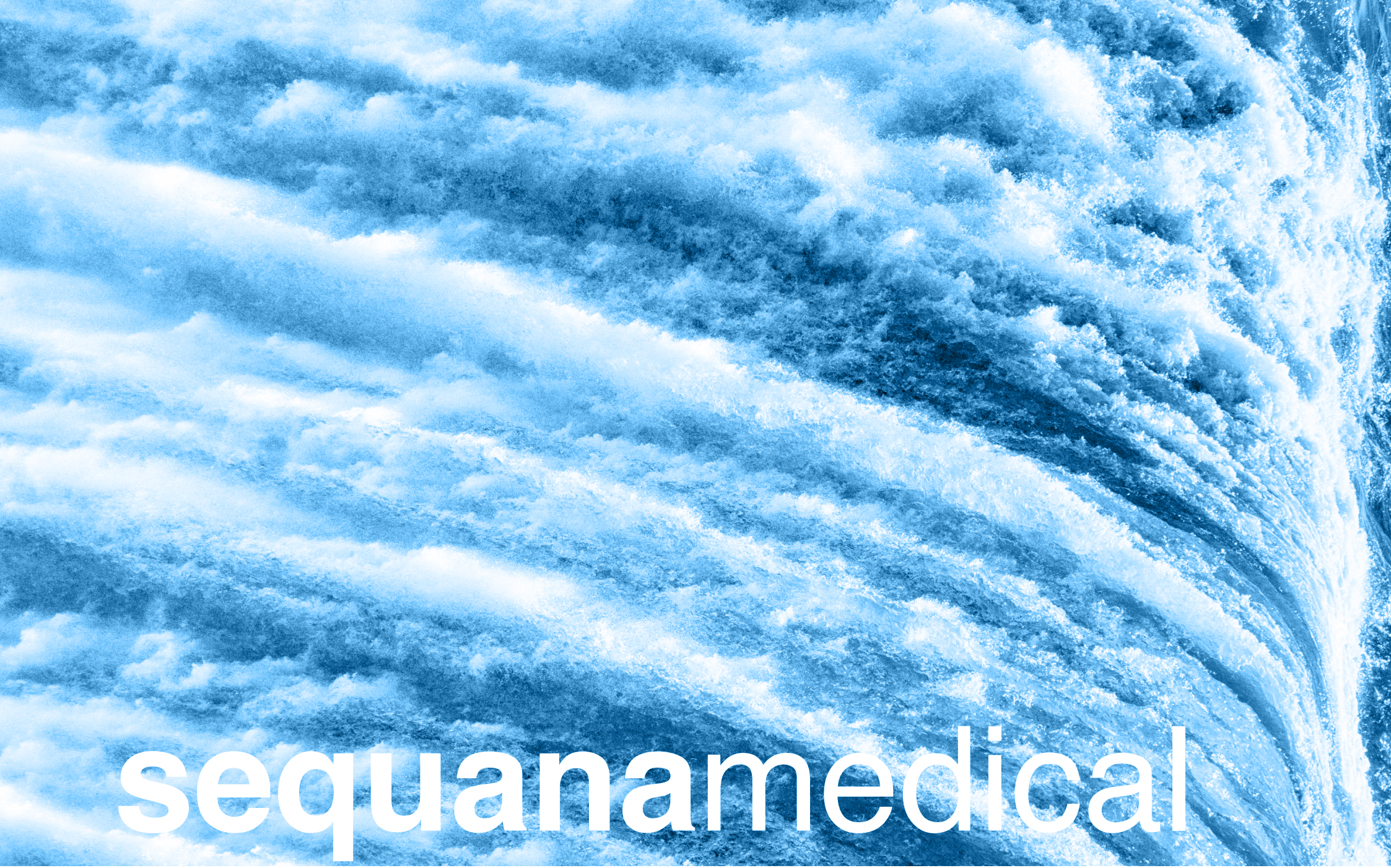


annual report 2022

Our Strategy & Key Objectives

Develop and commercialize innovative treatments for patients with diuretic-resistant fluid overload, focusing on improved clinical outcomes, better quality of life for patients and cost savings for healthcare systems.

- Commercialize **alfa**pump® in North America for the treatment of recurrent and refractory ascites due to liver cirrhosis, using our own specialty salesforce.

- Develop DSR® (Direct Sodium Removal) therapy as a disease-modifying treatment for congestive heart failure, using our proprietary DSR product and establish a strategic partnership for further clinical development and commercialization.

- Explore the use of DSR in other indications where diuretic-resistant fluid overload is a key clinical challenge, such as chronic kidney disease.

Table of Contents

Sequana Medical at a glance

We are pioneers in treating fluid overload, a serious and frequent clinical complication in patients with liver disease, heart failure, renal failure and cancer. These patients can have up to 15 liters of extra fluid in their bodies, causing major medical issues including increased mortality, repeated hospitalizations, severe pain, difficult breathing and restricted mobility that severely impacts their daily life. Although diuretics are standard of care, the problem is that in many patients they are no longer effective and / or tolerable. There are limited effective treatment options for these patients resulting in poor clinical outcomes, high costs and major impact on their quality of life. We are focused on developing innovative treatment options for this large and growing "diuretic-resistant" patient population.

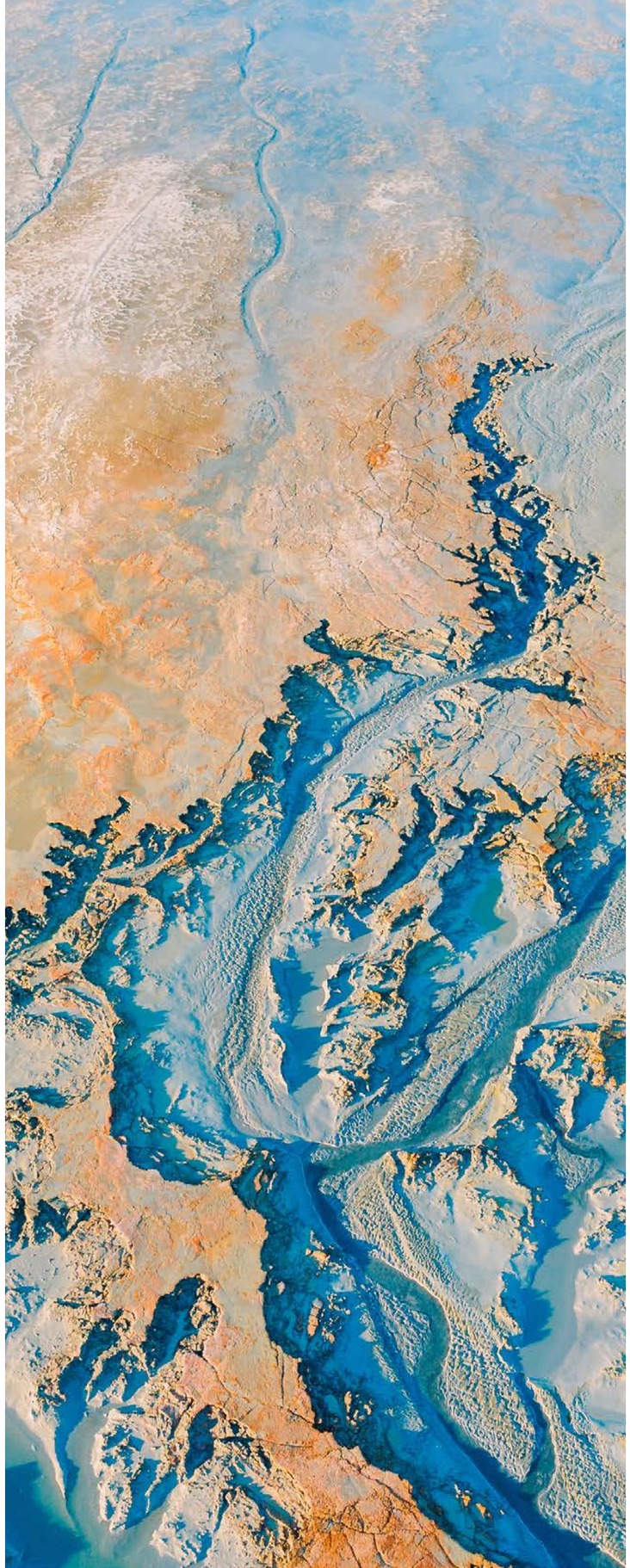
alfapump and DSR are our two proprietary platforms that work with the body to treat diuretic-resistant fluid overload and are protected by our strong intellectual property (IP) portfolio. Our **alfa**pump is a fully implanted device that works in partnership with the bladder to eliminate fluid build-up in the peritoneal cavity (e.g. ascites due to liver cirrhosis). DSR or Direct Sodium Removal is our disease-modifying heart failure drug therapy that works in partnership with the kidneys to eliminate excess fluid spread across the body (e.g. congestion due to heart failure).

The **alfa**pump, a fully implanted, wirelessly charged device, automatically pumps fluid from the peritoneal cavity into the bladder, where it is naturally eliminated through urination. It is protected by a portfolio of patents granted in the US and Europe and more than 950 devices have been implanted to date.

In Europe, the **alfa**pump has received CE mark approval for the treatment of refractory ascites due to liver cirrhosis and malignant ascites and has been included in key European treatment guidelines. In the US, our key growth market, the **alfa**pump has been granted breakthrough device designation by the Food and Drug Administration (FDA) for the treatment of recurrent or refractory ascites due to liver cirrhosis. Our pivotal POSEIDON study, intended to support the approval of the **alfa**pump in North America, reported strong top-line results meeting all primary efficacy endpoints with statistical significance and safety in line with expectations. Filing of the Pre-Market Approval (PMA) application with the US FDA is planned for H2 2023. We plan to commercialize the **alfa**pump directly in the US, using a specialized in-house sales force targeting 90 liver transplant centers (covering 95% of adult liver transplants). The North American market for the **alfa**pump is forecast to grow at a Compound Annual Growth Rate (CAGR) of 6-7%, from over 75,000 patients in 2025, reaching a market opportunity of over $2.5 billion by 2035, with NASH being the major driver of growth[1].

Fluid accumulation in heart failure patients is caused by the retention of too much sodium. Our DSR therapy uses a proprietary sodium-free dextrose / icodextrin solution administered into the peritoneal cavity to remove excess sodium from the body via diffusion, to which the kidneys respond and eliminate excess free water naturally through urination, leading to reduced fluid overload. Composition of matter and method patents have been granted for DSR therapy in the US and Europe.

Heart failure is the leading cause of US hospitalizations in patients over 65 years old with over one million hospitalizations per year[22] at a cost of over $14 billion[17], and 90% of these admissions are due to fluid overload (AKA congestion). In the US alone, we



anticipate an estimated 200,000 heart failure patients with drug-resistant congestion requiring repeated hospitalization. DSR is expected to be complementary to existing heart failure therapies. Clinical proof-of-concept studies using our first-generation DSR product (DSR 1.0) have shown that DSR can i) safely, effectively and rapidly eliminate fluid overload in heart failure patients, ii) improve the health of the heart and preserve renal function, and iii) restore the ability of the kidney to manage the fluid and sodium naturally, resulting in a large and long-lasting reduction in the need for diuretic drugs.

There have been no congestion-related re-hospitalizations during our study follow-up period and all patients improved their NYHA[2] status by at least one class following DSR therapy. The clinical benefits observed in the clinical studies resulted in a 75% reduction in predicted one-year mortality of patients pre- vs. post-intensive DSR therapy based on the Seattle Heart Failure Model[3]. We are currently planning to begin a US randomized controlled Phase 1/2a clinical trial (MOJAVE) using our second-generation DSR product (DSR 2.0) in Q2 2023. Based on the results of the MOJAVE trial, we plan to partner DSR to leverage the strengths of an established heart failure player to realize commercial potential of DSR.

We are headquartered in Ghent, Belgium and listed on Euronext Brussels, supported by local and international life sciences investors and industry experts. We are led by an experienced management team and a Board of Directors with significant industry experience. We have strong endorsement for our technology and clinical approach from international Key Opinion Leaders (KOLs).

Key Figures

US launch of **alfa**pump anticipated in H2 2024

US randomized controlled Phase 1/2a study of DSR planned to start in Q2 2023

Founded in 2006

Proprietary **alfa**pump & DSR products with multi € billion market opportunities

alfapump – fully implanted device for liver and malig-nant ascites

Highly experienced leadership team and board of directors with vast industry and business expertise

Over 70 employees

Headquarters in Ghent, Belgium

DSR – disease-modifying heart failure drug therapy

Pioneers in the treatment of fluid overload

80 patents granted across 20 patent families

Manufacturing in Zurich, Switzerland

Listed on Euronext Brussels since February 2019

Message from the Chairman and the CEO

Dear Shareholders, Colleagues and Business Partners,

We are very pleased to report on another successful year for Sequana Medical, where we have continued to demonstrate the unique capabilities of our **alfa**pump and DSR technologies for the treatment of fluid overload. We remain focused on approval and commercialization of the **alfa**pump in North America for recurrent and refractory ascites due to liver cirrhosis and delivering the clinical evidence for DSR as a disease-modifying therapy for congestive heart failure to secure the right strategic partnership.

Early in 2022, the **alfa**pump was one of the first novel Class III active implantable medical devices to be certified under the new European Medical Device Regulation (MDR), a significantly more stringent regulatory standard. This followed the Quality Management System (QMS) certification under the Medical Device Single Audit Program (MDSAP), clearly demonstrating our progress towards meeting the standards required for approval of the **alfa**pump in the US.

In April, we completed the **alfa**pump implantations in patients with recurrent or refractory ascites that had been enrolled in POSEIDON, our pivotal study to support the regulatory approval in the US and Canada. Top-line results from the 40 patients in the Pivotal Cohort were reported later in the year, with all primary endpoints successfully met. We demonstrated that our primary efficacy endpoint data substantially exceeded the predefined thresholds for study success and primary safety endpoints were in line with expectations. This allows us to prepare for PMA filing in H2 2023, with US market approval planned for 2024.

We also reported the preliminary interim analysis of patient survival following **alfa**pump implantation in the POSEIDON Roll-In Cohort, showing a mean survival probability of 70% at 12 months, which compares favourably to the published literature reporting a survival rate for refractory liver ascites patients of only 50% at 12 months.

In November, one of our principal investigators presented the safety, efficacy and quality of life data from the POSEIDON Roll-In Cohort at The Liver Meeting of the American Association for the Study of Liver Diseases (AASLD), the leading organization of scientists and healthcare professionals in preventing and curing liver disease. We believe that there is a clear need for improved treatment options for the large and growing number of patients suffering from recurrent or refractory ascites due to liver cirrhosis. The North American market is forecast to grow between 6-7% annually reaching over 170,000 patients in 2035, representing a total addressable market for the **alfa**pump of over US $2.5 billion. Fatty liver disease and NASH (non-alcoholic steatohepatitis) are predicted to be the major drivers of this strong growth.

2022 has been a breakthrough year for our DSR heart failure program with the reporting of data from our RED DESERT and SAHARA studies showing substantial long-lasting clinical benefits of our DSR therapy in decompensated heart failure patients. None of the patients treated with DSR therapy were readmitted to the hospital for congestion-related heart failure during the study follow-up periods and all had a dramatic reduction in the need for oral loop diuretics many months post-therapy. This is a clear indication of the long-lasting improvement in patients' cardiovascular and renal health as evidenced by the one class (or more) improvement in the New York Heart Association (NYHA) assessment for all patients, and a 75% reduction in the one-year predicted mortality as predicted by the highly respected and validated Seattle Heart Failure Model. These data demonstrate that DSR not only reduces fluid overload in congestive heart failure patients but also improves the health of their heart and the kidneys. We therefore believe that DSR has the potential to be a disease-modifying heart failure drug therapy that could help the estimated 200,000 US heart failure patients suffering from diuretic-resistant persistent congestion.

The experience from our first-generation DSR product used in RED DESERT and SAHARA gave us great confidence to move forward with our second-generation DSR product (DSR 2.0), intended to have an improved safety and therapeutic profile. In early 2023 we announced positive results from the GLP animal and Phase 1 CHIHUAHUA studies, showing that DSR 2.0 is well-tolerated and indicates a compelling dosing profile.

We are planning to start MOJAVE, a Phase 1/2a randomized controlled multi-center study of DSR 2.0 during the second quarter of 2023 following approval of the Investigational New Drug (IND) submitted at the end of March 2023. Our intention is to enrol 30 patients with chronic heart failure who have persistent congestion despite their high doses of diuretics, with 20 patients treated with our DSR 2.0 product administered via a peritoneal catheter and 10 patients with intravenous loop diuretics, both on top of their usual care, for four weeks followed by a three-month safety follow-up period. We believe that these data will deliver the clinical data package required for partnering the DSR program with an established heart failure player.

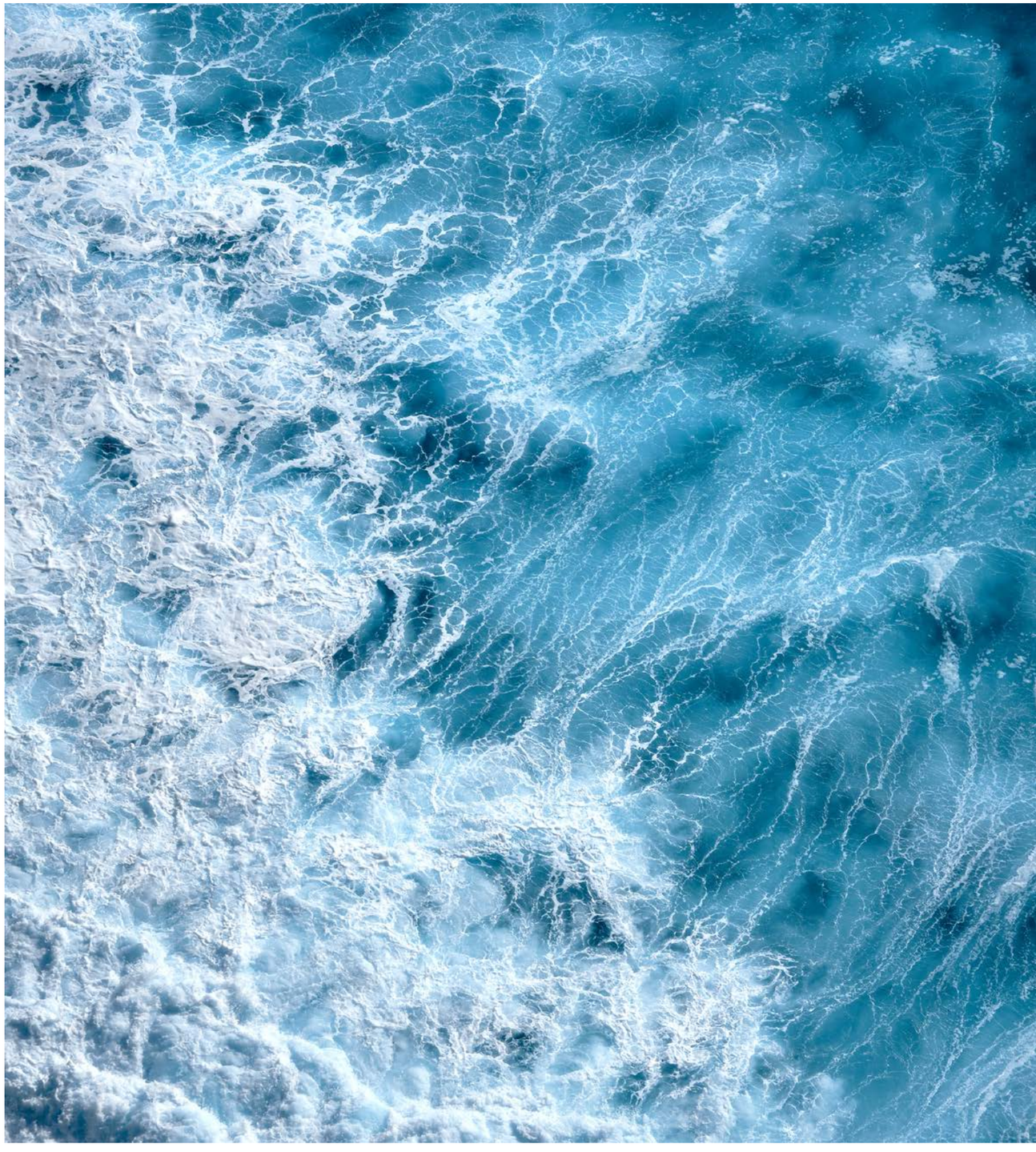
We continued to build the strength and depth of the Board by appointing two seasoned US medtech executives, Doug Kohrs and Alexandra Clyde, both with a strong track record and expertise in the commercialization and reimbursement aspects of medical devices. This will be instrumental as we build towards the commercial launch of our **alfa**pump in North America.

We would like to thank Erik Amble for his contributions to the Board over many years. Erik stepped down from the Board in September last year, but will continue to attend Board meetings as an observer.

We would also like to thank our shareholders, clinical investigators, and other partners who continue to support us during this exciting time for Sequana Medical. Finally we would like to thank our employees for their contribution, hard work and commitment during 2022, as they are key to the Company's success. We would not have been able to achieve these important milestones without their efforts.

2023 promises to be another exciting year, with important milestones such as the **alfa**pump PMA submission to the FDA and initial data from our MOJAVE DSR study, both anticipated in the second half of the year. We are confident that we can continue to demonstrate the benefits of our proprietary **alfa**pump and DSR technologies, and move closer to launching **alfa**pump in the US and establishing a strategic partnership for DSR. We are committed to innovating the treatment of diuretic-resistant fluid overload, improving the clinical outcomes and quality of life for patients who otherwise have limited treatment options.

Pierre Chauvineau Ian Crosbie



Our Business

Achievements

Achievements in 2022

ALFAPUMP LIVER PROGRAM

POSEIDON – North American pivotal study of the alfapump in patients with recurrent or refractory ascites due to liver cirrhosis successfully met primary endpoint data:

- Reported positive top-line results in October 2022 from 40 patients of the Pivotal Cohort at six months post-implantation, including primary effectiveness endpoints substantially exceeding the predefined thresholds for study success and safety in line with expectations:
  - 100% median per-patient reduction in therapeutic paracentesis (TP) post- vs. pre-implantation ($p<0.001$), vs. hypothesis of at least 50% reduction.
  - 77% of patients with at least 50% reduction in number of TP post- vs. pre-implantation ($p<0.001$), vs. hypothesis of at least 50% of patients.
  - Six primary safety events of which three involved explants due to wound or skin erosion, and three explants due to patient-reported discomfort (all patient-reported discomfort events were adjudicated by the independent Clinical Events Committee as moderate severity), in line with expectations.
- Reported results of a preliminary interim analysis(I) of patient survival from the Roll-In Cohort in April 2022 including 70% survival rate at one year post-implantation, comparing favorably to published literature of 50% survival rate for refractory ascites patients after one year.[4]
- Prof. Wong presented safety, efficacy and quality of life data from the Roll-In Cohort at the AASLD The Liver Meeting® in November 2022.
- US patient preference study initiated:
  - Survey study to quantify patients' preferences for the **alfa**pump including treatment effectiveness and risks of treatment-related adverse events. The results of this study are expected to be presented in H2 2023.
- European PMSR data published in Liver International:
  - Final safety and efficacy results of the Post Marketing Surveillance Registry (PMSR) study of the **alfa**pump published in Liver International, the peer-reviewed publication of the International Association for the Study of the Liver.

(I) Date of analysis 25 March 2022, as part of a general safety assessment

DSR HEART FAILURE PROGRAM

SAHARA – Phase 2a study of DSR 1.0 in diuretic-resistant heart failure patients with persistent congestion showed important and long-lasting clinical benefits:

- Reported positive top-line data from ten evaluable patients with our first-generation DSR product (DSR 1.0) in November 2022, including i) safe, effective and rapid elimination of fluid overload and restoration of euvolemia, ii) improvement of cardiovascular and renal health, iii) restoration of the diuretic-response of the kidney, and iv) dramatic reduction in the need for oral loop diuretics up to 15 months post-therapy – demonstrating a durable improvement in the heart failure status of these patients.

Strong clinical observations from RED DESERT and SAHARA studies in diuretic-resistant heart failure patients support heart failure disease-modifying profile of DSR therapy:

- No heart failure congestion-related re-hospitalizations during study follow-up.
- All patients improved their $NYHA^2$ status by at least one class.
- Clinical benefits result in a 75% reduction in predicted one-year mortality pre- vs. post-intensive DSR therapy based on the Seattle Heart Failure Model.[3]

Focus on Short Term DSR therapy with proprietary DSR 2.0:

- Based on the results of RED DESERT and SAHARA, we expect that an intensive treatment period of three to four weeks of DSR therapy may deliver at least twelve months of important clinical benefits.
- As a result of the strong, durable clinical signals observed, we will focus the heart failure development program on Short Term DSR with our proprietary second-generation DSR product (DSR 2.0) administered via a peritoneal catheter.
- DSR 2.0 is expected to have an improved therapeutic and favorable safety profile with robust intellectual property protection.

MOJAVE – US Phase 1/2a randomized controlled multi-center study of DSR 2.0 in diuretic-resistant chronic heart failure patients with persistent congestion, planned to start in Q2 2023:

- Good progress of DSR 2.0 in product development and Good Laboratory Practices (GLP) animal studies.
- Approval to start two Phase 1 single-arm, open-label, single-dose studies in Canada (YUKON) and Mexico (CHIHUAHUA) to evaluate the safety, tolerability and efficacy of DSR 2.0, with first patient dosed successfully in YUKON.

CORPORATE

European Medical Device Regulation (MDR) certification:

- Received MDR certification from our Notified Body, BSI, in February 2022, confirming that our QMS and **alfa**pump system are compliant with the latest regulatory standards required for medical devices in Europe. **alfa**pump is one of the first novel Class III active implantable medical devices to receive such certification.

Expanding the Board of Directors with seasoned US medtech executives:

- Appointed two highly experienced US medtech leaders as independent Non-Executive Directors. Doug Kohrs brings more than 40 years of experience from his many roles as a founder and executive of leading medical technology companies. Alexandra Clyde brings more than 30 years of experience and has an exceptional understanding and track record of successfully navigating health economics and reimbursement in the medical device industry.

Extending our cash runway:

- Raised €28.4 million in gross proceeds in March 2022 by means of an equity placement via an accelerated bookbuild offering from a new investor, Partners in Equity V B.V., and existing shareholders.
- Secured €10 million loan facility with Kreos Capital, a leading growth debt provider for life sciences and healthcare companies, in July 2022.

Cash position of €18.9 million at the end of December 2022, compared to €9.6 million at the end of December 2021.

2023 year-to-date

Granting of additional DSR patents in the US and China:

- Additional US patent granted in January 2023 covering among other, the expansion of the composition of matter and method for our DSR therapy, including additional oncotic and osmotic agents and an additional US patent granted in March 2023 covering the expansion of the method of operation for our DSR therapy using an implantable pump system.
- A key composition of matter patent was allowed in China in March 2023 covering the use of a sodium-free or low-sodium infusate administered in a patient's peritoneal cavity to directly remove sodium, and thereby fluid from the body to alleviate fluid overload in heart failure patients with residual renal function.

Successful completion of pre-clinical studies of DSR 2.0:

- Reported data from two GLP animal studies in mice and sheep in February 2023 demonstrating safety of DSR 2.0. No difference in systemic and local toxic effects were observed in animals treated repeatedly with DSR 2.0, compared to animals in the control group, concluding that DSR 2.0 had consistent safety with the standard peritoneal dialysis solution used in the control group.

Positive results reported from the CHIHUAHUA study – Phase 1 single-arm, open-label, single-dose study of DSR 2.0 in Mexico:

- Reported data from this Phase 1 study in March 2023, demonstrating that a single dose of DSR 2.0 is safe and well-tolerated, and indicates a compelling dosing profile.

Submission of IND application for DSR 2.0 for treatment of congestive heart failure:

- The IND application, submitted at the end of March 2023, includes data from the GLP animal and Phase 1 CHIHUAHUA studies as well as manufacturing information of DSR 2.0 and an outline of the MOJAVE study design.
- Preparations ongoing to start the MOJAVE study, planned for Q2 2023, assuming FDA approval of the US IND application. The intention is to enroll 30 diuretic-resistant chronic heart failure patients with persistent congestion. Of these, 20 randomized patients will receive DSR 2.0 administered via a peritoneal catheter on top of usual care for congestive heart failure (CHF) for up to four weeks and ten randomized patients will receive intravenous loop diuretic treatment as part of maximized usual care for CHF alone.

Extending cash runway:

- We envision to conclude a capital increase by means of a private placement through an accelerated book building procedure in the coming days. We refer to the press release available on our website dated 24 April 2023 and will regularly provide an update on the envisioned equity placement via our website.

Outlook for 2023

2023 is a pivotal year for Sequana Medical as it builds upon the successful clinical data published for both programs in 2022. We are working towards the PMA submission for the alfapump program to the US FDA planned for H2 2023. For the DSR heart failure program, the key next step is the Phase 1/2a MOJAVE randomized controlled study expected to commence in Q2 2023, with Short Term DSR therapy using DSR 2.0.

- North American liver program of the **alfa**pump – PMA filing to US FDA planned for H2 2023:
  - Analysis of additional secondary efficacy and safety endpoints from the North American pivotal POSEIDON study and submit for presentation at a forthcoming medical liver meeting in 2023.
  - Top-line data from the US patient preference study expected in H2 2023.
- Heart failure program of DSR 2.0 – on track to start US Phase 1/2a MOJAVE study in Q2 2023:
  - Start MOJAVE study expected in Q2 2023 assuming approval of the IND by the FDA, and initial data expected in H2 2023.

Proprietary **alfa**pump & DSR technologies

alfapump®

Liver disease

Market potential growing to over $2.5 billion by 2035[1]

- NASH is changing liver cirrhosis market and driving growth
- Approved in EU / FDA breakthrough designation in US
- North American Pivotal study - met all primary effectiveness endpoints with statistical significance and primary safety endpoint data in line with expectations
- PMA filing to US FDA planned for H2 ‘23
- Direct commercialization in US through salesforce targeting liver transplant centres

DSR®

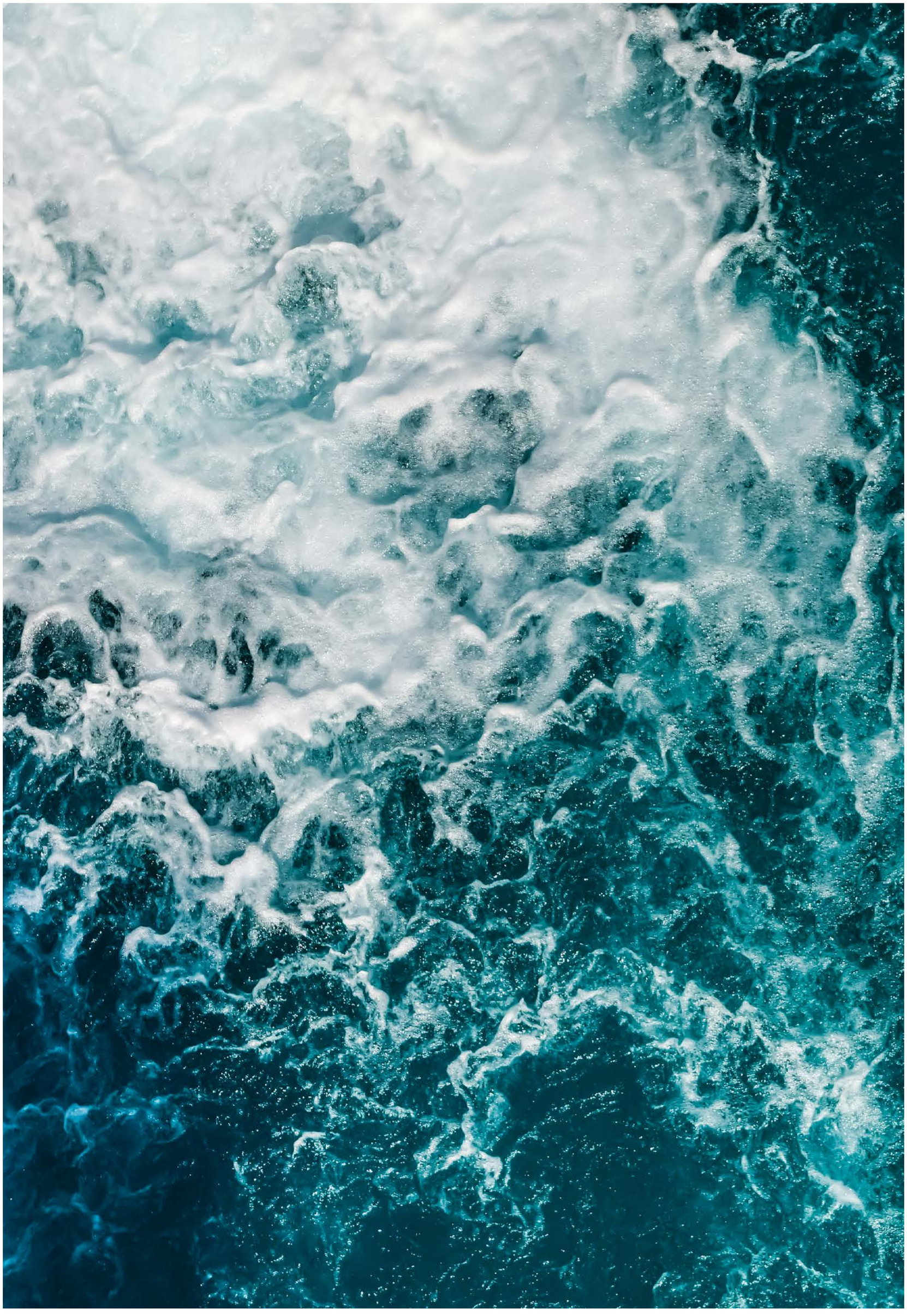
Heart failure

Multi-billion market opportunity in EU and US

- Disease-modifying heart failure drug therapy; short course of therapy
- 1st generation DSR 1.0 - cilinical proof of concept
- 2nd generation DSR 2.0 - safe and well tolerated; planning to start US Phase 1/2 study in Q2 ‘23
- Establish partnership based on MOJAVE readout

We have developed our **alfa**pump and DSR therapy to treat fluid overload, a serious and frequent clinical complication in patients with liver disease, heart failure and cancer. These patients can have up to 15 liters of extra fluid in their bodies, causing major medical issues including increased mortality, repeated hospitalizations, severe pain, difficult breathing and restricted mobility that severely impacts daily life. Although diuretics are standard of care, the problem is that in many patients they are no longer effective and / or tolerable. There are limited effective treatment options for these patients resulting in poor clinical outcomes, high costs and major impact on their quality of life.

alfapump and DSR are innovative treatment options that work with the body to treat this large and growing “diuretic-resistant” patient population, delivering major clinical and quality of life benefits for patients and reducing costs for healthcare systems.



alfapump®

Eliminating fluid from the peritoneal cavity – working in partnership with the bladder

Our alfapump is one of the first medical devices designed to treat the build-up of fluid in the abdomen. It is a battery-powered pump that is implanted just under the skin for the controlled and continuous removal of fluid from the peritoneal cavity into the bladder where it is simply urinated away. The alfapump system provides an automated system for the removal of fluid without the need for repeated needle punctures, needles or external tubes.

Fully implantable pump system

The **alfa**pump is implanted under the patient's skin using minimally invasive surgery. It is a simple procedure taking approximately 60 minutes that can be performed under local anaesthesia with sedation. In North America, we expect the procedure to be performed by interventional radiologists. Because the **alfa**pump is fully implanted, patients are able to retain normal mobility and activity. Once the **alfa**pump has been implanted, it is programmed wirelessly by the physician to ensure that the optimal amount of fluid is removed each day. The schedule can be designed to suit patients' individual daily routine. In 2020, the **alfa**pump surgical implantation technique was published in Langenbeck's archives of Surgery by a group of experienced European implanting surgeons, providing the clinical community with their accumulated experience.

Wirelessly charged through the skin

The only patient interaction is the need to recharge the battery each day with a wireless charger (the Smart Charger) through the skin for approximately 20 minutes (depending on the amount of fluid extracted each day). While charging, data from the **alfa**pump are transferred to the Smart Charger and transmitted wirelessly via the mobile phone network to secure servers using our proprietary DirectLink technology.

Remote pump performance monitoring

Using DirectLink technology, **alfa**pump performance data are collected and transferred via the mobile phone network to secure servers for analysis – 24 hours a day, 7 days a week. Our data specialists receive pump performance information (e.g. volume pumped and pump charging) and report this information to clinicians enabling them to manage patients more effectively through closer monitoring and notification of changes in pump performance data.

Unique capabilities

- ✓ Fully implanted
- ✓ Automatic operation
- ✓ Battery charged wirelessly through the skin
- ✓ Pump settings easily and wirelessly adjusted
- ✓ Remote pump performance data monitoring
- ✓ Easy, long-term implantation & catheter patency
- ✓ Monitors bladder and peritoneal pressure via pressure sensors
- ✓ Moves up to four litres of fluid per day
- ✓ Virtually non-clogging
- ✓ No significant heating during charging and operation
- ✓ Strong IP barriers through extensive patent portfolio & know-how

1. Automatic and continuous removal of fluid from the abdomen
2. Fluid is pumped into bladder
3. Fluid leaves the body through normal urination
4. Wireless charging and communication for monitoring

Secure 24/7 monitoring

During charging, data are transferred from the **alfa**pump to the Smart Charger

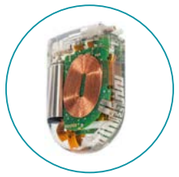
alfapump data transferred via mobile phone network to Sequana Medical's DirectLink server

alfapump data specialists analyse data. Reports sent to clinicians as often as requested

Closer monitoring by physicians

Components

The extensive research and development that went into the **alfa**pump is reflected in the sophisticated workings of the pump mechanics and controls. The **alfa**pump is programmed, charged and monitored wirelessly.



alfapump

The **alfa**pump is an automatic and programmable pump implanted under the skin and can pump up to four litres of fluid per day. The **alfa**pump monitors pressure in the bladder and the abdominal cavity via pressure sensors to ensure optimal fluid management and contains anti-clogging control algorithms to reduce blockage. The housing of the pump is made of biocompatible plastic, which enables efficient wireless charging and communication.

Supply Chain

The large majority of sub-components of the **alfa**pump are sourced externally, from a total of approximately 70 external suppliers, including experienced and well-respected manufacturers for the critical components.

Catheters

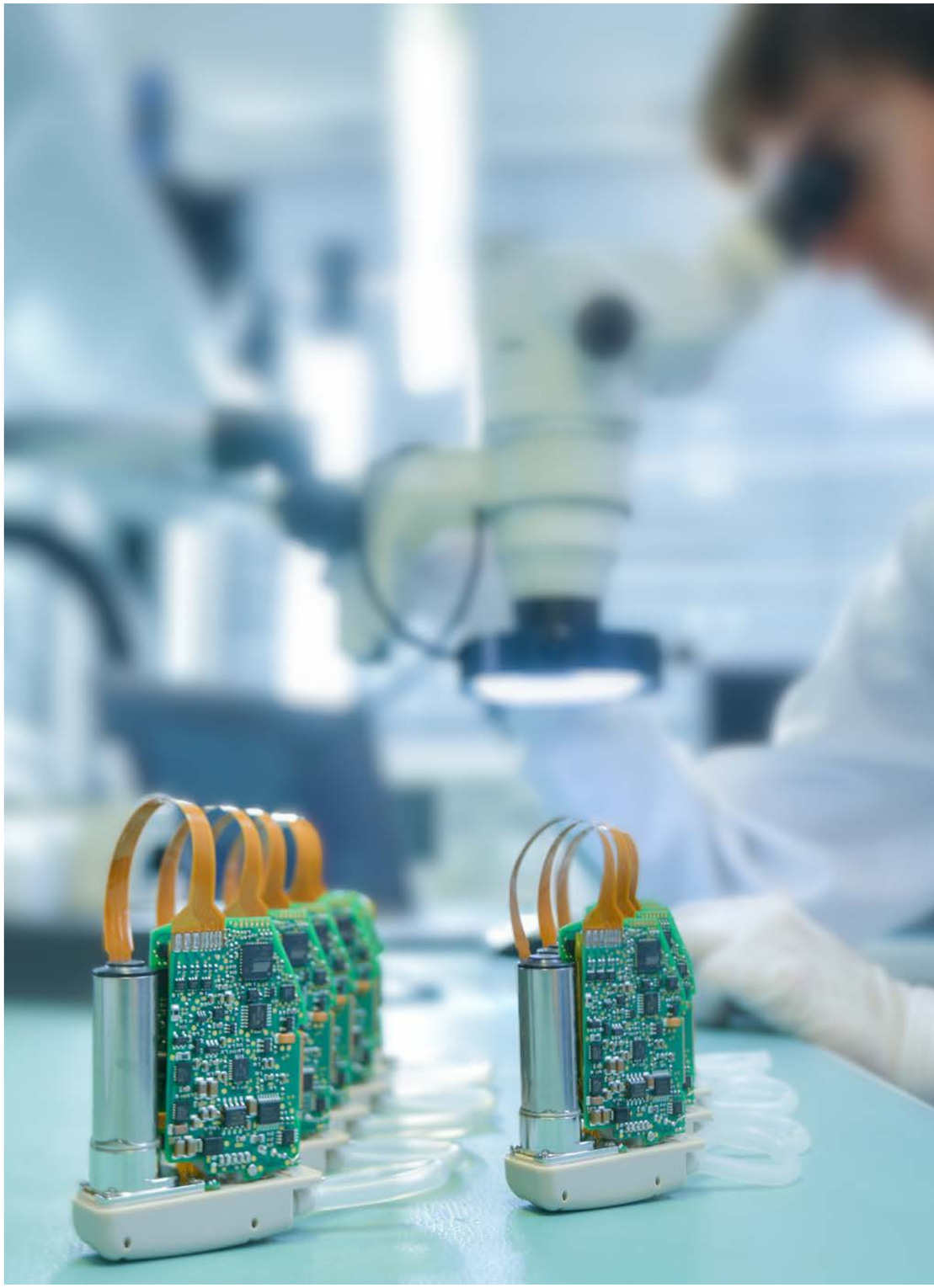
Implantable grade silicone catheters are used to collect fluid from the abdominal cavity (white/blue catheter) and transfer it to the bladder (yellow catheter). These catheters are implanted inside the body.

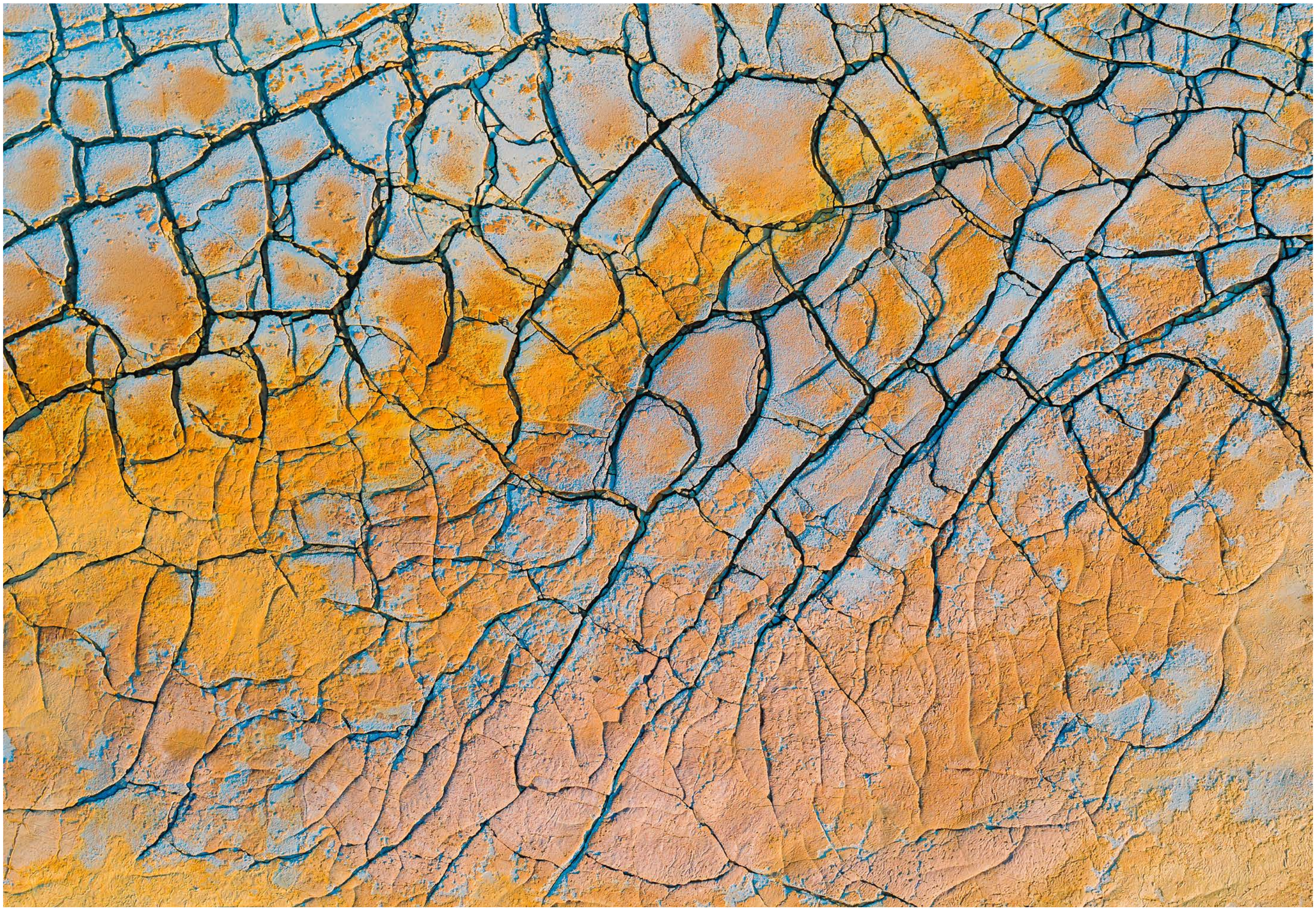
Smart Charger

The Smart Charger is a hand-held charging device that charges the **alfa**pump through the skin. While charging, data from the **alfa**pump are transferred to the Smart Charger. When placed on the docking station, these data are transmitted wirelessly via the mobile phone network to secure servers for analysis, using our DirectLink Technology.

