision with a car at a combined speed of around 120 kilometres per hour (almost 75 miles per hour). The patient had a severe pelvic injury, resulting in massive blood loss and no measurable blood pressure upon arrival.

"Luckily, we carry a cooler with blood products when attending emergencies," says Dr Viersen. "I had the ability to provide two packed red blood cells, two thawed units of plasma and two grams of fibrinogen. So that's almost a litre of volume that we could provide and, after we pushed that in, we had a blood pressure of 40 over 20 (mmHg). That's how I managed, along with some crystalloid fluids – because I had run out of blood products – to get him to a hospital where he made a full neurological recovery."

Mixed evidence

The necessity of pre-hospital transfusion was evident in this case; however, the results of clinical studies into the benefits of transfusion in a pre-clinical setting are not so evident. Some studies have demonstrated a benefit of transfusion on morbidity and mortality, whereas others have not. However, it is becoming apparent that transfusion is likely to have a role in a pre-hospital setting, but only in carefully selected patient groups and certain situations.

One such group was identified through a post hoc combined analysis of the Control of Major Bleeding After Trauma (COMBAT) and Prehospital Air Medical Plasma (PAMPer) trials, comprising a total of 626 patients with trauma and haemorrhagic shock.[1,2,3] Patients had been randomly assigned to receive either standard care or two units of thawed plasma followed by standard care in the pre-hospital setting.

The PAMPer trial found a reduction in mortality of almost 30% with plasma transfusion in the pre-hospital setting, whereas the COMBAT trial found no survival improvement. In the post hoc combined analysis, in patients for whom the benefit–risk ratio was favourable for the use of pre-hospital plasma, pre-hospital plasma was associated with a survival benefit when transport times were longer than 20 minutes.

Looking at the recent randomised controlled trials on pre-hospital transfusion in general, it suggests that pre-hospital transfusion has no benefit. However, when looking more closely at the data, it is apparent that a lot of patients were transfused who, in hindsight, did not need a transfusion.

1 Moore HB, Moore EE, Chapman MP, et al. Plasma-first resuscitation to treat haemorrhagic shock during emergency ground transportation in an urban area: a randomised trial. Lancet. 2018 Jul 28;392(10144):283-291. doi: 10.1016/S0140-6736(18)31553-8. Epub 2018 Jul 20. PMID: 30032977; PMCID: PMC6284829.
2 Sperry JL, Guyette FX, Brown JB, et al; PAMPer Study Group. Prehospital Plasma during Air Medical Transport in Trauma Patients at Risk for Hemorrhagic Shock. N Engl J Med. 2018 Jul 26;379(4):315-326. doi: 10.1056/NEJMoa1802345. PMID: 30044935.
3 Pusateri AE, Moore EE, Moore HB, et al. Association of Prehospital Plasma Transfusion With Survival in Trauma Patients With Hemorrhagic Shock When Transport Times Are Longer Than 20 Minutes: A Post Hoc Analysis of the PAMPer and COMBAT Clinical Trials. JAMA Surg. 2020 Feb 1;155(2):e195085. doi: 10.1001/jamasurg.2019.5085. Epub 2020 Feb 19. PMID: 31851290; PMCID: PMC6990948.

Ensuring optimal benefit
As Dr Viersen explains, "Pre-hospital transfusion could be beneficial, but not when given to any patients with hypotension and suspected bleeding. We are just not that good at predicting who needs transfusion." This is an issue not least because blood products in general are costly, in short supply and desperately needed in other settings.

However, as evidence emerges regarding those patients and situations where pre-hospital transfusion is most likely to be beneficial, efforts are under way to optimise its use and cost effectiveness.

Lyophilised plasma
Octapharma has been working on a solution to this dilemma. A study published on October 1, 2022 showed that a new freeze-dried (lyophilised) form of OctaplasLG® – a unique pharmaceutical-grade human plasma for infusion – is a viable alternative to frozen plasma, offering a comparable quality profile with the tremendous logistical advantage of a relatively long shelf life at room temperature.[4] In February 2023, medical authorities in Europe approved the lyophilised presentation of octaplasLG® for transfusion, also in a pre-hospital setting.

"OctaplasLG® is already a trusted product in emergency situations where plasma resuscitation is indicated," says Oliver Hegener, Vice President IBU Critical Care. "OctaplasLG® in lyophilised powder form, our new product, can be kept at room temperature in the emergency room or in the back of an ambulance for 24 months and deployed as needed. The product can be quickly reconstituted by simply adding the accompanying water. This makes it a much more flexible and efficient option for use in pre-hospital settings and for situations or in regions with austere infrastructure. We look forward to filling this gap in the treatment of severely injured patients."

4 Heger A, Gruber G. Frozen and freeze-dried solvent/detergent treated plasma: Two different pharmaceutical formulations with comparable quality. Transfusion. 2022 Dec;62(12):2621-2630. doi: 10.1111/trf.17139. Epub 2022 Oct 1. PMID: 36181447.

The decision to transfuse or not remains a challenging one to make, and Oliver's team is working with leading experts in critical care and trauma to help healthcare professionals make more informed choices about when a transfusion is called for and which products to use. This includes a rich programme of educational courses, including masterclasses in bleeding management, workshops, congresses and tailored educational programmes such as octaCARE designed to provide medical practitioners with access to the insights and expertise of leading experts in their field.

"OctaplasLG® is already a trusted product in emergency situations where plasma resuscitation is indicated."

Oliver Hegener
Vice President IBU Critical Care

It started with a belief! Octapharma was founded 40 years ago to provide haemophilia patients with a safer, higher-quality factor VIII (FVIII) concentrate. In the four decades since, Octapharma has grown into a global company, driven by that same belief and vision to provide new health solutions advancing human life.

40 years

It started with a **belief**

When Dr Judith Pool, then a research associate at Stanford University, first developed in 1964 a technique for producing cryoprecipitate from a single donor's plasma in an ordinary blood bank, it represented a major improvement in the treatment for haemophilia patients.[1] Prior to this time, haemophilia patients could receive transfusions of fresh whole blood or fresh frozen plasma in hospital. Cryo from single donors became widely available for patients with haemophilia.

The advances with cryo sparked a wave of interest in plasma-based therapies and a handful of companies moved quickly to commercialise this new opportunity. Development of commercial fractionation technologies in the late 1960's and 1970's yielded lyophilised clotting factor concentrates that immediately raised the missing clotting factor to normal levels, could be carried with patients on trips and could be self-administered.[2] For the first time, haemophilia patients could be treated prior to a bleed (prophylactically), reducing the likelihood of a bleed and the resulting joint damage.[3]

A partnership is born

It was at Baxter's Travenol Laboratories that Wolfgang Marguerre and Robert Taub first crossed paths.

"That's where I started getting a taste for medicine and plasma-derived healthcare," recalls Robert, who joined Travenol in 1973. In 1975, the year Wolfgang joined the company, Robert moved into the plasma derivatives business which Wolfgang was managing. During these initial years, the two young managers formed a lasting bond based on trust and mutual respect.

Their careers became ever more closely intertwined. When Wolfgang left Baxter in 1978 to take up a position as Senior Executive Vice President at French cosmetics giant Revlon, in charge of its plasma division, Robert followed a year later to become General Manager of the German subsidiary, again reporting to, and working closely with, Wolfgang.