Programmer

The **alfa**pump programmer is a medical-grade notebook with proprietary FlowControl software that is used to change the **alfa**pump settings. The FlowControl software enables the quick and easy adaption of a fluid-transport program to the needs of each patient.





DSR®

Eliminating fluid spread across the body – working in partnership with the kidneys

DSR or Direct Sodium Removal is our novel therapy to treat fluid overload spread across the body. Fluid accumulation is the result of an increase of sodium levels in the body. If the amount of sodium increases, the body responds by accumulating water to keep a constant concentration of sodium in the blood. With our DSR therapy, we remove excess sodium from the body, which lowers the concentration of sodium in the blood, so the brain and kidneys step in to quickly and accurately remove the exact amount of water to restore the correct sodium concentration in the blood, resulting in reduced fluid overload.

Key principle

Maintaining a constant concentration of sodium in the body (“homeostasis”) is a key physiological parameter, vital to patient health. A concentration that is too high will result in hypernatremia and a concentration that is too low will result in hyponatremia, both of which are serious medical conditions.

When the sodium levels in the body increase, the body responds by accumulating water to keep a constant sodium concentration in the body, leading to fluid overload. So in patients with fluid overload, the amount of sodium and water is in balance but there is just too much of both.

DSR Therapy

DSR therapy involves the use of the peritoneal cavity for the removal of sodium via diffusion. The peritoneal cavity, just like the lungs, has a large surface area, rich blood supply and thin walls, which makes it highly effective in removing soluble compounds from the blood stream. The utility of the peritoneal cavity is supported by the long-standing technique of peritoneal dialysis, for the removal of toxins from the blood of patients with renal failure.

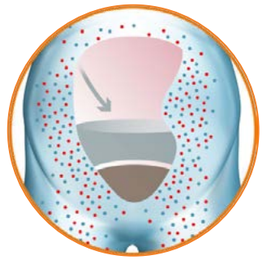
DSR approach

DSR removes excess sodium in patients with residual renal function leading to lower sodium concentration in the body.

As a result, the body acts to restore the sodium concentration in the body by eliminating fluid through urination and osmotic ultrafiltration, resulting in a sustained level of fluid loss.

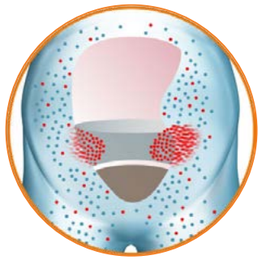
How DSR works

● water ● sodium



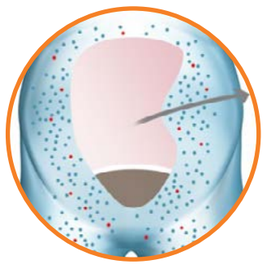
1 Sodium-free DSR product administered to peritoneal cavity

In DSR, the objective is to remove sodium. To do this, we administer our sodium-free DSR product to the peritoneal cavity and allow it to dwell for a pre-defined period.



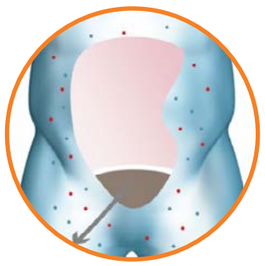
2 Sodium diffuses from body into DSR product

Sodium diffuses from the body down a steep diffusion gradient into the DSR product. The blood circulation keeps the blood sodium concentration high so the diffusion remains effective.



3 DSR product + extracted sodium removed from the body

The DSR product and the extracted sodium are then removed, resulting in a removal of sodium from the body.



4 Body eliminates free water to restore sodium balance reducing the fluid overload

The body responds by eliminating free water via osmotic ultrafiltration (the movement of water, together with sodium, from the bloodstream to the peritoneal cavity) and/or urination to restore the sodium balance reducing the fluid overload.

DSR therapy treatment overview

The sodium-free DSR product is administered to the peritoneal cavity via a standard peritoneal catheter. The DSR product remains in the peritoneal cavity for a pre-determined time before the DSR product and the extracted sodium is removed using the same peritoneal catheter.

DSR Therapy steps

Step 1: Peritoneal catheter placement

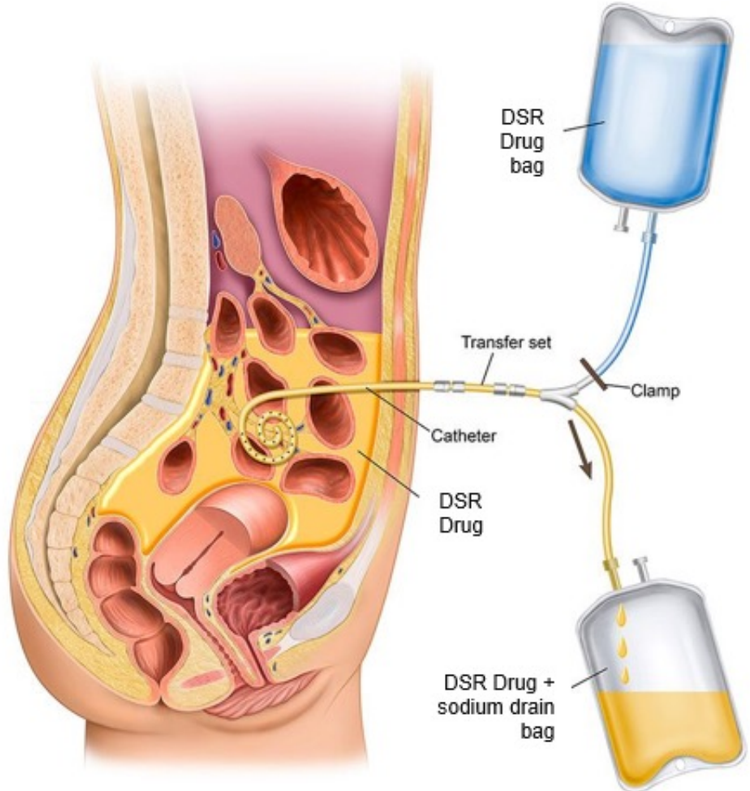
Step 2: Potential DSR treatment episode

1. Infusion of DSR Drug
2. 24 hour Dwell
3. Drainage

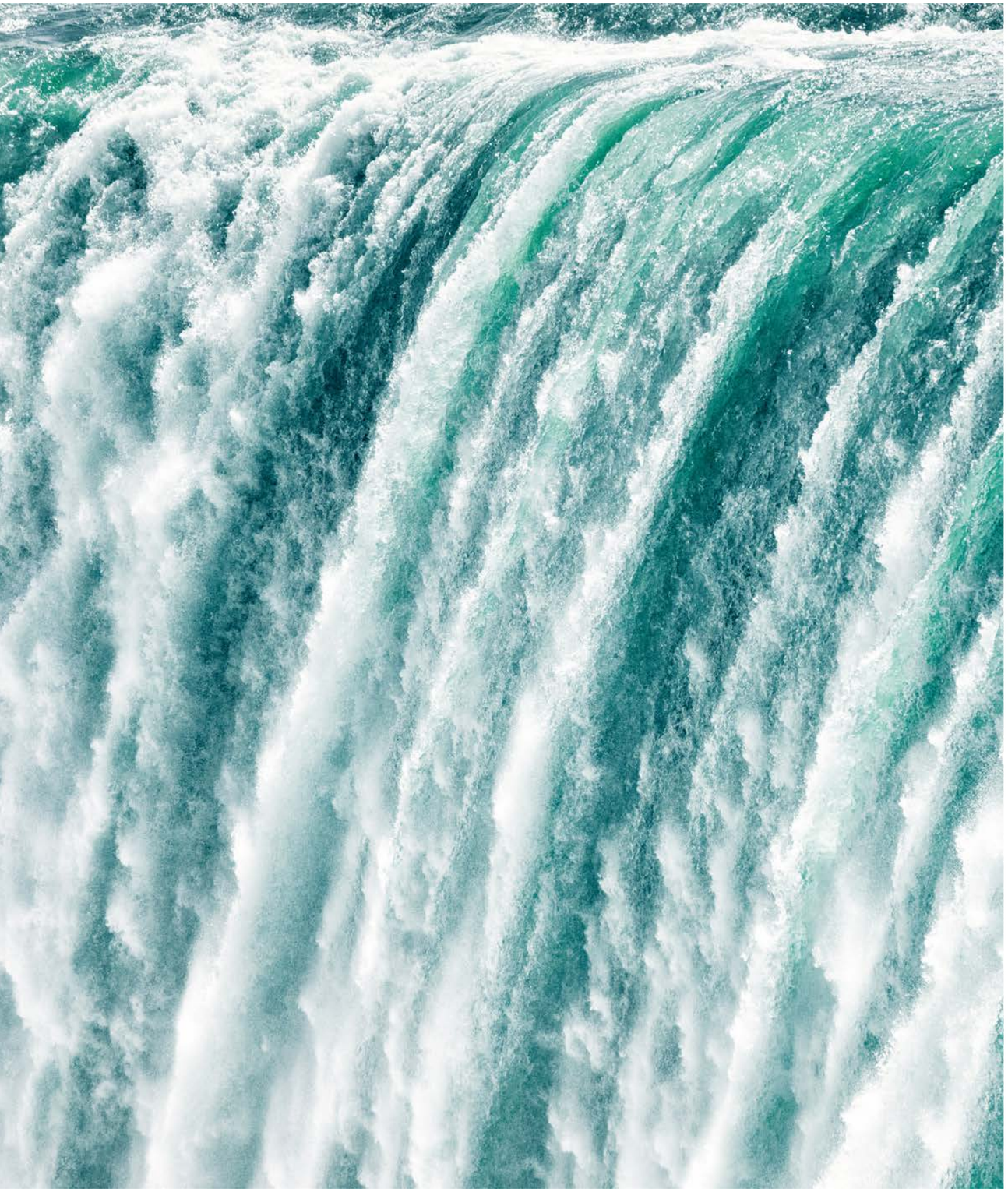
Week 1: 5x DSR Therapy

Week 2-4: 3x/week DSR Therapy

Step 3: Catheter removal



Our patent portfolio consists of 80 patents being granted across 20 patent families and a further 21 patent applications pending for our **alfa**pump and DSR.



alfapump in liver disease and cancer

Proven step change for treatment of refractory ascites due to liver cirrhosis and malignant ascites

The **alfa**pump provides an innovative treatment solution for the management of refractory ascites due to liver cirrhosis and malignant ascites with proven safety, efficacy and quality of life benefits demonstrated in multiple clinical studies. By automatically and continuously moving ascites from the abdomen to the bladder where it is eliminated via urination, the **alfa**pump prevents fluid build-up and possible complications, improving patients' quality of life and nutrition, and potentially reducing hospital visits and healthcare costs. To date, over 950 **alfa**pump systems have been implanted.

In the US, the **alfa**pump has been granted breakthrough device designation by the FDA for treatment of recurrent and refractory ascites due to liver cirrhosis. The North American pivotal study (POSEIDON) reported positive top-line results meeting all primary endpoints of the study with statistical significance and safety in line with expectations. We are currently planning to submit the PMA to the US FDA in H2 2023, with a potential US approval in 2024. We plan to commercialize the **alfa**pump directly in the US, using a specialized in-house sales force targeting 90 liver transplant centers (covering 95% of adult liver transplants). The North American market for the **alfa**pump is forecast to grow at a CAGR of 6-7%, from over 75,000 patients in 2025, reaching a market opportunity of over $2.5 billion by 2035[1], with NASH being the major driver of growth.

In Europe, the **alfa**pump is CE-marked for the treatment of refractory ascites due to liver cirrhosis and malignant ascites and has been endorsed by key independent third parties including the European Association for the Study of the Liver (EASL) clinical practice guidelines for decompensated cirrhosis, the DGVS (German Society of Gastroenterology Digestive and Metabolic Diseases) treatment guidelines for complications of liver cirrhosis and the UK National Institute for Health and Care Excellence (NICE) interventional procedure guidance for treatment of refractory ascites caused by cirrhosis. Although the European market is not our commercial focus, we are gaining significant real-world experience which will be invaluable for our US commercialization strategy.

Market opportunity and limitations of existing therapies

Liver cirrhosis/NASH and refractory ascites

The number of people affected by liver disease is large and growing. In 2018, more than 4.5 million US adults aged 18 and older were diagnosed with chronic liver disease.[5]

Cirrhosis, one of the leading manifestations of liver disease, is the progressive scarring of the liver. Traditionally, the key causes of liver cirrhosis have been alcoholic liver disease and viral hepatitis. However, this is changing dramatically due to the rise of non-alcoholic steatohepatitis (NASH), in particular in North America.

NASH is a severe form of non-alcoholic fatty liver disease (NAFLD) with a poor prognosis and extremely limited treatment options. NAFLD is characterised by an accumulation of fat in the liver and associated with obesity, high fat, fructose-rich diets and a sedentary lifestyle.

Approximately one-third of the US population is affected by NAFLD and approximately a quarter to one-third of NAFLD cases are classified as NASH[6]. NASH is a silent disease due to the difficulty in diagnosing it, making early-stage intervention challenging. Currently, there are no drugs approved for treatment of NASH and data from recently developed drugs have failed to demonstrate sufficient efficacy. It is estimated that about 10% of the NASH population will progress to liver cirrhosis in the near-to medium-term[7], making the US NASH-related cirrhosis market an attractive market for the **alfa**pump.

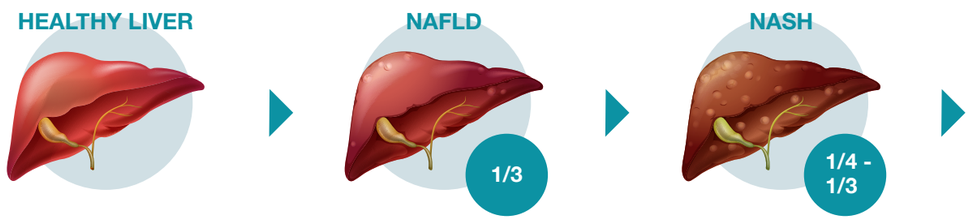
We believe that the growing importance of NASH as the cause of cirrhosis will transform attitudes to liver cirrhosis. In particular, the similar causes to coronary artery disease, e.g. obesity, poor diet and lack of exercise, are expected to make liver cirrhosis a "mainstream" disease and result in the need for improved therapies, with greater focus on quality of life for patients. It is expected that despite significant investments in the development of therapeutics for NASH, there will be a strong, growing need for ascites treatments.

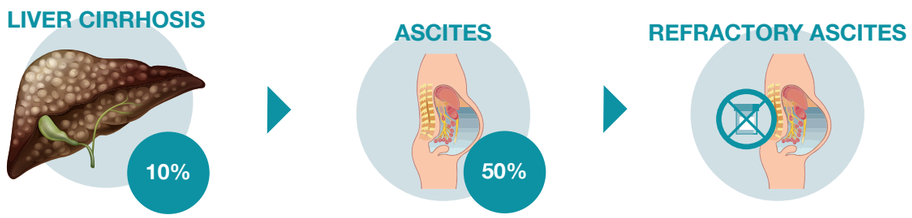
A key complication of liver cirrhosis is ascites. Around 50% of cirrhotic patients develop ascites within 10 years of the diagnosis of cirrhosis.[8] Management of ascites is based on a low-sodium diet and diuretic treatment. However, approximately 10% of patients with cirrhosis and ascites will develop refractory liver ascites[9],which is ascites that is unresponsive to a sodium-restricted diet and high-dose diuretic treatment, or which recurs rapidly after paracentesis. An additional portion of this market is recurrent ascites, those patients where it is difficult to comply with the diuretic or dietary treatment, resulting in frequent paracentesis.

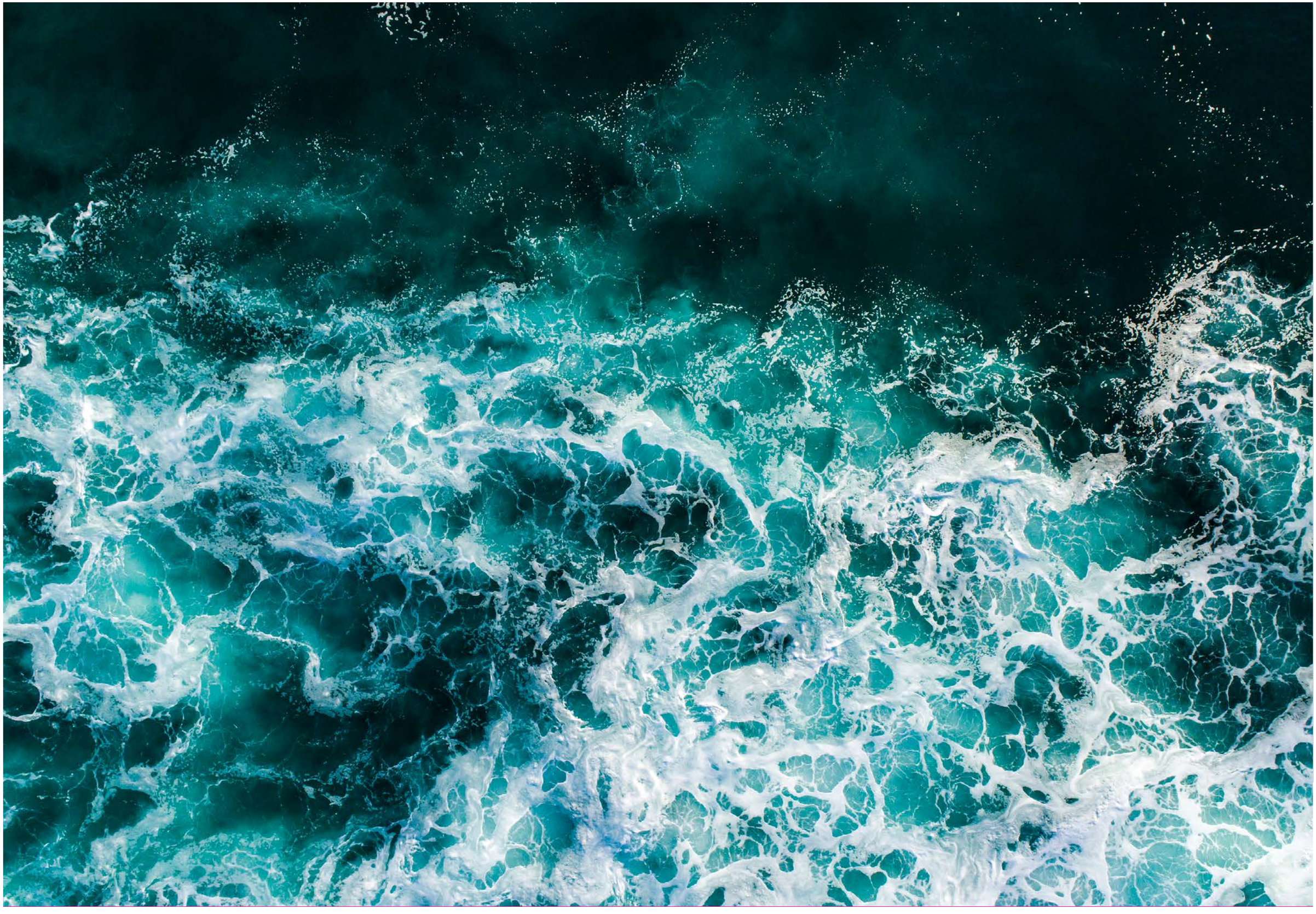
Ascites

Ascites is a condition where excess fluid builds up in your abdomen, making your belly swell and stick out.

Ascitic fluid is a protein-containing fluid that leaks from the liver as a result of advanced cirrhosis. Due to the scarring of the liver, the pressure inside the liver's blood vessels increase, forcing fluid into the abdominal cavity. Patients may accumulate as much as 10-15 litres of fluid within the abdomen every 15 days. This has a dramatic negative impact on a patient's quality of life due to the severe swelling of the abdomen, resulting in pain, difficulty in breathing, sleeping and eating, severe nausea and constipation as well as increased risk of severe infection including spontaneous bacterial peritonitis.

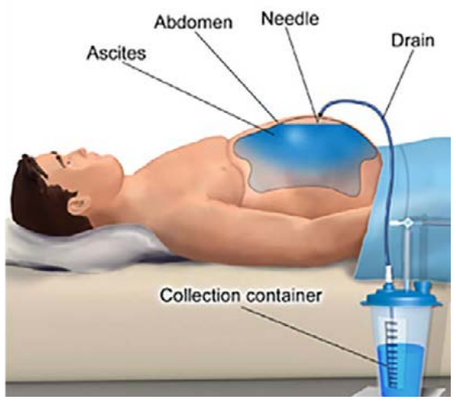






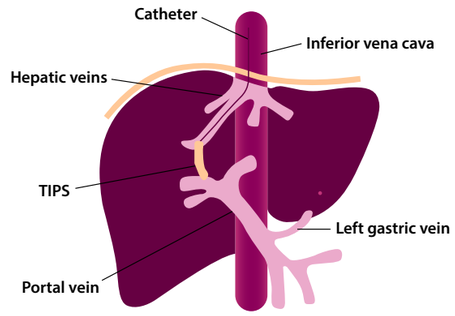
Existing therapies have severe limitations

When drug therapy and dietary restriction are no longer effective, the common treatment of ascites is drainage (“paracentesis”).



Paracentesis is a bedside or clinic procedure in which a needle is inserted into the peritoneal cavity to remove the ascitic fluid.

In selected patients with refractory ascites, a therapeutic alternative to repeated LVPs is the use of a transjugular intrahepatic portosystemic shunt (TIPS).



TIPS is a procedure that connects the inflow portal vein to the outflow hepatic vein in the liver via an artificial channel.

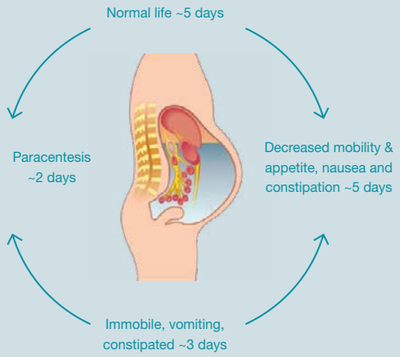
There are a wide variety of complications that can be encountered with TIPS, such as haemorrhage, hepatic encephalopathy (up to 50% of patients)[10], TIPS blockage, and liver failure. The hepatic encephalopathy complications arise primarily from the significant reduction in the cleaning of the blood by the liver and the consequent accumulation of toxins that particularly impact the brain. Development of hepatic encephalopathy, one of the main drawbacks of TIPS, causes devastating physical and mental changes such as mood and personality changes, anxiousness, concentration deficit, loss of orientation, dementia-like memory loss, tremor, and may ultimately lead to coma. The risk of developing hepatic encephalopathy increases with age. As a result, TIPS is associated with significant risks for patients over 65 years old[11], and many patients with recurrent or refractory ascites due to NASH are forecast to exceed this age bracket, which we believe makes TIPS a less attractive treatment option for these patients. Furthermore, TIPS is not recommended in patients with heart failure, which is expected to represent a significant proportion of NASH patients.

Liver transplantation remains the only curative treatment for liver disease. However, availability is extremely limited and transplants result in large healthcare costs. Furthermore, lifelong use of immunosuppressive drugs is required to reduce the risk that the recipient’s body will reject the transplant.

The **alfa**pump can serve as a bridge to liver transplantation. Due to the high cost of the liver transplantation procedure and the scarcity of donor organs, the **alfa**pump provides support for patients waiting for a liver transplantation and can also improve a patient’s condition, such as their nutrition and physical condition, ahead of transplantation.

Large Volume Paracentesis treatment cycle

Paracentesis of more than 5 litres is referred to as Large Volume Paracentesis (LVP). In addition to being a painful, burdensome and costly procedure, paracentesis has the severe limitation of only providing temporary relief of symptoms. Patients undergoing recurrent cycles of fluid build-up and paracentesis are only able to experience a normal life for one-third of the time before the debilitating symptoms of ascites return.



Physician stories

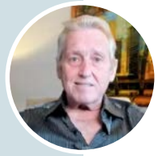
“It goes without saying, based on testimonials and the way we interact with our patients that the alfapump is very well accepted, the concept is easy to understand, the comparison with other therapies is easy to see, the patient population has a strong interest in this.”

Dr. Hugo Vargas, Mayo Clinic, US

“Patients are very satisfied and feel a significant improvement in their quality of life. Moreover it seems to significantly improve their nutritional status as they do not have the abdominal pain or discomfort anymore they had a few days before paracentesis.”

Prof. Edouard Bardou-Jacquet, Transplantation CHU, France

Patient Testimonials



“The alfapump changed my life, I thought I was going to die, I thought I was done, I got lucky with the alfapump, my daily routine is getting back, with no pain and suffering, feeling good and taking care of myself. My approach to life totally changed since the alfapump, I look at it as a second chance in life.”

63-year old patient, Canada

Cancer and Malignant ascites

Ascites is also a common complication of certain late-stage cancers as a result of fluid accumulation in the peritoneal cavity due to a number of causes including draining of the lymph system. While life expectancy for many cancer patients with malignant ascites is short (less than 3 months), ovarian and breast cancer patients often have longer life expectancies[12], making the **alfa**pump a viable and attractive option.

In 2018, there were an estimated 232,000 and 269,000 new cases of breast cancer diagnosed in the US and EU5 and an estimated 24,000 and 26,000 new cases of ovarian cancer diagnosed in the US and EU5, respectively.[13] The estimated prevalence of malignant ascites due to ovarian and breast cancer is approximately 16,000 cases in the US and 18,000 cases across the EU5.[12] [13]

As with liver ascites, paracentesis is often used to eliminate the ascites that accumulates when drugs are not effective. The impact of ascites on a patient’s health reduces the patient’s ability to withstand anti-cancer therapies, thereby potentially reducing survival. In addition, the regular hospital visits that are required place a huge burden on the patient and their quality of life.

The **alfa**pump offers a new and much-needed treatment option for the management of malignant ascites in this patient population.

A further benefit of the **alfa**pump in malignant ascites is that physicians are able to conduct easy and regular liquid biopsies for therapy monitoring through the analysis of urine samples. These will contain significant material direct from the peritoneal cavity, including cancer cells.

Living with refractory ascites, before and after alfapump implantation

Refractory ascites has a dramatic impact on the quality of life of patients. Patients suffering from ascites are immobile and very restricted in their daily activity, and often report feelings of isolation and depression. Family members are also affected because of the need for extensive care and frequent hospital visits for paracentesis, and they constantly worry about their relatives’ condition.

Patients with refractory liver ascites who were implanted with the **alfa**pump experienced a substantial improvement in quality of life. Patients testified about their improved activity and mobility, and generally felt much better than before their implantation with the **alfa**pump. These patients also experienced improvements in their eating, breathing and sleeping and were able to perform everyday tasks like cooking for their family and going on vacation without worrying about getting back in time for paracentesis. Family members also experienced a positive change and were able to enjoy life together with their relatives again.

In short, the **alfa**pump makes patients strong and independent enough to do anything they want and lead regular lives.

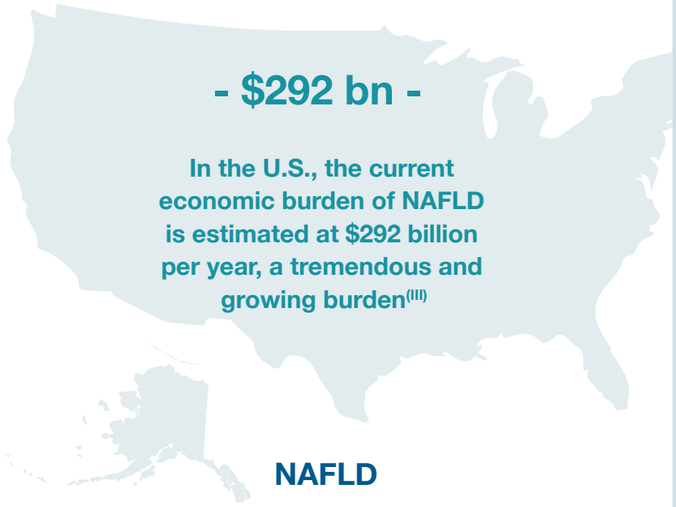
NASH 101

Incidence of obesity has more than doubled worldwide since 1980 (source WHO) and more than two billion adults are currently overweight. As a result, non-alcoholic steatohepatitis (NASH), a severe form of non-alcoholic fatty liver disease (NAFLD) where the liver becomes inflamed due to the accumulation of fat, is a major threat to global health systems. It is estimated that 25-30% of obese patients and 25-30% of type 2 diabetes patients develop NASH[(I)].

In a similar manner to diabetes - which has become a worldwide epidemic - NASH is expected to affect 30-40 million patients in the U.S. by 2030.

Due to the invasive nature of a liver biopsy required to properly diagnose the disease, NASH has been overlooked for too long and remains a silent disease that can progress for decades without being noticed. This also creates a serious challenge in developing drug therapies as the disease is often well advanced before diagnosis.[(II)]

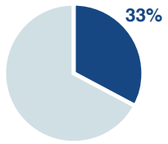
If left untreated, NASH can lead to serious complications such as cirrhosis, liver failure and ultimately death. It is now the second-leading cause of liver transplants and will soon become the leading cause in the U.S. Although diet measures and increased physical activity are key components of NASH risk reduction, they have proven difficult to implement and there are still no approved drug therapies.



- $292 bn -

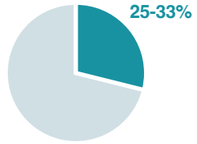
In the U.S., the current economic burden of NAFLD is estimated at $292 billion per year, a tremendous and growing burden[(III)]

NAFLD



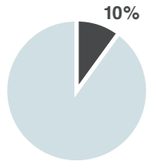
1/3 of US citizens has NAFLD, the hepatic manifestation associated with type-2 diabetes and obesity

NASH



1/4 - 1/3 of NAFLD patients develop NASH, the most severe form of NAFLD characterized by inflammation and hepatocyte degeneration

CIRRHOSIS



1/10 of NASH patients will develop cirrhosis, the extensive fibrotic scarring that inhibits liver function

(I) The NASH education program
(II) Younossi et al., Journal of Hepatology, 2016
(III) Management estimate based on Global Data Heart Failure Epidemiology Forecast to 2026; Costanzo et al. (2007); Kiglore et al (2017)

“Millions of people are living with a ‘silent’ disease they’ve likely never heard of”
Business insider

“The $35 billion race to cure a silent killer that affects 30 million Americans”
CNBC

“A Big, Fatty Opportunity for Big Pharma”
The Wallstreet Journal

“Prepare for ‘the coming tsunami’ of NAFLD”
The Hospitalist

“Nonalcoholic Steatohepatitis (NASH): An Overlooked Disease”
Int. J. Clin. Pharmacol. Pharmacother.

“Why fatty liver disease could be the next public health crisis”
The Telegraph

“NASH – a silent killer: 150 world experts sign a global call to action to promote awareness of deadly liver disease”
The Nash Education Program

“An estimated 80 to 100 million Americans have non-alcoholic fatty liver disease [...] seven million of those are adolescents and teenager”
The New York Times

“NASH will become the largest pharmaceutical market of the coming decade”
KBC Securities

“NASH is on a trajectory to become the most common indication for liver transplantation in the United States”
Gastroenterology

“Non-alcoholic fatty liver disease: a pandemic disease with multisystem burden”
Hepatobiliary Surg. Nutr.

Proof-of-concept studies of **alfa**pump in liver disease and cancer

We have invested significant resources in clinical studies to demonstrate the safety and efficacy of the **alfa**pump in patients with recurrent or refractory liver ascites and malignant ascites.

Name of Study	Description	Number of Patients
Recurrent or refractory ascites due to liver cirrhosis		
PIONEER Study	Prospective, multi-centre, open-label, uncontrolled study to assess the safety and performance of the **alfa**pump in patients with refractory liver ascites and diuretic resistance (completed in 2013).	40
Gines Study	Prospective, single-centre, uncontrolled study to evaluate the effects of the **alfa**pump on kidney and circulatory function in patients with liver cirrhosis and refractory ascites (completed in 2014).	10
European Randomised Controlled Trial (RCT)	6-month open-label, randomised and controlled study in Europe on the **alfa**pump versus LVP for the treatment of refractory liver ascites (completed in 2016).	58
Post Marketing Surveillance Registry (PMSR)	Multi-centre, open-label observational study in Europe designed to follow patients implanted with an **alfa**pump for up to 24 months (completed in 2018).	100
Retrospective Study at Hannover Medical School	Retrospective, single-centre study at Hannover Medical School to investigate the **alfa**pump as an alternative for LVP in a real-world setting (published in 2018).	21
MOSAIC (North American IDE feasibility) Study	12-month open-label, single-arm study in the U.S. and Canada to assess the safety and efficacy of the **alfa**pump in patients with recurrent or refractory liver ascites (completed in 2018).	30
Malignant ascites due to cancer		
Retrospective Malignant Ascites Study	Retrospective open-label study in Europe to assess the performance and safety of the **alfa**pump for the treatment of malignant ascites (completed in 2017).	17

The key findings from clinical studies in recurrent or refractory liver ascites include:

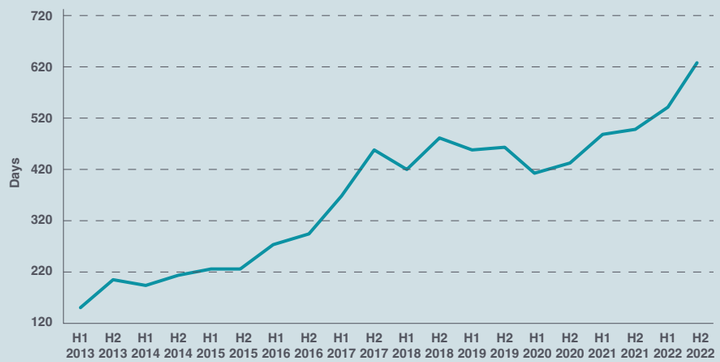
- Approximately 90% reduction in the mean number of LVPs per month for refractory liver ascites patients treated with the **alfa**pump versus patients treated with LVP standard of care.
- Clinically significant improvement in quality of life for patients treated with the **alfa**pump versus patients treated with LVP standard of care.
- Refractory liver ascites patients treated with the **alfa**pump demonstrated a clear nutritional benefit versus patients treated with LVP standard of care over 30-day and 90-day periods.

The retrospective study in patients with malignant ascites demonstrated that the **alfa**pump was effective in palliative patients with malignant ascites and has the potential to improve quality of life and clinical outcomes for late-stage cancer patients.

To date, 11 publications on clinical study results have been issued in peer-reviewed journals, which we believe are a strong endorsement of the clinical benefit of the **alfa**pump and are essential to support the acceptance of the **alfa**pump.

Average duration of alfapump therapy

Through the significant experience gained from clinical studies and extensive commercial use, we have continually worked on improvements to the **alfa**pump therapy. Following these improvements, there has been a clear increase in clinical outcomes.



Source: Sequana Medical internal statistical analysis of market feedback/implant duration

Ongoing clinical studies of **alfa**pump in liver disease

We are currently running additional clinical studies in patients with recurrent or refractory ascites due to liver cirrhosis, to obtain regulatory approval of the **alfa**pump in North America and to further support the acceptance and reimbursement of the **alfa**pump in Europe.

Name of Study	Description[I]	2022	2023	2024
POSEIDON (NCT 03973866)	North American pivotal study including 40 Pivotal Cohort patients (and an additional 29 Roll-In Cohort patients) with recurrent or refractory liver ascites implanted with the **alfa**pump to demonstrate the safety and efficacy of the **alfa**pump and support approval in US and Canada.	✓ *Primary endpoints*		• *Secondary endpoints*
Patient preference study	Survey study to quantify patients' preferences for the **alfa**pump including treatment effectiveness and risks of treatment-related adverse events.			
ARIA Pump Study[II] (NCT 03506893)	Randomized, open-label health economic study in France in 90 patients with refractory liver ascites to evaluate the cost utility of the **alfa**pump vs. standard of care over 12 months to support French reimbursement (60 patients not waiting for liver transplant and 30 patients as bridge to transplant).			
TOPMOST (NCT 04326946)	European registry study in cirrhosis patients that have been implanted with the **alfa**pump.			
Step Counter Study (part of TOPMOST)	Quality of life study in 20 patients to measure the impact of the **alfa**pump vs. standard of care on patient activity.			

(I) The descriptions and timing of these studies are based on circumstances that may or may not occur in the future and remain subject to change and/or feedback from applicable regulatory authorities. The dashed shading of the arrow indicates that the study is expected to extend beyond 2024.

(II) Funded by the French government and conducted by leading French clinicians. Estimated study completed date Dec 2025 as per clintrials.gov (NCT03506893).

North American approval of the **alfa**pump expected in 2024

Breakthrough Device Designation by the US FDA

In January 2019, we received breakthrough device designation from the US FDA for the **alfa**pump for the treatment of recurrent and refractory ascites due to liver cirrhosis. This program is designed to facilitate the development and expedite the review of devices that provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and to provide patients and healthcare providers with timely access to these medical devices. Devices that receive this designation are eligible for more frequent interactions with the FDA's experts to identify areas of agreement in a timely way. In addition, breakthrough devices will also benefit from the reimbursement initiatives launched by Centers for Medicare and Medicaid Services (CMS).

POSEIDON – North American pivotal study to support approval of the **alfa**pump in the US and Canada

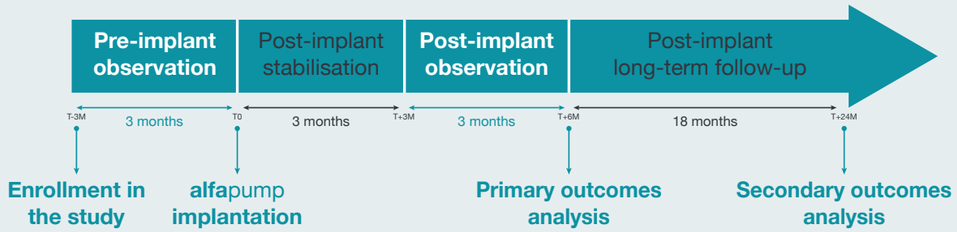
Study design

POSEIDON is a single-arm, open-label, within-subject crossover study of the **alfa**pump in patients with recurrent and refractory ascites due to liver cirrhosis in approximately 20 centers across the US and Canada. The study consists of a Pivotal Cohort for primary endpoint analysis and an additional Roll-In Cohort for new centers to become familiarized with the implantation procedure before they enrol patients in the Pivotal Cohort. Pivotal Cohort patients enter into a three-month pre-implant observation period in which they receive standard of care therapy (consisting of paracentesis) before the **alfa**pump is implanted. Patients from the Roll-In Cohort are immediately implanted with the **alfa**pump.

The study is designed to demonstrate in Pivotal Cohort patients 1) a median per-patient ratio of post-implant three-month observation period (month four to six) ("Post-Implant Observation Period") to the pre-implant three-month observation period ("Pre-Implant Observation Period") with respect to number of therapeutic paracentesis ("TP") less than 0.5 (or a median reduction of at least 50%); and 2) at least 50% of patients achieve a 50% reduction in the requirement for TP in the same period.

The primary safety endpoint is the combined rate of i) open surgical re-intervention (requiring general anesthesia or laparotomy) due to pump system related adverse event or to restore pump functionality, ii) pump explant (without replacement) due to pump system related adverse event, or iii) pump system related death from time of pump implant through six months post-implantation as adjudicated by the Clinical Events Committee (CEC).

Patients will be followed for up to two years for analysis of secondary outcome measurements including safety (device and/or procedure-related adverse events), quality of life (assessed by general SF-36 as well as disease-specific Ascites-Q questionnaires), patients' nutritional status, health economics and overall survival.



In total, 40 patients implanted in the Pivotal Cohort and 29 patients in the Roll-In Cohort

Of the 71 patients enrolled in the Pivotal Cohort, 40 patients have been implanted with the **alfa**pump and have been evaluated for primary endpoint analysis at six months post-implantation. A further 29 patients have been implanted with the **alfa**pump in the Roll-In Cohort and are included in the overall safety analysis.

Looking at the underlying cirrhosis etiology of the 40 Pivotal Cohort patients (over one third had NASH or combined NASH etiology) and of the first 26 Roll-In patients (50% alcohol, 23% NASH, 4% NASH-alcohol, 4% hepatitis C and 19% other/mixed etiology), it is clear that NASH is already an important driver of the North American liver cirrhosis market.

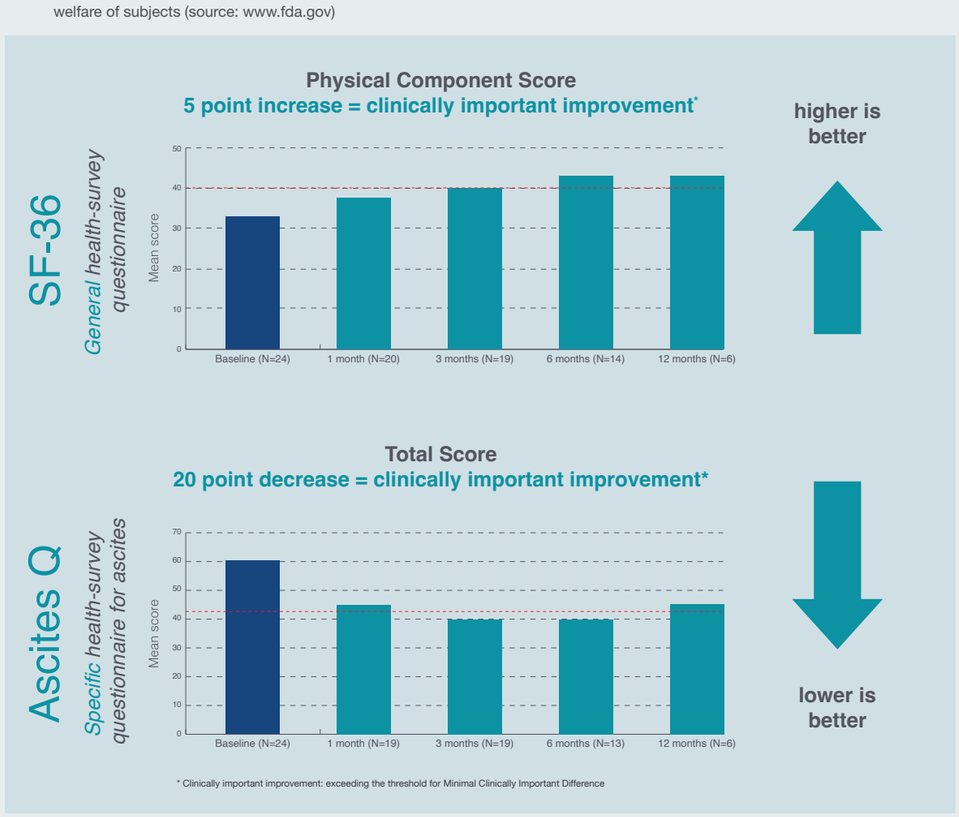
Positive interim data reported from the first 26 patients in the Roll-In Cohort

In 2021, we reported data from the Roll-In Cohort as part of an interim analysis. Patients from the Roll-In Cohort must fulfil the same inclusion and exclusion criteria as patients enrolled into the Pivotal Cohort, with the only difference that the historical medical records are used as baseline since patients from the Roll-In Cohort don't enter a pre-implant observation period first.

These interim data demonstrated a mean reduction in the frequency of therapeutic paracentesis post-implant vs. pre-implant of over 90%, with all patients having at least a 50% reduction in the average frequency of therapeutic paracentesis per month[I].

Patients' quality of life was assessed using two validated methods, SF36 (a general health quality questionnaire) and Ascites Q (a questionnaire developed for patients with ascites) confirming the rapid positive impact of the **alfa**pump on patient's quality of life. Both, the mean physical component score of SF36 and the mean score of Ascites Q, showed a clinically important improvement (exceeding the threshold for Minimal Clinically Important Difference) from baseline to 6 months post-implantation and the improvement in quality of life measures was maintained for up to 12 months post-implantation (n=6 patients at 12 months).

Safety profile was in line with expectations with no unanticipated adverse device effects (UAD[II]) during the course of the study. Three out of the 26 Roll-In patients experienced a composite primary safety event as adjudicated by the Clinical Events Committee (CEC), including one patient who died due to an implant procedure-related event and the other two patients having the **alfa**pump explanted, one due to wound dehiscence and the other due to persistent hematuria after a car accident.Data from the Roll-In Cohort have been selected for a poster presentation at the AASLD The Liver Meeting in Washington DC in November 2022 and presented by Prof. Wong, Principal Investigator of the POSEIDON study.



Encouraging survival data at 12 months vs. published literature

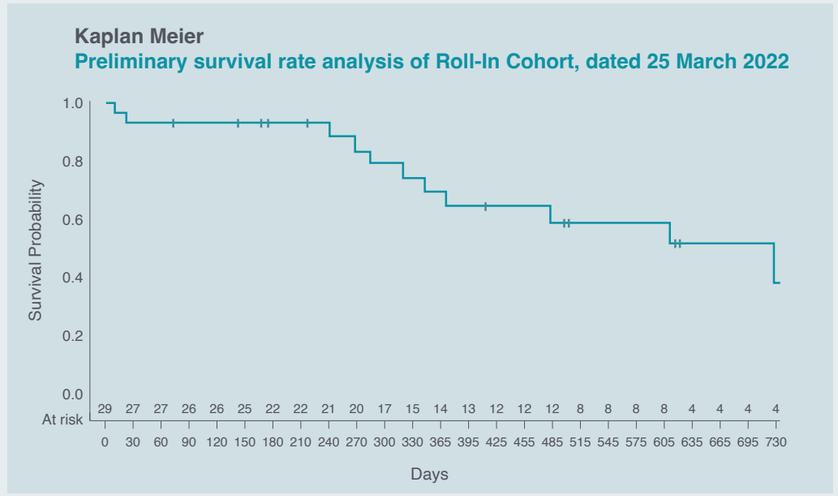
A preliminary interim analysis[III] of patient survival following **alfa**pump implantation in the Roll-In Cohort indicated a mean survival probability of 70% at 12 months. This compares favourably with the published literature reporting a survival rate for refractory ascites patients of only 50% at 12 months.