An emerging health crisis for haemophilia patients

While factor VIII concentrates had brought new hope to patients with haemophilia, they also brought a new scourge: hepatitis. The factor concentrates were manufactured from pools of up to 40,000 donors, at a time before donor screening and virus testing were available. Viral inactivation and removal techniques were also not yet implemented in manufacturing.

By 1980, almost all patients being treated with clotting factor concentrates such as factor VIII had been exposed to hepatitis. It is thought that anybody who used a factor concentrate before 1985 was exposed to hepatitis C and most of these patients were infected with the virus.[4] It was not until 1990, for example, that testing for hepatitis C was introduced.

In the USA, towards the end of 1980, a new blood borne disease – acquired immune deficiency syndrome (AIDS) – began to be observed. By 1982, no direct proof yet existed that showed that AIDS was infectious or transmitted by blood. No agent had been found and no tests existed to screen potentially infected persons.[5] However, in 1982, the first death of a haemophilia patient infected with AIDS was reported in the USA and the first warning of the danger of contracting AIDS from contaminated blood products was published. This was followed in 1983 by other warnings in *The Lancet* and from the WHO which said that haemophilia patients should be warned of the dangers.[6]

Call to action: An urgent need for viral inactivation

Wolfgang and Robert were quick to understand and grasp the enormity of what was happening to the haemophilia community. Patients were being infected every day with hepatitis and HIV. Confronted by the grim reality, they decided that they had to act fast to find a technology capable of inactivating these various pathogens.

The seeds of an idea

During 1981, when they were working together at Revlon, Wolfgang got the approval to send Robert for his MBA at Insead, where Wolfgang himself had earned his MBA in the class of 1972. In 1982, while working on an MBA module, Robert wrote the five-page outline of a business model that would become the initial blueprint for Octapharma.

Both men had by 1983 come to a similar conclusion: they no longer saw their futures wasting time and effort working in large corporations. "I was fed up with all the bureaucracy at large pharmaceutical companies," comments Wolfgang, "and I realised that the fastest way to find a solution to this crisis would be to leave my job at Revlon and go it alone in search of the holy grail of viral inactivation technology for haemophilia patients."

"We started with nothing and had to push hard to get the business off the ground. At the beginning, I only had a desk, the same desk I still work at today, and little else."

Wolfgang Marguerre

40 years

Andy Smith, Octapharma's first full-time employee

1989

150
employees

By 1995

€100m
annual sales

Octapharma is born
Robert and Wolfgang decided to join forces and on June 2, 1983, they founded their company, called Octapharma – the name being a nod to factor VIII, in Switzerland. The two entrepreneurs had also become increasingly aware of the growing need for innovation in the plasma industry.

A chance discussion with a haematologist friend in Paris brought research being done at the New York Blood Center (NYBC) to their attention.

We thought the solvent/detergent (S/D) method had the potential to be a very elegant viral inactivation method for lipid-coated viruses like hepatitis and HIV," remembers Robert. "In the S/D method, the solvent breaks down the lipid layer and the detergent inactivates the virus, but it does not affect the biological properties of the FVIII protein."

Launching the team
Recognising the urgent medical need for virally inactivated clotting factor concentrates for haemophilia patients, Robert and Wolfgang decided to invest and work together with the team of scientists at the NYBC (which included Drs Bernard Horowitz, Richard Bonomo and Alfred Prince). Recognising the great potential of S/D to deliver virally safe clotting factor concentrates, Robert and Wolfgang purchased a licence for the use of the S/D method from the NYBC.

At the same time, they hired Octapharma's first full-time employee: Andy Smith, a protein chemist, who was working at Revlon's fractionation plant in Illinois. Andy was quickly sent to the NYBC to study the S/D method with a view to further improving it and scaling it up for commercial production. Andy recalls the moment when they were able to test the S/D method: "We obtained a sample of the HIV virus. With some trepidation, we took it into the lab at the NYBC to test whether the S/D method could inactivate it. We were elated when we discovered that S/D killed the virus," he says. "So we could demonstrate that Octapharma had a process to kill both the hepatitis and HIV viruses, and could be the first company on the market with a virus-safe product."

Andy, who still works for Octapharma, then moved to Paris from where he commuted every week to the German Red Cross's laboratory in Haagen to further refine his modified S/D method in a commercial scale.

First steps in manufacturing
Armed with a licence for the S/D method and Andy's manufacturing process and know how, Octapharma began to work together with various European plasma fractionation companies. In return for providing access to the S/D method and know how, Octapharma received a certain volume of the ensuing virally inactivated FVIII concentrate on a contract manufacturing basis. In 1985, only two years after founding Octapharma with nothing but a dream to provide safer products for patients, the first virally inactivated FVIII concentrate produced using the S/D method – "octavi" – was made available to haemophilia patients. Wolfgang and Robert had delivered on their quest to provide the safe and efficacious product that haemophilia patients deserved.

Some 40 years later, the S/D method – as initially developed by the NYBC and then refined and perfected by Andy Smith and Octapharma – remains the current gold standard used by the plasma fractionation industry for safety from highly infectious lipid enveloped viruses,[7] such as hepatitis B and C, HIV 1/2, as well as more recently emerging viruses such as West Nile virus, Chikungunya virus, Ebola virus, SARS-CoV-2 and many others.

Those early years were challenging. Wolfgang recalls, "We started with nothing and had to push hard to get the business off the ground. At the beginning, I only had a desk, the same desk I still work at today, and little else."

Nevertheless, the hard work and long days and nights paid off. Octapharma grew steadily and, in 1989, bought our first fractionation plant in Vienna. "This transformed the company," says Wolfgang, "from a 12-person company; suddenly we had 150 employees, and with our own production facility, we could get to work further improving and developing new plasma-derived medicines for patients."

In 1995, after more than a decade together building the company from nothing, Octapharma's two founders went their separate ways, with Robert agreeing to sell Wolfgang his stake in Octapharma. Robert went on to enjoy an extremely successful career in his various endeavours, including the sale of his company Omrix Biopharmaceuticals to Johnson & Johnson in 2008.

By 1995, Octapharma had annual sales in the region of €100 million and, despite many challenges along the way, was on a stable long-term path to continued growth.

"I was fed up with all the bureaucracy at large pharmaceutical companies, and I realised that the fastest way to find a solution to this crisis, would be to leave my job at Revlon and go it alone in search of the holy grail of viral inactivation technology for haemophilia patients."

Wolfgang Marguerre

“Today, driven by a vision to provide new health solutions advancing human life, we continue to find new ways in which to help people with life-changing medical conditions and to further grow our business.”

Wolfgang Marguerre

Today

>190
plasma donation centres in the USA and Germany

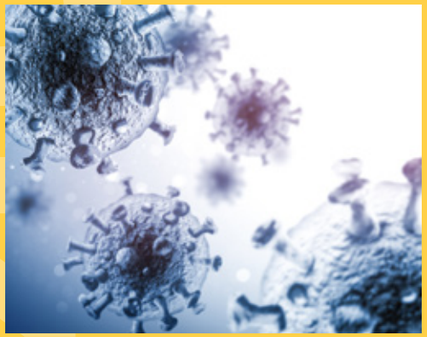
13
medicines

>11,000
employees

>€3bn
expected sales

Still driven by our vision…
Today, the company operates five production sites in Europe and collects most of its own plasma through more than 190 plasma donation centres in the USA and Germany. Octapharma has a broad portfolio of 13 medicines (both plasma-derived and our recombinant FVIII, Nuwiq®) across our three therapy areas of Immunotherapy, Haematology and Critical Care, and employs more than 11,000 people around the world. With expected sales of more than €3 billion in 2023, we are one of the largest human protein manufacturers in the world, providing medicines to hundreds of thousands of patients annually in over 118 countries.”