"Ascites imposes a heavy burden and devastating impact on patients' quality of life. These interim results further demonstrate that the alfapump could provide great benefit to patients and help limit their visits to the hospital for paracentesis."

Prof Wong, Hepatologist at Toronto General Hospital and PI of the POSEIDON study

"We believe that this survival data, combined with the dramatic reduction in the rate of therapeutic paracentesis and the clinically relevant improvement in quality of life in the interim analysis of the first 26 Roll-in patients, suggest that the alfapump is a highly attractive treatment option for this patient group that has been overlooked for too long."

Dr. Gijs Klarenbeek,
Senior Medical Adviser of
Sequana Medical



(I) Pre- and post-implant periods for this analysis of the Roll-In Cohort differ from those that is used for the Pivotal Cohort analysis

(II) UADE: Unanticipated adverse device effect is any serious adverse effect on health or safety, any life-threatening problem or death caused by, or associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the application; or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects (source: www.fda.gov)

(III) Date of analysis 25 March 2022

Positive top-line data from 40 patients in the Pivotal Cohort, meeting all primary endpoints at six months post-implantation

Data from the Pivotal Cohort patients substantially exceeded the pre-defined thresholds for study success as shown in the table below.

Pivotal Cohort N=40	%[I]	p-value[II]
Median per-patient ratio of frequency of TP	**100% reduction**	**P<0.001**
Proportion of patients with a 50% reduction in number of TP Post- vs. Pre-Implant	**77% of patients**	**P<0.001**

Of the 40 patients implanted with the **alfa**pump in the Pivotal Cohort, 26 patients completed **alfa**pump therapy through day 180 post-implantation. The distribution of reduction in TP Post- vs. Pre-Implant in these 26 patients is provided in the graph below, with 80% of the patients requiring no TP Post-Implant. These 26 patients have a median reduction of 100% (mean reduction of 93%) in frequency of TP in the Post-Implant Observation Period vs Pre-Implant Observation Period and 92% of patients have at least a 50% reduction in number of TP in the same period[III].

"The safety data regarding the primary safety endpoint are in line with expectations and are reassuring for the potential of the alfapump as a long-term treatment in this patient population."

Prof. Wong, Hepatologist at Toronto General Hospital and PI of the POSEIDON study

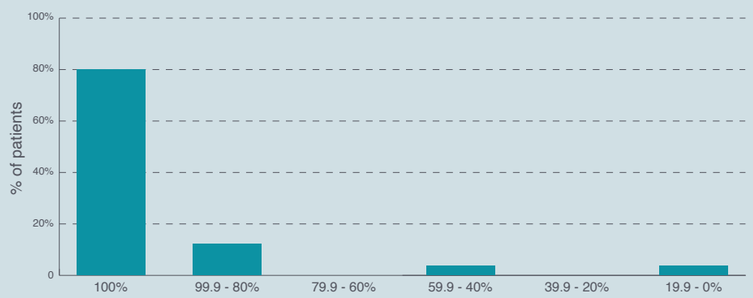
Pre-specified imputation methods were used to calculate the primary effectiveness endpoints in the other 14 patients that had exited the study prior to completing the six months post-implantation period. Of these 14 patients, eight were due to reasons such as death or withdrawal due to unrelated adverse event or for liver transplant and six were due to **alfa**pump system, procedure or therapy related reasons and counted as primary safety event.

(I) Using pre-specified imputation methods

(II) As per primary effectiveness endpoint hypotheses. Per protocol, testing conducted using nonparametric methods for data that is not normally distributed

(III) These observed patient data are not part of the main primary effectiveness endpoint analysis.

Distribution of reduction in Therapeutic Paracentesis post-implant vs pre-implant (N = 26)



Of the six primary safety events, three were explants due to wound or skin erosion, and three were explants due to patient-reported discomfort (all patient-reported discomfort events were adjudicated by the independent CEC as moderate severity). At the time of the primary endpoint analysis, no UADE[IV] occurred during the course of the POSEIDON study.

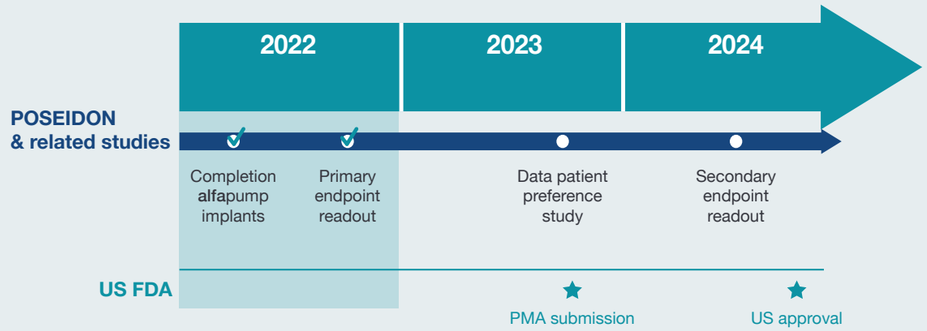
Additional secondary efficacy and safety endpoints are being analysed and detailed results from the POSEIDON study will be submitted for presentation at a forthcoming medical liver meeting in 2023.

North American approval expected in 2024

The positive primary endpoint data reported from the POSEIDON study enables us to file a PMA application with the FDA, planned for H2 2023, and is intended to support the approval of the **alfa**pump in the US.

As per request of the FDA, we are also conducting a survey study to quantify patients' preferences for the **alfa**pump including treatment effectiveness and risks of treatment-related adverse events. The results of this study are expected to be presented in H2 2023 and will be included in the PMA application.

(IV) UADE: Unanticipated adverse device effect is any serious adverse effect on health or safety, any life-threatening problem or death caused by, or associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the application; or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects (source: www.fda.gov)



US commercialization – Going direct to 90 adult liver transplant centers

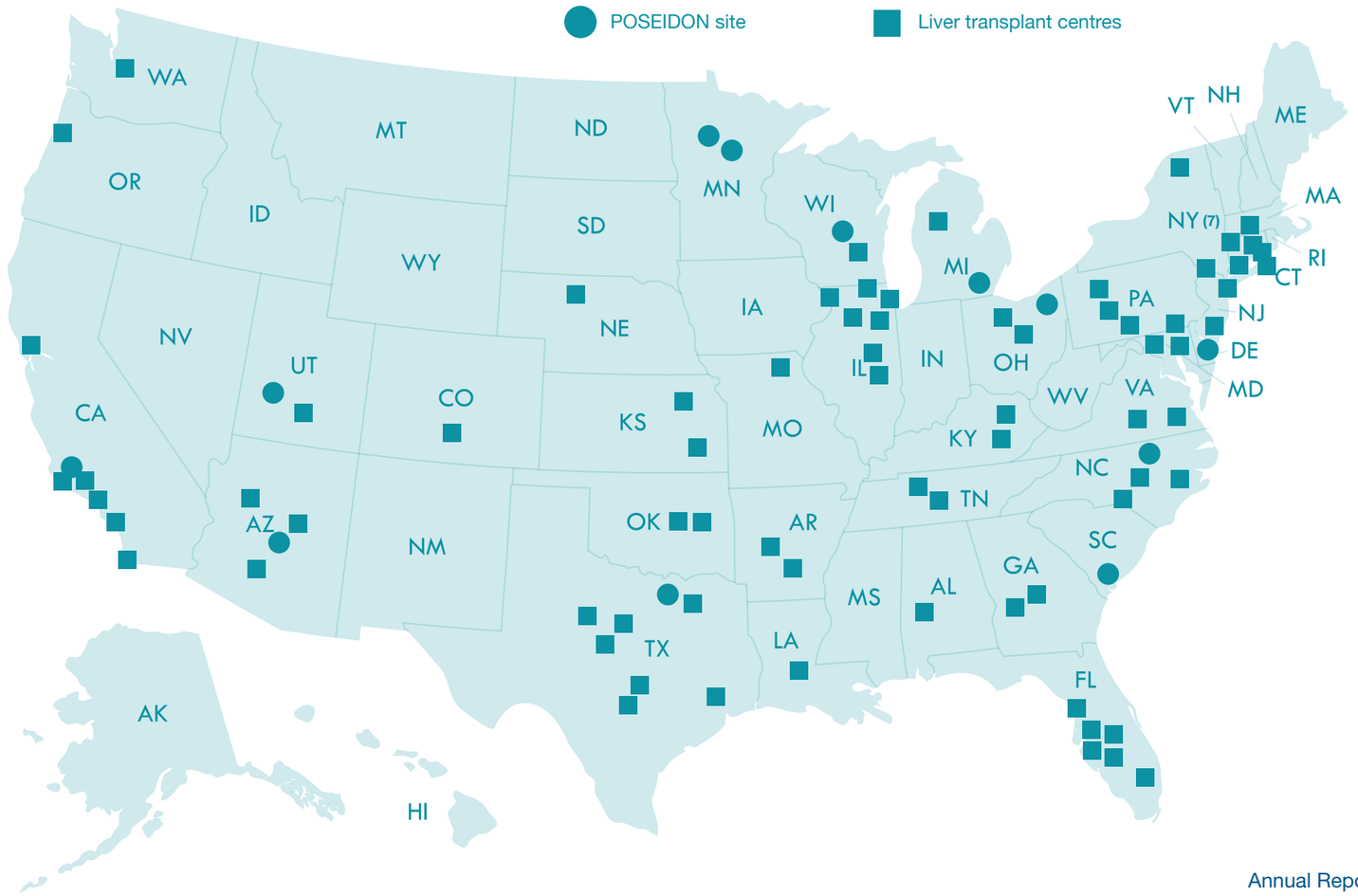
We plan to directly commercialize the **alfa**pump in the US by establishing our own specialty sales force, leveraging our experience from Europe and the North American studies. As per clinical practice guidelines for the management of patients with decompensated cirrhosis, our target population will be referred to the liver transplant centers by their hepatologist. In the US, there are 125 US adult liver transplant centers[14], with 90 of those centers covering 95% of the implants. We will initially focus on these specialist centres allowing coverage of the market with a lean commercial US team of about 50 people.

For any company commercialising a novel treatment, it is essential that medical practitioners are supportive of the approach, the product and the clinical use. We have established strong relationships with KOLs in North America and we actively use our network of KOLs and patient advocacy groups to support the development and market adoption of the **alfa**pump. We are working with the NACSELD (North American Consortium for the Study of End stage Liver Disease) registry to properly understand the cost and clinical impact of decompensated liver cirrhosis – building the links with the North American hepatology community.

In the US, the **alfa**pump will be reimbursed through Current Procedural Terminology (CPT) codes for the physician services and bundled Diagnosis Related Group (DRG) payments for the hospital services. ICD-10 diagnosis and procedure codes, and severity of patients' condition during their stay are bundled into the DRGs.

Based on existing ICD-10 codes we can use for the **alfa**pump, the likely DRG coding will be "Other hepatobiliary or pancreas O.R. procedures", including DRG 423 with major complications or comorbidities. The average Medicare payment for DRG 423 in 2018 was approximately $30,000. Taking into account the Medicare inflation rates, this will likely increase to $37,000 by 2025. We consider this as our base case scenario upon FDA approval. FDA-designated breakthrough devices, such as the **alfa**pump that meet certain cost criteria are eligible for incremental reimbursement through the New Technology Add-on Payment (NTAP), an initiative from CMS. If approved, NTAP can provide 65% of costs not covered by DRG payment.

CMS is also working on an alternate pathway to coverage for new and innovative medical technologies, called Transitional Coverage for Emerging Technologies (TCET). An expedited coverage process through TCET would help ensure that Medicare beneficiaries, who will be our principal patient population, have timely access to breakthrough devices such as the **alfa**pump once approved by the FDA while real-world evidence continues to emerge.



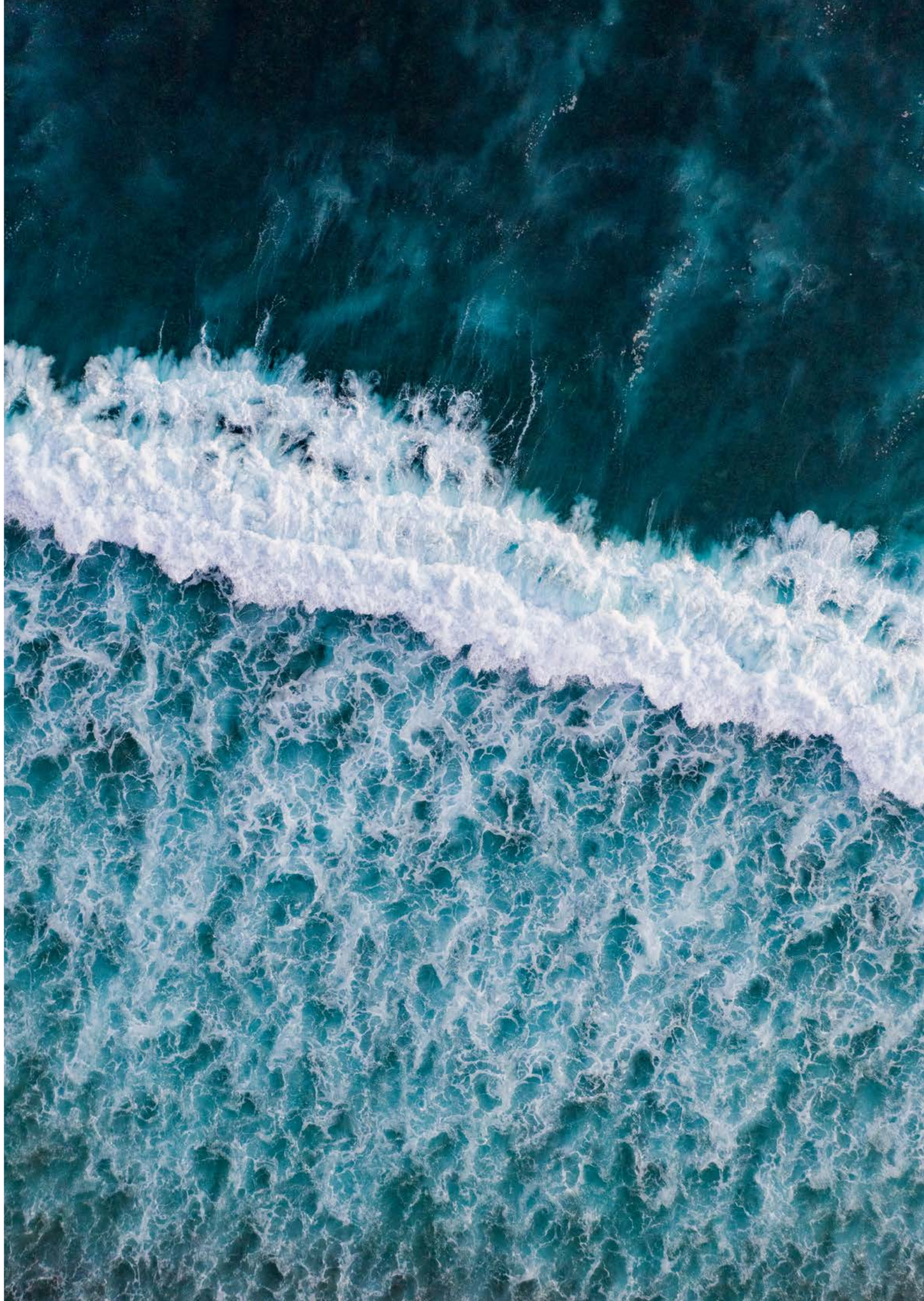
Commercial operations in Europe

The **alfa**pump has a CE-mark for the treatment of refractory ascites in patients with liver cirrhosis or malignant ascites and received certification under the new European Medical Device Regulation (MDR) in February 2022. This certification is proof that our QMS and **alfa**pump system are compliant with the latest regulatory standards required for medical devices in Europe and ensures continuous market access of the **alfa**pump system in the European Union (EU). We also received Medical Device Single Audit Program (MDSAP) certification in November 2021, thereby expanding our QMS towards the US and Canada.

The **alfa**pump is currently reimbursed in Switzerland and Germany. In Switzerland, the **alfa**pump is reimbursed for approximately CHF 30,000 through a Swiss DRG code, which covers both the **alfa**pump and the implantation procedure. In Germany, the **alfa**pump is reimbursed through the German NUB (Neue Untersuchungs- und Behandlungsmethode) – an add-on payment to the German DRG for new treatment methods – providing reimbursement of €27,000, covering both the pump and the implantation procedure which is renewed annually.

In France, the ARIA pump study (an investigator-initiated study and funded by the French government), is ongoing and is expected to support French reimbursement upon study completion.

Although the European market is not our commercial focus, we are gaining significant real-world experience which will be invaluable for our US commercialization strategy.



DSR in heart failure

A disease-modifying heart failure drug therapy

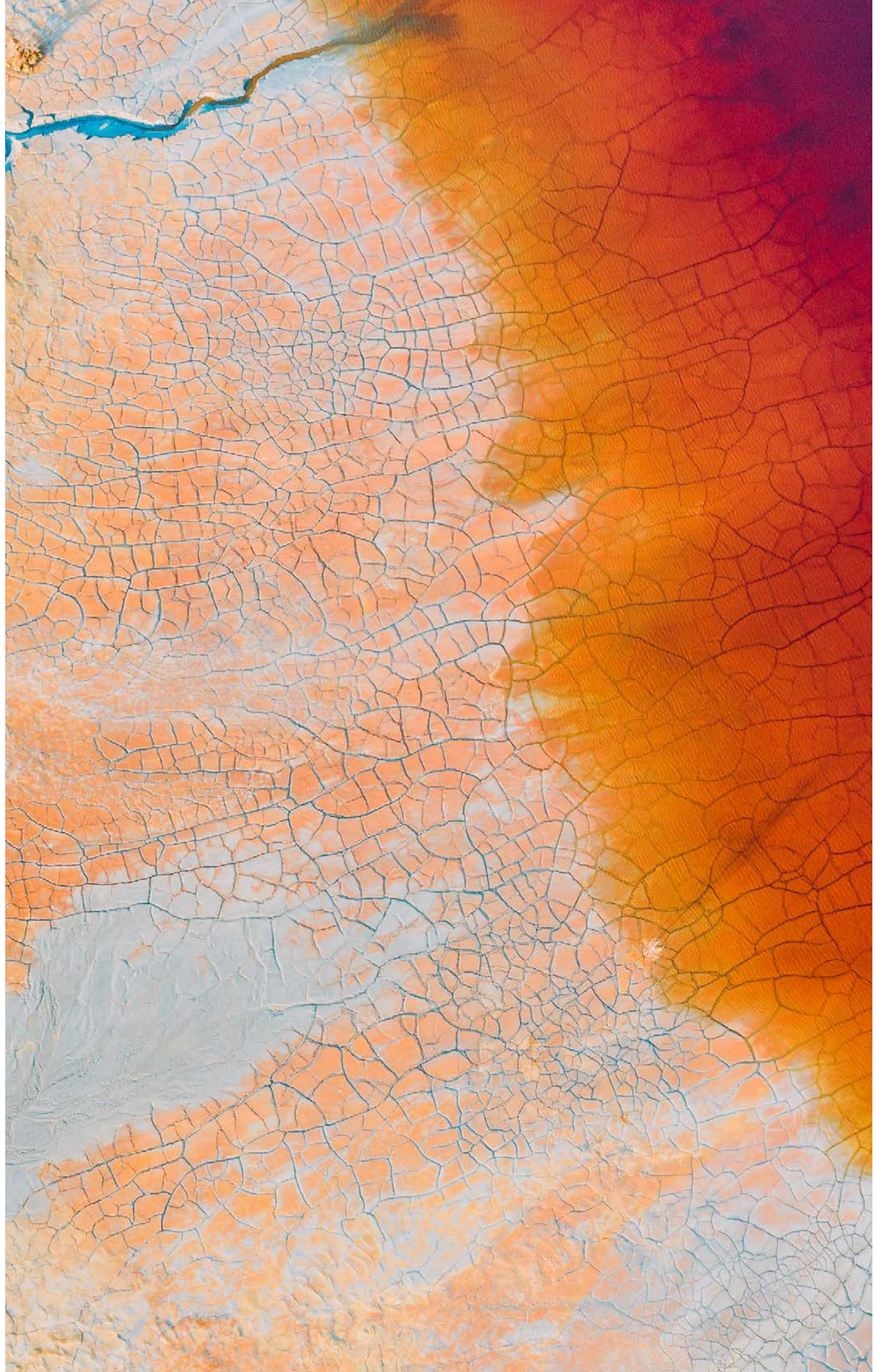
We are developing DSR (Direct Sodium Removal) to treat patients with congestive heart failure who have become resistant to diuretic drugs. DSR is a simple and elegant therapy that works in partnership with the kidneys to eliminate excess fluid spread across the body, thereby improving the health of the heart and the kidneys.

Fluid accumulation (AKA congestion) is the leading cause of morbidity and hospitalization in heart failure patients, and a key driver of disease progression. There are over one million hospitalizations per year in the US due to heart failure, and 90% of these are due to congestion. The key problem is widespread resistance to diuretics - the standard of care. Approximately half of acute decompensated heart failure patients do not respond effectively to even intravenous (IV) loop diuretics. As a consequence, one in four patients is readmitted within 30 days of discharge and there are few effective clinical options for these patients.

Congestion is caused by the retention of too much sodium. Our DSR drug-based approach directly tackles this key clinical problem of sodium overload by removing the excess sodium from the body, causing the kidneys to step in and eliminate free water to maintain the correct sodium concentration in the body. We believe that our novel, proprietary DSR approach could become a best-in-class treatment for diuretic-resistant heart failure patients, keeping them out of the hospital and with better control over their fluid balance and improving their heart failure status.

Pre-clinical and clinical proof-of-concept data from single dose DSR therapy were published in the high impact cardiovascular journal, Circulation in 2020.

Top-line data from RED DESERT, a proof-of-concept study of repeated dose DSR therapy in diuretic-resistant heart failure patients, using our first-generation DSR product (DSR 1.0), were reported in May 2021. Eight patients diagnosed with stable chronic heart failure on high dose oral diuretics underwent up to six weeks of DSR therapy whilst their loop diuretic treatment was withheld. The study demonstrated that DSR therapy was safe and effective at maintaining the fluid and sodium balance of these patients without the need of any loop diuretics. Moreover, there was a significant improvement in patients' cardiovascular and renal function and a dramatic and sustained improvement in their diuretic response were reported following the six-week DSR therapy. These positive results were presented at the "Heart Failure 2021 Online Congress", as part of the "Late Breaking Science Results" and were also selected for the congress' "Highlights" session.



Based on the success of RED DESERT, we initiated the SAHARA study in diuretic-resistant heart failure patients with persistent congestion, our target population, receiving two to six weeks of intensive DSR therapy with DSR 1.0. Top-line data from ten evaluable patients were reported in November 2022 and indicated that DSR could safely, effectively and rapidly eliminate fluid overload and restore euvolemia without the need of any loop diuretics, as well as deliver a considerable benefit in patients' cardiovascular and renal status and a dramatic and sustained improvement in their diuretic responsiveness, thereby dramatically reducing the need for oral loop diuretics for many months post-therapy. In both RED DESERT and SAHARA studies, there were no congestion-related hospital readmissions, all patients improved their NYHA status by at least one class, and the predicted one year mortality was reduced by 75% (calculated using the Seattle Heart Failure model).

In parallel, we developed a second-generation DSR product (DSR 2.0), a proprietary sodium-free dextrose / icodextrin solution expected to have an improved therapeutic and favourable safety profile and with a robust intellectual property protection.

Based on the results of the RED DESERT and SAHARA studies, we expect that an intensive treatment period of three to four weeks of DSR therapy may deliver at least twelve months of important clinical benefits and are therefore focusing the DSR heart failure development program on Short Term DSR therapy with our DSR 2.0 product administered via a peritoneal catheter.

GLP animal studies and a single-dose Phase 1 CHIHUAHUA study demonstrated that DSR 2.0 was safe and well-tolerated, and indicated a compelling dosing profile. We have submitted an IND application for DSR 2.0 to the FDA in March 2023 and plan to begin MOJAVE, a US multi-center, randomized controlled Phase 1/2a clinical trial of DSR 2.0 in Q2 2023, with initial data in H2 2023. Based on the results from the MOJAVE study, we plan to establish a strategic partnership for further clinical development and commercialization of our DSR therapy. This will enable us to leverage the strengths of an established heart failure player to realize the strong commercial potential of our DSR therapy.

Market opportunity and limitations of current therapies

Heart failure is a progressive and chronic disease that results in the heart being unable to pump enough blood and thereby supply oxygen to support other organs in the body. Patients with heart failure commonly experience shortness of breath, fatigue, difficulty exercising and swelling of the ankles or legs. The American Heart Association estimates that six and a half million adults in the US aged 20 and over are affected by heart failure and that number is expected to rise to over eight million adults by 2030[15].

Heart failure often disturbs the normal functioning of the kidney by diminishing its ability to excrete sodium from the body and triggering compensatory mechanisms that result in water retention in order to maintain the correct concentration of sodium in the body. Simply put, the water accumulation follows the sodium retention. This fluid accumulates all across the body including in the arms, legs, lungs and abdomen. The increase in fluid volume increases the burden on the weakened heart, worsening the problem clinically. One of the key problems is fluid accumulating in the lungs causing patients to feel as if they are drowning often resulting in them being admitted to the emergency room. This fluid accumulation due to heart failure leads to frequent hospitalizations, poor quality of life and high healthcare costs.

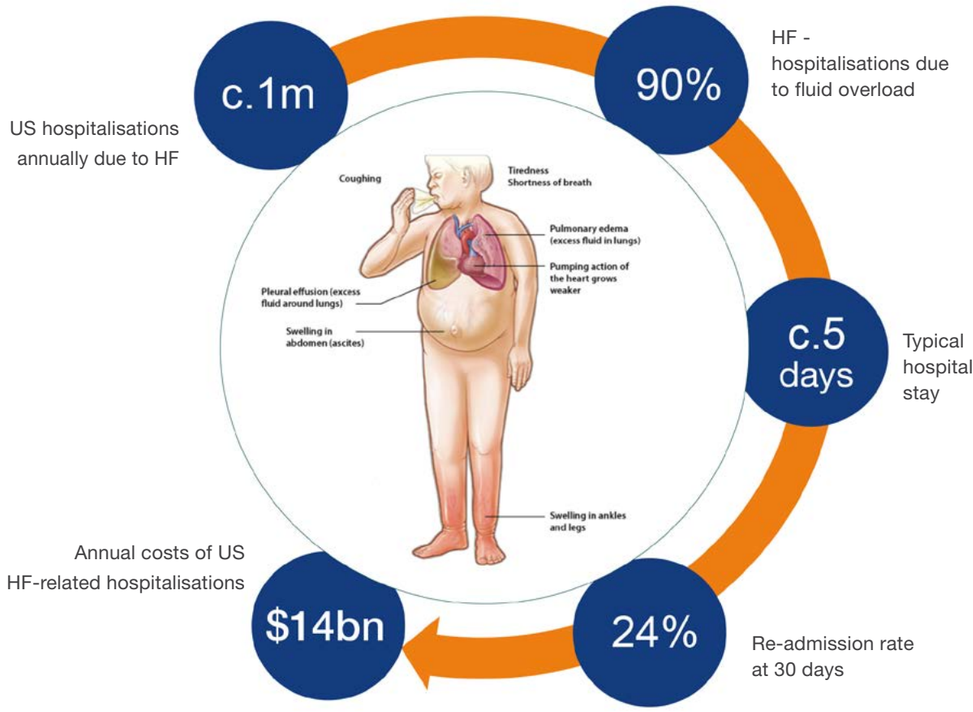
There are approximately one million hospitalizations for heart failure annually in the US,[16] costing approximately $14 billion each year.[17] Of these admissions, 90% are due to symptoms of fluid overload,[18] with an average five days length of stay.[19] The problem is that in many cases the treatment is not effective at reducing the fluid overload, often due to diuretic-resistance, and as a result approximately one in four patients are being readmitted to hospital within 30 days of discharge.[20] An estimated 40% of heart failure patients on intravenous loop diuretics experience diuretic resistance or intolerance[21] and nearly 50% of hospitalized patients with heart failure are discharged with residual fluid excess.[16]

We estimate that there are about 200,000 chronically congested heart failure patients per year in the US and a similar number in Europe, which cause a major burden on the healthcare systems, payors and patients.

Existing therapies have severe limitations

One other therapy that is used in patients resistant or intolerant to diuretics is extracorporeal ultrafiltration. This therapy consists of the extraction of plasma water from whole blood across a semipermeable membrane (hemofilter) in response to a transmembrane pressure gradient, with the focus on removing water and sodium from the blood. The limitations of this therapy include requirement for vascular access, high cost of inpatient care and trained hospital staff, limited clinical evidence and treatment-related adverse effects.[22]

There is a significant unmet medical need for a safe and effective, long-term treatment for heart failure patients with fluid overload who do not respond to diuretics, reducing the number of hospitalizations and improving patient quality of life. This is the opportunity for DSR, our disease-modifying heart failure drug-based therapy.



Diuretic-resistant fluid overload

Fluid overload is a frequent complication of many severe diseases, including advanced liver and kidney disease, heart failure and cancer. Diuretics are the mainstay of therapy for fluid overload but in many patients, they stop being effective and patients become diuretic-resistant over time. Diuretic resistance is common and other treatment options are generally limited. We are developing our **alfa**pump and DSR technologies as innovative treatment solutions for these patients with diuretic-resistant fluid overload.

What are diuretics?

How do diuretics work?

- Most diuretics inhibit the re-absorption of sodium from primary urine in the renal tubular system leading to increased sodium excretion (natriuresis) and water excretion (diuresis). There are different classes of diuretics which act at different renal segments. Blocking one segment can alter the sodium re-absorption at another segment and therefore a combination of different diuretics is sometimes required.
- Loop diuretics are the most powerful diuretics, inhibiting the sodium re-absorption in the loop of Henle, which is responsible for re-absorption of ~25% of the urine sodium load.

Characteristics

- Bioavailability of diuretics is highly variable: absorption of diuretics and diuretic delivery are variable amongst patients leading to different diuretic responses.
- Loop diuretics are short-acting drugs: most diuresis occurs over the first few hours after administration.

What is Diuretic Resistance?

Diuretic Resistance is the condition where patients fail to decongest despite adequate and escalating doses of diuretics. In other words, diuretics fail to control the salt and water excretion even when used in appropriate doses.

Causes of Diuretic Resistance

- **Pharmacokinetic changes:** a decrease in renal function can cause a reduced rate of diuretic drug response leading to delay in time to achieve peak concentrations
- **Pharmacodynamic changes:** drug-drug interactions can cause reduced sodium and/or water excretion
- **'Diuretic braking' phenomenon:** repeated diuretic dosing can cause augmented sodium re-absorption and diminished natriuresis, shifting the dose-response curve (i.e., higher doses required to achieve same diuretic effect)
- **Post-diuretic sodium retention:** short-acting effect and an inappropriate salt diet can cause sodium retention after diuretic treatment
- **Pharmacogenetics** may also play a role

Management of Diuretic Resistance

- Increase dose to overcome reduced absorption of diuretics
- Increase frequency of diuretics to overcome post-diuretic sodium retention. Studies have shown that continuous vs bolus administration caused rapid development of diuretic resistance
- Change route of administration from oral to IV
- Combine different diuretics for synergistic effect and to prevent re-absorption of sodium at another renal segment
- Strict salt diet

None of these strategies have proven to be very effective.

Diuretic resistance is a major cause of recurrent hospitalisations in patients with chronic heart failure and presents a heavy burden on hospitals & patients leading to prolonged hospital stay and to an increase in mortality.

$14bn

Annual costs of U.S. HF-related hospitalisation

90%

HF-related hospitalisations due to fluid overload

20-50%

hospitalised patients with a poor initial response to IV loop diuretics

50%

patients leaving the hospital with residual congestion

1 in 4

patients re-admitted to hospital within 30 days

Sources[23]

Pre-clinical and clinical studies of DSR 1.0

DSR therapy, and the resulting sodium and fluid removal, was evaluated in pre-clinical and clinical studies. These studies used our first-generation DSR product (DSR 1.0), a sodium-free 10% dextrose (D10%) solution, to deliver fast clinical proof-of-concept of our DSR therapy.

Name of Study	Description	Number
Pre-clinical studies		
Healthy pig DSR proof-of-concept study	Single-dose, single-arm proof-of-concept study to assess impact of direct sodium removal therapy in healthy pigs (completed in 2018).	15
Heart failure pig DSR proof-of-concept study	Single-dose, single-arm proof-of-concept study to assess impact of direct sodium removal therapy in pigs with experimentally induced heart failure (completed in 2018).	5
Clinical studies		
Single Dose DSR proof-of-concept study	First-in-human clinical study to demonstrate the safety, tolerability and dynamics of a single dose DSR therapy in patients who underwent peritoneal dialysis (completed in 2019).	10
Repeated Dose DSR proof-of-concept study (RED DESERT)	Study in euvolemic heart failure patients on high dose diuretics to demonstrate the safety, tolerability and efficacy of repeated dose DSR therapy over a 6-week period (completed in 2021).	8
Phase 2a DSR study (SAHARA)	Study in diuretic-resistant heart failure patients with persistent congestion to demonstrate the safety, tolerability and efficacy of 2-6 weeks of intensive DSR therapy (completed in 2022).	12

RED DESERT – repeated dose proof-of-concept study in euvolemic heart failure patients on high dose diuretics

Study design

RED DESERT is our single-arm, first-in-human study to evaluate the safety and feasibility of repeated DSR therapy in patients diagnosed with stable chronic heart failure on high dose oral diuretics. A surgical port and the **alfa**pump system were implanted to administer the DSR product into the peritoneal cavity and remove the DSR product from the peritoneal cavity via the bladder, with the intention to develop a Long Term DSR therapy.

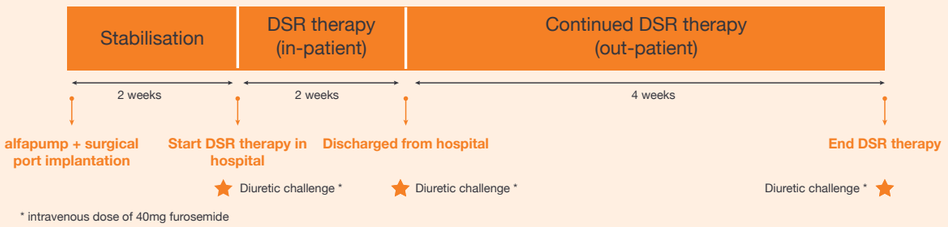
Patients underwent a diuretic challenge to evaluate their response to diuretics, before, during and after DSR therapy. This was determined by the six-hour excretion of fluid and sodium following intravenous administration of 40mg of furosemide (i.e., diuretic challenge). Following implantation of the surgical port and **alfa**pump system, patients underwent a first diuretic challenge. Two weeks post-implantation, the patients were admitted for a 14-day in-patient period in which diuretics were withheld and patients were put on a strict low-sodium diet. During the first 14 days, patients were treated with DSR 1.0 on Monday, Wednesday and Friday. The DSR product remained in the peritoneal cavity for a two-hour dwell time, after which fluid was eliminated from the peritoneal cavity through the bladder using the **alfa**pump system.

Following the 14-day in-patient period, patients underwent a second diuretic challenge. Thereafter, diuretics continued to be withheld and patients came into clinic for their DSR therapy over the subsequent four weeks. After completion of the study period, patients underwent a third diuretic challenge to quantify their response to diuretics.

The primary safety endpoints included absence of device, procedure and/or therapy related serious adverse events through day 14 and the rate of device, procedure and/or therapy related serious adverse event through day 42. Secondary feasibility endpoints included the ability of DSR therapy to maintain a neutral sodium balance in the absence of diuretic therapy and the sustained effect of DSR to maintain euvolemia through week six. Additional exploratory endpoints evaluated the potential impact of DSR to restore response to diuretics following DSR therapy.

Eight euvolemic heart failure patients on high dose oral diuretics (mean furosemide equivalent dose of 323 mg/day) underwent up to six weeks of DSR therapy whilst their loop diuretic treatment was withheld. The heart failure patients enrolled in the study had an overall high disease severity at baseline, including a mean left ventricular ejection fraction of 24% and mean NT-proBNP(I) of 4,589 /mL.

(I) NT-proBNP: N-terminal pro B-type natriuretic peptide, a key cardiac function parameter.



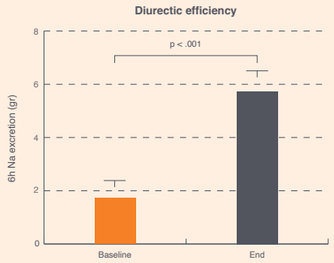
Strong top-line results from RED DESERT

During the course of the six-week therapy, none of the patients required any loop diuretics, demonstrating the ability of repeated DSR therapy to effectively manage their fluid and sodium balance.

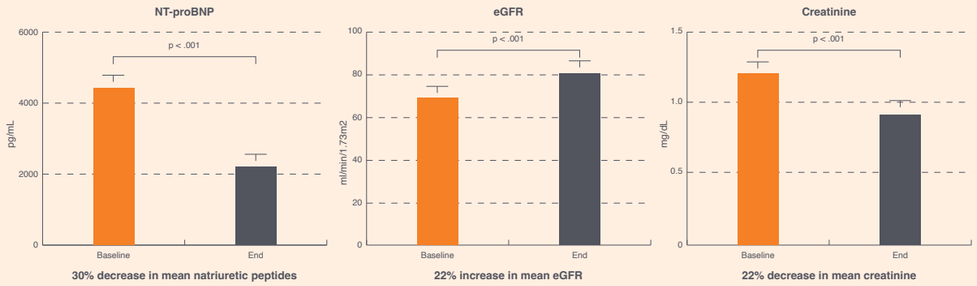
Repeated dosing of DSR therapy was well tolerated in all patients. There were no clinically relevant changes in serum sodium levels or progressive hyponatremia in any of the implanted patients. There were two serious adverse events in two of the last three patients, both having advanced heart failure. There was one transient ischemic attack (fully recovered) and one sudden cardiac death three days after start of the study treatment. The independent Data Monitoring Committee assessed both events as possibly related to the study therapy or procedure but unlikely to be related to the device. The site Principal Investigator assessed that neither event was related to the study therapy, procedure or device.

The results also showed a significant benefit to the cardiovascular and renal function of these patients with a mean 30% reduction in NT-proBNP ($p<0.001$ vs. baseline, N=7), mean 22% improvement in eGFR(l) rate ($p<0.001$ vs. baseline, N=7) and mean 22% reduction in creatinine ($p<0.001$ vs. baseline, N=7). Typically, managing the fluid balance in these patients through aggressive diuretic use would be associated with declining cardiovascular and renal function, whilst RED DESERT showed that both of these functions were improved following repeated DSR therapy.

After the six-week study, the mean response to a standard diuretic challenge (40 mg intravenous furosemide) improved by more than 150% ($p<0.001$ vs. baseline, N=7) as measured by the six-hour excretion of sodium.



Following the six-week study, patients continued to be followed for up to 23 months. One patient died nine months after the end of the six-week study (unrelated to DSR therapy). All patients had a reduction in their oral loop diuretic dose ranging from 40% to 87% at their last visit within the follow-up period (18-23 months after six-week study), showing a clear durability to the improvement in diuretic responsiveness following DSR therapy.



(l) eGFR: estimated Glomerular Filtration Rate, a measure of kidney function

“The simultaneous normalization of diuretic response and improvement in cardio-renal status of the RED DESERT patients is a never before seen treatment effect and could translate into important long-term clinical benefits in heart failure patients.”

Dr. Jeffrey Testani, Associate Professor at Yale University

SAHARA – Phase 2a study in diuretic-resistant heart failure patients with persistent congestion

Study design

SAHARA is a Phase 2a study to evaluate the safety and feasibility of our DSR therapy in heart failure patients with persistent congestion and resistance to loop diuretic treatment. As in the RED DESERT study, a surgical port and the **alfa**pump system were implanted to respectively administer the DSR product into the peritoneal cavity and remove the DSR product from the peritoneal cavity via the bladder.

Following implantation of the surgical port and the **alfa**pump system, patients underwent a diuretic challenge to quantify their response to diuretics, which was repeated at specific time points throughout the study. At the start of the study treatment period, loop diuretics were withheld. Patients underwent an intensive DSR therapy with DSR 1.0 for two weeks (phase 1) which was repeated up to two times depending on patients' euvolemic state, diuretic response and stable DSR dosing at the end of phase 1. Patients who have achieved euvolemia and have adequate diuretic response entered the maintenance DSR treatment phase with monthly DSR dosing for 16 weeks (phase 2).

The primary safety and tolerability endpoints include the rate of treatment-, device- or procedure-related serious adverse events through the end of the maintenance phase. Secondary feasibility endpoints include the ability of DSR therapy to restore and maintain euvolemia without the need for additional loop diuretic treatment.

At baseline, all ten[I] evaluable patients with persistent congestion due to heart failure were on high dose loop diuretics (mean furosemide equivalent dose of 360 mg/day) and had an overall high disease severity, including a mean left ventricular ejection fraction of 23% and mean NT-proBNP of 6,628 pg/mL.

Strong top-line results from SAHARA

All ten evaluable patients safely, effectively and rapidly eliminated the persistent congestion and achieved euvolemia within one week of commencing intensive DSR therapy, resulting in a mean weight loss of 7kg at the end of phase 1. During the intensive DSR period (phase 1), the diuretic response of the kidney was near-normalized, with mean six-hour excretion of sodium increasing more than 160% vs. baseline, as well as a considerable improvement in cardiovascular and renal health, with a mean reduction in NT-proBNP of 38% vs. baseline and a mean improvement in eGFR of 7% vs. baseline despite the dramatic fluid loss.

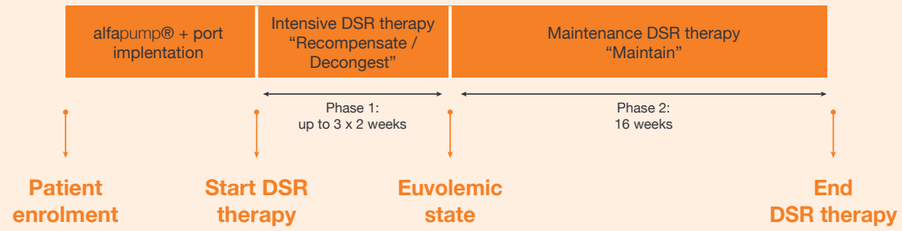
The improvement in cardiovascular and renal health was broadly maintained at the end of phase 2 (16 weeks post intensive DSR period) demonstrated by a mean 33% reduction in NT-proBNP and a stable eGFR.

The need for loop diuretics was dramatically reduced for many months following completion of the intensive DSR therapy (see table below), which we believe is a demonstration of the durable improvement in cardiovascular and renal health.

Evaluable patient	No. of months post intensive DSR period	Reduction in diuretic dose vs. baseline
01-01	15	90%
01-03	13	100%
01-04	12	90%
01-05	12	100%
01-06	10	100%
01-08	10	90%
01-09	9	67%
01-10	9	95%
01-11	6	93%
01-12	6	100%

No clinically relevant changes in serum sodium levels or progressive hyponatremia were observed in any of the evaluable patients. There were three serious adverse events in three of the evaluable patients, including two having a blocked peritoneal catheter (both during phase 2) and one with stable angina (started post phase 2). The independent Data Monitoring Committee assessed both peritoneal catheter blockages as definitely related to the study device but unrelated to the implant procedure or study treatment, and the stable angina as unrelated to the study device, implant procedure, or treatment.

(I) In total, 12 patients were dosed in SAHARA but one patient died due to a cardiac arrest three days after study initiation and for one patient the study protocol was not correctly applied.



"The SAHARA results are highly encouraging and indicate the potential for DSR therapy to deliver clinically meaningful decongestion and durable improvements in cardio-renal function and thus diuretic response."

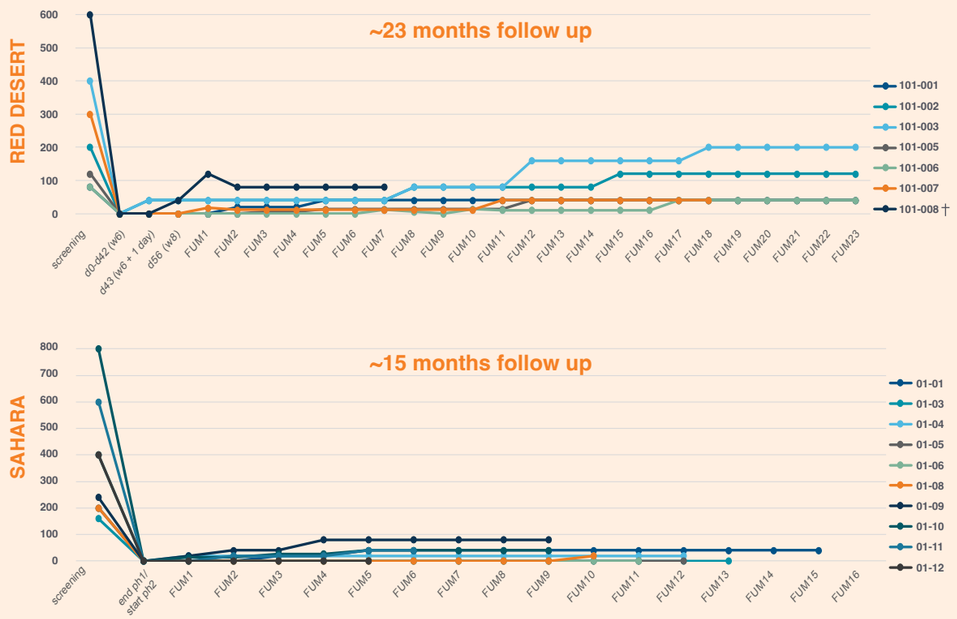
Dr. Jeffrey Testani, Associate Professor at Yale University

Strong clinical observations from **RED DESERT** and **SAHARA** studies in diuretic-resistant heart failure patients support heart failure disease-modifying profile of Short Term DSR therapy

In both RED DESERT and SAHARA, patients' loop diuretics were withheld and replaced by intensive DSR therapy (up to six weeks). During this intensive DSR treatment period, none of the patients required any loop diuretics. We followed the patients for many months post DSR therapy and the need for loop diuretic dosing up to 23 months follow-up in RED DESERT and up to 15 months follow-up in SAHARA are presented in the graph below.