“When I started this company together with my business partner Robert Taub in 1983, we could never have imagined that Octapharma would achieve such incredible sustained success,” reflects Wolfgang. “It started with a belief that we could provide haemophilia patients with a safer, higher-quality FVIII concentrate,” says Wolfgang, who remains Chairman and CEO of Octapharma some 40 years later. “Today, driven by a vision to provide new health solutions advancing human life, we continue to find new ways in which to help people with life-changing medical conditions and to further grow our business. We remain as determined as ever to further improve and grow, so that we can provide our life-changing medicines to even more patients around the world.”



Haemophilia during the AIDS epidemic

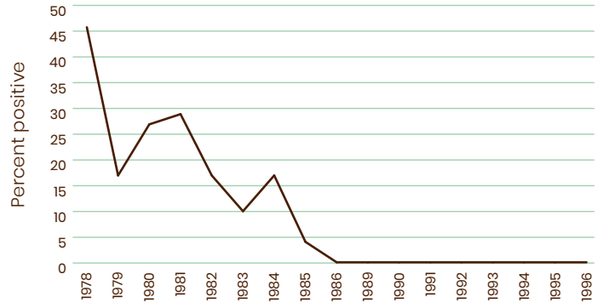
Tragically, during the period 1981 to 1984, more than 50% of the population of haemophilia patients in the USA were infected with HIV.[8] Similar tragedies also happened around the world, including in Europe and Canada.

For example, in Canada, when AIDS appeared in the early 1980’s and soon became an epidemic, the entire Canadian blood supply system was affected. With the advent of HIV testing in 1985, it was recognised that a very high percentage of patients with severe haemophilia and others receiving blood products had been infected. An even larger number of patients were infected with hepatitis C through blood products before testing was introduced in 1990.[9]

In 1993, a public inquiry into the Canadian blood system was established and Justice Horace Krever was named Commissioner. The Commission spent four years investigating the tainted blood tragedy, issuing its final report on November 21, 1997. The infection of more than 2,000 Canadian recipients of blood products with HIV between 1980 and 1985, and more than 30,000 Canadian recipients of blood products with hepatitis C between 1980 and 1990, remains Canada’s worst ever preventable public health disaster.[10]

With the introduction of virus testing and viral inactivation technologies, including Octapharma’s S/D method, the HIV epidemic in the haemophilia community ceased. Subsequent studies of birth cohorts demonstrated that no haemophilia patients born in the USA in 1985 and later were infected with HIV.[11]

Frequency of human immunodeficiency virus (HIV) infection in USA haemophilia birth cohorts



Proportions of persons in each birth cohort, for whom the results of laboratory testing for HIV were available in medical records, and who tested positive among 2,772 males with haemophilia in six USA states.

Tainted blood tragedies

1981–1984

+50%
of the population of haemophilia patients in the USA had already become infected with HIV

1980–1985

2,000
Canadian recipients of blood products were infected with HIV

1 Kasper, CK “Judith Graham Pool and the Discovery of Cryoprecipitate”, Haemophilia (2012) 18, 833-835.
2 Evatt BL, “The tragic history of AIDS in the hemophilia population, 1982-1984”, J Thromb Haemost 2006; 4: 2295-2301.
3 “The Contaminated Blood Scandal”, https://haemophilia.org.uk/public-inquiry/the-infected-blood-inquiry/the- contaminated-blood-scandal/
4 “What is the contaminated blood scandal?”, https://www.factor8scandal.uk/contaminated-blood-scandal
5 Evatt BL, “The tragic history of AIDS in the hemophilia population, 1982-1984”, J Thromb Haemost 2006; 4: 2295-2301.
6 “The Contaminated Blood Scandal”, https://haemophilia.org.uk/public-inquiry/the-infected-blood-inquiry/the- contaminated-blood-scandal/
7 “Guide for the Assessment of Clotting Factor Concentrates 3rd ed (2017).” Prepared by Albert Farrugia, BSc, PhD for the World Federation of Hemophilia; https://www1.wfh.org/publication/files/pdf-1271.pdf
8 Evatt BL, “The tragic history of AIDS in the hemophilia population, 1982-1984”, J Thromb Haemost 2006; 4: 2295-2301.
9 “Commemoration of the Tainted Blood Tragedy”, Canadian Hemophilia Society, https://www.hemophilia.ca/commemoration-of-the-tainted-blood-tragedy/
10 Andre Picard, “Krever Inquiry”, 30 November 2021, https://www.thecanadianencyclopedia.ca/en/article/krever-inquiry
11 Evatt BL, “The tragic history of AIDS in the hemophilia population, 1982-1984”, J Thromb Haemost 2006; 4: 2295-2301.

"For 40 years, Octapharma's growth has been made possible by our people, our donors and our values. As we celebrate what has made Octapharma today, we also look towards the future."

Wolfgang Marguerre
Chairman and CEO, Octapharma Group

Resonating with our donors

"The rebrand has been comprehensive and touches every donor touchpoint. Over 165 donor centre interiors were rebranded, as well as the OPI website, our social media channels, donor communications and advertising."

Tom Hewitt
Senior Director for Marketing & Donor Relations, OPI

In 2022, Octapharma Plasma, Inc. (OPI) relaunched its brand to make it more easily recognisable and to clearly differentiate it from its competitors.

"The rebrand has been comprehensive and touches every donor touchpoint," says Tom Hewitt, Senior Director for Marketing & Donor Relations at OPI. "Over 165 donor centre interiors were rebranded, as well as the OPI website, our social media channels, donor communications and advertising."

The new OPI brand has a very different look and feel. It uses lifestyle imagery that is designed to resonate with donors. "We bring relationships, emotions and impact to the forefront, and we have introduced distinctive graphical elements and designs that will unmistakably identify OPI," says Bre Byrne, Director of Brand Strategy and Donor Experience at OPI.

OPI messaging has also significantly changed, focusing more on the outcomes of donating plasma. It explores the impact on patients benefiting from plasma-based therapies and how donors can use the supplemental income from plasma donations to improve the lives of their families, friends and communities.

"Compared with the 'transactional' messaging that dominates our industry, our new messaging is quite unique and more fully reflects the significance of donating and the incredible impact it has on donors' own lives as well as those of our patients," says Tom.

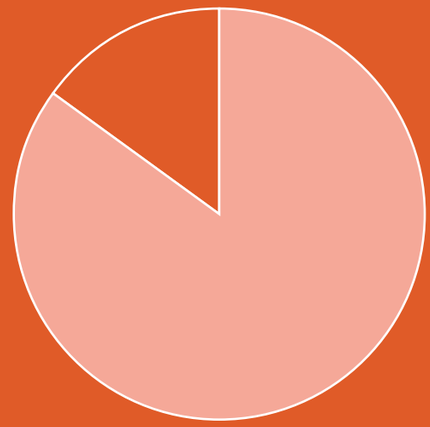
Although the rebrand has only been in the market a few months, early donor and employee responses are very positive.

Engagement with OPI's new advertising has nearly doubled, and feedback on the remodelled centres has been extraordinary. The new brand is now more closely aligned to the founding Octapharma mission and is a source of pride for employees and donors alike.

"We bring relationships, emotions and impact to the forefront, and we have introduced distinctive graphical elements and designs that will unmistakably identify OPI."

Bre Byrne
Director of Brand Strategy and Donor Experience, OPI

Creating a safe and welcoming experience



>85%
of the plasma used to manufacture Octapharma products is sourced from company-owned donation centres.

>170
OPI donation centres in the USA.

165,000
donors donate plasma at our OPI donation centres each month.

Without plasma I would not be alive today

"The amount of plasma donations needed to treat the tens of thousands of people experiencing a traumatic accident in the USA every year just truly makes you realise how important this industry is."

Elyse
Quality Assurance Supervisor,
Octapharma Plasma

Powerlifters are strong. It's not just about physical ability – mental strength is key too. When Elyse, an Octapharma Plasma employee, won her first powerlifting competition, she had conquered most of the obstacles she had faced to make her a winner before she ever set foot in a gym.

In 2008, Elyse was in a horrific car accident which left her unable to walk for over 18 months. She suffered several broken bones and fractures, a collapsed lung, and deep lacerations to her left leg. While she doesn't remember much from that day, she distinctly recalls what saved her life: a plasma transfusion.

On the way to the hospital and during her numerous surgeries, Elyse received several plasma transfusions as she had lost a lot of blood. Approximately 40 separate plasma donations were needed to make the life-saving medicines she received.

Plasma: an incredibly valuable resource

Plasma is an incredibly valuable resource to the medical community, both in treating trauma patients and for those with rare and chronic diseases. The supply of plasma relies solely on human donations.

Car accidents such as the one that Elyse was in are unfortunately common. The National Highway Traffic Safety Administration (NHTSA) estimates nearly 43,000 people died in motor accidents in the USA in 2021, and that figure is 1.4 million globally.

"The amount of plasma donations needed to treat the tens of thousands of people experiencing a traumatic accident in the USA every year just truly makes you realise how important this industry is," Elyse says.

A few years after her own accident, Elyse joined Octapharma Plasma where she now works as a Quality Assurance Supervisor. In her role, she coaches and develops her team while ensuring the wellbeing of donors and, ultimately, the safety of patients. While she began the job independently of her own relationship with plasma, Elyse now sees educating the public about the importance of plasma donation as her life's work.

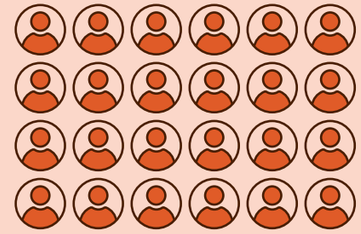
Each donation truly matters

In the years since her accident, Elyse has spent a lot of time rehabilitating her body. Through countless hours in the gym, she has become an accomplished powerlifter. She believes the transfusions she received helped her push past the physical limitations inflicted by the accident. Today, Elyse wants to show the world the radical and life-altering change plasma can make in a person's life, and she takes every chance she gets to tell Octapharma Plasma donors that their donation truly matters: "Without plasma, simply put, I would not be alive today."

Number of donations needed to treat one patient for one year

Based on a 68kg adult

130
primary immunodeficiency disease



1,200
Haemophilia A

= 50 donations

Source: https://www.pptaglobal.org/plasma

My son is a warrior!

Danielle describes her son, Isaiah, as the nicest boy in the world. "He's kind and creative but, most importantly, he's a warrior," she says with pride.

Isaiah, now eight, has been sick since he was two. For years he struggled to gain weight, but his doctors could not explain why. Danielle, now a patient advocate, did all she could to connect him with the right specialists and treatments, but nothing seemed to have an effect.

It wasn't until blood tests revealed that Isaiah had a rare form of systemic sclerosis that real progress could be made, and Isaiah successfully began octagam® intravenous immunoglobulin (IVIg) infusion therapy in 2018.

"Donating plasma saves lives. I will be forever grateful to all the donors who have stepped up and ask everyone to seriously think about doing it. Your donation helps a child like mine live a normal and happy life."

Danielle
Isaiah's mother

COVID-19 threat to plasma donations put patients at risk

With a treatment plan in place, everything finally seemed to be looking up… until the COVID-19 pandemic resulted in a drastic drop in US plasma collections that disrupted the global supply of IVIg. While plasma collections have since recovered and are now exceeding pre-pandemic levels, the plasma shortage in 2020 and 2021 highlighted the very real risk to thousands of patients like Isaiah who depend on plasma for their life-saving therapies.

Due to the plasma shortage, Isaiah went three months without receiving an infusion and quickly became very ill. Frustrated, scared and desperate for a solution, Danielle organised a plasma drive at her local Octapharma Plasma donation centre to shed light on the plasma shortage and encourage donations. More than 50 people showed up to support Isaiah and the thousands of other patients worried about the security of their next treatments.

Donating saves lives

"Donating plasma saves lives," says Danielle. "I will be forever grateful to all the donors who have stepped up and ask everyone to seriously think about doing it. Your donation helps a child like mine live a normal and happy life."

Educating others on the importance of plasma donation is now ingrained in Danielle's family – so much so that Isaiah's aunt now works at an Octapharma Plasma donation centre and his stepdad, Larry, donates twice a week. Isaiah himself has used some of his creative skills to design artwork for his local donation centre.

For many of us, the idea of a plasma shortage is little more than another remote, depressing item on the news. But for Isaiah and countless other patients and their families, it was a very real and present problem which, in some cases, could have had a deadly outcome.

As Danielle continues to encourage her community to donate, she reflects: "You never think something like this will happen to your child until it does and, with it, your world and your child's world change forever. Please do what you can."

A culture of entrepreneurship

"I'm sure we succeeded because we believed in the project and in ourselves, and because we come to work each day motivated to support our patients."

Doris Hinterberger
Senior Global Clinical Project Manager

Doris Hinterberger, Senior Global Clinical Project Manager

Patients at risk of thrombosis are often treated with an anticoagulation agent such as warfarin. This can lead to an increased risk of bleeding when these patients require emergency surgery, which is typically managed by infusion of a four-factor prothrombin complex concentrate (4F-PCC) to restore the blood's ability to clot.

At the request of the US Food and Drug Administration (FDA), Octapharma's Clinical R&D team initiated the development of the LEX-209 clinical trial in 2016. The trial was designed to investigate the efficacy of the company's 4F-PCC, octaplex®, compared to a similar product.

The study, Octapharma's first head-to-head comparison, delivered strong results and was brought to an early conclusion in 2022, paving the way for the product to be offered to patients in the USA.

"Forecasting demand in a particular region was a challenge as emergency patients are hard to predict, but I'm proud to say we managed it successfully over the duration of the study."

Romana Wesenauer
Director, Clinical Supply Chain

Developed in a culture of entrepreneurship

This success was not always guaranteed. From the beginning, recruitment of patients proved to be difficult as it is not easy to predict where or when in the world a patient treated on warfarin will need urgent surgery.

"We simply needed to engage a lot of hospitals and fish for patients," says Dmitrii Matveev, VP and Head of Clinical R&D for Immunology & Critical Care. "In addition, it was also difficult to convince anyone to take part in such urgent settings."