All patients had a major and long-term reduction in their oral loop diuretic dose, which is a clear demonstration of the improvement in their cardiovascular and renal health.

Long-term and major reduction in loop diuretic dosing



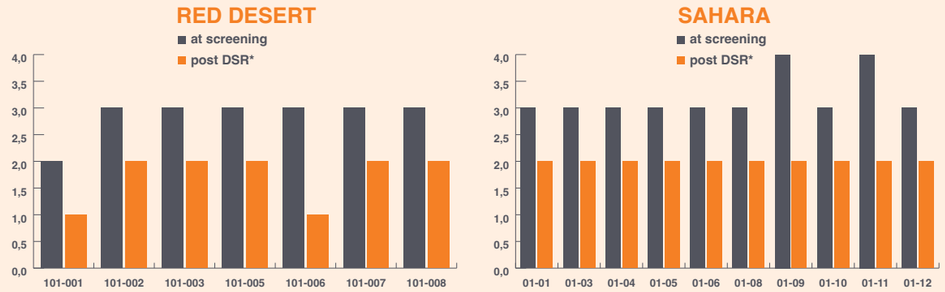
This is also shown in their NYHA[2] status which was improved by at least one class in all patients pre- vs. post DSR therapy.

All evaluable patients treated with DSR therapy in the RED DESERT and SAHARA clinical studies experienced no congestion-related heart failure hospital re-admissions during the entire study period. This is remarkable given that normally one in four patients are re-admitted to hospital within 30 days of discharge.

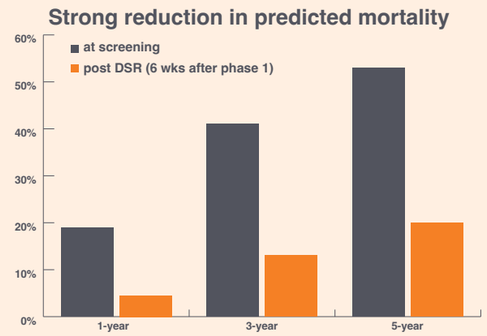
We put the data from RED DESERT and SAHARA(l) in the Seattle Heart Failure Model, which is a highly validated model to predict survival in heart failure. The model has been validated in approximately 10,000 heart failure patients in over 46 countries with more than 17,000 person-years follow-up. It has excellent accuracy, with predicted vs. actual one-year survival rate of respectively 90.5% vs. 88.5%. The clinical benefits observed in RED DESERT and SAHARA resulted in a 75% reduction in predicted one-year mortality of patients pre- vs. post-intensive DSR therapy based on the Seattle Heart Failure Model, as illustrated in the graph below.[3]

Based on the results of RED DESERT and SAHARA, we expect that an intensive treatment period of three to four weeks of DSR therapy may deliver at least twelve months of important clinical benefits. As a result of these strong, durable clinical signals observed, we will focus the DSR heart failure development program on Short Term DSR administered via a peritoneal catheter. Short Term DSR therapy will also simplify the regulatory approval process, accelerate time to market, and support faster adoption of DSR in the clinical community.

Consistently improved NYHA class



Strong reduction in predicted mortality



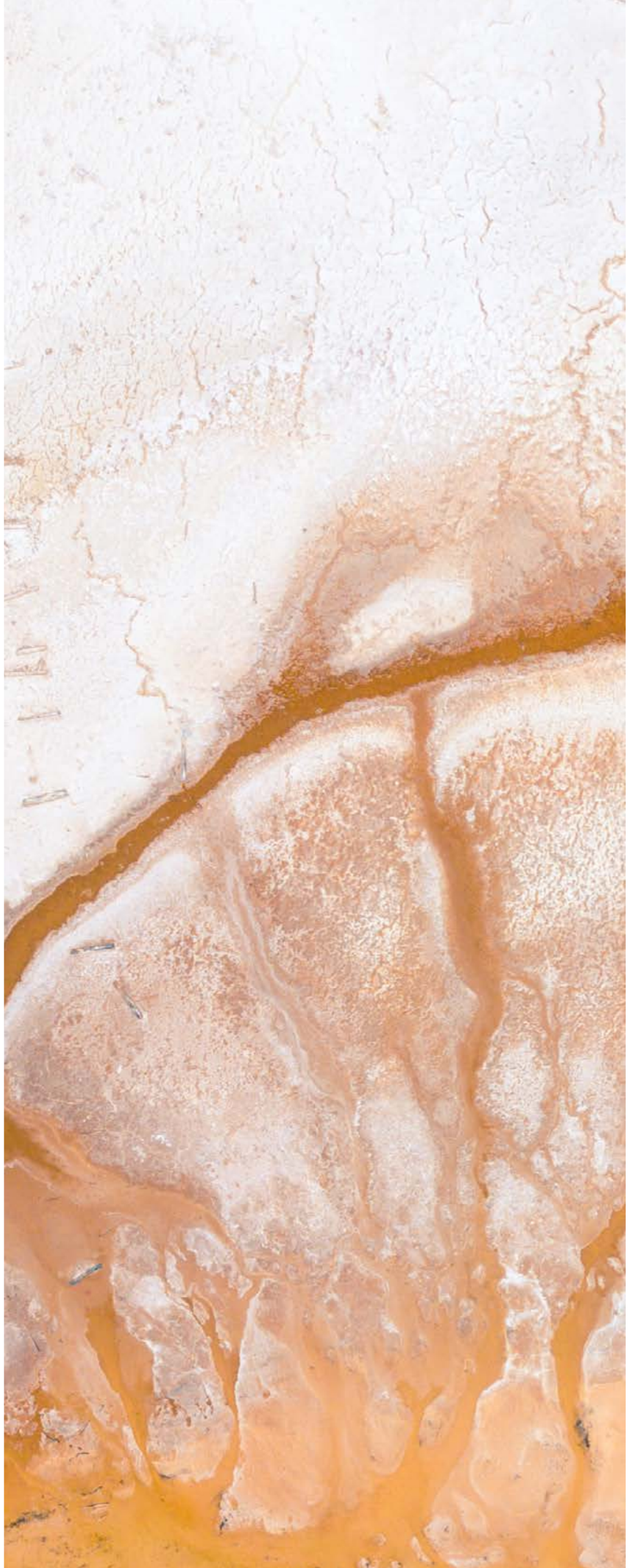
(l) Seven patients from RED DESERT and ten patients from SAHARA pre- and post-intensive DSR therapy; analysis includes physician-assessed data collected post hoc

Pre-clinical and clinical studies of DSR 2.0

Following clinical proof-of-concept of our DSR therapy using DSR 1.0, we developed our proprietary second-generation DSR product (DSR 2.0), a sodium-free dextrose/icodextrin solution, for which composition of matter and method patents have been granted in the US and Europe, and which are under review elsewhere in the world. The intention is to deliver a product with a superior therapeutic profile and a favourable safety profile that will be better positioned for broad commercial acceptance with high margin recurring revenues.

Chemistry, Manufacturing and Controls (CMC) activities and pre-clinical and Phase 1 clinical studies using DSR 2.0 have been completed, and we have submitted an IND application to the US FDA to start our US randomized controlled Phase 1/2a study (MOJAVE), planned for Q2 2023.

Name of Study	Description	Number
Pre-clinical studies		
GLP study in mice	Repeated dose, controlled study in healthy mice evaluating safety of DSR 2.0 compared to standard peritoneal dialysis (PD) solution, following chronic exposure of 30 days (completed in 2023).	30
GLP study in sheep	Repeated dose, controlled study in healthy sheep evaluating safety of DSR 2.0 compared to standard PD solution, following chronic exposure of up to 45 days (completed in 2023).	18
Clinical studies		
Phase 1 study in Mexico (CHIHUAHUA)	Interventional, single-centre, single-arm, single-dose study in stable PD patients to evaluate safety and tolerability of DSR 2.0 over a 24-hour dwell period (completed in 2023).	10
Phase 1 study in Canada (YUKON)	Interventional, single-centre, single-arm, single-dose study in stable PD patients to evaluate safety and tolerability of DSR 2.0 over an 8-hour dwell period (ongoing).	10
Phase 1/2a study in US (MOJAVE)	Randomized controlled Phase 1/2a US study in diuretic-resistant chronic heart failure patients with persistent congestion to evaluate safety and efficacy of up to four weeks of DSR 2.0 therapy on top of usual care vs. usual care alone (planned).	30



“In addition to positive safety and tolerability findings, with no serious adverse events or discontinuations, the amount of fluid and sodium removed following a single treatment is an indication of the effectiveness of DSR 2.0 as a potential treatment for patients with congestive heart failure.”

Dr. Oliver Gödje, MD, PhD, A. Professor, FCCP, Chief Medical Officer at Sequana Medical

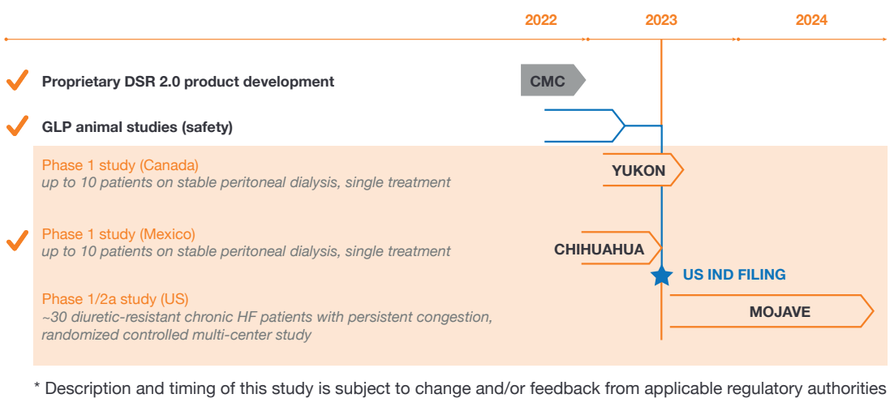
The purpose of the GLP animal studies was to evaluate the chronic exposure of DSR 2.0 on animal health and tissue of peritoneum, kidneys, omentum, and peritoneal cavity to support the IND application to the US FDA. Data from both studies reported that no difference in systemic and local toxic effects were observed in animals treated repeatedly with DSR 2.0, compared to animals in the control group, concluding that DSR 2.0 had consistent safety with the standard PD solution.

Data from the Phase 1 CHIHUAHUA study demonstrated that a single treatment of DSR 2.0, administered via their pre-existing peritoneal dialysis catheter, was safe and well-tolerated and indicated a compelling dosing profile. On average, a total of approximately 3L of fluid was removed per patient including 9g of sodium following a single treatment with 0.5L DSR 2.0 and a 24-hour dwell period.

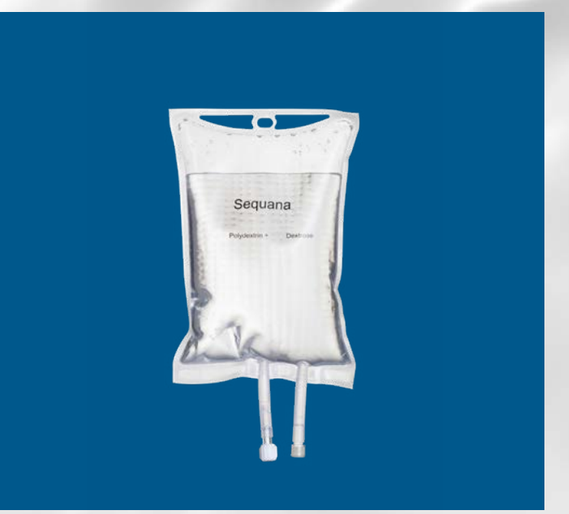
Data from the GLP animal and Phase 1 CHIHUAHUA studies were included in the filing of the US IND application which was submitted to the US FDA in March 2023.

MOJAVE, a US multi-centered randomized controlled Phase 1/2a clinical trial of DSR 2.0, is planned to start in Q2 2023, assuming FDA approval of the IND application. The intention is to enrol 30 diuretic-resistant chronic heart failure patients with persistent congestion. Of these, 20 randomized patients will receive DSR 2.0 administered via a peritoneal catheter on top of usual care for congestive heart failure (CHF) for up to four weeks and ten randomized patients will receive intravenous loop diuretic treatment as part of maximized usual care for CHF alone. Following four weeks of treatment, there will be a three-month safety follow-up period. Prior to enrolment of these 30 patients, the intention is for three additional patients to be enrolled in a non-randomized safety cohort and to receive DSR 2.0 administered via a peritoneal catheter on top of CHF usual care for up to four weeks. Progression to the enrolment of the 30 randomized patients is anticipated to be dependent upon DSMB approval following their review of the initial three patients. More details on the final trial design will be announced following the FDA approval of the US IND application. Initial data of MOJAVE are expected in H2 2023.

Based on the results from the MOJAVE study, we plan to establish a strategic partnership for further clinical development and commercialization of our DSR therapy. This will enable us to leverage the strengths of an established heart failure player to realize the strong commercial potential of our DSR therapy.



* Description and timing of this study is subject to change and/or feedback from applicable regulatory authorities



Other potential applications

Fluid overload is a serious clinical complication of multiple conditions and when diuretics are no longer effective or are poorly tolerated, there are limited clinical options available. We intend to continue leveraging our proprietary **alfa**pump and DSR platforms to explore innovative treatment solutions for other indications complicated by fluid overload in order to maximise the potential of our innovative and patented technologies. We may either undertake such development ourselves or seek to partner or out-license the **alfa**pump and DSR technologies for specific applications.

Furthermore, it is well understood that use of diuretics results in undesired side-effects and in many cases may lead to diuretic-resistance. We believe that DSR therapy may be able to reverse such resistance leading to increased treatment options. This may lead to use of DSR therapy in conditions such as fluid overload related to chronic kidney disease.

Investor Relations

The shares in 2022

The shares of Sequana Medical are traded on Euronext Brussels since our IPO on 11 February 2019, under the ticker symbol SEQUA (ISIN code BE0974340722).

On 31 December 2022, the share capital of the Company amounted to €2,460,486.98 represented by 23,746,528 shares.

In addition to the outstanding shares, the total number of outstanding subscription rights on 31 December 2022 amounted to 2,217,628 entitling their holders (if exercised) to subscribe to 2,691,546 new shares with voting rights in total.

More information on the Company's stock options and warrants can be found in the Remuneration Report.

Trading volume in 2022

Average daily volume	4,747
Average daily value	€30,017
Total traded volume	1,220,029
Total traded value	€7,714,409

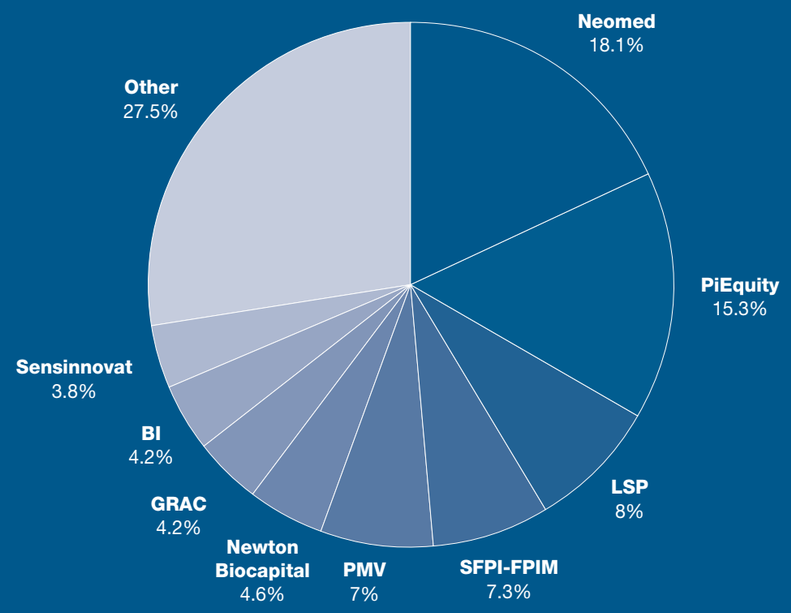
Analyst coverage

Sequana Medical was covered by five analysts at the end of 2022:

Broker	Analyst
Degroof Petercam	Laura Roba
Edison Investment Research	Pooya Hemami
H.C. Wainwright	Yi Chen
KBC Securities	Jeroen Van den Bossche
Van Lanschot Kempen	Suzanne van Voorthuizen

Major Shareholders

Sequana Medical has an international shareholder base and is supported by experienced life sciences investors and industry experts, and a broad base of local retail investors. Based on the number of shares as at 31 December 2022 and the transparency notifications received until that date, the shareholder structure of the Company as per 31 December 2022 was as follows:



Investor Relations Contact

For all your investor relations questions, please contact us at IR@sequanamedical.com or via:

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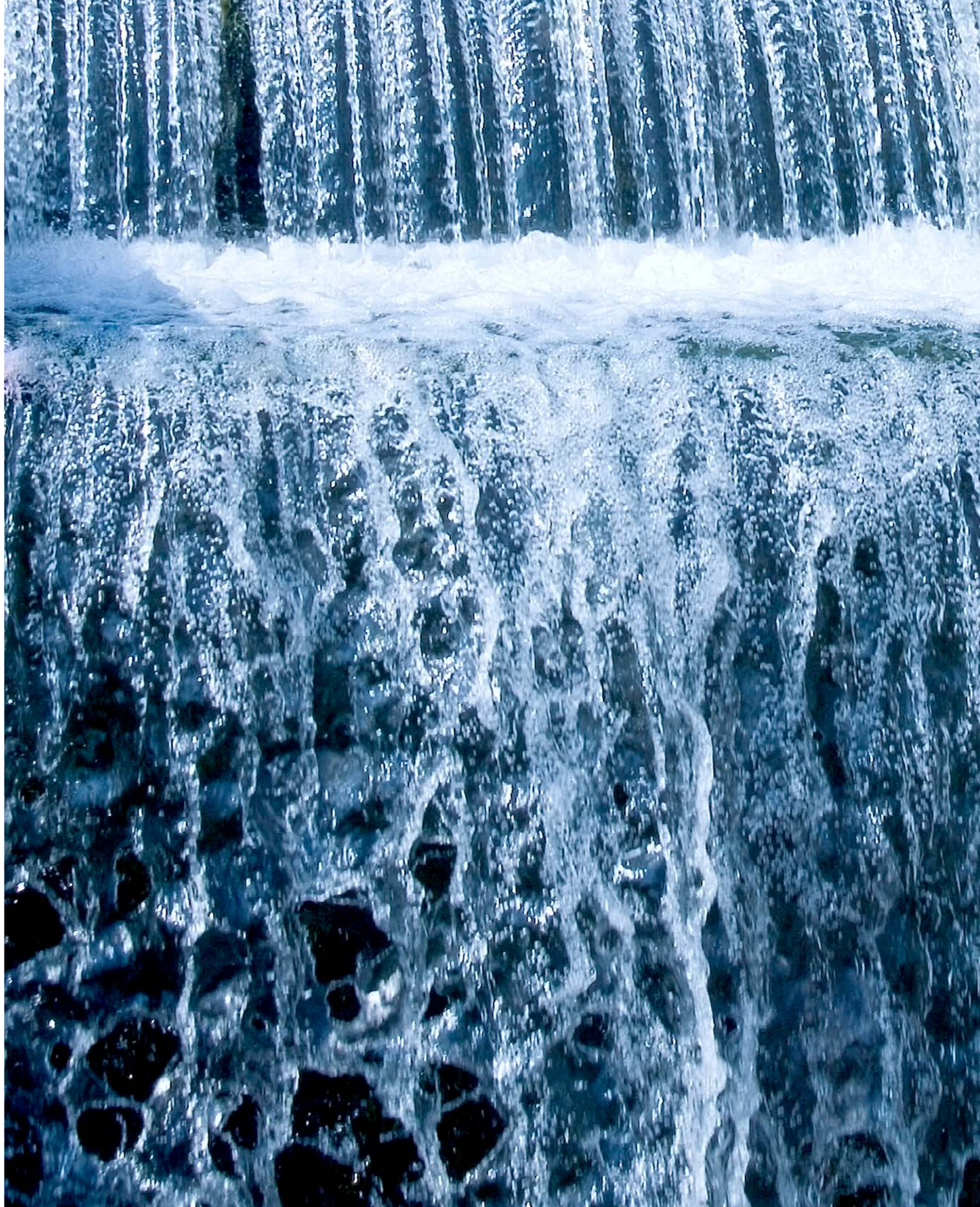
Sequana Medical NV
Kortrijksesteenweg 1112
9051 Sint-Denijs-Westrem, Belgium
T: +32 498 053579

Corporate Governance



1 Report of the Board of Directors

This report of the Board of Directors has been prepared in accordance with the Articles 3:5, 3:6, §1 and 3:32, §1 of the Belgian Companies and Associations Code of 23 March 2019 (as amended) (the "**Belgian Companies and Associations Code**" or "**BCAC**") and relates to the position of **Sequana Medical** NV, a company domiciled and incorporated in Belgium (the "**Company**" or "**Sequana Medical**", and together with its subsidiaries, the "**Sequana Medical Group**"), and the Company's annual accounts for the financial year ended on 31 December 2022.

1.1 Developments, results, risks and uncertainties (Article 3:32, 1° BCAC)

1.1.1 Operational review in the year 2022

alfapump in liver disease

- POSEIDON – North American pivotal study of the **alfa**pump in patients with recurrent or refractory ascites due to liver cirrhosis successfully met primary endpoint data:
  - Reported positive top-line results in October 2022 from 40 patients of the Pivotal Cohort at six months post-implantation, including primary effectiveness endpoints substantially exceeding the predefined thresholds for study success and safety in line with expectations:
    - ◊ 100% median per-patient reduction in therapeutic paracentesis (TP) post- vs pre-implantation ($p<0.001$), vs hypothesis of at least 50% reduction.
    - ◊ 77% of patients with at least 50% reduction in number of TP post- vs pre-implantation ($p<0.001$), vs hypothesis of at least 50% of patients.
    - ◊ Six primary safety events of which three involved explants due to wound or skin erosion, and three explants due to patient-reported discomfort (all patient-reported discomfort events were adjudicated by the Clinical Events Committee as moderate severity), in line with expectations.
  - Reported results of a preliminary interim analysis[I] of patient survival from the Roll-In Cohort in April 2022 including 70% survival rate at one year post-implantation, comparing favorably to published literature of 50% survival rate for refractory ascites patients after one year[II].
  - Prof. Wong presented safety, efficacy and quality of life data from the Roll-In Cohort at the AASLD The Liver Meeting® in November 2022.

(I) Date of analysis 25 March 2022, as part of a general safety assessment
(II) Biggins et al., Hepatology, Vol. 74, No. 2, 2021, AASLD Practice Guidance; Moreau R et al., Liver International 2004: 24: 457-464

- US patient preference study initiated:
  - Survey study to quantify patients' preferences for the **alfa**pump including treatment effectiveness and risks of treatment-related adverse events. The results of this study are expected to be presented in H2 2023.
- European PMSR data published in Liver International[III]:
  - Final safety and efficacy results of the Post Marketing Surveillance Registry (PMSR) study of the **alfa**pump published in Liver International, the peer-reviewed publication of the International Association for the Study of the Liver.

DSR in heart failure

- SAHARA – Phase 2a study of DSR 1.0 in diuretic-resistant heart failure patients with persistent congestion showed important and long-lasting clinical benefits:
  - Reported positive top-line data from ten evaluable patients with its first-generation DSR product (DSR 1.0) in November 2022, including i) safe, effective and rapid elimination of fluid overload and restoration of euvolemia, ii) improvement of cardiovascular and renal health, iii) restoration of the diuretic-response of the kidney, and iv) dramatic reduction in the need for oral loop diuretics up to 15 months post-therapy – demonstrating a durable improvement in the heart failure status of these patients.
  - Strong clinical observations from RED DESERT and SAHARA studies in diuretic-resistant heart failure patients support heart failure disease-modifying profile of DSR therapy:
    - No heart failure congestion-related re-hospitalizations during study follow-up.
    - All patients improved their NYHA[IV] status by at least one class.
    - Clinical benefits result in a 75% reduction in predicted one-year mortality pre- vs. post-intensive DSR therapy based on the Seattle Heart Failure Model[V].
  - Focus on Short Term DSR therapy with proprietary DSR 2.0:
    - Based on the results of RED DESERT and SAHARA, the Company expects that an intensive treatment period of three to four weeks of DSR therapy may deliver at least twelve months of important clinical benefits.
    - As a result of the strong, durable clinical signals observed, the Company will focus the heart failure development program on Short Term DSR with its proprietary second-generation DSR product (DSR 2.0) administered via a peritoneal catheter.
    - DSR 2.0 is expected to have an improved therapeutic and favorable safety profile with robust intellectual property protection.
  - MOJAVE – US Phase 1/2a randomized controlled multi-center study of DSR 2.0 in diuretic-resistant chronic heart failure patients with persistent congestion, on track to start in Q2 2023:

(III) Liver International promotes all aspects of the science of hepatology from basic research to applied clinical studies and provides an international forum for the publication of high quality original research in hepatology.
(IV) NYHA: New York Heart Association classification, data collected outside study protocols of RED DESERT and SAHARA
(V) Predicted one-year survival analysis using Seattle Heart Failure Model of seven patients from RED DESERT and eight patients from SAHARA pre- and post-intensive DSR therapy. Analysis includes physician-assessed data collected *post hoc*

- Good progress of DSR 2.0 in product development and GLP[I] animal studies.

- Approval to start two Phase 1 single-arm, open-label, single-dose studies in Canada (YUKON) and Mexico (CHIHUAHUA) to evaluate the safety, tolerability and efficacy of DSR 2.0, with first patient dosed successfully in YUKON.

- Data from the GLP animal and Phase 1 CHIHUAHUA studies are intended to support the US IND[II] application filing of DSR 2.0, planned for Q1 2023.

- Preparations ongoing to start the MOJAVE study, planned for Q2 2023, assuming FDA approval of the US IND application. The intention is to enroll 30 diuretic-resistant chronic heart failure patients with persistent congestion, with 20 patients randomized to DSR 2.0 administered via a peritoneal catheter on top of usual care for congestive heart failure (CHF) for up to four weeks and ten patients randomized to usual care for CHF alone.

Corporate

- European Medical Device Regulation (MDR) certification:

  - Received MDR certification from the Company's Notified Body, BSI, in February 2022, confirming that its QMS[III] and **alfa**pump system are compliant with the latest regulatory standards required for medical devices in Europe. **alfa**pump is one of the first novel Class III active implantable medical devices to receive such certification.

- Expanding the Board of Directors with seasoned US medtech executives:

  - Attracted two highly experienced US medtech leaders as independent Non-Executive Directors (which appointment was officially approved by the extraordinary shareholders' meeting of 10 February 2023). Doug Kohrs brings more than 40 years of experience from his many roles as a founder and executive of leading medical technology companies. Alexandra Clyde brings more than 30 years of experience and has an exceptional understanding and track record of successfully navigating health economics and reimbursement in the medical device industry.

- Extending the Company's cash runway:

  - Raised €28.4 million in gross proceeds in March 2022 by means of an equity placement via an accelerated bookbuild offering from a new investor, Partners in Equity V B.V., and existing shareholders.

  - Secured €10 million loan facility with Kreos Capital, a leading growth debt provider for life sciences and healthcare companies, in July 2022.

- Cash position of €18.9 million at the end of December 2022, compared to €9.6 million at the end of December 2021.

(I) GLP: Good Laboratory Practice
(II) IND: Investigational New Drug
(III) QMS: Quality Management System

1.1.2 Commentary on the consolidated annual accounts

Consolidated statements of profit and loss

Revenue

Revenue increased from €0.37 million in 2021 to €0.92 million in 2022 as a result of resumed commercial activity in Europe as the impact of COVID declines.

Cost of goods sold

Cost of goods sold increased from €0.08 million in 2021 to €0.21 million in 2022 in line with the increase in revenue.

Operating expenses

Total operating expenses increased from €24.11 million in 2021 to €29.34 million in 2022 mainly due to i) the preparations of the submissions for marketing approval of the **alfa**pump in the US and Canada, and ii) pre-clinical and clinical development work for Sequana Medical's proprietary DSR therapy.

Sales and marketing expenses increased from €2.08 million in 2021 to €2.24 million in 2022 due to the resumption of European commercial activities.

Clinical expenses increased from €7.80 million in 2021 to €9.77 million in 2022 mainly as a result of costs related to the POSEIDON North American pivotal study of the **alfa**pump, the SAHARA Phase 2a study of DSR and pre-clinical and clinical development work for the Company's proprietary DSR therapy.

Quality and Regulatory expenses increased from €3.22 million in 2021 to €3.63 million in 2022, mainly driven by external advice for the preparation of the submissions for marketing approval of the **alfa**pump in the US and Canada.

Supply chain expenses increased from €2.72 million in 2021 to €3.16 million in 2022 largely driven by additional staffing for the preparation of the submissions for marketing approval of the **alfa**pump in the US and Canada.

Engineering expenses increased from €3.21 million in 2021 to €3.85 million in 2022, largely driven by external advice and additional staffing for the preparations of the submissions for marketing approval of the **alfa**pump in the US and Canada.

General and administration expenses increased from €5.10 million in 2021 to €6.69 million in 2022 mainly due to costs relating to the equity and debt financings in 2022, and additional staffing.

Other income decreased from €1.21 million in 2021 to €0.53 million in 2022 related to the one-off termination of a distribution agreement by mutual agreement in 2021.

EBIT[IV]

As a result of the above, earnings before interest and taxes (EBIT) evolved from a loss of €22.61 million in 2021 to a loss of €28.09 million in 2022.

Total net finance expenses

Net finance cost increased from €0.61 million in 2021 to €2.28 million in 2022, mainly resulting from valuation of the Bootstrap Warrants and Kreos Subscription Rights (approved by the extraordinary shareholders meeting of 10 February 2023), both non-cash items, as well as, the increased realized foreign exchange losses following the weakening of the EUR compared to CHF and USD.

Income tax expense

Income tax expense remained stable at €0.39 million in 2022 compared to 2021.

(IV) EBIT is defined as revenue less cost of goods sold and operating expenses

Net loss for the period

As a result of the above, the net loss increased from €23.62 million in 2021 to €30.76 million in 2022.

Basic losses per share (LPS)

Basic losses per share increased from €1.30 in 2021 to €1.35 in 2022.

Consolidated balance sheet

Net debt

Net debt[I] at 31 December 2022 increased by €0.23 million compared to 31 December 2021.

Working Capital

Working capital[II] decreased by €0.99 million in 2022 compared to 2021, mainly as a result of an increase in trade payables and accrued liabilities, partially compensated by an increase in inventory and other receivables and prepaid expenses.

Consolidated statement of cash flows

Net cash outflow from operating activities was €27.48 million in 2022 compared to €23.62 million in 2021. The outflow was mainly driven by higher net loss of the period.

Cash flow from investing activities resulted in a net outflow of €0.65 million in 2022, compared to a net outflow of €0.34 million in 2021.

Cash flow from financing activities resulted in a net inflow of €37.32 million in 2022, mainly as a result of the proceeds from the equity placement in H1 2022, and the €10 million loan facility with Kreos Capital secured in H2 2022. In 2021, the net inflow of €22.44 million was mainly a result of the February 2021 equity placement.

The Company ended 2022 with a total cash and cash equivalents amount of €18.88 million (2021: €9.60 million).

1.1.3 Information regarding major risks and uncertainties

Sequana Medical is subject to numerous risks, in addition to other risks that are mentioned elsewhere in this report, such as:

Risks relating to global events

- The Russian invasion of Ukraine could have a destabilising impact on Sequana Medical's operations, both directly as a result of the conduct of studies in neighbouring countries and indirectly due to the impact on global macroeconomic conditions.
- The outbreak of the coronavirus (COVID-19) or any other infectious disease outbreak or other serious public health concern could result in delays to Sequana Medical's clinical studies and could adversely affect its supply chain and work force, as well as macroeconomic conditions generally, which could have an adverse effect on demand for the **alfa**pump®, the DSR® product and/or any future products.

(I) Net debt is calculated by adding short-term, long-term financial and lease debt and deducting cash and cash equivalents.
(II) The components of working capital are inventory + trade receivables + other receivables and prepaid expenses - trade payables - other payables - accrued liabilities and provisions.

Risks relating to Sequana Medical's financial situation

- Sequana Medical has incurred operating losses, negative operating cash flows and an accumulated deficit since inception and may not be able to achieve or subsequently maintain profitability.
- Changes in currency exchange rates could have a material negative impact on the profitability of Sequana Medical.

Risks relating to clinical development

- Sequana Medical is required to conduct clinical studies for regulatory approvals and other purposes. Clinical studies require approvals, carry substantial risks and may be costly and time consuming, with uncertain results.
- If Sequana Medical experiences delays or difficulties in the recruitment of Investigators, obtaining necessary approvals from study sites or the enrolment of subjects in clinical studies, or study sites failure to adhere to trial protocols and good clinical practices (GCP) regulations or similar regulations its receipt of necessary regulatory approvals could be delayed or prevented.
- If Sequana Medical is unable to enter into a partnership or strategic alliance for the further development and commercialisation of the DSR® product, as is currently contemplated, it may incur additional costs and/or the development of these products might be delayed.
- Adverse events may result in delays to the completion of clinical studies regarding the **alfa**pump®, the **alfa**pump DSR® or the DSR® product or may prevent completion.

Legal and regulatory risks

- Seeking and obtaining regulatory approval for medical devices and drugs can be a long, expensive and uncertain process. Strict or changing regulatory regimes, government policies and legislation in any of Sequana Medical's target markets may delay, prohibit or reduce potential sales.
- Sequana Medical intends to develop a proprietary DSR 2.0 product, which will require approval as a drug by the FDA and likely by regulatory authorities in other jurisdictions where Sequana intends to market the DSR® product
- Sequana Medical is and will be subject to certain post-approval regulatory obligations in relation to the **alfa**pump®, the **alfa**pump DSR® and the DSR® product.
- Sequana Medical's manufacturing facility and those of its third party suppliers are subject to significant regulations and approvals. If Sequana Medical or its third-party manufacturers or suppliers fail to comply with these regulations or maintain these approvals, Sequana Medical's business will be materially harmed.
- Sequana Medical is subject to the risk of product liability claims or claims of defectiveness, which could result in uninsured losses for Sequana Medical or recalls of the relevant product.
- Compliance with regulations and standards for quality systems for medical device and drug companies is complex, time consuming and costly. Sequana Medical may be found to be non-compliant, for example as a result of future changes in or interpretation of the regulations regarding quality systems in certain jurisdictions.
- The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about medical devices and drugs. If Sequana Medical is found to have made false or misleading claims about the **alfa**pump®, the DSR® product and/or any future products, or otherwise have violated promotion or advertising restrictions, it may become subject to significant fines and/or other liabilities.
- Sequana Medical is subject to healthcare fraud and abuse and other laws applicable to Sequana Medical's business activities. If Sequana Medical is unable to comply with such laws, it could face substantial penalties.
- Sequana Medical faces risks related to environmental matters and animal testing activities.

Risks relating to the Sequana Medical's dependence on third parties and on key personnel

- Sequana Medical depends on third party suppliers for services, components and pharmaceutical ingredients used in the production and operation of the **alfa**pump® and DSR® product and some of those services, components and pharmaceutical ingredients are supplied from a single source. Disruption of the supply chain, unavailability of third party services required for the production of the **alfa**pump® and DSR® product, component modifications or failure to achieve economies of scale could have a material adverse effect on Sequana Medical.
- Sequana Medical relies on third parties to conduct its clinical studies, perform data collection and analysis, and provide regulatory advice and other services that are crucial to its business.
- For the marketing of the **alfa**pump®, Sequana Medical will be largely dependent on Vingmed in Denmark.

Risks relating to commercialisation and reimbursement

- Sequana Medical's success is largely contingent on third party payment from government providers, healthcare insurance providers or other public or private sources and it could fail to achieve or maintain reimbursement levels sufficient to support commercialisation on a large scale.
- Sequana Medical is reliant on the Neue Untersuchungs- und Behandlungsmethoden (the "NUB") (New Research and Treatment Methods) reimbursement mechanism in Germany and will seek to obtain a German Diagnosis Related Group ("G-DRG") code for the **alfa**pump® when its operations in Germany reach sufficient scale, which may not be granted.
- Sequana Medical's future financial performance will depend on the commercial acceptance of the **alfa**pump®, the DSR® product and/or any future products in target markets.
- The success of the **alfa**pump®, the DSR® product and/or any future products depends on their acceptance and adoption by physicians.
- Sequana Medical may not be able to manufacture or outsource manufacturing of the **alfa**pump®, the DSR® product and/or any future products in sufficient quantities, in a timely manner or at a cost that is economically attractive.
- If Sequana Medical is unable to expand its sales, marketing and distribution capabilities for the **alfa**pump®, DSR® product and/or any future products, whether it be with internal infrastructure or an arrangement with a commercial partner such as the ones that Sequana Medical has entered into with Vingmed, Sequana Medical may not be successful in commercialising the **alfa**pump®, DSR® product and/or any future products in its target markets, if and when they are approved.

Risks relating to intellectual property

- Any inability to fully protect and exploit Sequana Medical's intellectual property may adversely impact Sequana Medical's financial performance and prospects.
- Sequana Medical could become subject to intellectual property litigation that could be costly, result in the diversion of management's time and efforts, require Sequana Medical to pay damages, prevent Sequana Medical from marketing the **alfa**pump®, the DSR® product and/or any future products, and/or reduce the margins for the **alfa**pump®, the DSR® product and/or any future products.
- Intellectual property rights do not necessarily address all potential threats to Sequana Medical's competitive advantage.

Risks relating to business activities

- Security breaches and other disruptions could compromise Sequana Medical's information and expose Sequana Medical to liability, which would cause Sequana Medical's business and reputation to suffer.
- Information technology forms a key support requirement within Sequana Medical's business. Any failure of Sequana Medical's IT systems could present a substantial risk to its business continuity.

Risks relating to surgical procedures

- Active implantable medical devices such as the **alfa**pump® carry risks associated with the surgical procedure for implant or removal of the device, use of the device, or the therapy delivered by the device.

Risks relating to the market in which Sequana Medical operates

- Competition from medical device companies, pharmaceutical and biotechnology companies, and medical device subsidiaries of large healthcare and pharmaceutical companies is intense and expected to increase.

Risks relating to the Company's shares and the stock market

- An active market for the Company's shares may not be sustained.
- The market price of the Company's shares may fluctuate widely in response to various factors.
- Future sales of substantial amounts of the Company's shares, or the perception that such sales could occur, could adversely affect the market value of the Company's shares.
- The Company will likely not be in a position to pay dividends in the near future and intends to retain all earnings.
- Certain significant shareholders of the Company may have different interests from the Company and may be able to control the Company, including the outcome of shareholder votes.
- Any future capital increases by the Company could have a negative impact on the price of the Company's shares and could dilute the interests of existing shareholders.

1.2 Information about important events after the closing of the financial year (Article 3:32, 2° BCAC)

We refer to note 15 under the 'Notes to the consolidated financial statements' in the financial report section.

1.3 Information on the circumstances that could significantly influence the development of the Sequana Medical Group (Article 3:32, 3° BCAC)

We refer to note 14 under the 'Notes to the consolidated financial statements' in the financial report section.

1.4 Research and development (Article 3:32, 4° BCAC)

The following R&D programs have been undertaken in the course of 2022 with the objective to further develop the **alfa**pump and the DSR® product:

alfapump in liver disease

- POSEIDON – North American pivotal study of the **alfa**pump in patients with recurrent or refractory ascites due to liver cirrhosis successfully met primary endpoint data:
  - Reported positive top-line results in October 2022 from 40 patients of the Pivotal Cohort at six months post-implantation, including primary effectiveness endpoints substantially exceeding the predefined thresholds for study success and safety in line with expectations:

◊ 100% median per-patient reduction in therapeutic paracentesis (TP) post- vs pre-implantation (p<0.001), vs hypothesis of at least 50% reduction.

◊ 77% of patients with at least 50% reduction in number of TP post- vs pre-implantation (p<0.001), vs hypothesis of at least 50% of patients.

◊ Six primary safety events of which three involved explants due to wound or skin erosion, and three explants due to patient-reported discomfort (all patient-reported discomfort events were adjudicated by the Clinical Events Committee as moderate severity), in line with expectations.

o Reported results of a preliminary interim analysis[I] of patient survival from the Roll-In Cohort in April 2022 including 70% survival rate at one year post-implantation, comparing favorably to published literature of 50% survival rate for refractory ascites patients after one year[II].

o Prof. Wong presented safety, efficacy and quality of life data from the Roll-In Cohort at the AASLD The Liver Meeting® in November 2022.

- US patient preference study initiated:

o Survey study to quantify patients' preferences for the **alfa**pump including treatment effectiveness and risks of treatment-related adverse events. The results of this study are expected to be presented in H2 2023.

- European PMSR data published in Liver International[III]:

o Final safety and efficacy results of the Post Marketing Surveillance Registry (PMSR) study of the **alfa**pump published in Liver International, the peer-reviewed publication of the International Association for the Study of the Liver.

DSR in heart failure

- SAHARA – Phase 2a study of DSR 1.0 in diuretic-resistant heart failure patients with persistent congestion showed important and long-lasting clinical benefits:

o Reported positive top-line data from ten evaluable patients with its first-generation DSR product (DSR 1.0) in November 2022, including i) safe, effective and rapid elimination of fluid overload and restoration of euvolemia, ii) improvement of cardiovascular and renal health, iii) restoration of the diuretic-response of the kidney, and iv) dramatic reduction in the need for oral loop diuretics up to 15 months post-therapy – demonstrating a durable improvement in the heart failure status of these patients.

- Strong clinical observations from RED DESERT and SAHARA studies in diuretic-resistant heart failure patients support heart failure disease-modifying profile of DSR therapy:

o No heart failure congestion-related re-hospitalizations during study follow-up.

o All patients improved their NYHA[IV] status by at least one class.

(I) Date of analysis 25 March 2022, as part of a general safety assessment
(II) Biggins et al., Hepatology, Vol. 74, No. 2, 2021, AASLD Practice Guidance; Moreau R et al., Liver International 2004: 24: 457-464
(III) Liver International promotes all aspects of the science of hepatology from basic research to applied clinical studies and provides an international forum for the publication of high quality original research in hepatology.
(IV) NYHA: New York Heart Association classification, data collected outside study protocols of RED DESERT and SAHARA

o Clinical benefits result in a 75% reduction in predicted one-year mortality pre- vs. post-intensive DSR therapy based on the Seattle Heart Failure Model[V].

- Focus on Short Term DSR therapy with proprietary DSR 2.0:

o Based on the results of RED DESERT and SAHARA, the Company expects that an intensive treatment period of three to four weeks of DSR therapy may deliver at least twelve months of important clinical benefits.

o As a result of the strong, durable clinical signals observed, the Company will focus the heart failure development program on Short Term DSR with its proprietary second-generation DSR product (DSR 2.0) administered via a peritoneal catheter.

o DSR 2.0 is expected to have an improved therapeutic and favorable safety profile with robust intellectual property protection.

- MOJAVE – US Phase 1/2a randomized controlled multi-center study of DSR 2.0 in diuretic-resistant chronic heart failure patients with persistent congestion, on track to start in Q2 2023:

o Good progress of DSR 2.0 in product development and GLP[VI] animal studies.

o Approval to start two Phase 1 single-arm, open-label, single-dose studies in Canada (YUKON) and Mexico (CHIHUAHUA) to evaluate the safety, tolerability and efficacy of DSR 2.0, with first patient dosed successfully in YUKON.

o Data from the GLP animal and Phase 1 CHIHUAHUA studies are intended to support the US IND[VII] application filing of DSR 2.0, planned for Q1 2023.

- Preparations ongoing to start the MOJAVE study, planned for Q2 2023, assuming FDA approval of the US IND application. The intention is to enroll 30 diuretic-resistant chronic heart failure patients with persistent congestion, with 20 patients randomized to DSR 2.0 administered via a peritoneal catheter on top of usual care for congestive heart failure (CHF) for up to four weeks and ten patients randomized to usual care for CHF alone.

1.5 Use of financial instruments (Article 3:32, 5° BCAC)

We refer to note 2.3.1.15 and 8.7 under the 'Notes to the consolidated financial statements' in the financial report section.

1.6 The justification of the independence and expertise in the field of accounting and audit of the audit committee (Article 3:32, 6° BCAC)

We refer to section 2.6 in the Corporate Governance Statement.

1.7 Internal control and risk management (Article 3:32, 7° BCAC)

We refer to section 2.13 in the Corporate Governance Statement.

(V) Predicted one-year survival analysis using Seattle Heart Failure Model of seven patients from RED DESERT and eight patients from SAHARA pre- and post-intensive DSR therapy. Analysis includes physician-assessed data collected *post hoc*
(VI) GLP: Good Laboratory Practice
(VII) IND: Investigational New Drug

1.8 Information that has an impact in case of public takeover bids (Article 3:32, 9° BCAC)

We refer to section 2.16 in the Corporate Governance Statement.

1.9 Branch offices (Article 3:6,5° BCAC)

The Company has a branch in Switzerland, Technoparkstrasse 1, 8005 Zurich.

1.10 Justification of valuation rules (Article 3:6,6° BCAC)

The Company is still in its development phase for its **alfa**pump® and DSR® products, and is conducting clinical trials in order to achieve regulatory marketing approvals for these products. This entails various risks and uncertainties, including but not limited to the uncertainty of the development process and the timing of achieving profitability. The Company's ability to continue operations also depends on its ability to raise additional capital and to refinance existing debt, in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows.

The impact of macroeconomic conditions and the geopolitical situation on the Company's ability to secure additional financing rounds or undertake capital market transactions remains unclear at this point in time and will remain under review by the Executive Management and the Board of Directors.

The Consolidated Statement of Financial Position as at 31 December 2022 shows a negative equity in the amount of EUR 2.2 million and ending cash balance of EUR 18.9 million. Reference is also made to section 14 "Events after the Reporting Period" below.