Romana Wesenauer, Director, Clinical Supply Chain, shares the same view. "My team was responsible for sourcing and planning for the LEX-209 study on a global level, and coordinated drug supplies for all study countries to ensure study sites were equipped at all times to be ready for emergency patients participating in the trial. Forecasting demand in a particular region was a challenge as emergency patients are hard to predict, but I'm proud to say we managed it successfully over the duration of the study."

Looking back at the LEX-209 trial, Dmitrii recalls despairing moments when enrolment completely stalled. "Nobody had fully anticipated that it would be so difficult to enrol patients for this new study," he admits. "This was a high-risk trial from the start. And during all these years, it has been a journey of persistence and strong belief."

Romana Wesenauer, Director, Clinical Supply Chain

Dmitrii Matveev, VP and Head of Clinical R&D for Immunology & Critical Care

Staying agile in an unpredictable environment

2016
Octapharma's Clinical R&D team initiated the development of the LEX-209 clinical trial.

September 2021
Octapharma submitted the interim analysis of 185 patients and requested a pre-biologics licence application (pre-BLA) meeting with the FDA to ask for the study to be concluded.

February 2022
The FDA agreed to end the study based on the favourable interim analysis data.

July 2022
The BLA was submitted.

July 2023
Final FDA approval expected.

"Nobody had fully anticipated that it would be so difficult to enrol patients for this new study. This was a high-risk trial from the start. And during all these years, it has been a journey of persistence and strong belief."

Dmitrii Matveev
VP and Head of Clinical R&D for Immunology & Critical Care

Succeeding despite the difficulties
Nevertheless, the team persevered. "We have always been committed to providing the critical care community with the life-saving therapies they need," Dmitrii explains. Each setback came with an insight that brought them one step closer to their goal.

Staying agile in a constantly changing and unpredictable environment was the only way to succeed for the LEX-209 team. "Closing and reopening the study in several countries, dealing with the COVID-19 pandemic and the consequent lack of study site personnel, and the shutdown of logistic routes are just a few of the challenges we were faced with," recalls Romana. "Close communication with all stakeholders was our key to running the study successfully and efficiently."

By introducing local country champions, Dmitrii's team was able to get closer to local physicians and practitioners. "At some point, we also switched to patients in Eastern Europe and did a lot of searching for patients ourselves at Octapharma," says Dmitrii.

Furthermore, the team decided to take over some tasks performed by external vendors. "Monitoring of data and medical reviews were then done internally," says Dmitrii. "It has been a lot of additional work, but it eventually turned out to be of great value."

On September 21, 2021, Octapharma was finally able to submit the interim analysis of 185 patients and requested a pre-BLA meeting with the FDA to ask for the study to be concluded early. Five months later, on February 22, 2022, the FDA agreed to end the study based on the favourable interim analysis data. The BLA was submitted on July 28, 2022, and final FDA approval is now expected in July 2023.

An important milestone for octaplex®
"We are really happy about the positive outcome of the interim analysis and fully prepared to take on the challenges that lie ahead of us in the coming months," says Doris Hinterberger, Senior Global Clinical Project Manager, who took the lead in preparing documents for FDA submission.

"I am truly inspired by my team who produced their best work at a time when we were facing the COVID-19 pandemic and all that that entailed," says Doris. "I'm sure we succeeded because we believed in the project and in ourselves, and because we come to work each day motivated to support our patients."

Driven by curiosity

When Octapharma launched the ATN-106 clinical study in 2021, it made perfect sense to turn to Martina Jansen, Senior Clinical Project Manager for Haematology, to lead this critical project even though much of her expertise lay in a completely unrelated field.

ATN-106 aims to establish the safety and efficacy of atenativ®, Octapharma's human antithrombin concentrate, for the treatment of patients with congenital antithrombin deficiency. The study faces enormous challenges, not least in finding patients to participate. With more than 26 years at Octapharma and many successful projects under her belt, however, Martina is confident that she and her team will bring it to a successful conclusion.

"I'm driven by curiosity, and that has a high value for me. If you lose it, you've lost interest and focus, which are both essential."

Martina Jansen
Senior Clinical Project Manager for Haematology

A rare genetic disorder

Antithrombin is a protein in the blood that prevents abnormal blood clots from forming. It helps the body maintain a healthy balance between bleeding and clotting.

Congenital antithrombin deficiency is a rare inherited disease that is commonly associated with unprovoked thrombotic events (TEs) and thromboembolic events (TEEs). These can present significant risks during surgical procedures and childbirth which can be effectively managed through antithrombin replacement therapy, such as that offered by intravenous infusion of atenativ®.

Octapharma initiated a study of atenativ® for use in patients with congenital antithrombin deficiency undergoing a surgical procedure or parturition (childbirth). "atenativ® has a long heritage of indispensable use in critical clinical settings since 1982," Oliver Hegener, VP Head of IBU Critical Care, explains. "The product is available for treatment in 30 countries worldwide, but it is currently not registered in the USA. With the ATN-106 study results, Octapharma will seek market authorisation to make this product available to physicians in the USA."

Martina Jansen, Senior Clinical Project Manager for Haematology

What is congenital antithrombin deficiency?

Hereditary antithrombin deficiency is a disorder of blood clotting. People with this condition have a higher than average risk of developing abnormal blood clots.

It is estimated that

0.03–0.05%

of people have hereditary antithrombin deficiency.

Of people who have experienced an abnormal blood clot

0.5–5%

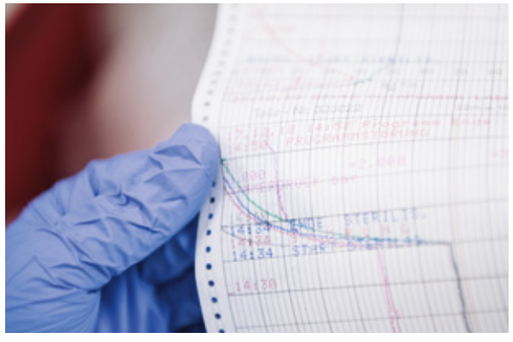
have hereditary antithrombin deficiency.

Cause

Hereditary antithrombin deficiency is caused by mutations in the SERPINC1 gene. This gene provides instructions for producing a protein called antithrombin. Antithrombin blocks the activity of proteins that promote blood clotting, especially a protein called thrombin.

Most of the mutations that cause hereditary antithrombin deficiency change single protein building blocks (amino acids) in antithrombin, which disrupts its ability to control blood clotting. Individuals with this condition do not have enough functional antithrombin to inactivate clotting proteins, which results in the increased risk of developing abnormal blood clots.

Source: https://medlineplus.gov/genetics/condition/hereditary-antithrombin-deficiency



A slow but confident start
In November 2021, negotiations with the US Food and Drug Administration (FDA) were finalised and Octapharma received the green light to proceed with ATN-106. Earlier in 2021, the study team had begun selecting vendors, including an operational contract research organisation (CRO) to manage submissions to ethics committees and health authorities, a data management supplier and a central laboratory.

"The first patient was enrolled in the study at The Bleeding & Clotting Disorders Institute (BCDI), Peoria, Illinois, under Principal Investigator Dr Michael Tarantino, MD, on September 12, 2022," says Martina. "We have already identified a second patient, also from the USA. Most of the European study sites involved are now activated, which means they are ready to enrol as soon as patients are identified."

"Octapharma has consistently invested in people, providing a safe and stable environment in which they can flourish. As a result, we're now in the happy position to have people who are ready and eager to resolve the challenges the congenital antithrombin deficiency community are currently facing."

Wolfgang Frenzel
Board Member for R&D

The primary objective of the ATN-106 study is to assess the incidence of TEs and TEEs in 20 patients with congenital antithrombin deficiency under cover of atenativ® for surgical procedures or parturition. In addition, a minimum of 14 adult patients between 18 and 80 years of age with congenital antithrombin deficiency who are not pregnant will be enrolled in a pharmacokinetic phase of the study. A further four patients between 12 and 16 years of age will also be enrolled in this phase in the USA. Ultimately, patients will be enrolled in seven European countries in addition to the USA.

"The biggest challenge facing ATN-106 is that congenital antithrombin deficiency is a rare disease that presents issues rarely. There are very few patients, with very few specialists, and the only established product on the market in the USA was authorised more than 30 years ago," says Wolfgang Frenzel, Board Member for R&D. "Fortunately, Octapharma has consistently invested in people, providing a safe and stable environment in which they can flourish. As a result, we're now in the happy position to have people who are ready and eager to resolve the challenges the congenital antithrombin deficiency community are currently facing."

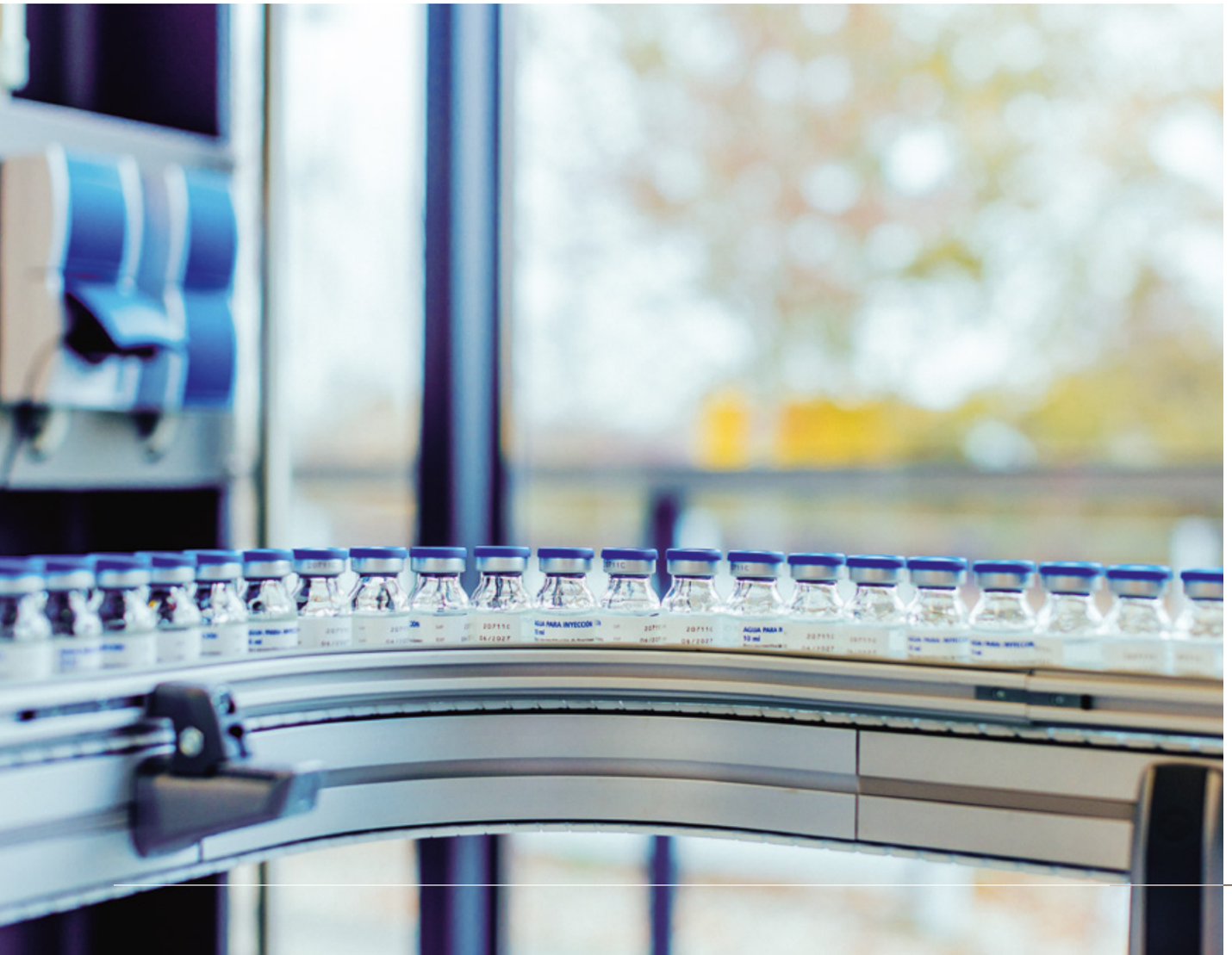
"We have two and a half years to enrol 40 patients," says Martina. "I'm confident that we can achieve this goal by the end of 2024 but, of course, we already have a strategy in place to collaborate with further study sites if needed."

Gratifying experience
Carrying out a clinical trial in such a rare disease requires a huge amount of patience and an awareness of the entire project. "I'm driven by curiosity," says Martina, "and that has a high value for me. If you lose it, you've lost interest and focus, which are both essential."

She relishes the spirit at Octapharma. "There's a curiosity to be creative here, to be flexible, that leads teams at Octapharma to grow and to constantly challenge themselves," she says.

That curiosity and drive is motivating much of the continuing study of atenativ®. "This product has a huge potential beyond congenital deficiency and further possible clinical programmes are already under discussion," adds Martina. "That is very exciting."

Driving sustainability at Octapharma



One of Octapharma's five core values puts environmental sustainability at the heart of our operations and serves as a foundation for sustainable business practices.

The UN's global environmental sustainability goals are the guiding force for Octapharma's sustainability initiatives. Our long-term focus is primarily on the global goals where we as a company can contribute the most: fighting climate change; working towards sustainable water consumption; and contributing to sustainable energy use.

Johan Lindgren, Head of Corporate Technical Organisation, explains: "On a group level, Octapharma has set four key energy and environmental goals, which are all linked to the UN Sustainable Development Goals:

— Reducing the emission of greenhouse gases
— Reducing energy consumption
— Reducing water consumption
— Reducing contaminants in the waste flow.

"Each year, each of our sites sets its own actions and improvements to contribute to the corporate KPI goals to minimise its impact on climate, waste and water, thus significantly reducing the company's global environmental impact, while also helping to double our production volumes."

Towards an energy-efficient future at Octapharma Vienna
Octapharma Vienna has launched several initiatives to improve the site's CO_2e footprint and energy balance. First amongst these was the creation of the Vienna Site Energy Team (SET VIE) at the end of 2021. Led by Sebastian Ortner, with members from divisions across the site, the team aims to:

- Provide ideas and suggestions on how to improve energy savings
- Support the site energy manager in implementing various measures
- Bring in its own department-specific expertise
- Actively participate in the SET VIE meetings

Several other projects have already been implemented or developed in Vienna, including:

Replacement of refrigeration systems
At the Vienna site, machines using high global warming potential (GWP) refrigerants are gradually being replaced by new systems with natural refrigerants (e.g., ammonia and CO_2). In 2022, the PSA101 facility for basic fractionation was replaced by two CO_2 chillers in order to reduce the site's environmental emissions.