Equity placement

The Company envisions to conclude a capital increase by means of a private placement through an accelerated book building procedure in the coming days. We refer to the press release available on the Company's website dated 24 April 2023. The Company will regularly provide an update on the envisioned equity placement via its website.

The above conditions indicate the existence of material uncertainties, which may also cast significant doubt about the Company's ability to continue as a going concern.

The Executive Management and the Board of Directors made an assessment of the Company's ability to continue as a going concern. Several measures have already been carried out in order to reduce costs and expenditures, and the Company intends to carry out further savings. These measures include:

- Heart Failure / DSR: Slowing down the further progression of the MOJAVE clinical study. The Board of Directors notes that (i) the Company still targets results from the first 3 patients by Q4 2023 for the safety cohort, (ii) the first patients are most important as the Company is looking for confirmation that DSR 2.0 in US patients has same dramatic treatment effect as DSR 1.0 in the patients from Republic of Georgia (cfr. SAHARA and RED DESERT studies).
- US **alfa**pump program: Delaying the establishment of a new production facility.
- EU **alfa**pump commercial strategy: Reducing the Company's European commercial team by moving to a "reactive" rather than "proactive" commercial stance (i.e., ready to act on clinician interest and maintaining dialogue with key centres, instead of actively promoting the therapy). The Board of Directors notes that (i) the platform for training US clinicians and implanting teams remains available, and (ii) it intends to scale-up the European commercial teams in the future (when additional financing has been attracted).

The Company is also assessing to what extent partnerships or licensing arrangements could be entered into regarding its **alfa**pump® and DSR® products in order to support the further development, regulatory approval process, and subsequent marketing. While on the date hereof no concrete plans are on the table, the Company continuously engages with potential partners, which could also provide further funding to the Company's business.

The Board of Directors believes that a combination of one or more of the foregoing measures will help in addressing the Company's liquidity and funding structure. It also believes that these may further help in finding additional equity and/or debt financing from existing and/or new investors, as well as to renegotiate and/or refinance existing debt financing arrangements. Efforts in that respect are ongoing continuously. The Company has also control over its spendings, and management can timely and adequately reduce budgeted expenditures should this be necessary in the context of the Company's going concern and/or should it be necessary to have more time to obtain additional financing.

We also refer to note 14 Events after the reporting period in the Notes to Consolidated Financial Statements.

With the existing cash resources, the current cash runway is sufficient into mid-2023.

The Executive Management and the Board of Directors remain confident about the strategic plan, which comprises additional financing measures including equity and/or other financing sources, and therefore consider the preparation of the present Consolidated Financial Statements on a going concern basis as appropriate.

1.11 Conflicts of interests procedure (Articles 7:96 and 7:97)

On 7 March 2022, the Board of Directors of the Company decided to approve (in principle) the increase of the share capital of the Company in the framework of the authorised capital by the issuance of new shares in the framework of a private placement through an accelerated bookbuilding procedure. On 8 March 2022, the Board of Directors of the Company decided, before a notary public and subject to a number of condition precedents, to increase the share capital of the Company in the framework of the authorised capital with the issuance of new shares to be offered via a private placement through an accelerated bookbuilding procedure. On 8 March 2022, 5,167,268 new shares were effectively issued.

The conflicts of interests procedure of Articles 7:96 and 7:97 of the Belgian Companies and Associations Code was applied during each of the aforementioned board meetings. Within the context of the aforementioned procedures, prior to the launch of the relevant transaction, a committee of three independent directors of the Company issued an advice to the Board of Directors pursuant to Article 7:97 of the Belgian Companies and Associations Code in which the committee assessed the participation of a related party in the relevant transaction. The Company's Board of Directors did not deviate from the committee's favourable and unqualified conclusion. The Company published the required information in accordance with Article 7:97, §4/1 of the Belgian Companies and Associations Code through the following press release dated 7 March 2022: https://www.sequanamedical.com/wp-content/uploads/2022/03/Stratus-IV-Launch-PR-ENG.pdf.

In accordance with the Articles 7:96 and 3:6 of the Belgian Companies and Associations Code, the sections below contain the relevant parts of the aforementioned board decisions.

1.11.1 Extract of the Minutes of the Meeting of the Board of Directors of 7 March 2022

[…]

3.1. Prior declarations by Dr. Erik Amble

Prior to the deliberation and resolutions by the Board of Directors, Dr. Erik Amble, a director of the Company, as aforementioned, made the following declarations as far as needed and applicable, in accordance with Articles 7:96 and 7:97 of the Belgian Companies and Associations Code:

- Dr. Erik Amble informed the meeting that the agenda refers to a new fund raising via the proposed Transaction, and that he supports the Transaction. Dr. Erik Amble noted that, subject to the launch of the Transaction, he committed to submit a subscription order for new shares in the Transaction for an amount of EUR 100,000.00. Dr. Erik Amble's commitment is not subject to an undertaking by the Company to guarantee the allocation of new shares to him.
- Dr. Erik Amble indicated that it is contemplated that the new shares shall need to be admitted to listing and trading on the regulated market of Euronext Brussels. For this purpose, the Company is to make the necessary filings and applications, and, as the case may be, prepare a listing prospectus, all as required by applicable regulations, in order to permit an admission to listing and trading following the issue of the new shares. Dr. Erik Amble informed the meeting that if the Company is able to offer and allocate an aggregate number of new shares in the offering that is greater than ca. 16.5% of its currently outstanding shares of the Company, then the Company and Underwriters will have the right and ability to allocate to Dr. Erik Amble new shares that shall not be immediately admitted to listing upon their issuance (such new shares, the "Unlisted New Shares"), provided that in such case the Company undertakes to (i) apply to Euronext Brussels for the admission to trading and listing of the Unlisted New Shares, as soon as practicable after their issuance and in any event within 90 days after their issuance, and (ii) prepare as soon as reasonably possible after the date of their issuance, and submit as soon as practicable after their issuance to the Belgian Financial Services and Markets Authority (FSMA), a listing prospectus.
- Dr. Erik Amble informed the meeting that, as a result, he may have a conflict of interest within the meaning of Article 7:96 of the Belgian Companies and Associations Code in relation to the resolutions to be passed by the Board of Directors with respect to the Transaction. Further, as a director of the Company, Dr. Erik Amble is a "related party" in the sense of the International Financial Reporting Standards, as adopted by the European Union ("**IFRS**"), as referred to in article 7:97 of the Belgian Companies and Associations Code. Dr. Erik Amble will therefore also inform the Company's statutory auditor of the foregoing, as far as needed and applicable in accordance with the provisions of Article 7:96 and/or 7:97 of the Belgian Companies and Associations Code. Despite this potential conflict, however, Dr. Erik Amble stated that he believed that the proposed private placement and his potential participation in the Transaction are in the Company's interest, as it will allow the Company to complete the Transaction and raise new funds.

Subsequently, Dr. Erik Amble no longer took part in the further deliberation and resolutions of the Board of Directors with respect to the Transaction.

3.2. Prior declarations by the other directors

None of the other directors declared to have an interest in the proposed Transaction that would require the application of the procedure set out in the provisions of Article 7:96 and/or 7:97 of the Belgian Companies and Associations Code.

3.3. Considerations by the Board of Directors in relation to the prior declarations

The remaining members of the Board of Directors took note of the prior declarations by Dr. Erik Amble.

The Board of Directors noted that the Company has received a commitment from Dr. Erik Amble to submit a subscription order for new shares in the framework of the Transaction for an amount of EUR 100,000.00, subject to the launch of the Transaction. In this respect and without prejudice to the Guaranteed Allocation to the Pre-Committing Investor (as defined below), Dr. Erik Amble has agreed that (a) the new shares will be allocated to investors in the offering on the basis of objective allocation criteria, without guarantee as to allocation of new shares to the investors subscribing in the offering (before the closing of the bookbuilding procedure), (b) the applicable issuance price of the new shares to be issued in the offering is still to be determined in the offering on the basis of the accelerated bookbuilding that is to be organised as further referred to above, and (c) the same issuance price shall apply to all new shares and all investors subscribing for the new shares in the offering. Dr. Erik Amble also agreed and accepted that (i) the Company and Underwriters will have the right and ability to allocate to Dr. Erik Amble Unlisted New Shares, provided that, in such case, the Company will undertake to (i) apply to Euronext Brussels for the admission to trading and listing of the Unlisted New Shares, as soon as practicable after their issuance and in any event within 90 days after their issuance, and (ii) prepare as soon as reasonably possible after the date of their issuance, and submit as soon as practicable after their issuance to the Belgian Financial Services and Markets Authority (FSMA), a listing prospectus. This will allow the Company to issue new shares in excess of the aforementioned 16.5% threshold in the contemplated Transaction, and hence to raise more funds in the Transaction than would otherwise be possible, given that investors in the accelerated offering expect that these new shares will be immediately admitted to listing and trading. This is in the interest of the Company.

The Board of Directors considered that the commitment from Dr. Erik Amble provides additional evidence of support, which can be used in the solicitation of interest from other potential investors. A successful Transaction would be in the interest of the Company as, amongst other things, it allows the Company to have access to equity financing in a fast and efficient manner to fund its activities (requiring continuous investments), as further explained in the Board Report.

In addition, as far as needed and applicable, in accordance with the procedure set out in Article 7:97 of the Belgian Companies and Associations Code, an ad hoc committee of three independent directors of the Company (consisting of Pierre Chauvineau, WIOT BV (represented by its permanent representative Wim Ottevaere) and Jackie Fielding) have, prior to this meeting, evaluated in the Independent Directors Advice the proposed Transaction and have concluded that the Transaction and Dr. Erik Amble's potential participation and related pre-commitment are in the interest of the Company. The conclusions of the committee of independent directors are as follows:

For all of the above reasons, the Committee comes to the following conclusion:

"The Committee believes that the envisaged transaction, including the commitment of Dr. Erik Amble, is in the interest of the Company and of its shareholders, and is not manifestly abusive. The commitment from Dr. Erik Amble provides evidence of the personal support for the Company's business and strategy by an existing director of the Company. The commitment is therefore an important means that can be used in the solicitation of interest with other potential investors for the purpose of the envisages capital raising. While the envisaged capital raising may entail a dilution for the shareholders and holders of subscription rights (share options) of the Company, a successful capital raising would be in the interest of the Company as, amongst other things, it would allow the Company to have access to equity financing in a fast and efficient manner to fund its activities and its ongoing working capital requirements. The Committee also notes that the Company did not undertake to a guaranteed allocation of new shares to Dr. Erik Amble. The Committee notes in particular that, subject to the launch of the transaction, the offering will be open to institutional, qualified, professional and/or other investors as permitted under the applicable private placement exemptions, and that any final allocation to investors in excess of any guaranteed allocation will be made on the basis of customary objective and pre-identified criteria, and that upon successful completion of the capital raising, the same issue price of the new shares shall apply to all investors to which shares will be allocated, as the case may be. In view hereof, the Committee issues a favourable and unqualified opinion to the Board of Directors of the Company."

The Board of Directors agrees with, and does not deviate from, the abovementioned conclusions and considerations of the committee of independent directors, which have also been reflected in the abovementioned Board Report.

4. DELIBERATION AND RESOLUTIONS

[…]

After deliberation, it was unanimously:

(a) RESOLVED to approve in principle the issue of the new shares within the context of the Transaction, subject to the finalisation of the terms of the Transaction and the Documents, taking into account, however, the following:

(i) the capital increase will be for a maximum amount of EUR 45,000,000.00 (including issue premium). The maximum number and issue price of the new shares to be issued are to be determined as a result of the accelerated bookbuilding procedure which is further detailed in the Board Report and in these minutes.
(ii) without prejudice to the Guaranteed Allocation to the Pre-Committing Investor, the new shares are to be offered by the Underwriters to a broad group of currently unidentified Belgian and foreign institutional, qualified, professional and/or other investors, in and outside of Belgium, on the basis of applicable private placement exemptions, including (i) qualified investors in the member states of the European Union (as defined in the EU Prospectus Regulation), (ii) qualified investors in the United Kingdom (as defined in the UK Prospectus Regulation), (iii) "professional clients" in Switzerland (as defined in the FinSa), (iv) "Qualified Institutional Buyers" (QIBs) in the United States, and (v) subject to applicable securities law rules and regulations, natural and legal persons other than those mentioned in (i) to (iv), in and outside of Belgium, to whom the shares may be offered, it being understood that in Belgium and the United Kingdom, the minimum investment amount per investor should be at least EUR 100,000.00, with dis-application of the statutory preferential subscription right of the Company's existing shareholders and, insofar as required, of the Company's existing holders of subscription rights (stock options), and whereby (a) any final allocation of new shares to investors (as the case may be) must be made on the basis of customary objective and pre-identified criteria, and (b) with the exception of the Pre-committing Investor, no guarantee shall be given, by or on behalf of the Company or the Underwriters, as to any allocation of new shares to any party. It may also be provided that investors who have committed to submit a subscription order to the Underwriters and to whom new shares will ultimately be allocated (if any) will have the opportunity to subscribe directly for the new shares at the time of completion of the offering;
(iii) subject to the completion of the proposed Transaction, an application will be made and all steps will be taken as shall be required (including, as the case may be, the preparation of a listing prospectus as required by the EU Prospectus Regulation) in order to admit the new shares to listing and trading on the regulated market of Euronext Brussels in accordance with the applicable rules and regulations.

(b) RESOLVED to approve, or, insofar as required, ratify, the following:

(i) the Documents, the execution thereof (where relevant), and the performance of the obligations that the Company is to assume and perform in that regard;
(ii) the Board Report and the execution thereof;
(iii) the negotiation and execution of all other documentation and agreements to which the Company is or must become a party within the framework of the Transaction, including, but not limited to, the Placement Agreements;

in each case in accordance with the substantive terms set out in the Documents submitted to the Board of Directors or, as the case may be, as further negotiated, finalised or changed in accordance with the provisions in section (e) below.

(c) RESOLVED to confirm the assignment to the statutory auditor to draw up a report in accordance with Article 7:198 juncto Articles 7:179, 7:191 and 7:193 of the Belgian Companies and Associations Code with respect to the Transaction, as well as a report in accordance with Article 7:97 of the Belgian Companies and Associations Code with respect to the prior investment commitment of Dr. Erik Amble, and it being noted that, as far as needed and applicable, in accordance with Article 3:63, §5 of the Belgian Companies Code, the members of the audit committee agree that this assignment, in accordance with the rules and conditions necessary for such reports, is given to the statutory auditor of the Company.
(d) RESOLVED, subject to the finalisation of the Board Report and the report of the statutory auditor of the Company in relation thereto and subject to a final decision to be taken by the Placement Committee (as defined under section (e) below), to approve the passing of the Notarial Board Resolutions before a notary public.

1.11.2 Extract of the Notarial Deed recording the Minutes of the Meeting of the Board of Directors of 8 March 2022

Prior declarations by Mr. Erik Amble

Prior to the deliberation and resolutions by the Board of Directors, Mr. Erik Amble, a director of the Company, made the following declarations, as far as needed and applicable, in accordance with Articles 7:96 and 7:97 of the Belgian Companies and Associations Code:

Mr. Erik Amble informed the Board of Directors that the agenda refers to new fundraising through the proposed capital increase, and that he supports the capital increase. Mr. Erik Amble noted that he has undertaken to submit a subscription order for new shares in the capital increase in the amount of EUR 100,000.00. The undertaking of Mr. Erik Amble is not subject to an obligation of the Company to guarantee the allotment of new shares to him.

Mr. Erik Amble indicated that it is contemplated that the new shares should be admitted to listing and trading on the regulated market of Euronext Brussels. To this end, the Company will make the necessary application, and, as the case may be, prepare a listing prospectus, as required by the applicable regulations, for the purpose of admission to listing and trading following the issuance of the new shares. Mr. Erik Amble informed the Board of Directors that if the Company is able to offer and allot an aggregate number of new shares in the offering that is greater than approximately 16.5% of the Company's currently outstanding shares, the Company and the Underwriters will have the right and possibility to allot to Mr. Erik Amble new shares which will not be immediately admitted to listing upon their issuance (such new shares, the "Non-listed New Shares") provided that in such event, the Company undertakes to (i) apply for admission to trading and listing of the Non-Listed New Shares with Euronext Brussels as soon as practicably possible following their issuance and in any event within 90 days following their issuance, and (ii) proceed as soon as practicably possible following the date of their issuance with the preparation, and as soon as practicably possible following their issuance, with the submission to the Belgian Financial Services and Markets Authority (FSMA) of a listing prospectus.

Mr. Erik Amble has informed the Board of Directors that, as a result, he could potentially have a conflict of interest within the meaning of Article 7:96 of the Belgian Companies and Associations Code, in relation to the resolutions to be taken by the Board of Directors in relation to the capital increase. Furthermore, as a director of the Company, Mr. Erik Amble is a related party within the meaning of the International Financial Reporting Standards, as adopted by the European Union ("IFRS"), as referred to in Article 7:97 of the Belgian Companies and Associations Code. Mr. Erik Amble will therefore also inform the Company's statutory auditor of the foregoing as far as needed and applicable in accordance with the provisions of Article 7:96 and/or 7:97 of the Belgian Companies and Associations Code. However, despite this potential conflict of interest, Mr. Erik Amble has stated that he is of the opinion that the proposed private placement and his potential participation in the capital increase are in the interest of the Company, as it will enable the Company to complete the transaction and raise new funds.

Subsequently, Mr. Erik Amble no longer participated in the further deliberation and resolutions of the Board of Directors in relation to the capital increase.

Prior declarations by the other directors

None of the other directors declared to have an interest in the capital increase that would require the application of the procedure of the provisions of Article 7:96 and/or 7:97 of the Belgian Companies and Associations Code.

Considerations by the board in relation to the prior declarations

The other members of the Board of Directors have taken note of the preliminary declarations by Mr. Erik Amble.

The Board of Directors has noted that the Company has received a commitment from Mr. Erik Amble to submit a subscription order for new shares within the framework of the capital increase in the amount of EUR 100,000.00. In this regard, and without prejudice to the Secured Allotment to the Investor with Prior Undertaking (as defined below), Mr. Erik Amble has agreed that (a) the new shares will be allotted to the investors in the offering on the basis of objective allotment criteria, without guarantee as to the allotment of new shares to the investors subscribing in the offering (prior to the closing of the order book procedure), (b) the applicable issue price of the new shares to be issued in the offering is yet to be determined in the offering on the basis of the accelerated order book procedure which will be organised as further mentioned above, and (c) the same issue price will apply to all new shares and all investors subscribing for the new shares in the offering. Mr. Erik Amble has also agreed and accepted that (i) the Company and the Underwriters will have the right and possibility to allot Non-listed New Shares to Mr. Erik Amble, provided that, in such event, the Company undertakes to (i) apply for admission to trading and listing of the Non-listed New Shares with Euronext Brussels as soon as practicably possible following their issuance and in any event within 90 days following their issuance, and (ii) proceed as soon as practicably possible following the date of their issuance with the preparation, and as soon as practicably possible following their issuance, with the submission to the Belgian Financial Services and Markets Authority (FSMA) of a listing prospectus. This will enable the Company to issue new shares above the aforementioned threshold of 16.5% in the capital increase, and therefore raise more funds than would otherwise be possible, as investors in the accelerated offering expect that these new shares will be admitted to listing and trading immediately. This is in the interest of the Company.

The Board of Directors is of the opinion that the commitment of Mr. Erik Amble provides additional evidence of support, which can be used in the verification of potential interest from other potential investors. A successful capital increase would be in the interest of the Company, as it, among other, enables the Company to have access to capital in a quick and efficient manner in order to be able to fund its business (which requires ongoing investments), as further explained in the Report of the Board of Directors.

In addition, as far as needed and applicable, in accordance with the procedure of Article 7:97 of the Belgian Companies and Associations Code, an ad hoc committee of three independent directors of the Company (consisting of Pierre Chauvineau, WIOT BV (represented by its permanent representative Wim Ottevaere) and Jackie Fielding) has evaluated the capital increase prior to this meeting and, in relation to the capital increase within the framework of the authorised capital, concluded that the capital increase and the potential participation of Mr. Erik Amble and the prior undertaking relating thereto are in the interest of the Company. The conclusions of the committee of independent directors are as follows:

"The Committee is of the opinion that the proposed Transaction, including the undertaking of Dr. Erik Amble, is in the interest of the Company and its shareholders, and is not manifestly unlawful. The undertaking of Dr. Erik Amble provides evidence of the personal support of an existing director of the Company for the Company's business and strategy. The undertaking is therefore an important tool that can be used in the garnering of interest from other potential investors. Although the proposed capital increase may entail a dilution for the Company's shareholders and holders of subscription rights (stock options), a successful capital increase would be in the Company's interest as it would, among other, allow the Company to have access to equity financing in a quick and efficient manner to fund its business and its ongoing working capital needs. The Committee also notes that the Company has not agreed to a secured allotment of new shares to Dr. Erik Amble. In particular, the Committee notes that subject to the commencement of the transaction, the offering will be open to institutional, qualified, professional and/or other investors as permitted on the basis of

applicable exemptions for private placements, and that any final allotment to investors in excess of any secured allotment will be made on the basis of customary objective and pre-identified criteria, and that following the successful completion of the capital increase, the same issue price of the new shares will apply to all investors to whom shares will be alloted, as the case may be. In light of this, the Committee provides a favourable and approving advice to the Board of Directors of the Company."

The Board of Directors agrees with, and does not deviate from, the above conclusions and considerations of the committee of independent directors, which are also reflected in the abovementioned report of the Board of Directors mentioned in agenda item 1(a) in accordance with Article 7:198 juncto Article 7:179, 7:191 and 7:193 of the Belgian Companies and Associations Code.

[…]

After deliberation, the Board of Directors has unanimously decided as follows:

FIRST DECISION: Reports

The report of the Board of Directors of the Company in accordance with to Article 7:198 juncto Articles 7:179, 7:191 and 7:193 of the Belgian Companies and Associations Code dated 23 March 2019, as amended (the "Companies and Associations Code") in relation to the proposal of the Board of Directors of the Company to increase, within the framework of the authorised capital, the capital of the Company in cash by a maximum amount of EUR 45,000,000.00 (including issue premium) through the issuance of new shares, the maximum number and issue price of which are still to be determined, and to dis-apply, in the interest of the Company, the statutory preferential subscription right of the existing shareholders of the Company and, to the extent necessary, of the existing holders of subscription rights (stock options) of the Company, however without prejudice to the Secured Allotment (as defined below) of new shares in favour of Partners in Equity V B.V. (the "Investor with Prior Undertaking"), in order to offer the new shares via a private placement, through an accelerated order book procedure, to a broad group of as of present not yet identified Belgian and foreign institutional, qualified, professional and/or other investors, within and outside Belgium, based on the applicable exemptions for private placements, including (i) qualified investors in the member states of the European Union (as defined in Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market and repealing Directive 2003/71/EC, as amended (the "EU Prospectus Regulation")), (ii) qualified investors in the United Kingdom (as defined in the EU Prospectus Regulation and the delegated acts, implementing acts and technical standards within the framework thereof, as such legislation forms part of the enforced EU law as defined in the EU (Withdrawal) Act 2018, as amended (the "UK Prospectus Regulation")), (iii) "professional clients" in Switzerland (as defined in the Swiss Federal Financial Services Act (Finanzdienstleistungsgesetz) of 15 June 2018 as amended (the "FinSa")), (iv) "Qualified Institutional Buyers" (QIBs) in the United States and (v) subject to applicable securities laws and regulations, natural and legal persons other than those mentioned in (i) to (iv), within and outside Belgium, to whom the shares may be offered, it being understood that in Belgium and the United Kingdom, the minimum investment amount per investor must amount to at least EUR 100,000.00, is submitted to the Board of Directors for approval.

The Board of Directors declares to already have approved this report prior to this meeting of the Board of Directors. It takes note of it again, and no comments are formulated.

The Board of Directors approves this report again.

The Board of Directors subsequently takes note of the report of the Company's statutory auditor in accordance with Article 7:198 juncto Articles 7:179, 7:191 and 7:193 of the Companies and Associations Code, as well as the report of the Company's statutory auditor in accordance with, as far as needed and applicable, Article 7:97 of the Companies and Associations Code, whereby both reports were prepared in relation to the proposal of the Company's Board of Directors to increase, within the framework of the authorised capital, the capital of the Company in cash by a maximum amount of EUR 45.000,000.00 (including issue premium) through the issuance of new shares, the maximum number and issue price of which are still to be determined, and to dis-apply, in the interest of the Company, the statutory preferential subscription right of the existing shareholders of the Company and, as far as needed, of the existing holders of subscription rights (stock options) of the Company, however without prejudice to the Secured Allotment of new shares for the benefit of the Investor with Prior Undertaking, in respect of the proposal to issue new shares.

The directors declare to have received a draft of this report from the Board of Directors prior to this meeting of the Board of Directors and to have taken note of it. They declare no formulate no comments on it.

[…]

SECOND DECISION: Increase of the company's capital within the authorised capital

The Board of Directors resolves to increase the Company's capital in cash within the framework of the authorised capital as set out in Article 8 of the Company's articles of association by a maximum amount of forty-five million euros (EUR 45,000,000.00) (including issue premium) through the issuance of new shares, the maximum number and issue price of which are still to be determined, with the dis-application of the statutory preferential subscription right of the existing shareholders of the Company and, as far as needed, of the existing holders of subscription rights (stock options) of the Company, subject to the following terms and conditions:

[…]

1.12 Acquisition of own shares (Article 7:220 BCAC)

Neither the Company nor any person acting in his own name but on behalf of the Company has acquired shares of the Company during the financial year 2022.

1.13 Transactions under the authorised capital (Article 7:203 BCAC)

On 10 March 2022, the Board of Directors of the Company increased the share capital of the Company in the framework of the authorised capital with the issuance of 5,167,268 new shares, with dis-application of the preferential subscription right of the shareholders of the Company and, in so far as required, of the holders of subscription rights (stock options) of the Company, that were offered to a broad group of Belgian and foreign institutional, qualified, professional and/or other investors, in and outside of Belgium, on the basis of applicable private placement exemptions, in the framework of a private placement through an accelerated bookbuilding procedure. In this context, the Board of Directors prepared a report in accordance with Article 7:198 juncto Article 7:179, 7:191 and 7:193 of the Belgian Companies and Associations Code in relation to the transaction, providing notably (i) a justification of the transaction, including notably a justification of the issue price of the new shares (taking into account the financial situation of the Company, the identity of the pre-committing investor that obtain guaranteed allocation, and the nature and importance of the contribution of said pre-committing investor), (ii) a description of the consequences of the transaction for the financial and shareholder rights of the shareholders of the Company, (iii) a justification of the proposed dis-application of the statutory preferential subscription right of the shareholders and, in so far as required, of the holders of subscription rights (stock options) in connection with the proposed increase of the share capital in the framework of the transaction, and (iv) a description of the consequences of

the dis-application of the preferential subscription rights for the financial and shareholder rights of the shareholders. This board report must be read together with the report prepared by the Company's statutory auditor, PwC Bedrijfsrevisoren BV, a private company with limited liability organised and existing under the laws of Belgium, with registered office at Culliganlaan 5, 1830 Machelen, Belgium, represented by Mr. Peter D'hondt, auditor.

The abovementioned reports are available on the Company's website at: https://www.sequanamedical.com/investors/shareholder-information/.

2 Corporate Governance Statement

2.1 Introduction

This Corporate Governance Statement is included in the Company's report of the Board of Directors on the consolidated accounts for the financial year ended on 31 December 2022 (dated 21 April 2023) in accordance with Article 3:6, §2 of the Belgian Companies and Associations Code of 23 March 2019 (as amended) (the "**Belgian Companies and Associations Code**").

On 17 May 2019, the Belgian Royal Decree of 12 May 2019 designating the Corporate Governance code to be complied with by listed companies was published in the Belgian Official Gazette. On the basis of this royal decree, Belgian listed companies are required to designate the 2020 Belgian Corporate Governance Code (the "**2020 Belgian Corporate Governance Code**") as reference code within the meaning of Article 3:6, §2 of the Belgian Companies and Associations Code. The 2020 Belgian Corporate Governance Code applies to reporting years beginning on or after 1 January 2020.

On 23 April 2020, the Board of Directors approved an amended and restated version of the Company's Corporate Governance Charter to align it with the provisions of the 2020 Belgian Corporate Governance Code and the Belgian Companies and Associations Code.

The 2020 Belgian Corporate Governance Code can be accessed on the following website: www.corporategovernancecommittee.be/.

2.2 Corporate Governance Charter

The Company applied a Corporate Governance Charter that was in line with the 2020 Belgian Corporate Governance Code. The Company's Board of Directors approved this charter on 23 April 2020. The Corporate Governance Charter described the main aspects of the Corporate Governance of the Company, including its governance structure, the terms of reference of the Board of Directors and its committees and other important topics. The Corporate Governance Charter had to be read together with the Company's articles of association.

2.3 Deviations from the 2020 Belgian Corporate Governance Code

The Company applied the provisions set forth in the 2020 Belgian Corporate Governance Code except in relation to following:

- Pursuant to Article 7:91 of the Belgian Companies and Associations Code and provision 7.11 of the 2020 Belgian Corporate Governance Code, shares should not vest and share options should not be exercisable within three years as of their granting. Insofar as necessary, it is recalled that following the extraordinary shareholders' meeting of 28 May 2020, it has been expressly provided in the articles of association that the Board of Directors is explicitly authorised to deviate from the provisions of Article 7:91 of the Belgian Companies and Associations Code, for all persons who fall within

the scope of these provisions (whether directly or pursuant to Articles 7:108 and 7:121 of the Belgian Companies and Associations Code, or otherwise). The Company is of the opinion that this allows for more flexibility when structuring share-based awards. For example, it is customary for option plans to provide for a vesting in several instalments over a well-defined period of time, instead of vesting after three years only. This seems to be more in line with prevailing practice.

- In accordance with provision 7.6 of the 2020 Belgian Corporate Governance Code, non-executive directors should receive a part of their remuneration in the form of shares of the Company. The Company has however no distributable reserves and therefore does not meet the legal requirements to proceed to a shares buy-back. As a result, the Company does not any own treasury shares and is unable to grant existing shares to non-executive directors as part of their remuneration. The interests of the non-independent non-executive directors are however considered to be sufficiently oriented to the creation of long-term value for the Company. The directors are also paid in cash, leaving it their own initiative whether or not they wish to use such funds (in whole or in part) to acquire existing shares of the Company.
- On 10 February 2023 the Company's extraordinary shareholders' meeting approved an amendment to the Company's remuneration policy, allowing for the issuance of so-called "restricted share units" or "RSUs", which provide for a remuneration in the form of new shares whereby the relevant directors will have an obligation to subscribe for such shares at a value of EUR 0.11 per share (independent of the value of the share at that time). One restricted share unit or RSU represents the obligation of the relevant non-executive independent director to subscribe for one new share of the Company. The RSU remuneration is in addition to the cash component of the yearly remuneration of the directors. The issue of RSUs is designed to align the remuneration policy of the Company in respect of non-executive independent directors with provision 7.6 of the 2020 Code. The RSUs are not entirely equivalent to a share (no voting rights, no preferential subscription rights or other membership rights) but, in the opinion of the Company, the RSUs meet the objectives provided for in provision 7.6 of the 2020 Code.
- In accordance with provision 7.9 of the 2020 Belgian Corporate Governance Code, the Board of Directors should set a minimum threshold of shares to be held by the members of the Executive Management. A part of the remuneration of the members of the Executive Management consists of options to subscribe for the Company's shares, which should allow the members of the Executive Management over time to acquire shares of the Company, in line with the objectives of the option plans.
- In accordance with provision 7.12 of the Belgian Corporate Governance Code, the Board of Directors should include provisions in the contracts of the members of the Executive Management that would enable the Company to recover variable remuneration paid, or withhold the payment of variable remuneration, and specify the circumstances in which it would be appropriate to do so, insofar as enforceable by law. There are currently no contractual provisions in place between the Company and the Chief Executive Officer or the other member of the Executive Management that give the Company a contractual right to reclaim from said executives any variable remuneration that would be awarded. The Board of Directors does not consider that it is necessary to apply claw-back provisions as (x) the pay-out of the variable remuneration, based on the achievement of corporate targets as set by the Board of Directors, is paid only upon achievement of those corporate targets, and (y) the Company does not apply any other performance based remuneration or variable compensation. Furthermore, the share option plans do contain bad leaver provisions that can result in the share options, whether vested or not, automatically and immediately becoming null and void. Notwithstanding the Company's position that share options are not to be qualified as variable remuneration, the Board of Directors is of the opinion that such bad leaver provisions sufficiently protect the Company's interests and that it is therefore currently not necessary to provide for additional contractual provisions that give the Company a contractual right to reclaim any (variable) remuneration from the members of the Executive Management.

What constitutes good Corporate Governance will evolve with the changing circumstances of a company and with the standards of Corporate Governance globally, and must be tailored to meet those changing circumstances.

The Board of Directors intends to update the Corporate Governance Charter as often as required to reflect changes to the Company's Corporate Governance.

The articles of association and the Corporate Governance Charter are available on the Company's website (www.sequanamedical.com) and can be obtained free of charge at the Company's registered office.

2.4 Composition Board of Directors, Executive Management and Senior Management Team

2.4.1 Board of Directors

The table below gives an overview of the current members of the Company's Board of Directors and their terms of office:

Name	Age	Position	Start of Current Term	End of Current Term
Mr Pierre Chauvineau	59	Chair, Independent Non-Executive Director	2021	2025
Mr Ian Crosbie	55	CEO, Executive Director	2021	2025
Dr Rudy Dekeyser	61	Non-Executive Director	2021	2025
Mr Wim Ottevaere(I)	66	Independent Non-Executive Director	2021	2025
Mrs Jackie Fielding	58	Independent Non-Executive Director	2022	2026
Mr Doug Kohrs	64	Independent Non-Executive Director	2023	2026
Mrs Alexandra Clyde	58	Independent Non-Executive Director	2023	2026

Mr Pierre Chauvineau is an independent non-executive director and the chair of the Company's Board of Directors. Mr Chauvineau has over 31 years of international business leadership in corporate and start-up companies within the medical technology industry. He started his career with Medtronic where he spent 20 years before joining Cameron Health, a VC-funded medical device company based in California where he was responsible for commercialising their innovative implantable defibrillator across international markets. Cameron Health was acquired by Boston Scientific two years later in June 2012, after which Mr Chauvineau went on to lead Boston Scientific's largest European Business Unit for 5 years. Today, Mr Chauvineau continues to mentor and coach, he is also an executive board member with London based Rhythm AI and Lausanne based Comphya. He is also the chairman of Galway based Aurigen Medical and Grenoble based Aryballe. Pierre Chauvineau holds an MBA degree in International Management from the Monterey Institute of International Studies (Monterey, California, U.S.A.) and a BA degree from IPAG (Paris, France).

(I) Acting as permanent representative of WIOT BV.

Mr Ian Crosbie is an executive director of the Company since 2019 and the Company's Chief Executive Officer since 2016. Mr Crosbie has over 25 years of experience in the healthcare sector, both in-house at medical device and pharmaceutical companies, and as an investment banker at leading global firms. He has extensive expertise and a strong track record in capital markets, licensing and strategic transactions. Prior to joining Sequana Medical, Mr Crosbie was Chief Financial Officer of GC Aesthetics Ltd based in Dublin. Before that, Ian was Senior Vice President, Corporate Development at Circassia Pharmaceuticals plc, a late-stage biopharmaceutical company focused on allergy immunotherapy where he led the execution of the company's £210 million IPO, as well as the M&A and licensing activities. Prior to Circassia, Ian enjoyed a 20-year career in corporate finance, including Managing Director, Healthcare Investment Banking at Jefferies International Limited and Director, Healthcare Investment Banking at Deutsche Bank. He has a degree in Engineering, Economics and Management from Oxford University.

Dr Rudy Dekeyser is a non-executive director of the Company. He is managing partner of the LSP Health Economics Fund 2, a EUR 280 million fund investing in medical device, diagnostic and digital health companies in Europe and the US. Besides serving on the Company's Board of Directors, Dr Dekeyser currently also serves on the Board of Directors of Lumeon, Nobi, reMYND and EMBLEM and has served on many other biotech boards such as Ablynx (acquired by Sanofi), Devgen (acquired by Syngenta), CropDesign (acquired by BASF), Actogenix (acquired by Intrexon) and Multiplicom (acquired by Agilent). Prior to joining LSP, he was one of the founders of VIB and co-managing director of this leading life sciences research institute for 17 years, during which he was also responsible for all business development. Under his leadership VIB has built a patent portfolio exceeding 200 patent families, signed 800 R&D and license agreements, spun out twelve companies and laid the foundation for bio-incubators, bio-accelerators and the biotech association FlandersBio. Dr Dekeyser is member of the advisory board of several foundations investing in life sciences innovation and has been one of the catalysts in the foundation of Oncode, a Dutch cancer research institute. Dr. Dekeyser holds a Ph.D in molecular biology from the University of Ghent.

Mr Wim Ottevaere (WIOT BV) is an independent non-executive director of the Company. Mr Ottevaere is currently active as a non executive consultant for biotechs and CFO of Biotalys. Mr Ottevaere was the Chief Financial Officer of Ablynx until September 2018, a Belgian biopharmaceutical company engaged in the development of proprietary therapeutic proteins based on single-domain antibody fragments. Ablynx was listed on Euronext Brussels and Nasdaq and acquired by Sanofi in June 2018. From 1992 until joining Ablynx in 2006, Mr Ottevaere was Chief Financial Officer of Innogenetics (now Fujirebio Europe), a biotech company that was listed on Euronext Brussels at the time. From 1990 until 1992, he served as Finance Director of Vanhout, a subsidiary of the Besix group, a large construction enterprise in Belgium. From 1978 until 1989, Mr Ottevaere held various positions in finance and administration within the Dossche group. Wim Ottevaere holds a Master's degree in Business Economics from the University of Antwerp, Belgium.

Mrs Jackie Fielding is an independent non-executive director of the Company. Mrs Fielding spent 28 years with Medtronic, most recently as Vice President UK / Ireland, where she was responsible for more than 700 staff and revenue of approximately $750 million. She held a number of external posts alongside her role at Medtronic, including Chair of the BCIA (British Cardiovascular Intervention Association) and council member of the BCIS (British Cardiovascular Intervention Society). In 2010, she was elected to the Board of Directors of ABHI (Association of British HealthTech Industries) and in 2015 was appointed Vice Chair. Jackie has worked with the UK's NHS (National Health Service) Clinical Entrepreneur programme and was a member of the Ministerial Medical Technology Strategy Group. She is Non-Executive Director on the Boards of UK's NICE (National Institute for Health and Care Excellence), 3D Life Prints and Northumbria Primary Care, of which she is also Chair.

Mr Doug Kohrs is an independent non-executive director of the Company. Doug Kohrs currently serves as the President and CEO of Responsive Arthroscopy, a company he founded that focusses on innovative surgical solutions for orthopedic surgery centers. In 2013, he also founded Responsive Orthopedics, a value-based medical device company, where he served as CEO until it was acquired by Medtronic in June 2016. From 2006 to 2012, he was CEO and President of Tornier NV, and from 1999 to 2005 he was CEO and President of American Medical Systems. Doug was also a founder of Spine Tech, a pioneering spinal surgery company, where he worked in R&D and Marketing roles from 1991 to 1998. Prior to that, he spent seven years with Johnson and Johnson Orthopedics as the Chief Designer for the Press Fit Condylar (PFC) knee and PFC hip systems. Doug currently serves on the Board of Directors of Cerapedics, Lima Orthopedics, Osteal Therapeutics, UroTronic, and Vergent Bioscience. Doug has previously served on the public company boards of ev3 (acquired by Covidien), Kyphon (acquired by Medtronic), and Protolabs, and the private company boards of Imascap (acquired by Wright Medical), Pioneer Surgical (acquired by RTI Surgical), SpineCore (acquired by Stryker), and five other boards. Doug holds a B.S. in Bioengineering from Texas A&M University, a B.A. in Engineering Sciences from Austin College and an MBA from Northeastern University.

Mrs Alexandra Clyde is an independent non-executive director of the Company. She is Senior Vice President of Global Health Economics, Policy, and Reimbursement for Medtronic plc. In this role, she leads a global function of more than 300 reimbursement and health economics professionals and provides company-wide leadership on health and payment policy. She is a member of the Duke Margolis Value-Based Payment and Innovative Technology Consortium, the Health Technology Assessment International (HTAi) Policy Forum, and the Advisory Board for the Center for the Evaluation of Value and Risk in Health (CEVR) at the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center. She is a former member of the Health Care Payment Learning and Action Network's (HCP-LAN) Guiding Committee which is charged by the US Secretary of Health and Human Services with accelerating the health care system's transition to alternative payment models (APMs) by combining the innovation, power, and reach of the public and private sectors. She has also participated in various Centers for Medicare and Medicaid Services (CMS) technical advisory councils as well as other private and public sector initiatives to improve value in health care. Alex graduated from Colgate University with a B.A. in Economics and from Harvard University with a M.S. in Health Policy and Management.

The business address of each of the directors for the purpose of their mandate is the address of the Company's registered office: Kortrijksesteenweg 1112/102, 9051 Sint-Denijs-Westrem, Belgium.

The following persons attend the Company's board meetings as board observers (in a non-voting capacity):

- Erik Amble, as representative of NeoMed IV Extension L.P., shareholder of the Company;
- Ids van der Weij, as representative of Partners in Equity V B.V., shareholder of the Company; and
- Maurizio Petitbon, as representative of Kreos Capital VII (UK) Limited, a debt provider of the Company.

2.4.2 Executive Management and Senior Management Team

The Executive Management of the Company consists of the following members:

Name	Age	Position
Mr Ian Crosbie	55	Chief Executive Officer
Mrs Kirsten Van Bockstaele(I)	48	Chief Financial Officer

Mr Ian Crosbie is the Chief Executive Officer and a director of the Company. Please see his biography under the section "Board of Directors" above.

Mrs Kirsten Van Bockstaele is the Chief Financial Officer of Sequana Medical. She is a seasoned finance executive with extensive international experience in the healthcare industry. Mrs Van Bockstaele joined Sequana Medical from Fagron (formerly Arseus), an international pharmaceutical compounding company. Within Fagron, she held a number of senior financial roles, most recently as Vice President of Finance, North America. In this role, Mrs Van Bockstaele was responsible for creating and overseeing the company's financial strategy and policy, positioning Fagron's North American companies for growth. She also played a pivotal role in building out the North American headquarters, supporting the financial integration of acquisitions and assisting in redirecting the company's strategy. Mrs Van Bockstaele previously served as Chief Financial Officer for Arseus Dental & Medical Solutions, where she was instrumental in the coordination, support and control of financial activities in key European countries. Her previous roles include Financial Controller at Omega Pharma and Audit Manager at PwC. Kirsten Van Bockstaele has a degree in Business Economics from EHSAL and a degree in Financial and Fiscal Sciences from the University of Antwerp, Belgium.

The Senior management team of the Company consists of the members of the Executive Management, together with the following members:

Name	Age	Position
Dr Oliver Gödje	58	Chief Medical Officer
Dr Gijs Klarenbeek	46	Senior Medical Advisor
Mr Timur Resch	41	Global Vice President QM/QA/RA
Dr Andreas Wirth	54	Global Vice President Engineering
Mr Martijn Blom	49	Chief Commercial Officer
Mr Dragomir Lakic	40	Global Vice President Manufacturing

Dr. Oliver Gödje is the Chief Medical Officer of the Company. Dr. Gödje is a highly experienced clinician and medtech industry executive with 18 years of international experience in medical and commercial roles. Prior to joining Sequana Medical, Oliver served as Chief Medical Officer at Humedics GmbH, Medical Director and VP Sales & Marketing at Hepa Wash GmbH, Chief Medical Officer and Chief Marketing Officer at Tensys Medical Inc., and Medical & Marketing Director of PULSION Medical Systems AG, all medtech companies in the liver or cardiovascular field. He holds a PhD and Professorship in Human Medicine and built an extensive knowledge of cardiology during his time as a Cardiac Surgeon at leading German Universities. He was a Consultant and Vice Chairman of the Department of Cardiac Surgery at the University Hospital of Ulm until 2002.

(I) Acting as a permanent representative of Fin-2K BV.

Dr Gijs Klarenbeek is the Senior Medical Advisor of the Company. Dr Klarenbeek has over 14 years academic and healthcare industry experience. After his training in abdominal surgery at the University of Leuven, he held multiple positions in Medical Affairs, Clinical and Marketing at large pharmaceutical (Sanofi, AstraZeneca) and medical device companies. These include roles as Director of Medical Affairs Europe at Boston Scientific, providing leadership to the medical support for the portfolio of products in the Structural Heart and Medical / Surgical divisions, and as Worldwide Medical Director Clinical Research at Johnson & Johnson's medical device division (Cordis and Cardiovascular Care Franchise), supporting the clinical development of different products through regulatory submission (CE mark & IDE), post-market commitments and development. Dr Klarenbeek holds an MD from the University of Leuven, Belgium and a degree in Business Administration from the Institute for Pharmaceutical Business Administration (IFB).

Mr Timur Resch is the Global Vice President QM/QA/RA and Person Responsible for Regulatory Compliance (PRRC) of Sequana Medical. Timur has over 10 years of experience within quality management and regulatory affairs in the regulated medical device industry. In 2010, he graduated as an engineer in medical technology from the University of Applied Sciences in Lübeck, Germany and began his professional career as a process and management consultant at Synspace AG. Thereafter, Timur continued as Head of Quality Management & Regulatory Affairs at Schaerer Medical AG and prior to joining Sequana Medical held the position of Manager & Team Leader Regulatory Affairs at Medela AG. His experience includes the establishment of quality management systems, auditing, international product registrations for Class I to Class III medical devices, ensuring compliance with applicable regulatory requirements as well as being the liaison to Notified Bodies and Health Authorities. Timur serves as member of quality and regulatory task forces and expert groups within Germany and Switzerland.