Steam trap and safety valve audit
All of the approximately 650 steam traps and 50 safety valves for steam at the Vienna site are checked and maintained annually in order to avoid high energy (steam) losses.

Ethanol distillation
Ethanol is recycled at the Vienna site by recovering it from the waste "mash" (an ethanol-production waste–water mixture) with the help of a rectification column (distillery). Octapharma has been making an important contribution to the circular economy and resource conservation with this ethanol recycling for many years. This year, the recycling efficiency of the plant has been further improved by the addition of several new rectification columns.

"Due to the current energy and environmental situation, it is more important than ever to drive forward appropriate measures for the ongoing reduction of our environmental emissions," Sebastian explains.

"Due to the current energy and environmental situation, it is more important than ever to drive forward appropriate measures for the ongoing reduction of our environmental emissions."

Sebastian Ortner
Lead, Vienna Site Energy Team (SET VIE)

"Successful delivery of our environmental sustainability strategy will require leadership, innovation, investment and change."

Yann Veronneau
Head of Technical Unit and responsible for sustainability at the French production site

Focused on sustainability at Octapharma Lingolsheim (OSA)
Sustainability is central to OSA's strategy. "We've been integrating sustainability into our local corporate culture for several years and we encourage colleagues across our operations to adopt an environmentally sustainable mindset," says Amélie Blum, Corporate Social Responsibility Officer at OSA.

That mindset has driven several important initiatives in 2022, including:

- Better recovery of waste: 79% of non-hazardous waste (material and energy) is recovered at the site (compared to 50% in 2021)
- Local waste treatment: 95% of OSA's waste is treated within 20 kilometres of the site
- Better management of waste collection: waste skips are now only collected on demand
- Elimination of plastic bottles and distribution of reusable water bottles at the site

"Successful delivery of our environmental sustainability strategy will require leadership, innovation, investment and change," says Yann Veronneau, Head of Technical Unit and responsible for sustainability at the French production site.

An environmental sustainability journey for Octapharma Stockholm (OAB)
"We know that if we want to succeed, we must be sustainable," says Jacob Bergdahl, Head of Technical Unit. "That is why sustainability is built into our business strategy."

The core of the sustainability work is based on continuous improvement.

Since 2015, OAB has:

Reduced energy consumption by about 30% / tonne of plasma
A pre-column for ethanol distillation was installed in 2017 and production switched to LED lighting in 2019. Since 2021, energy mapping has identified future energy-saving measures.

Reduced water consumption by about 20% / tonne of plasma and worked to eliminate waterborne pollutants
Triton X-100 collection was introduced in 2018; the site optimised water consumption in cleaning processes in 2021 and transitioned to nitrogen-free pH adjustment of water in 2022.

Become a fossil fuel-free production facility
The site transitioned from an oil-fired to an electric steam boiler in 2016, moved to renewable electricity in 2018 and now uses 100% renewable electricity. OAB transitioned to 100% renewable biodiesel for backup power in 2021; heat surplus is now used for heating; and the site achieved fossil-free heating in 2022. As a result, total CO_2 equivalent emissions per year have been reduced from 8,157 tonnes to 943 tonnes.

F-gas compressors were replaced with more environmentally friendly coolants in 2021.

Solar collectors were introduced in the Arlanda Stad Logistic centre during 2022. The installation will cover 40% of total energy demand in the logistics centre.

"Today, Octapharma AB has a functional environmental management system and an established environmental and energy group that works systematically at a site-wide level," adds Jacob.

"Today, Octapharma AB has a functional environmental management system and an established environmental and energy group that works systematically at a site-wide level."

Jacob Bergdahl
Head of Technical Unit

Driving sustainability through process optimisation at Octapharma Springe
Octapharma Springe, like all Octapharma sites, evaluates the materials and processes used to manufacture our products and proactively seeks to reduce their environmental impact.

"We are united by a desire to push the boundaries of manufacturing to deliver life-changing medicines in a way that is respectful of our planet," says Ralf Brinkmann, Head of Technical Unit at Octapharma Springe. "By embedding sustainability in everything we do – from production facilities to the patient – we are helping to strengthen healthcare systems so that they are more accessible and resilient."

This integrated sustainable approach has already achieved a reduction of 900 tonnes of CO_2 emissions per year through the use of an exhaust gas neutralisation system for cleaning waste water. Other significant initiatives include: heat recovery from ventilation systems; the use of heat pumps in central cooling; the use of NH_3 (ammonia) as a natural refrigerant; and the consistent replacement of conventional lighting with LEDs.

"We are actively working on the development of a more sustainable energy supply by using renewable energies such as wind and solar power," adds Ralf. "Ultimately, this will enable us to generate steam without burning fossil materials."

In numbers

79%
of non-hazardous waste (material and energy) is recovered at the site in Lingolsheim.

95%
of OSA's waste is treated within 20 kilometres of the site in Lingolsheim.

30%
reduction in energy consumption/tonne of plasma in Stockholm.

Ensuring our future success

Norbert Müller
Board Member

Flemming Nielsen
President Octapharma USA Inc.

Wolfgang Frenzel
Research and Development

Tobias Marguerre
Managing Director, Octapharma Nordic AB

Roger Mächler
Chief Financial Officer

Josef Weinberger
Corporate Quality and Compliance Officer

Matt Riordan
Board Member

Olaf Walter
Board Member

Wolfgang Marguerre
Chairman and CEO, Octapharma Group

Olivier Clairotte
Corporate Production Officer

“The Octapharma Group once again delivered strong results in a challenging environment in 2022, with record sales, operating income, income before tax and net income. Sales increased by 13.7% to €2.854 billion, compared to the prior year, and the company generated an operating income of €522 million.”

Roger Mächler
Chief Financial Officer

“As we celebrate 40 years of Octapharma in 2023, we intend to build on that strength by optimising our plasma collection costs whilst maintaining strong plasma collection volumes, streamlining our operations, and increasing the utilisation of our new fractionation line in Springe.”

The Octapharma Group once again delivered strong results in a challenging environment in 2022, with record sales, operating income, income before tax and net income. Sales increased by 13.7% to €2.854 billion, compared to the prior year, and the company generated an operating income of €522 million.

These strong results came against the backdrop of soaring inflation and continuing supply chain disruptions resulting from the war in Ukraine and the increase in global trade in the aftermath of COVID restrictions. While these factors contributed to higher cost of sales of €1.921 billion compared to €1.702 billion in 2021, this was offset by a strong recovery in plasma collection and continuing strong demand for our products – most notably our immunoglobulin portfolio, fibryga®, wilate® and Nuwiq®.

Gross profit in 2022 was €933 million, up 15.5% from the prior year and gross margin increased by 0.5 percentage points to 32.7%. Operating expenses for the year increased to €412 million from €349 million in 2021. Income before tax was a record €503 million and net income a record €448 million, up from €438 million in 2021. Net cash from operating activities was €324 million. Our capital position remains extremely strong, with an equity ratio of 80.1%.

This strong growth was made possible by the continuing engagement and commitment of Octapharma employees around the globe, who have worked tirelessly to increase plasma collection, drive production, ensure the safe and timely delivery of our products, and engage with our customers and patients around the world. Their dedication has positioned our company strongly for future growth.