Dr Andreas Wirth is the Global Vice President Engineering of the Company. Andreas has over 12 years of experience within leading R&D departments in regulated industries. Most recently he was Director of R&D at Carl Zeiss Meditec and responsible for refractive surgery products. Previous to his time at Carl Zeiss Meditec he was the Head of metrology development at Schott and responsible for pharmaceutical primary packaging across 17 plants worldwide. Prior to this, he was head of R&D at medi Group managing seven small R&D groups in Germany, France and the US and project manager at Amaxa / Lonza Biologics of medical and laboratory devices. Andreas holds a PhD in applied science and studied physics at the University of Osnabrück, Germany.

Mr Martijn Blom is the Chief Commercial Officer of the Company. Mr Blom has over 15 years' experience in the life sciences industry. Most recently he was the Director of International Marketing at Myriad Genetics, responsible for the marketing development of genetic testing in the international markets. Previous to Myriad, Martijn worked as Director of Marketing and Market Development at PulmonX, a start up from Redwood City focusing on developing and marketing minimally-invasive medical devices and technologies to expand and improve treatment options for emphysema patients. Prior to this Martijn was Director, International Marketing with Alere where he spent more than 7 years leading the marketing, training and marketing communications teams, for all of their business units: Cardiology, Women's Health, Oncology, Infectious Diseases, Blood Borne Pathogens, Toxicology and Health Management.

Martijn studied economics at the MEAO in Breda and specialized at de Rooi Pannen in Marketing and Sales management.

Mr Dragomir Lakic is the Global Vice President Manufacturing of the Company. Dragomir spent almost his whole career in the field of medical devices, with 15 years at Zimmer Biomet and Smith + Nephew, and brings an in-depth knowledge of the medical device industry. He joined Sequana Medical from Smith + Nephew, a leading portfolio medical technology company where he was responsible for planning, procurement, logistics, and supply chain. Before joining Smith + Nephew, he had a successful 12-year career at Zimmer Biomet, holding progressively senior leadership positions in Engineering and Manufacturing. Dragomir holds a degree in Engineering and Management from the University of Applied Sciences and Arts of Italian Switzerland and a Master of Business Administration (MBA) degree from the ZHAW (Zurich University of Applied Sciences).

The business address of each of the members of the Executive Management for the purpose of their mandate is the address of the Company's registered office: Kortrijksesteenweg 1112 bus 102, 9051 Sint-Denijs-Westrem, Belgium.

2.5 Board of Directors

The Company has opted for a "one tier" governance structure whereby the Board of Directors is the ultimate decision making body, with the overall responsibility for the management and control of the Company, and is authorised to carry out all actions that are considered necessary or useful to achieve the Company's object. The Board of Directors has all powers except for those reserved to the general shareholders' meeting by law or the Company's articles of association. The Board of Directors acts as a collegiate body.

Pursuant to the Company's Corporate Governance Charter (approved by the Board of Directors on 23 April 2020), the role of the Board of Directors is to pursue sustainable value creation by the Company, by determining the Company's strategy, putting in place effective, responsible and ethical leadership, and monitoring the Company's performance. The Board of Directors decides on the Company's values and strategy, its risk appetite and key policies.

The Board of Directors is assisted by specialized committees in order to advise the board in respect of decisions to be taken, to give comfort to the board that certain issues have been adequately addressed and, if necessary, to bring specific issues to the attention of the board. The decision-making should remain the collegial responsibility of the Board of Directors.

The Board of Directors appoints and removes the Chief Executive Officer and determines his or her powers. The Chief Executive Officer is responsible for the day-to-day management of the Company and the implementation of the Company's mission, its strategy and the targets set by the Board of Directors, with a focus on the long-term future growth of the business. He or she may be granted additional well-defined powers by the Board of Directors. He or she has direct operational responsibility for the Company and oversees the organisation and day-to-day management of subsidiaries, affiliates and joint ventures. The Chief Executive Officer is responsible for the execution and management of the outcome of all decisions of the Board of Directors. The Chief Executive Officer reports directly to the Board of Directors.

Pursuant to the Belgian Companies and Associations Code and the Company's articles of association, the Board of Directors must consist of at least three directors. The Company's Corporate Governance Charter (approved by the Board of Directors on 23 April 2020), provides that the composition of the Board of Directors should ensure that decisions are made in the corporate interest. It should be determined so as to gather sufficient expertise in the Company's areas of activity as well as sufficient diversity of skills, background, age and gender. Pursuant to the 2020 Belgian Corporate Governance Code, at least half of the directors must be non-executive and at least three directors must be independent in accordance with the criteria set out in the Belgian Companies and Associations Code and in the 2020 Belgian Corporate Governance Code. By 1 January 2025, at least one third of the members of the Board of Directors must be of the opposite gender. On the date of this report, the composition of the Board of Directors complies with the aforementioned statutory rules on gender diversity.

The directors are elected by the Company's general shareholders' meeting. The term of the directors' mandates cannot exceed four (4) years. Resigning directors can be re-elected for a new term. Proposals by the Board of Directors for the appointment or re-election of any director must be based on a recommendation by the board. In the event the office of a director becomes vacant, the remaining directors can appoint a successor temporarily filling the vacancy until the next general shareholders' meeting.

The general shareholders' meeting can dismiss the directors at any time. The Belgian Companies and Associations Code provides however that the general shareholders' meeting may, at the occasion of the termination, determine the date on which the mandate ends or grant a severance pay.

The Board of Directors elects a chair from among its non-executive members on the basis of his knowledge, skills, experience and mediation strength. The chair should be a person trusted for his or her professionalism, independence of mind, coaching capabilities, ability to build consensus, and communication and meeting management skills. The chair is responsible for the leadership and the proper and efficient functioning of the Board of Directors. He or she leads the meetings of the Board of Directors and ensures that there is sufficient time for consideration and discussion before decision-making.

On the date of this report, Mr Pierre Chauvineau is chair of the Board of Directors and Mr Ian Crosbie is the Chief Executive Officer. If the Board of Directors envisages appointing a former Chief Executive Officer as chair, it should carefully consider the positive and negative implications of such a decision and disclose why such appointment will not hamper the required autonomy of the Chief Executive Officer.

The Board of Directors should meet as frequently as the interest of the Company requires, or at the request of one or more directors. In principle, the Board of Directors will meet sufficiently regularly and at least five (5) times per year. The decisions of the Board of Directors are made by a simple majority of the votes cast. The chair of the Board of Directors will have a casting vote.

During 2022, 12 meetings of the Board of Directors were held.

2.6 Committees of the Board of Directors

The Board of Directors has established two board committees which are responsible for assisting the Board of Directors and making recommendations in specific fields: the audit committee (in accordance with Article 7:99 of the Belgian Companies and Associations Code and provision 4.10 of the 2020 Belgian Corporate Governance Code) and the remuneration and nomination committee (in accordance with Article 7:100 of the Belgian Companies and Associations Code and provision 4.17 and 4.19 of the 2020 Belgian Corporate Governance Code). The terms of reference of these board committees are primarily set out in the Corporate Governance Charter of the Company (approved by the Board of Directors on 23 April 2020).

2.6.1 Audit Committee

The audit committee of the Company consists of three directors. According to the Belgian Companies and Associations Code, all members of the audit committee must be non-executive directors, and at least one member must be independent within the meaning of Article 7:87 of the Belgian Companies and Associations Code. The chair of the audit committee is to be appointed by the members of the audit committee. On the date of this report, the following directors are the members of the audit committee: Mr

Wim Ottevaere (WIOT BV), Mr Pierre Chauvineau and Mrs Alexandra Clyde. The composition of the audit committee complies with the 2020 Belgian Corporate Governance Code, which require that a majority of the members of the audit committee are independent.

The members of the audit committee must have a collective competence in the business activities of the Company as well as in accounting, auditing and finance, and at least one member of the audit committee must have the necessary competence in accounting and auditing. According to the Board of Directors, the members of the audit committee satisfy this requirement, as evidenced by the different senior management and director mandates that they have held in the past and currently hold.

The role of the audit committee is to:

- inform the Board of Directors of the result of the audit of the financial statements and the manner in which the audit has contributed to the integrity of the financial reporting and the role that the audit committee has played in that process;
- monitor the financial reporting process, and to make recommendations or proposals to ensure the integrity of the process;
- monitor the effectiveness of the internal control and risk management systems, and the Company's internal audit process and its effectiveness;
- monitor the audit of the financial statements, including the follow-up questions and recommendations by the statutory auditor;
- assess and monitor the independence of the statutory auditor, in particular with respect to the appropriateness of the provision of additional services to the Company. More specifically, the audit committee analyses, together with the statutory auditor, the threats for the statutory auditor's independence and the security measures taken to limit these threats, when the total amount of fees exceeds the criteria specified in Article 4 §3 of Regulation (EU) No 537/2014; and
- make recommendations to the Board of Directors on the selection, appointment and remuneration of the statutory auditor of the Company in accordance with Article 16 § 2 of Regulation (EU) No 537/2014.

The audit committee should have at least four regularly scheduled meetings each year. The audit committee regularly reports to the Board of Directors on the exercise of its missions, and at least when the Board of Directors approves the financial statements and the condensed or short form financial information that will be published. The members of the audit committee have full access to the Executive Management and to any other employee to whom they may require access in order to carry out their responsibilities.

Without prejudice to the statutory provisions which determine that the statutory auditor must address reports or warnings to the corporate bodies of the Company, the statutory auditor must discuss, at the request of the statutory auditor, or at the request of the audit committee or of the Board of Directors, with the audit committee or with the Board of Directors, essential issues which are brought to light in the exercise of the statutory audit of the financial statements, which are included in the additional statement to the audit committee, as well as any meaningful shortcomings discovered in the internal financial control system of the Company.

During 2022, 5 meetings of the audit committee were held.

2.6.2 *Remuneration and Nomination Committee*

The remuneration and nomination committee consists of at least three directors. In line with the Belgian Companies and Associations Code, the 2020 Belgian Corporate Governance Code (i) all members of the remuneration and nomination committee are non-executive directors, (ii) the remuneration and nomination committee consists of a majority of independent directors and (iii) the remuneration and nomination committee is chaired by the chair of the Board of Directors or another non-executive director appointed by the committee. On the date of this report, the following directors are the members of the remuneration and nomination committee: Dr Rudy Dekeyser, Mr Doug Kohrs and Mrs Jackie Fielding.

Pursuant to the Belgian Companies and Associations Code, the remuneration and nomination committee must have the necessary expertise in terms of remuneration policy, which is evidenced by the experience and previous roles of its current members.

The Chief Executive Officer participates in the meetings of the remuneration and nomination committee in an advisory capacity each time the remuneration of another member of the Executive Management is being discussed.

The role of the remuneration and nomination committee is to make recommendations to the Board of Directors with regard to the appointment and remuneration of directors and members of the Executive Management and, in particular, to:

- identify, recommend and nominate, for the approval of the Board of Directors, candidates to fill vacancies in the Board of Directors and Executive Management positions as they arise. In this respect, the remuneration and nomination committee must consider and advise on proposals made by relevant parties, including management and shareholders;
- advise the Board of Directors on any proposal for the appointment of the Chief Executive Officer and on the Chief Executive Officer's proposals for the appointment of other members of the Executive Management;
- draft appointment procedures for members of the Board of Directors and the Chief Executive Officer;
- ensure that the appointment and re-election process is organised objectively and professionally;
- periodically assess the size and composition of the Board of Directors and make recommendations to the Board of Directors with regard to any changes;
- consider issues related to succession planning;
- make proposals to the Board of Directors on the remuneration policy for directors and members of the Executive Management and the persons responsible for the day-to-day management of the Company, as well as, where appropriate, on the resulting proposals to be submitted by the Board of Directors to the shareholders' meeting;
- make proposals to the Board of Directors on the individual remuneration of directors and members of the Executive Management, and the persons responsible for the day-to-day management of the Company, including variable remuneration and long-term incentives, whether or not share-related, in the form of share options or other financial instruments, and arrangements on early termination, and where applicable, on the resulting proposals to be submitted by the Board of Directors to the shareholders' meeting;
- prepare a remuneration report to be included by the Board of Directors in the annual Corporate Governance Statement;
- present and provide explanations in relation to the remuneration report at the annual shareholders' meeting; and
- report regularly to the Board of Directors on the exercise of its duties.

In principle, the remuneration and nomination committee meets as frequently as necessary for carrying out its duties, but at least two times a year.

In 2022, 2 meetings of the remuneration and nomination committee were held.

2.7 Activity Report and Attendance at Board and Committee Meetings during 2022

The table summarises the attendance of meetings of the Board of Directors and the respective committees of the Board of Directors by their (former and current) members in person or by conference call. It does not take into account attendance via representation by proxy.

Name	Board Meeting[I]	Audit	Nomination and remuneration
Mr Pierre Chauvineau	12 out of 12 meetings	5 out of 5 meetings	2 out of 2 meetings[II]
Mr Ian Crosbie	11 out of 12 meetings	5 out of 5 meetings[II]	2 out of 2 meetings[II]
Mr Rudy Dekeyser[III]	11 out of 12 meetings	N/A[IV]	2 out of 2 meetings
Mr Erik Amble[V]	10 out of 12 meetings	3 out of 5 meetings	N/A[IV]
Mr Wim Ottevaere[VI] [VII]	12 out of 12 meetings	5 out of 5 meetings	1 out of 2 meetings
Mrs Jackie Fielding	11 out of 12 meetings	N/A[IV]	2 out of 2 meetings
Mrs Alexandra Clyde[VIII]	2 out of 12 meetings	2 out of 5 meetings	N/A[IV]
Mr Doug Kohrs[IX]	2 out of 12 meetings	N/A[IV]	1 out of 2 meetings

2.8 Independent Directors

A director in a listed company is considered to be independent if he or she does not have a relationship with that company or with a major shareholder of the Company that compromises his or her independence. If the director is a legal entity, his or her independence must be assessed on the basis of both the legal entity and his or her permanent representative. A director will be presumed to qualify as an independent director if he or she meets at least the criteria set out in Article 7:87 of the Belgian Companies and Associations Code and Clause 3.5 of the 2020 Corporate Governance Code, which can be summarised as follows:

1. Not being an executive, or exercising a function as a person entrusted with the daily management of the Company or an affiliated company or person, and not have been in such a position for the previous three years before their appointment. Alternatively, no longer enjoying stock options of the Company related to this position;
2. Not having served for a total term of more than twelve years as a non-executive board member;
3. Not being an employee of the senior management (as defined in Article 19,2° of the law of 20 September 1948 regarding the organisation of the business industry) of the Company or an affiliated company or person, and not have been in such a position for the previous three years before their appointment. Alternatively, no longer enjoying stock options of the Company related to this position;
4. Not receiving, or having received during their mandate or for a period of three years prior to their appointment, any significant remuneration or any other significant advantage of a patrimonial nature from the Company or an affiliated company or person, apart from any fee they receive or have received as a non-executive board member;
5. Not holding shares, either directly or indirectly, either alone or in concert, representing globally one tenth or more of the Company's share capital or one tenth or more of the voting rights in the company at the moment of appointment;
6. Not having been nominated, in any circumstances, by a shareholder fulfilling the conditions covered under point 5;
7. Not having, nor having had in the past year before their appointment, a significant business relationship with the Company or an affiliated company or person, either directly or as partner, shareholder, board member, member of the senior management (as defined in Article 19,2° of the law of 20 September 1948 regarding the organisation of the business industry) of a company or person who maintains such a relationship;
8. Not being or having been within the last three years before their appointment, a partner or member of the audit team of the Company or person who is, or has been within the last three years before their appointment, the external auditor of the Company or an affiliated company or person;
9. Not being an executive of another company in which an executive of the Company is a non-executive board member, and not have other significant links with executive board members of the Company through involvement in other companies or bodies;
10. Not being, in the Company or an affiliated company or person, a spouse, legal partner or close family member to the second degree, exercising a function as board member or executive or person entrusted with the daily management or employee of the senior management (as defined in Article 19,2° of the law of 20 September 1948 regarding the organisation of the business industry), or falling in one of the other cases referred to in the points 1 to 9 above, and as far as point 2 is concerned, up to three years after the date on which the relevant relative has terminated their last term.

If the Board of Directors submits the nomination of an independent director who does not meet the above-mentioned criteria to the general meeting, it shall explain the reasons why it assumes that the candidate is in fact independent.

Mr Pierre Chauvineau, Mr Wim Ottevaere (WIOT BV), Mrs Jackie Fielding, Mrs Alexandra Clyde and Mr Doug Kohrs are the Company's current independent directors.

The Company is of the view that the independent directors comply with each of the criteria of the Belgian Companies and Associations Code and the 2020 Belgian Corporate Governance Code.

2.9 Performance Review of the Board of Directors

The Board of Directors will evaluate, through a formal process and at least every three years, its own performance and its interaction with the Executive Management, as well as its size, composition, and functioning and that of its committees.

The evaluation assesses how the Board of Directors and its committees operate, checks that important issues are effectively prepared and discussed, evaluates each director's contribution and constructive involvement, and assesses the present composition of the Board of Directors and its committees against

(I) 1 of the 12 board meetings was a private board meeting of Independent Directors (as envisaged by article 7:97 BCAC). More information is included in section 1.11 of the Report of the Board of Directors.
(II) The board member attended the meeting as an observer.
(III) The board member is chairman of the Renumeration and Nomination Committee
(IV) The board member is not a member of the specific committee.
(V) On 25 August 2022, it has been announced that Mr Erik Amble resigned as member of the Board of Directors. Mr. Amble continued to be observer (in a non-voting capacity) to the Board of Directors.
(VI) Acting as permanent representative of WIOT BV.
(VII) The board member is chairman of the Audit Committee
(VIII) On 25 August 2022, it has been announced that Mrs Alexandra Clydes appointment as member of the Board of Directors would be submitted to a general shareholders meeting. Ms. Clydes appointment has been approved by the Extraordinary General Meeting of shareholders of 10 February 2023. Pending such approval, Mrs Clyde already participated to board and committee meetings.
(IX) On 19 July 2022, it has been announced that Mr Doug Kohrs appointment as member of the Board of Directors would be submitted to a general shareholders meeting. Mr Kohrs appointment has been approved by the extraordinary general meeting of shareholders of 10 February 2023. Pending such approval, Mr Kohrs already participated to board and committee meetings.

the desired composition. This evaluation takes into account the members' general role as director, and specific roles as chair, chair or member of a committee of the Board of Directors, as well as their relevant responsibilities and time commitment. At the end of each board member's term, the remuneration and nomination committee should evaluate this board member's presence at the board or committee meetings, their commitment and their constructive involvement in discussions and decision-making in accordance with a pre-established and transparent procedure. The remuneration and nomination committee should also assess whether the contribution of each board member is adapted to changing circumstances.

The board will act on the results of the performance evaluation. Where appropriate, this will involve proposing new board members for appointment, proposing not to re-appoint existing board members or taking any measure deemed appropriate for the effective operation of the board.

Non-executive directors assess their interaction with the Executive Management on a continuous basis.

2.10 Executive Management and Chief Executive Officer

2.10.1 Executive Management

The Executive Management is composed of two members and is led by the Chief Executive Officer. Its members are appointed by the Board of Directors on the basis of a recommendation by the remuneration and nomination committee. The Executive Management is responsible and accountable to the Board of Directors for the discharge of its responsibilities.

The Executive Management is responsible for:

- being entrusted with the operational leadership of the Company;
- formulating proposals to the board in relation to the Company's strategy and its implementation;
- proposing a framework for internal control (i.e. systems to identify, assess, manage and monitor financial and other risks) and risk management, and putting in place internal controls, without prejudice to the board's monitoring role, and based on the framework approved by the Board of Directors;
- presenting to the Board of Directors complete, timely, reliable and accurate financial statements, in accordance with the applicable accounting standards and policies of the Company;
- preparing the Company's mandatory disclosure of the financial statements and other material financial and non-financial information;
- presenting the Board of Directors with a balanced and understandable assessment of the Company's financial situation;
- preparing the Company's yearly budget to be submitted to the Board of Directors;
- timely providing the Board of Directors with all information necessary for it to carry out its duties;
- being responsible and accountable to the Board of Directors for the discharge of its responsibilities;
- implementing the decisions made and the policies, plans and policies approved by the board and deal with such other matters as are delegated by the Board of Directors from time to time.

2.10.2 Chief Executive Officer

The Chief Executive Officer is responsible for the day-to-day management of the Company and the implementation of the Company's mission, its strategy and the targets set by the Board of Directors, with a focus on the long-term future growth of the business. He or she may be granted additional well-defined powers by the Board of Directors. The Chief Executive Officer is responsible for the execution and management of the outcome of all decisions of the Board of Directors.

The Chief Executive Officer leads the Executive Management within the framework established by the Board of Directors and under its ultimate supervision. The Chief Executive Officer is appointed and removed by the Board of Directors and reports directly to it.

2.11 Conflicts of Interest

Directors are expected to arrange their personal and business affairs so as to avoid conflicts of interest with the Company. Any director with a conflicting financial interest (as contemplated by Article 7:96 of the Belgian Companies and Associations Code) on any matter before the Board of Directors must bring it to the attention of both the statutory auditor and fellow directors, and take no part in any deliberation or voting related thereto. The Corporate Governance Charter of the Company (approved by the Board of Directors on 23 April 2020), contains the procedure for transactions between the Company and the directors which are not covered by the legal provisions on conflicts of interest. The Corporate Governance Charter (approved by the Board of Directors on 23 April 2020), contains a similar procedure for transactions between the Company and members of the Executive Management.

To the knowledge of the Company, there are, on the date of this report, no potential conflicts of interests between any duties to the Company of the members of the Board of Directors and members of the Executive Management and their private interests and/or other duties.

On the date of this report, there are no outstanding loans granted by the Company to any of the members of the Board of Directors and members of the Executive Management, nor are there any guarantees provided by the Company for the benefit of any of the members of the Board of Directors and members of the Executive Management.

None of the members of the Board of Directors and members of the Executive Management has a family relationship with any other of the members of the Board of Directors and members of the Executive Management.

2.12 Dealing Code

With a view to preventing market abuse (insider dealing and market manipulation), the Board of Directors has established a dealing code. The dealing code describes the declaration and conduct obligations of directors, members of the Executive Management, certain other employees and certain other persons with respect to transactions in shares and other financial instruments of the Company. The dealing code sets limits on carrying out transactions in shares and other financial instruments of the Company, and allows dealing by the above mentioned persons only during certain windows.

2.13 Internal Control and Risk Management

2.13.1 Introduction

The Sequana Medical Group operates a risk management and control framework in accordance with the Belgian Companies and Associations Code and the 2020 Corporate Governance Code. The Sequana Medical Group is exposed to a wide variety of risks within the context of its business operations that can result in its objectives being affected or not achieved. Controlling those risks is a core task of the Board of Directors (including the audit committee), the executive management and the management Team and all other employees with managerial responsibilities.

The risk management and control system has been set up to reach the following goals:

- achievement of the Sequana Medical Group objectives;
- achieving operational excellence;
- ensuring correct and timely financial reporting; and
- compliance with all applicable laws and regulations.

2.13.2 Control Environment

Three lines of defence

The Sequana Medical Group applies the 'three lines of defence model' to clarify roles, responsibilities and accountabilities, and to enhance communication within the area of risk and control. Within this model, the lines of defence to respond to risks are:

- First line of defence: line management is responsible for assessing risks on a day-to-day basis and implementing controls in response to these risks.
- Second line of defence: the oversight functions like Finance and Controlling and Quality and Regulatory oversee and challenge risk management as executed by the first line of defence. The second line of defence functions provide guidance and direction and develop a risk management framework.
- Third line of defence: independent assurance providers such as external accounting and external audit challenge the risk management processes as executed by the first and second line of defence.

Policies, procedures and processes

The Sequana Medical Group fosters an environment in which its business objectives and strategy are pursued in a controlled manner. This environment is created through the implementation of different Company-wide policies, procedures and processes such as the Sequana Medical Group values, the Quality Management System and the Delegation of Authorities rule set. The Executive and Senior Management fully endorses these initiatives.

The employees are regularly informed and trained on these subjects in order to develop sufficient risk management and control at all levels and in all areas of the organization.

Group-wide Financial System

The Sequana Medical Group entities operate the same group-wide financial system which are managed centrally. This system embeds the roles and responsibilities defined at the Sequana Medical Group level. Through these systems, the main flows are standardized and key controls are enforced. The systems also allow detailed monitoring of activities and direct access to data.

2.13.3 Risk management

Sound risk management starts with identifying and assessing the risks associated with the Sequana Medical Group's business and external factors. Once the relevant risks are identified, the Company strives to prudently manage and minimize such risks, acknowledging that certain calculated risks are necessary to ensure that the Sequana Medical Group achieves its objectives and continues to create value for its stakeholders. All employees of the Sequana Medical Group are accountable for the timely identification and qualitative assessment of the risks within their area of responsibility.

2.13.4 Control activities

Control measures are in place to minimize the effect of risks on Sequana Medical Group's ability to achieve its objectives. These control activities are embedded in the Sequana Medical Group's key processes and systems to assure that the risk responses and the Sequana Medical Group's overall objectives are carried out as designed. Control activities are conducted throughout the organization, at all levels and within all departments.

Key compliance areas are monitored for the entire Sequana Medical Group by the Quality and Regulatory department and the Finance and Controlling department. In addition to these control activities, an insurance program is implemented for selected risk categories that cannot be absorbed without material effect on the Company's statement of financial position.

2.13.5 Information and communication

The Sequana Medical Group recognizes the importance of timely, complete and accurate communication and information both top-down as well as bottom-up. The Sequana Medical Group therefore put several measures in place to assure amongst others:

- security of confidential information;
- clear communication about roles and responsibilities; and
- timely communication to all stakeholders about external and internal changes impacting their areas of responsibility.

2.13.6 Monitoring of control mechanisms

Monitoring helps to ensure that internal control systems operate effectively.

The quality of the Sequana Medical Group's risk management and control framework is assessed by the following functions:

- **Quality and Regulatory**: Within the Quality Management System (QMS) according to ISO 13485:2016, MDSAP and MDR 2017/745, Sequana Medical has a systematic process for identifying hazards and hazardous situations associated with Sequana Medical devices and their use, estimating and evaluating the associated risks, controlling and documenting the risks, and monitoring the effectiveness of controls. This risk management process is based on the standard EN ISO 14971:2012 / ISO 14971:2019. Sequana Medical's QMS is subject to internal audits by the Quality and Regulatory department and external audits by the Notified Body and Auditing Organization BSI. The suitability and effectiveness of the QMS will also evaluated as part of the annual management review.
- **External Audit**: In Sequana Medical's review of the annual accounts, the statutory auditor focuses on the design and effectiveness of internal controls and systems relevant for the preparation of the financial statements. The outcome of the audits, including work on internal controls, is reported to management and the audit committee.
- **Audit Committee**: The Board of Directors and the audit committee have the ultimate responsibility with respect to internal control and risk management. For more detailed information on the composition and functioning of the audit committee, see section 2.4.1. of this Corporate Governance Statement.

2.13.7 Risk management and internal control with regard to the process of financial reporting

The accurate and consistent application of accounting rules throughout the Sequana Medical Group is assured by means of set of control procedures. On an annual basis, a bottom-up risk analysis is conducted to identify risk factors. Action plans are defined for all key risks.

Specific identification procedures for financial risks are in place to assure the completeness of financial accruals.

The accounting team is responsible for producing the accounting figures, whereas the controlling team checks the validity of these figures. These checks

include coherence tests by comparison with historical and budget figures, as well as sample checks of transactions according to their materiality.

Specific internal control activities with respect to financial reporting are in place, including the use of a periodic closing and reporting checklist. This checklist assures clear communication of timelines, completeness of tasks, and clear assignment of responsibilities.

Uniform reporting of financial information throughout the Sequana Medical Group ensures a consistent flow of information, which allows the detection of potential anomalies. The Group's financial systems and management information tools allow the central controlling team direct access to integrated financial information.

An external financial calendar is planned in consultation with the Board and the Executive Management, and this calendar is announced to the external stakeholders. The objective of this external financial reporting is to provide Sequana Medical Group stakeholders with the information necessary for making sound business decisions. The financial calendar can be consulted on https://www.sequanamedical.com/investors/financial-information.

2.14 Principal Shareholders

The Company has an international shareholder base with both large and smaller specialised shareholders focused on the healthcare and life sciences sectors, and a number of more local retail investors.

The table provides an overview of the shareholders that notified the Company of their shareholding in the Company pursuant to applicable transparency disclosure rules up to 31 December 2022.

It should be noted that the Company has received updated transparency notifications after 31 December 2022. The most recent update of principal shareholder overview, as well as the most recent transparency notifications, are available on Sequana Medical's website (https://www.sequanamedical.com/investors/shareholder-information/). Although the applicable transparency disclosure rules require that a disclosure be made by each person passing or falling under one of the relevant thresholds, it is possible that the information included in such transparency notifications in relation to a shareholder is no longer up-to-date.

		On a non-diluted basis
	Date of Notification	% of the voting rights attached to Shares[I]
NeoMed IV Extension L.P. / NeoMed Innovation V L.P. / Dr. Erik Amble[II]	14 March 2022	18.06
Partners in Equity V B.V.[III]	16 March 2022	15.31
Société Fédérale de Participations et d'Investissement SA – Federale Participatie- en Investeringsmaatschappij NV / Belfius Insurance NV/SA[IV]	18 February 2020	12.70
Participatiemaatschappij Vlaanderen NV[V]	18 February 2019	9.70
LSP Health Economics Fund Management B.V.[VI]	19 February 2021	9.25

(I) The percentage of voting rights is calculated on the basis of the number of outstanding Shares at the date of the notification. On 31 December 2022, the share capital of the Company amounts to EUR 2,460,486.98. It is divided into 23,746,528 Shares of no nominal value, each representing the same fraction of the share capital.

(II) A parent undertaking or a controlling person of NeoMed IV Extension L.P. ("**NeoMed IV**") and NeoMed Innovation V L.P. ("**NeoMed V**") and NeoMed Management (Jersey) Limited ("**NeoMed Management**") informed the Company, by means of a notification dated 14 March 2022, that on 10 March 2022 the aggregate shareholding of NeoMed IV and NeoMed V passively crossed belowthe threshold of 20% of the outstanding voting rights of the Company. Notably, it followed from the notification that an aggregate of 4,288,988 Shares, representing 18.06% of the 23,746,528 outstanding Shares and voting rights of the Company, is held through the following entities : NeoMed IV (holding 2,853,673 voting securities) and NeoMed V (holding 1,417,134 voting securities). The notification furthermore specified that NeoMed IV and NeoMed V are each a private limited company incorporated in Jersey, and are each controlled by their investment manager NeoMed Management (a private limited company incorporated in Jersey) and that NeoMed Management is controlled by Dr. Erik Amble, Claudio Nessi, Dina Chaya and Pål Jensen within the meaning of articles 1:14 and 1:16 of the Belgian Companies and Associations Code. The notification also stated that (a) NeoMed IV and NeoMed V do not own the securities of the Company but manage funds that own the voting rights attached to the securities, and (b) as general partners to their funds, NeoMed IV and NeoMed V exercise the voting rights attached to the securities at their discretion in the absence of specific instructions.

(III) A parent undertaking or a controlling person of PiE (as defined above) and Partners in Equity III B.V. ("**PiE III**"), informed the Company, by means of a notification dated 16 March 2022, that, on 10 March 2022 PiE's shareholding crossed the threshold of 15% of the outstanding voting rights of the Company. Notably, it followed from the notification that PiE held 3,636,363 Shares, representing 15.31% of the 23,746,528 outstanding Shares and voting rights of the Company. The notification furthermore specified that PiE V is 100% owned by PiE III and that no natural or legal person has exclusive control of PiE III.

(IV) A parent undertaking or a controlling person of Société Fédérale de Participations et d'Investissement SA / Federale Participatie- en Investeringsmaatschappij NV ("**SFPI-FPIM**"), Belfius Bank NV/SA and Belfius Insurance, informed the Company, by means of a notification dated 18 February 2020, that the aggregate shareholding of SFPI-FPIM and Belfius Insurance crossed the threshold of 10% of the outstanding voting rights of the Company on 17 February 2020. Notably, it followed from the notification that an aggregate of 2,004,358 Shares, representing 12.70% of the then 15,778,566 outstanding Shares and voting rights of the Company, were held through the following entities: SFPI-FPIM (holding 1,297,234 voting securities) and Belfius Insurance (holding 707,124 voting securities). The joint notification specified furthermore that SFPI-FPIM is the parent company of Belfius Bank NV/SA (ex Dexia Banque SA), which in its turn is the parent company of Belfius Insurance. The notification also stated that SFPI-FPIM acts in its own name, but on behalf of the Belgian State and that it is owned for 100% by the Belgian State. It followed from the notification that Belfius Bank NV/SA did not own any voting securities or voting rights in the Company.

(V) A parent undertaking or a controlling person of Participatiemaatschappij Vlaanderen NV ("**PMV**"), informed the Company, by means of a notification dated 18 February 2019 that, as a result of the completion of the initial public offering, on 11 February 2019, PMV's shareholding crossed the threshold of 5% of the outstanding voting rights of the Company. Notably, it followed from the notification that PMV held 1,223,906 Shares, representing 9.70% of the then 12,611,900 outstanding Shares and voting rights of the Company. The notification further specified that PMV is controlled by the Flemish Region within the meaning of the articles 5 and 7 of the Belgian Companies Code of 7 May 1999 and that the Flemish Region is not controlled.

(VI) A parent undertaking or a controlling person of LSP Management Group B.V. ("**LSP Management Group**") and LSP Health Economics Fund Management B.V. ("**LSP**"), informed the Company, by means of a notification dated 19 February 2021 that LSP's shareholding crossed belowthe threshold of 10% of the outstanding voting rights of the Company on 15 February 2021. Notably, it followed from the notification that LSP held 1,706,077 Shares, representing 9.25% of the then 18,438,435 outstanding Shares and voting rights of the Company. The notification specified furthermore that LSP is controlled by LSP Management Group within the meaning of the articles 1:14 and 1:16 of the Belgian Companies and Associations Code and that LSP Management Group is not a controlled company. The notification also stated that LSP was not an owner of the Shares of the Company, but manages the funds that own the Shares of the Company, that LSP exercises the voting rights of the Shares held by the funds as a management company, including the voting rights associated with the Company's Shares, that LSP can exercise the voting rights of the funds at its own discretion at the general meeting of shareholders of the Company, and that LSP HEF Sequana Holding B.V. is the fund that owns the shares in the Company as of the date of notification.

		On a non-diluted basis
	Date of Notification	% of the voting rights attached to Shares[I]
Newton Biocapital I SA[I]	15 March 2022	4.64
GRAC Société Simple[II]	22 March 2022	4.25
Sensinnovat BV[III]	15 March 2022	3.79

No other shareholders, acting alone or in concert with other shareholders, notified the Company of a participation or an agreement to act in concert in relation to 3% or more of the current total existing voting rights attached to the voting securities of the Company.

Copies of the abovementioned transparency notifications, are available on Sequana Medical's website (www.sequanamedical.com).

2.15 Share Capital and Shares

On 31 December 2022, the share capital of the Company amounted to EUR 2,460,486.98 and was fully paid-up. It was represented by 23,746,528 ordinary shares, each representing a fractional value of (rounded) EUR 0.1036 and representing one 23,746,528th of the share capital. The Company's shares do not have a nominal value.

In addition to the outstanding shares, the total number of outstanding subscription rights amounts to 2,465,508, which entitles their holders (if exercised) to subscribe to 2,636,623 new shares with voting rights in total, namely:

- 261,895 new shares can be issued upon the exercise of 90,780 share options that are still outstanding under the "Executive Share Options" plan for staff members and consultants of the Company, entitling the holder thereof to acquire ca. 2.88 shares when exercising one of his or her share options (the "**Executive Share Options**"); and
- 1,071,924 new shares can be issued upon the exercise of 1,071,924 2018 share options (each share option having the form of a subscription right) that are still outstanding under the "2018 Share Options" plan for directors, employees and other staff members of the Company and its subsidiaries, entitling the holder thereof to acquire one new share when exercising one of his or her share options (the "**2018 Share Options**")
- 1,000,000 new shares can be issued upon the exercise of 1,000,000 share options (each share option having the form of a subscription right) that are still outstanding under the "2021 Share Options" plan for directors, employees and other staff members of the Company and its subsidiaries, entitling the holder thereof to acquire one new share when exercising one of his or her share options (the "**2021 Share Options**")

(I) Newton Biocapital I SA ("**Newton Biocapital**") (acting as a person that notifies alone) informed the Company, by means of a notification dated 15 March 2022, of the passive crossing of a threshold. The notification furthermore specified that Newton Biocapital is not a controlled entity on 10 March 2022. Notably, it followed from the notification that Newton Biocapital held 1,102,529 Shares, representing 4.64% of the 23,746,528 outstanding Shares and voting rights of the Company. The notification also stated that Newton Biocapital acts as discretionary asset manager and holds the voting rights attached to the shares on behalf of its clients, which it can exercise at its own discretion without instructions from its clients.

(II) GRAC société simple ("**GRAC**") (acting as a person that notifies alone) informed the Company, by means of a notification dated 22 March 2022, that, on 10 March 2022, the shareholding of GRAC passively crossed belowthe threshold of 5% of the outstanding voting rights of the Company. Notably, it followed from the notification that GRAC held 1,008,333 Shares, representing 4.25% of the 23,746,528 outstanding Shares and voting rights of the Company. The notification further specified that GRAC is not controlled by another entity or holding.

(III) A parent undertaking or a controlling person of Sensinnovat BV ("**Sensinnovat**") informed the Company, by means of a notification dated 15 March 2022, that, on 10 March 2022 Sensinnovat's shareholding crossed the threshold of 3% of the outstanding voting rights of the Company. Notably, it followed from the notification that Sensinnovat holds 900,769 Shares, representing 3.79% of the 23,746,528 outstanding Shares and voting rights of the Company. The notification furthermore specified that Sensinnovat is jointly controlled by Rudi de Winter and Françoise Chombar via Maatschap Chione.

- 302,804 new shares can be issued to Bootstrap Europe S.C.SP. upon the exercise of 10 warrants (each warrant having the form of a subscription right) that are still outstanding (at the date of this report) that have been issued by the extraordinary shareholders meeting of 27 May 2022 (the "**Bootstrap Warrants**");
- 161,404 new shares can be issued to Kreos Capital VII Aggregator SCSp. upon the exercise of 875,000 warrants (each warrant having the form of a subscription right) that are still outstanding (at the date of this report) that have been issued by the extraordinary shareholders meeting of 10 February 2023 (the "**Kreos Subscription Rights**").

On 17 July 2020, the Company entered into a subordinated loan agreement with PMV/z-Leningen ("**PMV/z**") for an aggregate principal amount of maximum EUR 4.3 million, of which a loan for a principal amount of EUR 0.8 million can be converted by PMV/z for new ordinary shares of the Company in the event of a future equity financing or sale of the Company. The conversion can be carried out by means of a contribution in kind of the respective payable due by the Company under the loan (whether as principal amount or as interest) (the "**Convertible Loan Payable**") to the share capital of the Company. In December 2021, the Company entered into an amendment agreement, thereby (i) extending the duration of such loans, (ii) increasing the interest rates retroactively, and (iii) introducing payment by instalments. Consequently, the loans have a term of 60 months and are repayable in eight equal quarterly instalments between months 36 and 60. The convertible portion of the loan granted by PMV/z bears an interest rate of 5.5% per annum. The price per share at which the Convertible Loan Payable can be converted through a contribution in kind in the event of an equity financing or sale of the Company will be equal to 75% of the price of the Company's shares as will be reflected in the relevant equity financing or sale. PMV/z can exercise this right until 30 days as from the completion of such equity financing or sale of the Company.

2.15.1 Form and Transferability of the Shares

The shares of the Company can take the form of registered shares and dematerialized shares. All the Company's shares are fully paid-up and are freely transferable.

On 31 December 2022, all of the Company's shares have been admitted to trading on the regulated market of Euronext Brussels.

2.15.2 Currency

The Company's shares do not have a nominal value, but each reflect the same fraction of the Company's share capital, which is denominated in euro.

2.15.3 Voting Rights attached to the Shares

Each shareholder of the Company is entitled to one vote per share. Shareholders may vote by proxy, subject to the rules described in the Company's articles of association.

Voting rights can be mainly suspended in relation to shares:

- which are not fully paid up, notwithstanding the request thereto of the Board of Directors of the Company;
- to which more than one person is entitled or on which more than one person has rights in rem (zakelijke rechten/droits réels) on, except in the event a single representative is appointed for the exercise of the voting right vis-à-vis the Company;
- which entitle their holder to voting rights above the threshold of 3%, 5%, 10%, 15%, 20% and any further multiple of 5% of the total number of voting rights attached to the outstanding financial instruments of the Company on the date of

the relevant general shareholders' meeting, in the event that the relevant shareholder has not notified the Company and the FSMA at least 20 calendar days prior to the date of the general shareholders' meeting in accordance with the applicable rules on disclosure of major shareholdings; and
- of which the voting right was suspended by a competent court or the FSMA.

Pursuant to the Belgian Companies and Associations Code, the voting rights attached to shares owned by the Company, or a person acting in its own name but on behalf of the Company, or acquired by a subsidiary of the Company, as the case may be, are suspended.

Generally, the general shareholders' meeting has sole authority with respect to:

- the approval of the annual financial statements of the Company;
- the distribution of profits (except interim dividends);
- the appointment (at the proposal of the Board of Directors and upon recommendation by the remuneration and nomination committee) and dismissal of directors of the Company;
- the appointment (at the proposal of the Board of Directors and upon recommendation by the audit committee) and dismissal of the statutory auditor of the Company;
- the granting of release from liability to the directors and the statutory auditor of the Company;
- the determination of the remuneration of the directors and of the statutory auditor for the exercise of their mandate;
- the advisory vote on the remuneration report included in the annual report of the Board of Directors, the binding vote on the remuneration policy (which was approved for the first time by the general shareholders' meeting held on 27 May 2021, and was amended by the general shareholders' meetings held on 27 May 2022 and 10 February 2023), and subsequently upon every material change to the remuneration policy and in any case at least every four years, and the determination of the following features of the remuneration or compensation of directors, members of the Executive Management and certain other executives (as the case may be): (i) in relation to the remuneration of executive and non-executive directors, members of the Executive Management and other executives, an exemption from the rule that share based awards can only vest after a period of at least three years as of the grant of the awards, (ii) in relation to the remuneration of executive directors, members of the Executive Management and other executives, an exemption from the rule that (unless the variable remuneration is less than a quarter of the annual remuneration) at least one quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least two years and that at least another quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least three years, (iii) in relation to the remuneration of non-executive directors, any variable part of the remuneration (provided, however that no variable remuneration can be granted to independent non-executive directors), and (iv) any service agreements to be entered into with executive directors, members of the Executive Management and other executives providing for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration and nomination committee, eighteen (18) months' remuneration);
- the filing of a claim for liability against directors;
- the decisions relating to the dissolution, merger and certain other reorganisations of the Company; and
- the approval of amendments to the articles of association.

2.15.4 Dividends and Dividend Policy

All of the shares of the Company entitle the holder thereof to an equal right to participate in dividends (if any) in respect of the financial year ending 31 December 2022 and future years. All of the shares participate equally in the Company's profits (if any). Pursuant to the Belgian Companies and Associations Code, the shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the annual general shareholders' meeting, based on the most recent statutory audited financial statements, prepared in accordance with Belgian GAAP and based on a (non-binding) proposal of the Company's Board of Directors. In accordance with Belgian law, the right to collect dividends declared on shares expires five years after the date the Board of Directors has declared the dividend payable, whereupon the Company is no longer under an obligation to pay such dividends. The Belgian Companies and Associations Code and the Company's articles of association also authorise the Board of Directors to declare interim dividends without shareholder approval. The right to pay such interim dividends is, however, subject to certain legal restrictions. The Company has never declared or paid any cash dividends on its shares. The Company does not anticipate paying cash dividends on its equity securities in the foreseeable future and intends to retain all available funds and any future earnings for use in the operation and expansion of its business.

The Company's ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law on the basis of the Company's stand-alone statutory accounts prepared in accordance with Belgian GAAP. In particular, dividends can only be distributed if following the declaration and issuance of the dividends the amount of the Company's net assets on the date of the closing of the last financial year as follows from the statutory non-consolidated financial statements (i.e. summarised, the amount of the assets as shown in the statement of financial position, decreased with provisions and liabilities, all in accordance with Belgian accounting rules), decreased with, except in exceptional cases, to be disclosed and justified in the notes to the annual accounts, the non-amortised costs of incorporation and extension and the non-amortised costs for research and development, does not fall below the amount of the paid-up capital (or, if higher, the issued capital), increased with the amount of non-distributable reserves.

In addition, pursuant to Belgian law and the Company's articles of association, the Company must allocate an amount of 5% of its Belgian GAAP annual net profit (nettowinst/bénéfices nets) to a legal reserve in its stand-alone statutory accounts, until the legal reserve amounts to 10% of the Company's share capital. The Company's legal reserve currently does not meet this requirement. Accordingly, 5% of its Belgian GAAP annual net profit during future years will need to be allocated to the legal reserve, limiting the Company's ability to pay out dividends to its shareholders.

Furthermore, the aforementioned loan agreements entered into with PMV/z in July 2020 and amended in December 2021, also include protective covenants, which may limit the Company's ability (and require PMV/z's prior consent) to make distributions by way of dividends or otherwise and this so long as any monies or obligations, actual or contingent, are outstanding under the aforementioned loan agreements. Under the loan facility agreement entered into with Kreos Capital VII (UK) Limited on 19 July 2022, no distributions by way of dividend can be declared or made without consent of Kreos Capital VII (UK) Limited (other than the payment of a dividend to the Company by any of its directly or indirectly wholly owned subsidiaries)

Additional financial restrictions and other limitations may be contained in future credit agreements.

2.16 Information that has an impact in case of public takeover bids

The Company provides the following information in accordance with Article 34 of the Belgian Royal Decree dated 14 November 2007:

(i) The share capital (at the date of this report) of the Company amounts to EUR 2,460,487 and is fully paid-up. It is represented by 23,746,528 ordinary shares, each representing a fractional value of (rounded) EUR 0.1036 and representing one 23,746,528th of the share capital. The Company's shares do not have a nominal value.

(ii) Other than the applicable Belgian legislation on the disclosure of significant shareholdings and the Company's articles of association, there are no restrictions on the transfer of shares.