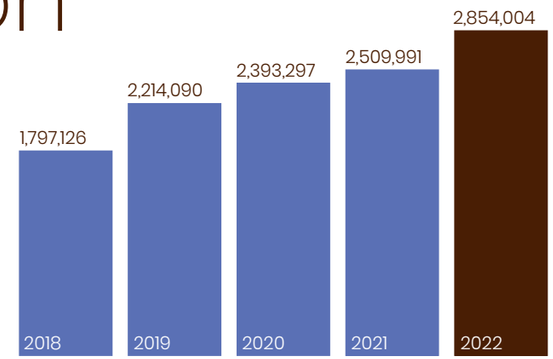
As we celebrate 40 years of Octapharma in 2023, we intend to build on that strength by optimising our plasma collection costs whilst maintaining strong plasma collection volumes, streamlining our operations, and increasing the utilisation of our new fractionation line in Springe. We will also continue to attract and retain the best talent by investing in our people.

We are confident that this will allow us to maintain our strong track record of year-on-year growth in 2023 and the years to come.

Roger Mächler
Chief Financial Officer

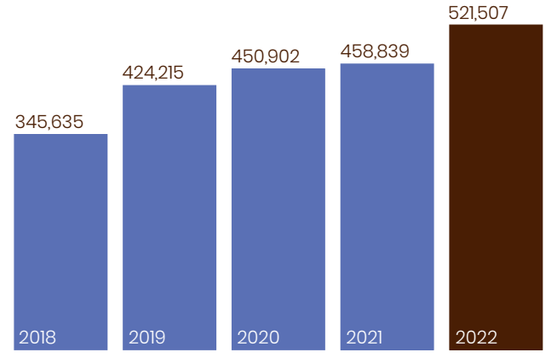
Sales in 1,000 EUR

€2.85bn



Operating income in 1,000 EUR

€522m



Key figures of the Octapharma Group

(Monetary figures are in 1,000 EUR)	2022	2021	2020	2019	2018
Operating income	**521,507**	458,839	450,902	424,215	345,635
Operating income margin*	**18.3%**	18.3%	18.8%	19.2%	19.2%
Net income	**448,026**	438,333	375,693	403,445	303,480
Year-end headcount	**11,573**	9,977	9,067	9,307	8,314
Return on investment*	**10.9%**	11.8%	11.1%	13.5%	11.5%
Income from operations per employee*	**48**	49	49	49	43
Cash ratio	**174%**	188%	193%	120%	174%
Return on capital employed (ROCE)*	**13.4%**	13.1%	14.4%	15.5%	14.5%
Days of sales in receivables*	**114**	133	117	141	126
Days of inventory range*	**228**	204	225	239	250
Cash flow from operations	**323,738**	480,859	600,496	257,180	261,393
Expenditures to ensure future prosperity	**280,926**	266,973	306,310	307,804	240,183
Research and development	**75,339**	77,915	79,471	75,748	87,291
Capital expenditures and investments in activities	**205,587**	189,058	226,839	232,056	152,892

* Key figures are determined as follows:
Operating income margin: Operating income/sales
Return on investment: (Net income + interest expense)/average total assets
Income from operations per employee: Operating income/average headcount
ROCE: Operating income/ (average total assets – average total current liabilities)
Days of sales in receivables: Trade receivables/sales * 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)	2022	2021
Sales	**2,854,004**	2,509,991
Cost of sales	**-1,920,513**	-1,701,783
Gross profit	**933,491**	808,208
Research and development	**-75,339**	-77,915
Selling and marketing	**-231,354**	-184,818
Regulatory affairs	**-29,166**	-20,441
General and administration	**-82,848**	-65,112
Other income	**7,900**	7,869
Other expenses	**-1,177**	-8,952
Total operating expenses	**-411,984**	-349,369
Operating income	**521,507**	458,839
Non-operating income and expenses	**-18,494**	5,500
Income before tax	**503,013**	464,339
Income tax	**-54,987**	-26,006
Net income	**448,026**	438,333

* 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 2022, 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)	2022	2021
Assets		
Cash and cash equivalents	**749,795**	777,867
Trade receivables	**891,360**	915,691
Other receivables and current assets	**78,742**	69,557
Loans granted	**37,597**	37,570
Derivative financial instruments	**2,423**	102
Inventories	**1,305,717**	913,984
Total current assets	**3,065,634**	2,714,771
Financial investments	**1,173**	3,750
Deferred tax assets	**182,164**	189,785
Derivative financial instruments	**940**	0
Loans granted	**691**	38,149
Property, plant and equipment	**1,252,137**	1,174,271
Intangible assets	**0**	809
Total non-current assets	**1,437,105**	1,406,764
Total assets	**4,502,739**	4,121,535

(All figures in 1,000 EUR)	2022	2021
Liabilities and equity		
Trade payables and other payables	**149,322**	115,136
Derivative financial instruments	**3,636**	11,580
Income tax payables	**18,936**	48,809
Short-term lease liabilities	**15,638**	13,724
Accruals	**195,107**	185,994
Current provisions	**48,688**	37,854
Total current liabilities	**431,327**	413,097
Non-current provisions	**94,570**	94,641
Derivative financial instruments	**347**	0
Long-term lease liabilities	**284,761**	257,067
Deferred tax liabilities	**82,479**	65,116
Other non-current liabilities	**1,759**	4,961
Total non-current liabilities	**463,916**	421,785
Total liabilities	**895,243**	834,882
Share capital	**120**	120
Retained earnings	**3,569,537**	3,281,760
Currency translation adjustments	**37,839**	4,773
Total equity	**3,607,496**	3,286,653
Total liabilities and equity	**4,502,739**	4,121,535

Consolidated statement of cash flows of the Octapharma Group

(All figures in 1,000 EUR)	2022	2021
Net income	**448,026**	438,333
Depreciation of property, plant and equipment and intangibles	**180,441**	167,987
Change in fair value of non-current assets	**-14,258**	19,435
(Profit) loss on sale of property, plant and equipment	**3**	-3,561
Changes in long-term liabilities and provisions	**29,945**	10,123
Finance cost	**18,961**	15,534
Tax expense	**54,987**	26,095
Unrealised foreign currency (gain) loss	**23,518**	-15,252
Cash flow before changes in working capital	**741,623**	658,694
(Increase) decrease of working capital	**-417,885**	-177,835
Net cash from operating activities	**323,738**	480,859
Acquisition of property, plant and equipment	**-205,587**	-189,058
Change of financial investments	**40,117**	-77,158
Proceeds from sales of property, plant and equipment	**288**	3,969
Interest received	**3,091**	2,861
Net cash used in investing activities	**-162,091**	-259,386
Financing activities	**-160,320**	-99,432
Payments of lease liabilities	**-34,197**	-29,953
Net cash used in financing activities	**-194,517**	-129,385
Net change in cash and cash equivalents	**-32,870**	92,088
Cash and cash equivalents beginning of period	**777,867**	682,783
Effect of exchange rate fluctuation on cash held	**4,798**	2,996
Cash and cash equivalents end of period	**749,795**	777,867

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 67 to 70, which comprise the summary balance sheet as at December 31, 2022, 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, 2022.

In our opinion, the accompanying summary financial statements are a fair summary of the audited financial statements, on the basis described on page 67 of the annual report 2022.

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 13, 2023.

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 67 of the annual report 2022.

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 Raphael Gähwiler

Zurich, 13 February 2023

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