(iii) There are no holders of any shares with special control rights.

(iv) There are no share option plans for employees other than the share option plans disclosed elsewhere in this report. These share option plans contain provisions on accelerated vesting in case of change of control.

(v) Each shareholder of the Company is entitled to one vote per share. Voting rights may be suspended as provided in the Company's articles of association and the applicable laws and articles.

(vi) There are no agreements between shareholders which are known by the Company that may result in restrictions on the transfer of securities and/or the exercise of voting rights, except transfer restrictions in relation to shares issuable upon exercise of the Executive Share Options, the 2018 Share Options and the 2021 Share Options (see also section 4.7 of the Remuneration Report).

(vii) The rules governing appointment and replacement of board members and amendment to articles of association are set out in the Company's articles of association and the Company's Corporate Governance Charter.

(viii) The powers of the Board of Directors, more specifically with regard to the power to issue or redeem shares are set out in the Company's articles of association. The Board of Directors was not granted the authorization to purchase its own shares "to avoid imminent and serious danger to the Company" (i.e., to defend against public takeover bids). The Company's articles of association of association do not provide for any other specific protective mechanisms against public takeover bids.

(ix) At the date of this report, the Company is a party to the following significant agreements which, upon a change of control of the Company or following a takeover bid can enter into force or, subject to certain conditions, as the case may be, can be amended, be terminated by the other parties thereto or give the other parties thereto (or beneficial holders with respect to bonds) a right to an accelerated repayment of outstanding debt obligations of the Company under such agreements:

◊ the employment agreement between the Company and Ian Crosbie (Chief Executive Officer) contains takeover provisions. Agreements concluded between the Company and certain of its employees also provide for compensation in the event of a change of control;

◊ the loan agreements entered into with PMV/z, Sensinnovat and Belfius Insurance in July 2020 and amended in December 2021, contain change of control provisions.

◊ The Kreos Loan Agreement contains a change of control clause, which has been approved by the shareholders on the extraordinary general meeting held on 10 February 2023.

◊ the 'Warrant Agreement', dated 2 September 2016, that was entered into between the Company and Bootstrap, and that has been amended and supplemented by an amendment agreement dated 28 April 2017, a second amendment agreement dated 1 October 2018, an amendment letter dated 20 December 2018, and an agreement dated 1 September 2021 (the "Former Bootstrap Warrant"), also contains take-over provisions. The extraordinary general shareholders' meeting held on 27 May 2022 resolved to renew the Former Bootstrap Warrant through the issuance of ten new warrants represented by ten separate subscription rights (the "Bootstrap Warrants"), including the take-over provisions.

◊ In addition, the Company's subscription rights plans provide for an accelerated vesting of the subscription rights in case of a change of control event. These plans are described in more detail in the Remuneration Report below.

(x) The employment agreement with the Chief Executive Officer provides that if within six months after the completion of an "Exit Transaction" the Chief Executive Officer is (i) no longer the Chief Executive Officer of the Company, or (ii) required to change his current work pattern (the events in (i) and (ii) shall be an "Enforced Redundancy"), the Chief Executive Officer shall be entitled to resign and shall no longer be required to work or perform until the end of the four months' notice period. The term "Exit Transaction" has been defined as (i) a transfer of more than 50% of the Company's shares or more than 50% of the voting rights to a third party or a group of persons exercising joint control in one or a series of related transactions to a propose acquirer who wishes to acquire a controlling majority of the shares, voting rights or assets pursuant to a bona fide purchase offer, (ii) the sale, lease, transfer, license or other disposition of all or substantially all of the Company's assets, or (iii) the consolidation or merger of the Company in which the Company is not the surviving entity or any other event pursuant to which the shareholders of the Company will have less than 50% plus one share of the voting power and/or of the shares of the surviving or acquiring company. In the event of an Enforced Redundancy, the Chief Executive Officer will be entitled to a pro rata bonus. In the event of an Enforced Redundancy, the Chief Executive Officer may also, at his sole discretion, elect to terminate the employment agreement with immediate effect and the Company shall then be required to make a payment in lieu of a notice equivalent to the basic salary only (but not the other benefits) to which the Chief Executive Officer would have been entitled. Furthermore, the agreements concluded between the Company and a few of its employees provide for compensation in the event of a change of control.

In addition, the Company's share-based plans also contain takeover protection provisions.

No takeover bid has been instigated by third parties in respect of the Company's equity during the current financial year.

2.17 Diversity & Inclusiveness

Due to the fact that the Company has only been listed for four years, no diversity policy has been introduced yet.

Although the Company does not have a diversity policy on the date of this report, it intends to put this in place in order to remain and foster diversity amongst its board members in accordance with Article 7:86 of the Belgian Companies and Associations Code.

The Company will also ensure that a diversity policy will exist for the members of the management committee, the other leaders and the individuals responsible for the daily management of the Company.

3 Remuneration Report

3.1 Introduction

The Company has prepared this remuneration report relating to the remuneration of directors and the Executive Management of the Company. This remuneration report is part of the Corporate Governance Statement, which is part of the Company's annual report of the Board of Directors on the consolidated accounts for the financial year ended on 31 December 2022 (dated 21 April 2023) in accordance with Article 3:6, §3 of the Belgian Companies and Associations Code of 23 March 2019 (as amended) (the "Belgian Companies and Associations Code"). The remuneration report will be submitted to the annual general shareholders' meeting on 25 May 2023 for approval.

3.2 Remuneration policy

On 16 May 2020 the new article 7:89/1 of the Belgian Companies and Associations Code, which provides that listed companies must establish a remuneration policy with respect to directors, other officers and delegates for day-to-day management, entered into force. This article details the objectives of, as well as the information that needs to be included in, the remuneration policy. The remuneration policy must be approved by a binding vote of the general shareholders' meeting and must be submitted to the general shareholders' meeting for approval whenever there is a material change and in any case at least every four years. In view hereof, in accordance with article 7:89/1 of the Belgian Companies and Associations Code, the nomination and remuneration committee prepared a remuneration policy which (most recent version) has been approved by the shareholders at the extraordinary general meeting held on 10 February 2023. The aforementioned remuneration policy can be consulted on the Company's website through the following link: https://www.sequanamedical.com/wp-content/uploads/2022/06/Remuneration-Policy-ENG-post-AGM-2022.pdf.

No significant change to the remuneration policy is envisaged for the following accounting years. However, the Company will continuously review the remuneration of directors and members of the Executive Management against market practice.

3.3 Directors

3.3.1 General

Upon recommendation and proposal of the remuneration and nomination committee, the Board of Directors determines the remuneration of the directors to be proposed to the general shareholders' meeting.

Pursuant to the provisions of the Belgian Code on Companies and Associations, the general shareholders' meeting approves the remuneration of the directors, including inter alia, each time as relevant:

(i) in relation to the remuneration of executive and non-executive directors, the exemption from the rule that share-based awards can only vest after a period of at least three years as of the grant of the awards;

(ii) in relation to the remuneration of executive directors, the exemption from the rule that (unless the variable remuneration is less than a quarter of the annual remuneration) at least one quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least two years and that at least another quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least three years;

(iii) in relation to the remuneration of non-executive directors, any variable part of the remuneration (provided, however, that no variable remuneration can be granted to independent non-executive directors); and

(iv) any service agreements to be entered into with executive directors providing for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration and nomination committee, eighteen months' remuneration).

The general shareholders' meeting of the Company has not approved any of the matters referred to in paragraphs (i) to (iv) with respect to the remuneration of the directors of the Company on the date of this report, except for the following matters:

- The general shareholders' meeting approved that share options issued pursuant to the Company's existing share option plans (for further information, see section 4.7 of this Remuneration Report) can, under certain conditions, vest earlier than three years as of their grant, as referred to in paragraph (i) above. Notably, pursuant to the Company's articles of association, the Board of Directors is explicitly authorised to deviate from the rule of Article 7:91 of the Belgian Companies and Associations Code in connection with share-based incentive plans, compensation, awards or issues to employees, directors and service providers of the Company and/or its subsidiaries. The Company is of the opinion that this allows for more flexibility when structuring share-based awards. For example, it is customary for option plans to provide for a vesting in several instalments over a well-defined period of time, instead of vesting after three years only. This seems to be more in line with prevailing practice.
- The general shareholders' meeting approved that the existing share options under the respective existing share option plans will not qualify as variable remuneration nor as annual remuneration for the purpose of the application of the rule set out in paragraph (ii) above under the former Belgian Companies Code of 7 May 1999.

The remuneration and compensation of the non-executive directors for the current financial year, which has been determined by the general shareholders' meeting, is as follows:

- Annual fixed fees:
  - The chair of the Board of Directors receives an annual fixed fee of €60,000.
  - The chair of the audit committee receives an annual fixed fee of €15,000.
  - The chair of the remuneration and nomination committee receives an annual fixed fee of €15,000.
  - Until 1 July 2022, the non-executive independent directors received an annual fixed fee of €25,000. Since 1 July, 2022, the non-executive independent directors (other than the chair of the Board of Directors) are entitled to an annual fixed fee of €34,000, plus €1,750 per meeting of the Board of Directors attended in person (pro rata temporis). The change has been approved by the extraordinary shareholders meeting held on 10 February 2023.
  - Until 1 July 2022, the members of the audit committee and the remuneration and nomination committee (other than the chair of such committees) received an additional annual fixed fee of €10,000. Since 1 July 2022, members of the audit committee and the remuneration and nomination committee (other than the chair of such committees) are entitled to an additional annual fixed fee of €11.500 (pro rata temporis). The change has

been approved by the extraordinary general shareholders' meeting held on 10 February 2023.

- The aforementioned remuneration of the non-executive directors can be reduced pro rata temporis depending on the duration of the director's mandate, the mandate of chair or the membership of a committee during a given year. All amounts are exclusive of VAT and similar charges.

- Share based awards: Each non-executive independent director is in principle entitled to receive so-called "restricted share units" or "RSUs", which provide for a remuneration in the form of new shares whereby the relevant directors will have an obligation to subscribe for such shares at a value of EUR 0.11 per share (independent of the value of the share at that time). One restricted share unit or RSU represents the obligation of the relevant non-executive independent director to subscribe for one new share of the Company.

The issue of RSUs is designed to align the remuneration policy of the Company in respect of non-executive independent directors with provision 7.6 of the 2020 Code. In accordance with provision 7.6 of the 2020 Code, non-executive directors should receive a part of their remuneration in the form of shares of the Company. The Company has however no distributable reserves and therefore does not meet the legal requirements to effect a share buy-back. As a result, the Company does not have any treasury shares and is unable to grant existing shares to non-executive directors as part of their remuneration. It should be noted that the RSUs are not entirely equivalent to a share (no voting rights, no preferential subscription rights or other membership rights), but, in the opinion of the Company, the RSUs meet the objectives provided for in provision 7.6 of the 2020 Code.

Pursuant to article 7:91 of the BCAC and provisions 7.6 and 7.11 of the 2020 Code, shares or options on shares should not vest and be exercisable within three years as of the grant thereof. The Board has been explicitly authorised in the Articles of Association to deviate from this rule. As indicated above, the proposed RSUs will vest on a yearly basis. Furthermore, while provision 7.6 of the 2020 Code also states that shares should be held until at least one year after the non-executive board member leaves the board, the RSUs and underlying shares are not subject to this restriction. The Company is of the opinion that the deviation from the aforementioned rules and principles allows for more flexibility when structuring share-based awards, in line with changing practices. The Company believes that the RSU plan provides for sufficient orientation of the beneficiaries to the creation of long-term value for the Company.

Ultimately, the ability to remunerate non-executive independent directors with RSUs allows the Company to limit the portion of remuneration in cash that the Company would otherwise need to pay to attract or retain renowned global experts with the most relevant skills, knowledge and expertise. The Company is of the opinion that granting non-executive independent directors the opportunity to be remunerated in part in share-based incentives rather than all in cash enables the non-executive directors to link their effective remuneration to the performance of the Company and to strengthen the alignment of their interests with the interests of the Company's shareholders. The Company believes that this is in the interest of the Company and its stakeholders. Furthermore, the Company believes that this is customary for directors active in companies in the life sciences industry.

As mentioned, a revised (stand-alone) remuneration policy (which includes the ability to remunerate non-executive independent directors with RSUs) has been approved on the extraordinary general shareholders' meeting of the Company held on 10 February 2023 in order to align the current remuneration policy of the Company with the requirements of Article 7:89/1 of the Belgian Companies and Associations Code.

The Company also reimburses reasonable out of pocket expenses of directors (including travel and accommodation expenses) incurred in performing the activity of director. Without prejudice to the powers granted by law to the general shareholders' meeting, the Board of Directors sets and revises the rules for reimbursement of directors' business-related out of pocket expenses.

There are currently no plans to change the remuneration of members of the Board of Directors. However, the Company will continuously review the remuneration of members of the Board of Directors against market practice.

The directors who are also a member of the Executive Management are remunerated for the Executive Management mandate, but not for their director mandate.

3.3.2 Remuneration and compensation in 2022

During 2022, the non-executive directors were entitled to the following compensation, based on the approved fees in 3.3.1.

	Gross amount (in €)[I]	Share options awarded
Pierre Chauvineau	70,750	-
Wim Ottevaere (WIOT BV)	55,500	-
Jackie Fielding	43,750	-
Doug Kohrs	20,037	-
Alexandra Clyde	18,331	-

No remuneration, compensation or other benefits were paid to the other directors of the Company, other than the reimbursement of (non-material) travel and hotel expenses incurred by the directors in connection with their attendance of meetings of the Board of Directors.

(I) The amounts are prorated to the term that the director is part of a committee.

3.4 Executive Management

3.4.1 General

The remuneration of the Chief Executive Officer and the other member of the Executive Management is based on recommendations made by the remuneration and nomination committee. The Chief Executive Officer participates in the meetings of the remuneration and nomination committee in an advisory capacity each time the remuneration of another member of the Executive Management is being discussed.

The remuneration is determined by the Board of Directors. As an exception to the foregoing rule, Belgian law provides that the general shareholders' meeting must approve, as relevant:

(i) in relation to the remuneration of members of the Executive Management and other executives, an exemption from the rule that share-based awards can only vest after a period of at least three years as of the grant of the awards;
(ii) in relation to the remuneration of members of the Executive Management and other executives, an exemption from the rule that (unless the variable remuneration is less than a quarter of the annual remuneration) at least one quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least two years and that at least another quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least three years; and
(iii) any service agreements to be entered into with members of the Executive Management and other executives (as the case may be) providing for severance payments exceeding

twelve months' remuneration (or, subject to a motivated opinion by the remuneration and nomination committee, eighteen months' remuneration).

Notwithstanding point (i) above, the Company's Board of Directors has been explicitly authorised in the Company's articles of association to deviate from the rule set out in Article 7:91 of the Belgian Companies and Associations Code in connection with share-based incentive plans, compensations, awards and issuances to employees, directors and service providers of the Company and/or its subsidiaries. The Company believes that this allows for more flexibility when structuring share-based awards.

In relation to point (ii) above, under the former Belgian Companies Code of 7 May 1999, the Company took the view that share options generally do not qualify as variable remuneration nor as annual remuneration for the purpose of the application of the rule set out in point (ii) above. This has been approved by the Company's general shareholders' meeting with respect to share-based awards that are outstanding on the date of this report. The general shareholders' meeting also approved that the variable remuneration of the members of the Executive Management could deviate from the principle described in point (ii) above.

An appropriate proportion of the remuneration package should be structured so as to link rewards to corporate and individual performance, thereby aligning the interest of the Executive Management with the interests of the Company and its shareholders. The Chief Executive Officer will determine whether the targets for the variable remuneration of the members of the Executive Management, as set by the Board of Directors, are met. In the past, approval by the general shareholders' meeting has been obtained in relation to the share plans.

The remuneration of the Executive Management currently consists of the following main remuneration components:

- annual base salary/fee (fixed);
- participation in share option plans;
- a performance bonus in cash; and
- other (fringe) benefits in whatever form (such as contribution for pension plan, insurance plan, car lease, transport allowance or medical plan).

The members of the Executive Management have a variable remuneration (i.e. remuneration linked to performance criteria) amounting to up to 50% of the base salary/fee for on target performance. The remuneration is closely linked to performance. Bonuses, if any, are linked to identifiable objectives and to special projects and are set and measured on a calendar-year basis. The performance objectives of the Executive Management members are primarily evaluated with regard to the following criteria: (i) respect of the Board-approved annual budget, and (ii) meeting measurable operational targets. The various objectives and their weighting may differ for the individual managers. The nomination and remuneration committee of the Board of Directors meets annually to review the performance of the managers, to compare the actual measurable results to the objectives that were pre-defined by the committee, and to establish the measurable objectives for the ensuing calendar year. This policy contributes to aligning the interests of the members of the Executive Management with those of the Company, amongst other things, by involving them in the risks and prospects of its activities in a long-term perspective. Their remuneration contributes to the Company's long-term performance.

The Chief Executive Officer is entitled to pension benefits. The contributions by the Company to the pension scheme amount to 5% of the annual salary. The Chief Financial Officer is not entitled to pension benefits.

The members of the Executive Management are also reimbursed for certain costs and expenses made in the performance of their function. There are currently no plans to change the remuneration of members of the Executive Management. However, the Company will continuously review the remuneration of members of the Executive Management against market practice.

3.4.2 Remuneration and compensation in 2022

In 2022, the following remuneration, compensation and other benefits were paid to the two members of the Executive Management. All amounts included in the table are gross amounts.

	Chief executive officer (€)		Other member of the executive management (€)	
	Amount[(I)]	%	Amount[(II)]	%
Annual base salary	299,029	65%	291,312	82%
Pension plan[(III)]	14,658	3%	N/A	N/A
Insurance plan[(IV)]	1,179	0%	N/A	N/A
Car lease/transport allowance	11,258	2%	N/A	N/A
Medical plan	5,548	1%	N/A	N/A
Bonus plan[(V)]	131,925	28%	62,832	18%
Total	463,597	100%	354,144	100%

In 2022, the Board of Directors has decided to establish the Company's performance at 66.67% (reflecting the level of achievement of the Company's 2021 objectives based on the progress made in our clinical programs and the financial performance). In function thereof, variable remuneration (in the form of a cash bonus) has been paid out in the course of 2022 to the members of the Executive Management.

In 2022, the members of the Executive Management were also reimbursed for certain costs and expenses made in the performance of their function, more specifically for an aggregate amount of €84,181.

(I) The amount is paid in GBP to the CEO. The conversion applied to EUR is performed on the average GBP/EUR rate of 2022 of the ECB.
(II) Acting as permanent representative of Fin-2K BV
(III) The pension plan amounts to 5% of the annual base salary of the CEO.
(IV) The Company pays a life insurance plan for the CEO.
(V) The bonus has been paid in cash

3.4.3 Annual evolution in remuneration, performance and average annual remuneration of employees

Evolution of the remuneration of the directors and executive managers on a full-time equivalent basis

	2018		2019		2020		2021		2022	
	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year
Directors and executive managers	586,794	39%	834,090	42%	901,035	8%	919,714	2%	1,026,109	12%

- No remuneration was in place for the non-executive directors prior to the Company's IPO of 2019.

- The remuneration is partially dependent on the fluctuation of the exchange rate of GBP/EUR.

Evolution of the average remuneration on a full-time equivalent basis of employees other than directors and members of the executive management

	2018		2019		2020		2021		2022	
	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year
Employees	114,071	-5%	109,695	-4%	109,886	0%	112,481	2%	117,388	4%

- The average remuneration on a full-time basis of 2018 is less comparable to 2019 and onwards as this was prior to the transfer to Belgium and the subsequent IPO (February 2019).

- In 2019 and onwards, some key positions are fulfilled by persons working via a consulting agreement, who are not included in the above average remuneration of employees.

- The remuneration is dependent on the fluctuation of the exchange rate of GBP/EUR and CHF/EUR.

Evolution of the performance of the Company

	2018		2019		2020		2021		2022	
	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year
Net loss for the period	-13,983,224	70%	-14,977,445	7%	-19,106,205	28%	-23,615,081	24%	-30,763,083	30%
Total Equity	-18,759,747	307%	925,932	-105%	112,761	-88%	-786,919	-798%	-2,153,252	174%
Paid dividends	-	-	-	-	-	-	-	-	-	-
Market capitalisation at 31 December	NA	NA	78,950,494	NA	186,305,079	136%	140,442,710	-25%	142,479,168	1%

The ratio between the highest and lowest remuneration in 2022 was equal to 10 in the European Union and 7 outside the European Union.

3.4.4 Claw-back right relating to variable remuneration

In accordance with provision 7.12 of the Belgian Corporate Governance Code, the Board of Directors should include provisions in the contracts of the members of the Executive Management that would enable the Company to recover variable remuneration paid, or withhold the payment of variable remuneration, and specify the circumstances in which it would be appropriate to do so, insofar as enforceable by law. There are currently no contractual provisions in place between the Company and the Chief Executive Officer or the other member of the Executive Management that give the Company a contractual right to reclaim from said executives any variable remuneration that would be awarded. The Board of Directors does not consider that it is necessary to apply claw-back provisions as (x) the pay-out of the variable remuneration, based on the achievement of corporate targets as set by the Board of Directors, is paid only upon achievement of those corporate targets, and (y) the Company does not apply any other performance-based remuneration or variable compensation. Furthermore, the share option plans do contain bad leaver provisions that can result in the share options, whether vested or not, automatically and immediately becoming null and void. Notwithstanding the Company's position that share options are not to be qualified as variable remuneration, the Board of Directors is of the opinion that such bad leaver provisions sufficiently protect the Company's interests and that it is therefore currently not necessary to provide for additional contractual provisions that give the Company a contractual right to reclaim any (variable) remuneration from the members of the Executive Management.

3.4.5 Payments upon termination

The employment agreement with the Chief Executive Officer provides that the agreement can be terminated by either the Company or the Chief Executive Officer subject to four months' notice. If within six months after the completion of an "Exit Transaction" the Chief Executive Officer is (i) no longer the Chief Executive Officer of the Company, or (ii) required to change his current work pattern (the events in (i) and (ii) shall be an "Enforced Redundancy"), the Chief Executive Officer shall be entitled to resign and shall no longer be required to work or perform until the end of the four months' notice period. The term "Exit Transaction" has been defined as (i) a transfer of more than 50% of the Company's shares or more than 50% of the voting rights to a third party or a group of persons exercising joint control in one or a series of related transactions to a propose acquirer who wishes to acquire a controlling majority of the shares, voting rights or assets pursuant to a bona fide purchase offer, (ii) the sale, lease, transfer, license or other disposition of all or substantially all of the Company's assets, or (iii) the consolidation or merger of the Company in which the Company is not the surviving entity or any other event pursuant to which the shareholders of the Company will have less than 50% plus one share of the voting power and/or of the shares of the surviving or acquiring company. In the event of an Enforced Redundancy, the Chief Executive Officer will be entitled to a pro rata bonus. In the event of an Enforced Redundancy, the Chief Executive Officer may also, at his sole discretion, elect to terminate the employment agreement with immediate effect and the Company shall then be required to make a payment in lieu of a notice equivalent to the basic salary only (but not the other benefits) to which the Chief Executive Officer would have been entitled. The employment agreement also provides for a number of instances in which the agreement can be immediately terminated by the Company, including for cause.

The services agreement with the chief financial officer of the Company provides that it has been entered into for an unlimited term, and that it may be terminated in mutual agreement by the Company and the chief financial officer at any time. In case of termination of the agreement by the Company, the chief financial officer is entitled to three months' notice or to the payment of a quarter of the annual compensation in lieu of notice, or the payment of a pro rata part of one quarter of the fixed annual compensation in lieu of part of the notice. The agreement may be terminated by the chief financial officer subject to a notice period of three months. The agreement may be terminated by either the Company or the chief financial officer with immediate effect and without notice period (or, in case of termination by the Company, without notice period or indemnity) in case of wilful or serious breach or violation by a party of any of its covenants, obligations or duties under the agreement, or any wilful or serious neglect of or refusal to perform any of such covenants, obligations or duties.

3.5 Indemnification and Insurance of Directors and Executive Management

As permitted by the Company's articles of association, the Company has entered into indemnification arrangements with the directors and relevant members of the Executive Management and has implemented directors' and officers' insurance coverage in order to cover liability they may incur in the exercise of their mandates.

3.6 Description of share option plans

The Company, as per 31 December 2022, has a number of outstanding options that are exercisable into ordinary shares, consisting of:

- 261,895 new shares can be issued upon the exercise of 90,780 share options that are still outstanding under the "Executive Share Options" plan for staff members and consultants of the Company, entitling the holder thereof to acquire ca. 2.88 shares when exercising one of his or her share options (the "**Executive Share Options**"); and
- 1,071,924 new shares can be issued upon the exercise of 1,071,924 2018 share options that are still outstanding under the "2018 Share Options" plan for staff members and consultants of the Company, entitling the holder thereof to acquire one share when exercising one of his or her share options (the "**2018 Share Options**").
- 1,000,000 new shares can be issued upon the exercise of 1,000,000 share options (each share option having the form of a subscription right) that are still outstanding under the '2021 Share Options' plan for directors, employees and other staff members of the Company and its subsidiaries, entitling the holder thereof to acquire one new share when exercising one share option (the "**2021 Share Options**").

The table below provides an overview of the number of shares which each member of the Executive Management is entitled to acquire upon exercise of the outstanding and granted Executive Share Options, 2018 Share Options and 2021 Share Options that are held by him or her on 31 December 2022.

	Number of shares		
Name	**Executive Share Options**	**2018 Share Options**	**2021 Share Options**
Ian Crosbie	216.442	135.809	5.030
Kirsten Van Bockstaele(I)	6.226	70.419	-

(I) Acting as permanent representative of Fin-2K BV.

In financial year 2022, 66,644 share options lapsed as a result of the termination of a number of employment contracts.

3.7 Terms and conditions of the share option plans

The key features of the Executive Share Options can be summarised as follows:

- The Executive Share Options could be granted to the employees, consultants and directors of the Company or its subsidiaries.
- The Executive Share Options are in registered form.
- The Executive Share Options are in principle non-transferable, and the holders of the Executive Share Options are not permitted to transfer the Executive Share Options nor the underlying Shares issuable upon exercise of the Executive Share Options for a period of two years as from the initial public offering of the Company's shares, except as provided otherwise in the grant agreement or by the Board of Directors, and except in case of death of the beneficiary and in the context of inheritance planning by the beneficiary. In case of death, only Executive Share Options that have vested prior to the time of death can be transferred.
- Each holder of an Executive Share Option will be entitled to subscribe to ca. 2.88 ordinary shares when exercising one of his or her share option. The exercise price of the Executive Share Options shall be determined by the Board of Directors of the Company, taking into account applicable laws.
- If an Executive Share Option which is not exercisable or which cannot be exercised pursuant to the issuance conditions (as determined in the Executive Share Option Plan or in the relevant Sub-Plan and/or Share Option Agreement) becomes prematurely exercisable on the basis of the provisions of Article 7:71 of the Belgian Companies and Associations Code (or any other provision having the same purport) and is also exercised pursuant to said provision, the shares obtained by exercising the Executive Share Options shall not be transferable, unless explicitly agreed upon by the Board of Directors of the Company, until the time the underlying Executive Share Options would have become exercisable in accordance with the Executive Share Option Plan and the relevant sub-plan or share option agreement.
- Pursuant to Belgian company law, the Executive Share Options have a maximum term of 10 years as of their issuance.
- All Executive Share Options have vested on the date of this report.
- The Executive Share Options of beneficiaries of whom the employment agreement, consultancy agreement or directorship with the Company is terminated for serious cause, breach of contract or breach of director responsibilities, shall automatically and immediately lapse and become null and void.
- The terms of the Share options are governed by the laws of Belgium.

The key features of the 2018 Share Options can be summarised as follows:

- The 2018 Share Options are subscription rights in registered form.
- The 2018 Share Options are in principle non-transferable, except as provided otherwise in the grant agreement or by the Board of Directors, and except in case of death of the beneficiary and in the context of inheritance planning by the beneficiary. In case of death, only 2018 Share Options that have vested prior to the time of death can be transferred.
- Each 2018 Share Option can be exercised for one new ordinary share.
- If a 2018 Share Option which is not exercisable or which cannot be exercised pursuant to the issuance conditions (as determined in the 2018 Share Option Plan or in the relevant sub-plan and/or share option agreement) becomes prematurely exercisable on the basis of the provisions of Article 7:71 of the Belgian Companies and Associations Code (or any other provision having the same purport) and is also exercised pursuant to said provision, the shares obtained by exercising the 2018 Share Options shall not be transferable, unless explicitly agreed upon by the Board of Directors, until the time the underlying 2018 Share Options would have become exercisable in accordance with the 2018 Share Option Plan, the relevant sub-plan or share option agreement.
- The exercise price of the 2018 Share Options shall be determined by the Board of Directors of the Company, taking into account applicable laws.
- The 2018 Share Options are granted for free, i.e. no consideration is due upon the grant of the 2018 Share Options, unless the grant agreement provides otherwise.
- Pursuant to Belgian company law, the 2018 Share Options have a maximum term of 10 years as of their issuance.
- Unless stipulated otherwise in the grant agreement, one third of the 2018 Share Options granted to a beneficiary shall vest one year after the date of grant, the remaining two thirds will vest in 8 equal instalments, whereby on each first calendar day of the 8 quarters following first anniversary of the date of grant falls, 1/8 of the total number of unvested 2018 Share Options granted to a beneficiary shall vest. However, unless determined otherwise in the grant agreement or by the Board of Directors, there is accelerated vesting of the 2018 Share Options in the event of a sale or other transfer of at least 50% of all of the then outstanding shares of the Company, whereby an (internal) reorganisation in which the Shares of the Company would be transferred to a person in which the then existing shareholders of the Company were to hold shares or other interest in a similar proportion as the proportion held by each of them in the Company will not result in accelerated vesting. Notwithstanding the foregoing, the Board of Directors can at all times decide to accelerate the vesting of (all or part of) the 2018 Share Options and determine the conditions of such accelerated vesting.
- The 2018 Share Options, whether vested or not, of beneficiaries of whom the employment agreement, consultancy agreement or directorship with the Company is terminated for serious cause, breach of contract or breach of director responsibilities, shall automatically and immediately lapse and become null and void.
- The 2018 Share Option Plan is governed by the laws of Belgium.

The key features of the 2021 Share Options can be summarised as follows:

- The 2021 Share Options are subscription rights in registered form.
- The 2021 Share Options are in principle non-transferable, except as provided otherwise in the grant agreement or by the Board of Directors, and except in case of death of the beneficiary and in the context of inheritance planning by the beneficiary. In case of death, only 2021 Share Options that have vested prior to the time of death can be transferred.
- Each 2021 Share Option can be exercised for one new ordinary share.
- If a 2021 Share Option which is not exercisable or which cannot be exercised pursuant to the issuance conditions (as determined in the 2021 Share Option Plan or in the relevant sub-plan and/or share option agreement) becomes prematurely exercisable on the basis of the provisions of Article 7:71 of the Belgian Companies and Associations Code (or any other provision having the same purport) and is also exercised pursuant to said provision, the shares obtained by exercising the 2021 Share Options shall not be transferable, unless explicitly agreed upon by the Board of Directors, until the time the underlying 2021 Share Options would have become exercisable in accordance with the 2021 Share Option Plan, the relevant sub-plan or share option agreement.
- The exercise price of the 2021 Share Options shall be determined by the Board of Directors of the Company, taking into account applicable laws.
- The 2021 Share Options are granted for free, i.e. no consideration is due upon the grant of the 2021 Share Options, unless the grant agreement provides otherwise.
- Pursuant to Belgian company law, the 2021 Share Options have a maximum term of 10 years as of their issuance.
- Unless stipulated otherwise in the grant agreement, one third of the 2021 Share Options granted to a beneficiary shall vest one year after the date of grant, the remaining two thirds will vest in 8 equal instalments, whereby on each first calendar day of the 8 quarters following first anniversary of the date of grant falls, 1/8 of the total number of unvested 2021 Share Options granted to a beneficiary shall vest. However, unless determined otherwise in the grant agreement or by the Board of Directors, there is accelerated vesting of the 2021 Share Options in the event of a sale or other transfer of at least 50% of all of the then outstanding shares of the Company, whereby an (internal) reorganisation in which the Shares of the Company would be transferred to a person in which the then existing shareholders of the Company were to hold shares or other interest in a similar proportion as the proportion held by each of them in the Company will not result in accelerated vesting. Notwithstanding the foregoing, the Board of Directors can at all times decide to accelerate the vesting of (all or part of) the 2021 Share Options and determine the conditions of such accelerated vesting.
- The 2021 Share Options, whether vested or not, of beneficiaries of whom the employment agreement, consultancy agreement or directorship with the Company is terminated for serious cause, breach of contract or breach of director responsibilities, shall automatically and immediately lapse and become null and void.
- The 2021 Share Option Plan is governed by the laws of Belgium.

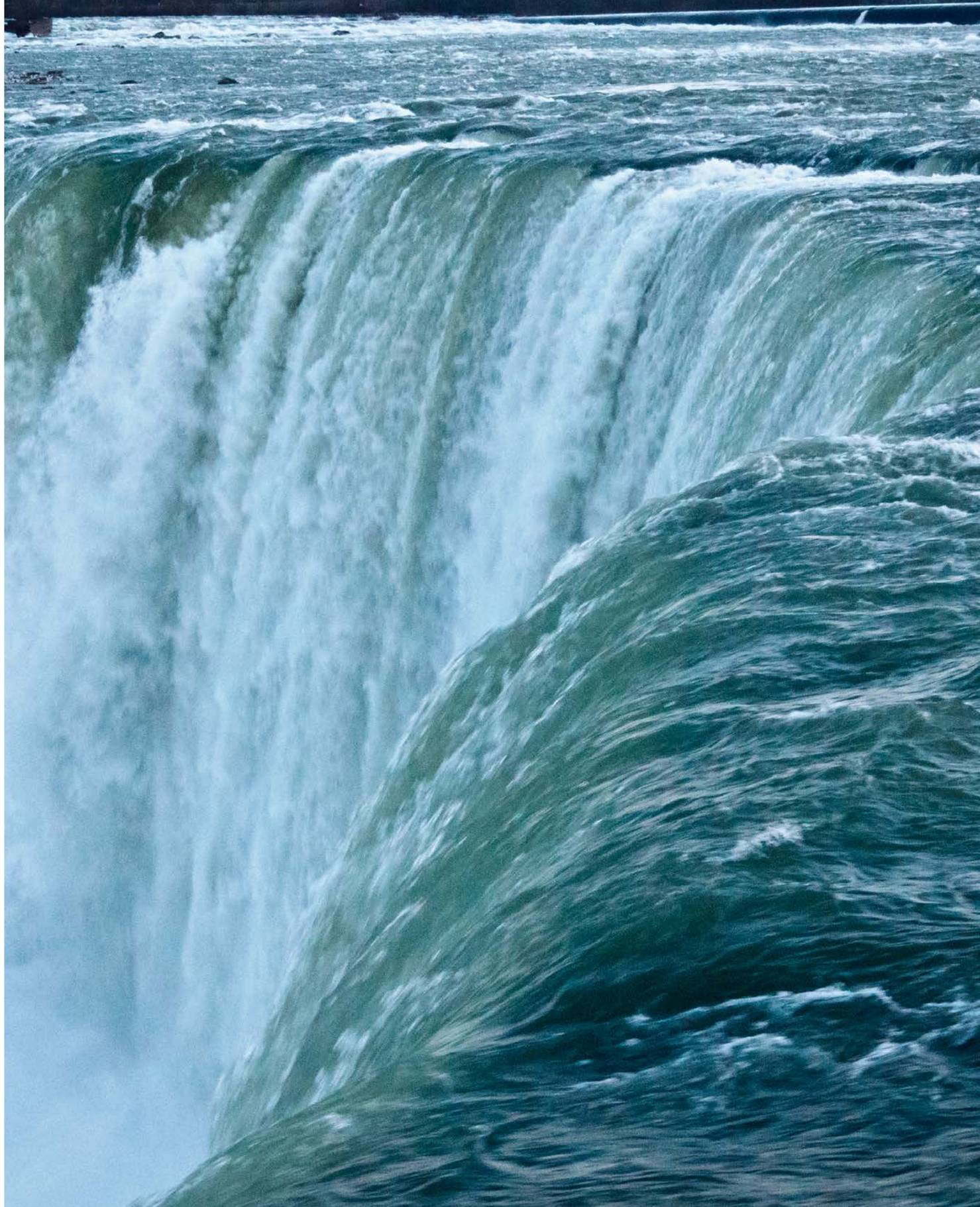
3.8 Shareholding and Share Options

As per 31 December 2022, with the exception of Mr Wim Ottevaere, who holds 21,000 shares of the Company and Pierre Chauvineau, who holds 7,664 shares of the Company, none of the directors of the Company hold shares. However, in 2019 (before the entry into force of the Belgian Companies and Associations Code), 2018 Share Options have been granted to non-executive directors Mr Wim Ottevaere (10,192) and Mr Pierre Chauvineau (10,192). No share options were granted to non-executive directors since 2020.

Furthermore, none of the members of the Executive Management of the Company hold shares. However, share options have been granted to both members of Executive Management. Please see above in the section “Description of share option plans”.

Financial Statements

For the years ended 31 December, 2022 and 2021



1
Statement of the Board of Directors

The Board of Directors of Sequana Medical NV certifies in the name and on behalf of Sequana Medical NV, that to the best of their knowledge:

- the Consolidated Financial Statements, established in accordance with International Financial Reporting Standards ('IFRS') as adopted by the European Union, give a true and fair view of the assets, financial position and results of Sequana Medical NV and of the entities included in the consolidation; and
- the annual review presents a fair overview of the development and the results of the business and the position of Sequana Medical NV and of the entities included in the consolidation, as well as a description of the principal risks and uncertainties facing them in accordance with Article 12 § 2 3°, a) and b) of the Royal Decree of 14 November 2007 on the obligations of issuers of financial instruments admitted to trading on a regulated market.

The amounts in this document are represented in euros (EUR), unless noted otherwise. The Dutch financial statements prepared by the Group in the ESEF format are the only official ESEF version of the financial statements.

Due to rounding, numbers presented throughout these Consolidated Financial Statements may not add up precisely to the totals provided and percentages may not precisely reflect the absolute figures. An accounting period comprises the period between 1 January and 31 December.

Pierre Chauvineau
Chairman

Ian Crosbie
CEO

Kirsten Van Bockstaele
CFO

2
Statutory auditor's report

STATUTORY AUDITOR'S REPORT TO THE GENERAL SHAREHOLDERS' MEETING OF SEQUANA MEDICAL NV ON THE CONSOLIDATED ACCOUNTS FOR THE YEAR ENDED 31 DECEMBER 2022

We present to you our statutory auditor's report in the context of our statutory audit of the consolidated accounts of Sequana Medical NV (the "Company") and its subsidiaries (jointly "the Group"). This report includes our report on the consolidated accounts, as well as the other legal and regulatory requirements. This forms part of an integrated whole and is indivisible.

We have been appointed as statutory auditor by the general meeting d.d. 27 May 2021, following the proposal formulated by the board of directors and following the recommendation by the audit committee. Our mandate will expire on the date of the general meeting which will deliberate on the annual accounts for the year ended 31 December 2023. We have performed the statutory audit of the Group's consolidated accounts for 5 consecutive years.

1. Report on the consolidated accounts

1.1. Unqualified opinion

We have performed the statutory audit of the Group's consolidated accounts, which comprise the consolidated statement of financial position as at 31 December 2022, the consolidated income statement, consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended, and notes to the consolidated financial statements, including a summary of significant accounting policies and other explanatory information, and which is characterised by a consolidated statement of financial position total of EUR 26,025,232 and a loss for the year of EUR 30,763,083.

In our opinion, the consolidated accounts give a true and fair view of the Group's net equity and consolidated financial position as at 31 December 2022, and of its consolidated financial performance and its consolidated cash flows for the year then ended, in accordance with International Financial Reporting Standards as adopted by the European Union and with the legal and regulatory requirements applicable in Belgium.

1.2. Basis for unqualified opinion

We conducted our audit in accordance with International Standards on Auditing (ISAs) as applicable in Belgium. Furthermore, we have applied the International Standards on Auditing as approved by the IAASB which are applicable to the year-end and which are not yet approved at the national level. Our responsibilities under those standards are further described in the "Statutory auditor's responsibilities for the audit of the consolidated accounts" section of our report. We have fulfilled our ethical responsibilities in accordance with the ethical requirements that are relevant to our audit of the consolidated accounts in Belgium, including the requirements related to independence.

We have obtained from the board of directors and Company officials the explanations and information necessary for performing our audit.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

1.3. Material Uncertainty Related to Going Concern

We draw attention to Note 4 in the consolidated accounts, which indicates that the Company is still in its development phase conducting clinical trials in order to achieve regulatory marketing approvals and is subject to various risks and uncertainties, including but not limited to the uncertainty of the development process and the timing of achieving profitability. The Company's ability to continue operations also depends on its ability to raise additional capital and to refinance existing debt, in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows.

The impact of macroeconomic conditions and the geopolitical situation in Ukraine on the Companys ability to secure additional financing rounds or undertake capital market transactions remains unclear at this point in time. The Consolidated Statement of Financial Position as at 31 December 2022 shows negative equity in the amount of EUR 2.2 million and ending cash balance of EUR 18.9 million.

These events or conditions as set forth in Note 4 indicate that a material uncertainty exists that may cast significant doubt on the Group's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

1.4. Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the consolidated accounts of the current period. These matters were addressed in the context of our audit of the consolidated accounts as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. In addition to the matter described in the "Material Uncertainty Related to Going Concern" section, we have determined the matter described below to be the key audit matters to be communicated in our report.

Accounting for the Kreos Loan Agreement and related Kreos Subscription Rights Agreement

Refer to notes 8.7.2 and 8.8.2 in the Group financial statements

Description of the Key Audit Matter

Sequana has entered into a secured loan facility agreement with Kreos (the "Kreos Loan Agreement") in the amount of EUR 10 million. In the framework of the Kreos Loan Agreement, the Company and Kreos Capital VII Aggregator SCSp entered into a subscription rights agreement in July 2022 (the "Kreos Subscription Rights Agreement").

Sequana has assessed that the loan facility classifies as a financial debt, to be recognized at fair value at its inception in accordance with IFRS 9 and subsequently accounted for at amortised cost. The amortised cost per fiscal year end 2022 amounts to 8.919 KEUR.

The subscription rights qualify as a financial instrument and are measured at fair value through profit & loss. The fair value amounts to 466 KEUR per financial year end 2022.

This is an area of focus for our audit due to the complexity of the accounting for this transaction.

How our audit addressed the key audit matter

We verified the contractual basis and documentation of the transaction by reading the board minutes, the Loan Agreement and the Subscription Rights Agreement.

We have discussed with management on the nature of the Kreos Loan Agreement (including the Subscription Rights Agreement) and the substance of the transactions.

We have assessed whether the accounting policies used by the Group are in accordance with IFRS and are appropriate and challenged management on its applied methodology and its compliance with IAS 32 and IFRS 9.

In performing the procedures outlined above, we involved our IFRS specialists for a review over the accounting method as applied by management.

We also considered the appropriateness and sufficiency of related disclosures in the consolidated financial statements.

1.5. Responsibilities of the board of directors for the preparation of the consolidated accounts

The board of directors is responsible for the preparation of consolidated accounts that give a true and fair view in accordance with International Financial Reporting Standards as adopted by the European Union and with the legal and regulatory requirements applicable in Belgium, and for such internal control as the board of directors determine is necessary to enable the preparation of consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated accounts, the board of directors is responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the board of directors either intends to liquidate the Group or to cease operations, or has no realistic alternative but to do so.

1.6. Statutory auditor's responsibilities for the audit of the consolidated accounts

Our objectives are to obtain reasonable assurance about whether the consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated accounts.

In performing our audit, we comply with the legal, regulatory and normative framework applicable to the audit of the consolidated accounts in Belgium. A statutory audit does not provide any assurance as to the Group's future viability nor as to the efficiency or effectiveness of the directors' current or future business management at Group level. Our responsibilities in respect of the use of the going concern basis of accounting by the board of directors are described below.

As part of an audit in accordance with ISAs, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the board of directors.
- Conclude on the appropriateness of the board of directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our statutory auditor's report to the related disclosures in the consolidated accounts or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our statutory auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the consolidated accounts, including the disclosures, and whether the consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the Group audit. We remain solely responsible for our audit opinion.

We communicate with the audit committee regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the audit committee with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the audit committee, we determine those matters that were of most significance in the audit of the consolidated accounts of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter.

2. Other legal and regulatory requirements

2.1. Responsibilities of the board of directors

The board of directors is responsible for the preparation and the content of the directors' report on the consolidated accounts and the other information included in the annual report on the consolidated accounts.

2.2. Statutory auditor's responsibilities

In the context of our engagement and in accordance with the Belgian standard which is complementary to the International Standards on Auditing (ISAs) as applicable in Belgium, our responsibility is to verify, in all material respects, the directors' report on the consolidated accounts and the other information included in the annual report on the consolidated accounts and to report on these matters.

2.3. Aspects related to the directors' report on the consolidated accounts

In our opinion, after having performed specific procedures in relation to the directors' report on the consolidated accounts, this directors' report is consistent with the consolidated accounts for the year under audit and is prepared in accordance with article 3:32 of the Companies' and Associations' Code.

In the context of our audit of the consolidated accounts, we are also responsible for considering, in particular based on the knowledge acquired resulting from the audit, whether the directors' report on the consolidated accounts is materially misstated or contains information which is inadequately disclosed or otherwise misleading. In light of the procedures we have performed, there are no material misstatements we have to report to you.

2.4. Statement related to independence

- Our registered audit firm and our network did not provide services which are incompatible with the statutory audit of the consolidated accounts, and our registered audit firm remained independent of the Group in the course of our mandate.
- The fees for additional services which are compatible with the statutory audit of the consolidated accounts referred to in article 3:65 of the Companies' and Associations' Code are correctly disclosed and itemized in the notes to the consolidated accounts.

2.5. European Uniform Electronic Format (ESEF)

We have also verified, in accordance with the draft standard on the verification of the compliance of the financial statements with the European Uniform Electronic Format (hereinafter "ESEF"), the compliance of the ESEF format with the regulatory technical standards established by the European Delegate Regulation No. 2019/815 of 17 December 2018 (hereinafter: "Delegated Regulation").

The board of directors is responsible for the preparation, in accordance with ESEF requirements, of the consolidated financial statements in the form of an electronic file in ESEF format (hereinafter "digital consolidated financial statements") included in the annual financial report.

Our responsibility is to obtain sufficient appropriate evidence to conclude that the format and marking language of the digital consolidated financial statements comply in all material respects with the ESEF requirements under the Delegated Regulation.

Since Sequana Medical NV does not prepare digital consolidated financial statements in English we are unable to express an opinion on these. However, we refer to our report on the consolidated financial statements for the year ended 31 December 2022 in Dutch. This contains our opinion on the official Dutch version of the digital consolidated financial statements of Sequana Medical NV which have been prepared in accordance with the ESEF requirements under the Delegated Regulation.

3. Other statements

This report is consistent with the additional report to the audit committee referred to in article 11 of the Regulation (EU) N° 537/2014.

Antwerp, 24 April 2023

The statutory auditor

PwC Reviseurs d'Entreprises SRL/PwC Bedrijfsrevisoren BV

Represented by

Peter D'Hondt

Réviseur d'Entreprises / Bedrijfsrevisor

3
Consolidated Income Statement

EUR	Notes	2022	2021
Revenue	6	**922,687**	**370,500**
Costs of goods sold		(204,597)	(76,663)
Gross Margin		**718,090**	**293,837**
Sales & Marketing		(2,240,029)	(2,079,049)
Clinical		(9,772,874)	(7,798,237)
Quality & Regulatory		(3,631,681)	(3,214,729)
Supply Chain		(3,157,666)	(2,716,090)
Engineering		(3,853,153)	(3,206,020)
General & administration		(6,687,346)	(5,098,351)
Total Operating Expenses	7.1	**(29,342,749)**	**(24,112,476)**
Other income	7.3	530,174	1,204,996
Earnings before interests and taxes (EBIT)		**(28,094,484)**	**(22,613,644)**
Finance income	7.4	450,553	246,384
Finance cost	7.4	(2,732,522)	(854,549)
Net Finance Cost		**(2,281,970)**	**(608,165)**
Income Tax Expense	7.5	(386,629)	(393,272)
Net loss for the period		**(30,763,083)**	**(23,615,081)**
Attributable to Sequana Medical shareholders		(30,763,083)	(23,615,081)
Basic loss per share	7.6	(1.35)	(1.30)

The accompanying notes are an integral part of the Consolidated Financial Statements.

4
Consolidated Statement of Comprehensive Income

EUR	Notes	2022	2021
Net loss for the period		**(30,763,083)**	**(23,615,081)**
Items that will not be reclassified to profit or loss:			
Remeasurements of defined benefit plans	8.9	413,370	95,572
Items that may be reclassified subsequently to profit or loss:			
Currency translation adjustments		726,751	(255,836)
Total other comprehensive income/ (loss)-net of tax		**1,140,121**	**(160,263)**
Total comprehensive income		**(29,622,962)**	**(23,775,344)**
Attributable to Sequana Medical shareholders		(29,622,962)	(23,775,344)

The accompanying notes are an integral part of the Consolidated Financial Statements.

5
Consolidated Statement of Financial Position

EUR	Notes	31 December 2022		31 December 2021	
Property, plant and equipment	8.4		**2,067,958**		**1,268,338**
Financial assets			**85,746**		**82,363**
Other non-current assets	8.5		**782,207**		**463,860**
Total non-current assets			**2,935,911**		**1,814,560**
Trade receivables	8.2		**113,871**		**81,882**
Other receivables and prepaid expenses			**1,479,294**		**1,068,941**
Other receivables	8.2	292,330		301,244	
Prepaid expenses	8.2	1,186,964		767,696	
Inventory	8.3		**2,621,197**		**2,139,425**
Cash and cash equivalents	8.1		**18,874,959**		**9,600,412**
Total current assets			**23,089,321**		**12,890,660**
TOTAL ASSETS			**26,025,232**		**14,705,221**

The accompanying notes are an integral part of the Consolidated Financial Statements.

EUR	Notes	31 December 2022		31 December 2021	
Share Capital	8.6	2,460,487		1,924,932	
Share premium	8.6	170,324,139		142,432,715	
Reserves		(2,425,934)		(2,668,955)	
Loss brought forward		(173,458,384)		(142,695,301)	
Cumulative Translation Adjustment		946,440		219,689	
Total Equity			**(2,153,252)**		**(786,919)**
Long term financial debts	8.7		12,192,829		**7,324,835**
Long term lease debts	8.7		609,458		**477,312**
Retirement benefit obligation	8.9		228,194		**509,851**
Total non-current liabilities			**13,030,481**		**8,311,998**
Short term financial debts	8.7		4,482,914		-
Short term lease debts	8.7		306,952		**283,010**
Other current financial liabilities	8.8		1,568,784		
Trade payables and contract liabilities			3,391,783		**2,367,110**
Trade payables	8.10	3,227,290		2,192,903	
Contract liabilities	5	164,492		174,207	
Other payables	8.8		1,811,940		**1,924,597**
Accrued liabilities and provisions			3,585,631		**2,605,426**
Provision warranty	8.10	71,088		83,361	
Accrued liabilities	8.10	3,514,543		2,522,065	
Total current liabilities			**15,148,003**		**7,180,142**
TOTAL EQUITY AND LIABILITIES			**26,025,232**		**14,705,221**

The accompanying notes are an integral part of the Consolidated Financial Statements.

6
Consolidated Statement of Changes in Equity

EUR	Notes	Share capital	Share premium	Reserves	Loss brought forward	Currency translation differences	Total share-holder equity
Balance at 1 January 2021		**1,635,006**	**119,332,864**	**(2,250,413)**	**(119,080,220)**	**475,525**	**112,761**
Net loss for the period					(23,615,081)		(23,615,081)
Other comprehensive income				95,572		(255,836)	(160,263)
February 2021 Equity Placement	8.6	274,235	22,225,766				22,500,002
Capital increase Share Options	8.6	5,633	265,226				270,859
Capital increase convertible loan to shares	8.6	10,058	608,859				618,917
Transaction costs for equity instruments	7.2			(1,050,503)			(1,050,503)
Share-based compensation	9			536,389			536,389
31 December 2021		**1,924,932**	**142,432,715**	**(2,668,955)**	**(142,695,301)**	**219,689**	**(786,919)**
Balance at 1 January 2022		**1,924,932**	**142,432,715**	**(2,668,955)**	**(142,695,301)**	**219,689**	**(786,919)**
Net loss for the period					(30,763,083)		(30,763,083)
Other comprehensive income				413,370		726,751	1,140,121
March 2022 Equity Placement	8.6	535,329	27,884,645				28,419,974
Capital increase Share Options	8.6	226	6,779				7,005
Transaction costs for equity instruments	7.2			(734,789)			(734,789)
Share-based compensation	9			564,440			564,440
31 December 2022		**2,460,487**	**170,324,139**	**(2,425,934)**	**(173,458,384)**	**946,440**	**(2,153,252)**

The accompanying notes are an integral part of the Consolidated Financial Statements.

7
Consolidated Statement of Cash Flows

EUR	Notes	2022	2021
Net loss for the period		**(30,763,083)**	**(23,615,081)**
Income tax expense	7.5	386,629	393,272
Financial result	7.4	1,923,083	612,541
Depreciation	8.4	311,514	408,535
Change in defined benefit plan	8.9	(102,110)	(40,476)
Share-based compensation	9	564,440	536,389
Changes in trade and other receivables	8.2	(456,622)	(163,487)
Changes in inventories	8.3	42,417	(864,873)
Changes in trade and other payables / accrued liabilities	8.10	989,998	(662,243)
Taxes paid	7.5	(378,111)	(221,943)
Cash flow used for operating activities		**(27,481,845)**	**(23,617,366)**
Investments in tangible fixed assets	8.4	(676,736)	(325,782)
Investments in financial assets		23,644	(12,420)
Cash flow used for investing activities		**(653,092)**	(338,201)
Proceeds from capital increase	8.6	28,419,974	22,770,861
(Repayments) from leasing debts	8.7	(407,217)	(335,369)
(Repayments) from financial debts	8.7	-	-
Proceeds from financial debts	8.7	9,626,085	-
Interest paid	8.7	(314,516)	-
Cash flow generated from/used in (-) financing activities		**37,324,326**	22,435,491
Net change in cash and cash equivalents		**9,189,389**	**(1,520,075)**
Cash and cash equivalents at the beginning of the period		**9,600,412**	**11,016,143**
Net effect of currency translation on cash and cash equivalents		85,158	104,344
Cash and cash equivalents at the end of the period		**18,874,959**	**9,600,412**

The accompanying notes are an integral part of the Consolidated Financial Statements.

8
Notes to the Consolidated Financial Statements

1. Corporate Information

The Consolidated Financial Statements incorporate the financial statements of Sequana Medical NV, a company domiciled and incorporated in Belgium, and its subsidiaries (together referred to as "Sequana" or "Sequana Group" or "Group" or the "Company").

Sequana Medical NV has the legal form of a limited liability company (naamloze vennootschap/société anonyme) organised under the laws of Belgium. The Company was established as a limited liability company (Aktiengesellschaft/société anonyme) organised under the laws of Switzerland in 2007, and transferred its registered office, without liquidation or dissolution, from Switzerland to Belgium in 2018 (effective 1 October 2018). As a result, Sequana Medical NV became a limited liability company organised under the laws of Belgium.

The registered office's address is Kortrijksesteenweg 1112 bus 102, 9051 Sint-Denijs-Westrem,Belgium.

Sequana Medical NV is a pioneer in treating fluid overload, a serious and frequent clinical complication in patients with liver disease, heart failure and cancer. These patients can have up to 15 liters of extra fluid in their bodies, causing major medical issues including increased mortality, repeated hospitalizations, severe pain, difficult breathing and restricted mobility that severely impacts daily life. Although diuretics are standard of care, the problem is that in many patients they are no longer effective and / or tolerable. There are limited effective treatment options for these patients resulting in poor clinical outcomes, high costs and major impact on their quality of life. Sequana Medical is seeking to provide innovative treatment options for this large and growing "diuretic-resistant" patient population.

alfapump® and DSR® are Sequana Medical's proprietary platforms that work with the body to treat diureticresistant fluid overload, delivering major clinical and quality of life benefits for patients and reducing costs for healthcare systems. The Company has reported positive primary endpoint data from the North American pivotal POSEIDON study of the **alfa**pump in recurrent or refractory ascites due to liver cirrhosis, enabling the filing of a Pre-Market Approval (PMA) application with the FDA, planned for H2 2023. Having delivered clinical proof-of-concept for DSR as a disease-modifying drug program for the treatment of heart failure, the Company is planning to commence MOJAVE, a US multi-centered randomized controlled Phase 1/2a clinical study of DSR 2.0, in Q2 2023.

Group information

Information about the subsidiaries

The Consolidated Financial Statements of Sequana Group include:

Company	Purpose	Share capital	Investment 2022	Investment 2021
Sequana Medical NV	Holding/Sales	EUR 2,460,487	n/a	n/a
Sequana Medical branch (Switzerland)	Production and research	n/a	n/a	n/a
Sequana Medical GmbH (Germany)	Distribution	EUR 25,000	100%	100%
Sequana Medical Inc (USA)	Administration	USD 0	100%	100%

There are no non-controlling interests or structured entities. All entities have been newly established by the Group and included in the Consolidated Financial Statement as from their respective date of incorporation.

The holding company

The ultimate parent of the Group is Sequana Medical NV (the "Company"). The Group has no associated companies nor joint arrangements to which the Group is a party.

Shareholder structure

The shareholder structure of the Company based on the transparency declarations, received in the period up to 31 December 2022, is as follows:

Shareholder	Shares	%
NeoMed IV Extension L.P. / NeoMed Innovation V L.P	4,288,988	18.1%
Partners in Equity V B.V.	3,636,363	15.3%
LSP Health Economics Fund Management B.V.	1,887,895	8.0%
Société Fédérale de Participations et d'Investissement SA - Federale Participatie- en Investeringsmaatschappij NV	1,744,961	7.3%
Participatiemaatschappij Vlaanderen NV	1,656,803	7.0%
Newton Biocapital I Pricav Privée SA	1,102,529	4.6%
GRAC Société Simple	1,008,333	4.2%
Belfius Insurance SA	995,893	4.2%
Sensinnovat BV	900,769	3.8%
Total threshold	**17,222,534**	**72.5%**
Other	*6,523,994*	*27.5%*

For the latest available update, refer to the Company's website.

2. Basis of preparation of the Consolidated Financial Statements

2.1. Basis of preparation

These Consolidated Financial Statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as endorsed by the EU. The Consolidated Financial Statements are presented in Euro ("EUR") and have been rounded to the next EUR.

The preparation of financial statements requires management to exercise judgment when applying accounting policies and to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

Actual results could differ from those estimated. Note 2.3 below includes further discussion of certain critical accounting estimates.

The operational expenses in the Consolidated Income Statement are presented by function and more specifically, according to the departments Sales & Marketing, Clinical Affairs, Quality & Regulatory, Supply Chain, Engineering and General & Administration.

Sales & Marketing expenses relate to the direct costs associated with the sales force of Sequana Medical, as well as the promotional activities to raise awareness of the **alfa**pump® amongst the medical community, patients and their relatives.

Clinical Affairs expenses relate to the expenses made for clinical studies to demonstrate the safety and efficacy of the **alfa**pump® and the DSR® product.

The costs of obtaining and maintaining regulatory approval for the **alfa**pump and the DSR® product are included within Quality & Regulatory expenses. Employee related costs, such as salaries, benefits and travel expenses, of Sequana Medical employees are a key part of Quality & Regulatory expenses. The cost of regular audits and regulatory filings, internal and external costs related to testing and validation, as well as costs associated with external consultants who are amongst others involved in the preparation of the submissions for marketing approval of the **alfa**pump in the U.S. and Canada, are also included within quality and regulatory expenses.

The cost of Supply Chain primarily includes employee-related costs, such as salaries and benefits of Sequana Medical employees, as well as external suppliers' services. Additionally, yield loss costs and material costs for internal use are included in Supply Chain expenses.

Sequana Medical's engineering expenses primarily include employee-related costs, such as salaries, benefits and travel expenses, of Sequana Medical employees, as well as external consultants and suppliers, involved in the design of the **alfa**pump. The expenses related to the preparation of the submissions for marketing approval of the **alfa**pump in the U.S. and Canada, are also included within Engineering expenses.

The principal components of General & administration expenses are salaries and related costs for personnel and external consultants in executive, finance, accounting, tax, audit, legal and human resources functions and their respective external advisers. General & administration expenses also include the costs related to the general information and communication technologies as well as lease, rental, insurance, general maintenance expenses and costs related to the activities of being a public company.

The Consolidated Financial Statements were approved for issue by the Board of Directors on 21 April 2023.

2.2. *Principles of consolidation*

The Consolidated Financial Statements of Sequana Medical include all entities that are controlled by the Group. The Group controls another entity when it is exposed, or has rights, to variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Newly acquired companies are consolidated starting from the date of acquisition. The results of companies over which control is lost, are included until the date of sale or actual loss of control.

All intercompany transactions and balances between Group companies are eliminated in full.

The individual financial statements of the Group Companies as of 31 December 2022 are prepared using uniform accounting policies.

2.3. *Significant accounting policies, judgments and estimates*

This note describes the impact on Sequana Medical's Consolidated Financial Statements of significant accounting judgments made when applying IFRS and critical assumptions and accounting estimates.

2.3.1. APPLICATION OF CRITICAL ACCOUNTING POLICIES

2.3.1.1. Revenue recognition

Sequana Medical recognizes revenue at the amount it expects to be entitled as it satisfies promises towards its customers, regardless of when the payment is received. The performance obligation is considered to be satisfied, once the device has been implanted into the patient, as no significant obligations are considered to exist for Sequana Medical after such time.

Revenue is measured at the fair value of the consideration received or receivable, taking into account contractually defined terms of payment and excluding taxes or duty. The Group has concluded that it is the principal in all of its revenue arrangements, including in its sales to distributors, if any since it is the primary obligor in all the revenue arrangements, has pricing latitude, and carries inventory risk.

The Group reduces revenue by the amount of expected returns, and records it as accrued liabilities and provisions. No cash refunds are offered for returns, but rather replacement products. The Group estimates returns on the basis of historical data, adjusted for any additional relevant information about the customer or delay in implant.

Contract liabilities refer to advances received from customers, for which revenue is recognized only upon implant to the final customer.

Refer to note 5 and 6 for detailed information concerning revenue recognition for the period.

2.3.1.2. Other income

As the Group is carrying out extensive research and development activities, it can benefit from several grants and R&D incentives from various governmental agencies. In general, these benefits aim to partially reimburse certain expenditures linked to our research and development activities and are credited towards Other income in the Consolidated Income Statement, when the relevant expenditure has been incurred and when it is reasonably certain that the grants or R&D incentives are receivable.

2.3.1.3. Sales tax

Expenses and assets are recognized net of the amount of sales tax, except when the sales tax incurred on a purchase of assets or services is not recoverable from the taxation authority, in which case, the sales tax is recognized as part of the cost of acquisition of the asset or as part of the expense item, as applicable. VAT on lease payments is not included in the right-of-use asset as described in note 2.3.1.18 Leases.

The net amount of sales tax recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the statement of financial position.

2.3.1.4. Foreign currency translation

The Group`s Consolidated Financial Statements are presented in EUR. For each entity, the Group determines the functional currency and items included in the financial statements of each entity are measured using that functional currency. Consequently, the functional currency of the subsidiaries does not necessarily correspond to the functional currency of the parent. The functional currencies as per 31 December 2022 are as follows:

Sequana Medical NV : EUR

Sequana Medical branch : CHF

Sequana Medical Gmbh : EUR

Sequana Medical Inc : USD

Transactions in foreign currencies are initially recorded by the Group's entities at their respective functional currency spot rates at the date the transaction first qualifies for recognition.

Items of income and cash flow statements are measured by entities at the date of transaction. For practical reasons for translation of income statement and cash flow statement the average exchange rate of the period is applied.

Differences arising on settlement or translation of monetary items are recognized in profit or loss, financial result line.

The results and financial position of foreign operations that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for each statement of financial position presented are translated at the closing rate at the date of that statement of financial position;
- income and expenses for each statement of profit or loss and statement of comprehensive income are translated at average exchange rates (unless this is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transactions); and
- all resulting exchange differences are recognised in other comprehensive income.

On consolidation, exchange differences arising from the translation of any net investment in foreign entities are recognised in other comprehensive income. The main currency translation differences arise from the movements in the CHF/EUR exchange rate.

When a foreign operation is sold, the associated exchange differences are reclassified to profit or loss, as part of the gain or loss on sale.

The following foreign exchange rates, which were applied for the Consolidated Financial Statements at 31 December 2022 and the comparative periods to translate the following currencies into EUR, are as follows:

Currency	31 December 2022		31 December 2021	
	Year-end	Average Rate	Year-end	Average Rate
Swiss Franc (CHF)	0.9847	1.0047	1.0331	1.0811
US Dollar (USD)	1.0666	1.053	1.1326	1.1827

2.3.1.5. Income tax

Current income tax assets and liabilities are measured at the amount expected to be recovered from or payable to the respective tax authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantially enacted at the reporting date in the countries where the Group operates and generates taxable income.

Current income tax relating to items recognized directly in equity is recognized in equity. Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

Deferred tax

Deferred tax is provided using the balance-sheet liability method on temporary differences at the reporting date between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes. Deferred tax liabilities are recognized for all temporary differences, except where the deferred tax liability arises from the initial recognition of goodwill or of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither accounting profit nor taxable profit or loss.

Deferred tax assets are recognized for all deductible temporary differences and carry-forwards of unused tax credits and unused tax losses to the extent that it is probable that taxable profit will be available. Deductible temporary differences, carry-forwards of unused tax credits and unused tax losses can be offset against taxable profit except where the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss.

Deferred tax positions associated with investments in subsidiaries are only recognized to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available, against which they can be utilized.

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilized.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year the asset is realized or the liability settled, based on tax rates (and tax laws) enacted or substantively enacted at the reporting date. Deferred tax assets and liabilities are offset if the Group has a legally enforceable right to offset current tax assets against current tax liabilities and the deferred tax relates to the same taxable entity and the same tax authority.

2.3.1.6. Property, plant and equipment

Property plant and equipment is stated at cost, net of accumulated depreciation and accumulated impairment losses. Costs for repair and maintenance are recognized in profit or loss as incurred.

Each item of property, plant and equipment with a cost that is significant in relation to the total cost of the item is depreciated over its useful life. Sequana Medical recognizes the depreciation charge in profit or loss unless it is included in the carrying amount of another asset. At least annually, the Group reviews depreciation method, useful life on an asset and residual value, and if appropriate adjusts prospectively.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets, as follows:

Asset class	Depreciation method	Useful life
Installation & Machinery	Straight-line	5 - 10 years
Furniture, fixtures & vehicles	Straight-line	3 - 10 years
Other tangible fixed assets	Straight-line	2 - 10 years
Leased assets	Straight-line	Contract lease term
Assets under construction	Not depreciated	N/A

Leasehold improvements are reported as Other tangible fixed assets. An item of property, plant and equipment and any significant part initially recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on de-recognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the statement of profit or loss when the asset is derecognised.

2.3.1.7. Internally generated intangible assets

Expenditures on research activities are recognized as an expense in the period in which they are incurred.

In accordance with IAS38, an intangible asset arising from development (or from the development phase of an internal project) shall be recognized if, and only if, an entity can demonstrate all of the following:

(a) the technical feasibility of completing the intangible asset so that it will be available for use or sale;
(b) its intention to complete the intangible asset and use or sell it;
(c) its ability to use or sell the intangible asset;
(d) how the intangible asset will generate probable future economic benefits. Among other things, the entity can demonstrate the existence of a market

for the output of the intangible asset or the intangible asset itself or, if it is to be used internally, the usefulness of the intangible asset;

(e) the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset;

(f) its ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for internally generated intangible assets is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria listed above. When no internally generated intangible asset can be recognized, development expenditures are recognized in the Consolidated Income Statement in the period in which they are incurred.

Subsequent to initial recognition, internally generated intangible assets are reported at cost less accumulated amortization and accumulated impairment losses.

Due to uncertainties inherent to the development and registration with the relevant healthcare authorities of its products, Sequana Medical estimates the conditions for capitalization are not met until the regulatory procedures required by such healthcare authorities have been finalized.

The Company currently has no development expenditures that have been capitalized.

2.3.1.8. Trade receivables

In accordance with IFRS 9, trade receivables are classified and measured at amortised cost. The measurement bases are contractual terms, payment history and other sales evidence. Adjustments for doubtful receivables are only allowed to the extent losses are expected in the future or individually determinable. Any losses caused by amortization of receivables are booked in income statements.

The Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables. To measure the expected credit losses, trade receivables have been grouped based on shared credit risk characteristics and the days past due. The historical loss rates are adjusted to reflect current and forward-looking information on macroeconomic factors affecting the ability of the customers to settle the receivables.

2.3.1.9. Other non-current assets

Other non-current assets are measured at amortized cost. They mainly consist of R&D incentives receivables. These receivables are future expected tax deductions or refunds resulting from tax incentives on research and development expenses. The non-current portion of these receivables are discounted over the period until maturity date according to appropriate discount rates. In the event the receivable (or part of) becomes current, it (the current part) is classified in current assets on the Consolidated Statement of Financial Position. The R&D incentives are accounted for in line with IAS12.

2.3.1.10. Inventory

Inventories are valued at the lower of initial cost and net realizable value. The cost of inventories shall comprise all costs of purchase (based on first-in, first- out method), costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

The net realisable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and the estimated costs necessary to make the sale.

2.3.1.11. Cash and cash equivalents

Cash and cash equivalents consists of cash on hand and cash equivalents. The cash is held with bank and financial institutions which have as a minimum an A rating.

2.3.1.12. Share capital

Financial instruments issued by the Group are classified as equity only to the extent that they do not meet the definition of a financial liability or financial asset. Ordinary shares are classified as equity.

Incremental costs directly attributable to the issue of new ordinary shares are presented in equity as a deduction, net of tax, from the proceeds.

2.3.1.13. Provisions

Provisions are recognized when:

1. the Group has a present legal or constructive obligation as a result of past events;
2. it is probable that an outflow of resources will be required to settle the obligation; and
3. the amount has been reliably estimated.

Provisions are measured at the present value of the expenditures expected to be required to settle the obligation using a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the obligation. The increase in the provision due to passage of time is recognized as finance cost.

If the Group has an onerous contract, it will be recognized as a provision.

Provisions are not recognized for future operating losses.

A provision for restructuring is only recorded if the Group demonstrates a constructive obligation to restructure at the date of the statement of financial position. The constructive obligation should be demonstrated by:

(a) A detailed formal plan identifying the main features of the restructuring; and

(b) Raising a valid expectation to those affected that it will carry out the restructuring by starting to implement the plan or by announcing its main features to those affected.

2.3.1.14. Employee benefits

Short-term employment benefits

Short-term employee benefits are recorded as an expense in the income statement in the period in which the services have been rendered. Any unpaid compensation is included in 'Other payables' in the Consolidated Statement of Financial Position.

Post-employment benefits

The Group has both defined contribution plans and defined benefit plans.

In the case of defined contribution plans, contributions are paid to publicly or privately administered pension plans on a statutory, contractual, or voluntary basis. The Belgian defined contribution plan contains a legally guaranteed minimum return, which is payable by the employer. The contributions are recognized as personnel expenses.

Defined benefit plans require the Group to contribute to individual plans, for which the ultimate benefit to the employee is based on a defined benefit, e.g., based on a final salary level, defined performance of the plan, etc. For defined benefit plans, the Group obtains actuarial valuations to determine the required defined benefit pension obligation.

General

Wages, salaries, social security contributions, paid annual leave and sick leave, bonuses, and non-monetary benefits are accrued in the year in which the associated services are rendered by employees of the Company.

Pension obligations

The cost of providing benefits under the defined benefit plan is determined using the projected unit credit method.

Remeasurements, comprising of actuarial gains and losses, the effect of the asset ceiling, excluding net interest and the return on plan assets (excluding net interest), are recognized immediately in the statement of financial position with a corresponding debit or credit to retained earnings through OCI in the period in which they occur. Re-measurements are not reclassified to profit or loss in subsequent periods.

Past service costs are recognized in profit or loss on the earlier of:

- the date of the plan amendment or curtailment; and
- the date that the Company recognizes restructuring-related costs.

Net interest is calculated by applying the discount rate to the net defined benefit liability or asset and is disclosed in the respective expense by function.

The Group recognizes the service costs comprising current service costs, past-service costs, gains and losses on curtailments and non-routine settlements in the net defined benefit obligation under the respective expenses by function.

2.3.1.15. Loans and borrowings

After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortized cost using the effective interest method. Gains and losses are recognized in profit or loss when the liabilities are derecognized as well as through the effective interest amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest method. The amortization is included as finance costs in the Consolidated Income Statement.

The convertible loans are hybrid instruments and contain a liability as well as an embedded derivative (conversion option). They can also be compound instruments and in case of Sequana Medical, these are the EUR denominated loans in particular. There are two methods with respect to the accounting treatment for hybrid instruments (liability with an embedded derivative i.c. the conversion option). The instrument as a whole can either be accounted for as follows:

1. both the liability (host contract) and embedded derivative are classified at FVTPL (fair value through Profit and Loss)

or

2. the derivative is split and shown separately and accounted for at FVTPL (fair value through Profit and Loss) while the liability part (host contract) is valued at amortised cost.

The Group has elected to apply the method 1.:

The entire instrument has been designated at fair value through profit or loss (FVTPL) on initial recognition and as such, the embedded conversion feature is not separated. The consideration received corresponds to the fair value at inception of the whole instrument.

Financial liabilities at fair value through profit or loss (FVTPL) (including derivatives that are liabilities) are subsequently measured at fair value at each year-end. A gain or loss resulting from this measurement shall be presented as follows (IFRS 9, 5.7.7):

(a) The amount of change in the fair value of the financial liability that is attributable to changes in the credit risk of that liability shall be presented in other comprehensive income, and
(b) the remaining amount of change in the fair value of the liability shall be presented in profit or loss unless the treatment of the effects of changes in the liability's credit risk described in (a) would create or enlarge an accounting mismatch in profit or loss (in which case paragraph 5.7.8 applies).

The Group has no other derivative financial instruments, in all material respect, to hedge interest rates and foreign currency risks.

Fair value measurement of financial instruments

a. Fair value hierarchy

This note presents the judgements and estimates made by the Group in determining fair values of the financial instruments recognized and measured at fair value in the financial statements. To provide an indication about the reliability of the inputs used in determining fair value, the Group has classified its financial instruments into the three levels prescribed under the accounting standards.

Recognized fair value measurements:

Level 1: The fair value of financial instruments traded in active markets is based on quoted market prices at the end of the reporting period.

Level 2: The fair value of financial instruments that are not traded in an active market is determined using valuation techniques, which maximize the use of observable market data and rely as little as possible on entity- specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.

Level 3: If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3. This is the case for unlisted debt securities.

There were no transfers between levels for recurring fair value measurements during last year.

The Group's financial instruments measured at fair value on a recurring basis are classified as level 3. This is due to the market interest rate, on which basis the valuation of the financial liabilities was performed, being based on the most current loans with related parties.

The following table presents the Group's financial liabilities measured and recognized at fair value at 31 December 2022 and 31 December 2021:

Description	Note	Level	At 31 December 2022 (EUR)	At 31 December 2021 (EUR)
EUR denominated convertible loans at fair value through PL	8.7	3	934,779	876,126
Bootstrap Warrants	8.8.1	3	1,103,277	-
Kreos Subscription Rights	8.8.2	3	465,508	-

The carrying amounts of other financial instruments that are not measured subsequently at fair value are not materially different from their fair values due to their nature.

b. Valuation techniques used to determine fair values

The fair value of the company's convertible loans is determined using discounted cash flow analysis, based on a market yield around 20% for similar loans, which is deemed to be the best indicator of the market interest rate for loans without conversion features for Sequana Medical. With respect to the valuation of the embedded derivative, the Company assumed that the conversion option will be exercised within the requirements set in the agreements.

For more details on valuation techniques used to determine fair values of Bootstrap Warrants and Kreos Subscription Rights, refer to notes 8.8.1. and 8.8.2.

c. Valuation inputs and relationships to fair value

Description/Financial statement	Liability component of convertible bond denominated EUR including the conversion option
Class of subsequent measurement	Fair value through profit or loss
Fair value at 31 December 2022	934,779
Unobservable inputs	Discount rate / market rate
Yield	20%
Relationship of unobservable inputs to fair value	An increase/decrease of the market interest rate of +2%pts/-2%pts would change the fair value of the liability by EUR – 39,289/+ 39,289

As the yield represents the only unobservable input, there are no inter-relationships between any unobservable inputs that affect fair values.

Decription/ Financial statement	Bootstrap warrants	Kreos Subscription rights
Class of subsequent measurement	Fair value through profit or loss	Fair value through profit or loss
Fair value at 31 Dec. 2022	1,103,277	465,508
Unobservable inputs	Volatility and market rate	Volatility and market rate
Relationship of unobservable inputs to fair value	An increase/ decrease of the volatility rate of +20%pts/-20%pts would change the fair value of the liability by EUR + 125,549/ - 73,514	An increase/ decrease of the volatility rate of +20%pts/-20%pts would change the fair value of the liability by EUR + 135,323/ - 145,982
	An increase/ decrease of the market interest rate of +2%pts/-2%pts would change the fair value of the liability by EUR + 46,636/ - 48,087	An increase/ decrease of the market interest rate of +2%pts/-2%pts would change the fair value of the liability by EUR + 38,606/ - 38,980

d. Valuation processes

The only level 3 inputs by the Group in measuring the fair value of financial liabilities are market interest rates. The inputs are derived and evaluated by recent comparable bonds having no conversion rights at the issue date.

2.3.1.16. Trade payables

Payables after and within one year are measured at amortised cost, i.e. at the net present value of the payable amount. Unless the impact of discounting is material, the nominal value is taken.

2.3.1.17. Share-based compensation transactions

The Group has offered equity-settled, share-based compensation plans to its employees, Executive Management and specific consultants.

The cost with respect to the employee services received in compensation for the grant of these warrants is recognized as an expense.

The total amount of the expense is recognized over the vesting period and determined on the basis of the fair value of the warrants at grant date. The fair value of each warrant is estimated on the date of grant using the Black-Scholes model, which take into account the exercise price of the option, the share price at date of grant of the option, the risk-free interest rate, the expected volatility of the share price over the life of the option and other relevant factors.

The total cost is initially estimated on the basis of the number of warrants that will become exercisable. At each balance date, the Group revises its estimates of the number of warrants that will become exercisable. The impact of the revision is recognised in the income statement over the remaining vesting period with a corresponding adjustment to equity.

When the options are exercised, the proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium.

The social security contributions payable in connection with the grant of the options are considered as a part of the grant itself.

2.3.1.18. Leases

The Group leases various company cars and buildings. Rental contracts for the cars are typically made for fixed periods of 3 to 5 years and the rental contracts for the offices are typically made for 2 to 9 years. The contracts may have extension options. Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. The lease agreements do not impose any covenants, but leased assets may not be used as security for borrowing purposes.

Leases are recognised as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Group. Each lease payment is allocated between the liability and finance cost. The finance cost is charged to profit and loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period. The right-of-use asset is depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments, if material:

- Fixed payments (including in-substance fixed payments), less any lease incentives receivable;
- Variable lease payment that are based on an index or a rate;
- Amounts expected to be payable by the lessee under residual value guarantees;
- The exercise price of a purchase option if the lessee is reasonably certain to exercise that option; and
- Payments of penalties for terminating the lease, if the lease term reflects the lessee exercising that option.

The lease payments are discounted using the interest rate implicit in the lease. If that rate cannot be determined, the lessee's incremental borrowing rate is used, being the rate that the lessee would have to pay to borrow the funds necessary to obtain an asset of similar value in a similar economic environment with similar terms and conditions. The Group uses the incremental borrowing rate as its discount rate. The discount rates applied range between 5.8% and 12%.

Right-of-use assets are measured at cost comprising the following:

- The amount of the initial measurement of lease liability;
- Any lease payments made at or before the commencement date less any lease incentives received;
- Any initial direct costs (if material); and
- Restoration costs (if material).

Payments associated with short-term leases and leases of low-value assets are recognised on a straight-line basis as an expense in profit or loss. Short-term leases are leases with a lease term of 12 months or less. Low-value assets comprise IT-equipment and small items of office furniture.

2.3.1.19. Earnings/(loss) per share

Basic net profit/(loss) per share is computed on the basis of the weighted average number of ordinary shares outstanding during the period, excluding treasury shares.

Diluted net profit/(loss) per share is computed based on the weighted-average number of ordinary shares outstanding including the dilutive effect of warrants and bonds. During 2022 and 2021 due to the losses

incurred by the Group, these instruments had an anti-dilutive effect on the loss per share. Instruments that can be converted into ordinary shares shall only be treated as dilutive when their conversion into ordinary shares would decrease earnings per share or increase loss per share from continuing operations.

2.3.2. SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS

For the preparation of the Consolidated Financial Statements it is necessary to make judgments, estimates and assumptions to form the basis of presentation, recognition and measurement of the Group's assets, liabilities, items of income statements, accompanying disclosures and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

In the process of applying Sequana Medical's accounting policies, management has made various judgments. Those which management has assessed to have the most significant effect on the amounts recognized in the Consolidated Financial Statements have been discussed in the individual notes of the related financial statement line items.

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial years, are also described in the individual notes of the related financial statement line items.

The Group based its assumptions and estimates on parameters available when the Consolidated Financial Statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond the control of the Group. Such changes are reflected in the assumptions when they occur.

Sequana Medical is subject to risks and uncertainties, which may lead to actual results differing from these estimates, both positively and negatively. Sequana Medical's specific estimates including pension liabilities, fair value of financial instruments or share-based compensation are discussed in the relevant sections of the management's review and in the notes.

Significant estimates and judgments of the Group include:

- Pensions (IAS 19) – key assumptions for measuring defined benefit for measuring post-employment benefit expense for a period and the defined benefit obligation at the period end;
- Share-based compensation;
- Accounting for research and development expenses.

2.3.2.1. Post-employment benefits

The aggregate of the present value of the defined benefit obligation and the fair value of plan assets for each plan is recognized in the Consolidated Financial Position as a net defined benefit liability or net defined benefit asset. The defined benefit obligation is determined annually by independent actuaries using the projected unit credit method. Employee contributions are recognized in the period in which the related service is rendered. Plan assets are not available to the creditors of the Group.

Pension costs consist of three elements: service costs, net interest, and re-measurements of employee benefits.

- Service costs are part of personnel expenses and consist of current service costs, past service costs (gains/losses from plan amendments or curtailments), and gains/losses from plan settlements.
- Net interest is recorded in the financial result and is determined by applying the discount rate to the net defined benefit liability or net defined benefit asset that exists at the beginning of the year.
- Gains and losses resulting from the actuarial valuation are recorded in other comprehensive income (OCI) as re-measurements of employee benefits. The return on plan assets (excluding interest based on the discount rate) and any change in the effect of an asset ceiling are also recorded in OCI.

Significant other non-current employee benefits (mainly jubilee benefits) are also measured using the projected unit credit method, however re-measurements are recorded in the Consolidated Income Statement.

Detailed information about the assumptions and measurement of post-employment benefits are included in note 8.9.

Termination benefits are recognized on the date on which the Group can no longer withdraw the offer of this type of benefit or on which restructuring provisions are recorded.

2.3.2.2. Share-based payments

The Group used the Black & Scholes model for share-based payment calculation purposes for the Executive share-based option plan, implemented early October 2018. The volatility parameter has been based on the volatility of peer shares, listed on the STOXX Medtech stock exchange.

The share price considered is EUR 9.25 and is the lowest based on the expected gross amount of IPO proceeds of EUR 30.0 million, whereas probability weighted scenarios between EUR 9.25 and EUR 10.50 per share have been applied. For more information refer to note 9.1.

Employee turnover as a parameter for share-based payment calculations is considered to be limited.

The Group used as well the Black & Scholes model for share-based payment calculation purposes for the 2018 Share Option plan, approved by the extra-ordinary shareholders meeting of 18 January, 2019. The volatility parameter has been based on the volatility of peer shares, listed on the STOXX Medtech stock exchange.

The weighted average share price considered is calculated as the average of the historical actual share prices for the thirty days period prior to the grant of the options. For more information refer to note 9.2.

Employee turnover as a parameter for share-based payment calculations is considered to be limited.

The Group used as well the Black & Scholes model for share-based payment calculation purposes for the 2021 Share Option plan, approved by the extra-ordinary shareholders meeting of May, 27 2021. The volatility parameter has been based on Company's shares.

The weighted average share price considered is calculated as the average of the historical actual share prices for the thirty days period prior to the grant of the options. For more information refer to note 9.3.

Employee turnover as a parameter for share-based payment calculations is considered to be limited.

2.3.2.3. Accounting for research and development expenses

Due to uncertainties inherent to the development and registration with the relevant healthcare authorities of its products, Sequana Medical estimates the conditions for capitalization are not met until the regulatory procedures required by such healthcare authorities have been finalized.

The Company currently has no development expenditures that have been capitalized.

2.3.3. ISSUED STANDARDS, AMENDMENTS OR INTERPRETATIONS ADOPTED AND NOT YET ADOPTED

The following amendments to standards are mandatory for the first time for the financial year beginning 1 January 2022 and have been endorsed by the European Union and have no material impact on the Group's Consolidated Financial Statements:

- Amendments to IAS 16 Property, Plant and Equipment; IAS 37 Provisions, Contingent Liabilities and Contingent Assets as well as Annual Improvements (effective 1 January 2022). The package of amendments includes narrow-scope amendments to three Standards as well as the Board's Annual Improvements, which are changes that clarify the wording or correct minor consequences, oversights or conflicts between requirements in the Standards.
  - o Amendments to IAS 16 Property, Plant and Equipment prohibit a company from deducting from the cost of property, plant and equipment amounts received from selling items produced while the company is preparing the asset for its intended use. Instead, a company will recognise such sales proceeds and related cost in profit or loss.
  - o Amendments to IAS 37 Provisions, Contingent Liabilities and Contingent Assets specify which costs a company includes when assessing whether a contract will be loss-making.
  - o Annual Improvements 2018-2020 make minor amendments to IFRS 1 First-time Adoption of International Financial Reporting Standards, IFRS 9 Financial Instruments, IAS 41 Agriculture and the Illustrative Examples accompanying IFRS 16 Leases.
- Amendment to IFRS 16 Leases Covid 19-Related Rent Concessions beyond 30 June 2021 (effective 01/04/2021, with early application permitted).

  The amendments extend, by one year, the May 2020 amendment that provides lessees with an exemption from assessing whether a COVID-19-related rent concession is a lease modification. In particular, the amendment permits a lessee to apply the practical expedient regarding COVID-19-related rent concessions to rent concessions for which any reduction in lease payments affects only payments originally due on or before 30 June 2022 (rather than only payments originally due on or before 30 June 2021). The amendment is effective for annual reporting periods beginning on or after 1 April 2021 (earlier application permitted, including in financial statements not yet authorised for issue at the date the amendment is issued).

The following new standards and amendments have been issued, are not mandatory for the first time for the financial year beginning 1 January 2022 but have been endorsed by the European Union and have no material impact on the Group's Consolidated Financial Statements:

- IFRS 17 'Insurance contracts' (effective 1 January 2023). This standard replaces IFRS 4, which currently permits a wide variety of practices in accounting for insurance contracts. IFRS 17 will fundamentally change the accounting by all entities that issue insurance contracts and investment contracts with discretionary participation features. On 17 March 2020, IASB decided to defer pop effective date to annual reporting periods beginning on or after 1 January 2023. The endorsement includes the amendments issued by the Board in June 2020, which are aimed at helping companies implement the Standard and making it easier for them to explain their financial performance. The EU regulation provides an optional exemption from applying the annual cohort requirement that relates to the timing of the recognition of the profit in the contract, the contractual service margin, in profit or loss. Entities making use of the exemption are not applying IFRSs as issued by the IASB and need to disclose the fact
- Amendments to IAS 1 Presentation of Financial Statements and IFRS Practice Statement 2: Disclosure of Accounting policies (effective 1 January 2023). The amendments aim to improve accounting policy disclosures and to help users of the financial statements to distinguish between changes in accounting estimates and changes in accounting policies. The IAS 1 amendment requires companies to disclose their material accounting policy information rather than their significant accounting policies. Further, the amendment to IAS 1 clarifies that immaterial accounting policy information need not be disclosed. To support this amendment, the Board also amended IFRS Practice Statement 2, 'Making Materiality Judgements', to provide guidance on how to apply the concept of materiality to accounting policy disclosures. The amendments are effective for annual reporting periods beginning on or after 1 January 2023. Earlier application is permitted (subject to any local endorsement process).
- Amendments to IAS 8 Accounting policies, Changes in Accounting Estimates and Errors: Definition of Accounting Estimates (effective 1 January 2023). The amendment to IAS 8, 'Accounting Policies, Changes in Accounting Estimates and Errors', clarifies how companies should distinguish changes in accounting policies from changes in accounting estimates. The amendments are effective for annual reporting periods beginning on or after 1 January 2023. Earlier application is permitted (subject to any local endorsement process).
- Amendments to IAS 12 Income Taxes: Deferred Tax related to Assets and Liabilities arising from a Single Transaction (effective 1 January 2023). The amendments clarify how companies account for deferred tax on transactions such as leases and decommissioning obligations. The main change in the amendments is an exemption from the initial recognition exemption of IAS 12.15(b) and IAS 12.24. Accordingly, the initial recognition exemption does not apply to transactions in which equal amounts of deductible and taxable temporary differences arise on initial recognition. The amendments are effective for annual reporting periods beginning on or after 1 January 2023. Early adoption is permitted.
- Amendments to IFRS 17 Insurance contracts: Initial Application of IFRS 17 and IFRS 9 – Comparative Information (issued on 9 December 2021, effective 1 January 2023). The amendment is a transition option relating to comparative information about financial assets presented on initial application of IFRS 17. The amendment is aimed at helping entities to avoid temporary accounting mismatches between financial assets and insurance contract liabilities, and therefore improve the usefulness of comparative information for users of financial statements.

The following amendments have been issued, but are not mandatory for the first time for the financial year beginning 1 January 2022 and have not been endorsed by the European Union and are currently not expected to have a material impact on the Group's Consolidated Financial Statements:

- Amendments to IAS 1 'Presentation of Financial Statements: Classification of Liabilities as current or non-current' (effective 01/01/2024), affect only the presentation of liabilities in the statement of financial position — not the amount or timing of recognition of any asset, liability income or expenses, or the information that entities disclose about those items. They:
  - o Clarify that the classification of liabilities as current or non-current should be based on rights that are in existence at the end of the reporting period and align the wording in all affected paragraphs to refer to the "right" to defer settlement by at least twelve months and make explicit that only rights in place "at the end of the reporting period" should affect the classification of a liability;
  - o Clarify that classification is unaffected by expectations about whether an entity will exercise its right to defer settlement of a liability;

and make clear that settlement refers to the transfer to the counterparty of cash, equity instruments, other assets or services.

- Clarify how conditions with which an entity must comply within 12 months after the reporting period, such as covenants, affect the corresponding liability's classification.

The Group is continuously assessing the impact of the upcoming standards. The Group expects currently no material impact on the Group's Consolidated Financial Statements.

There were no other standards, interpretations or amendments that are not yet effective and that would be expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

2.3.4. CHANGES IN ACCOUNTING POLICIES

New standards or interpretations applicable from 1 January 2022 do not have any significant impact on the Group's Consolidated Financial Statements.

3. *Financial instruments and financial risk management*

The nature of Sequana Medical's business and its global presence exposes the Group to market risks and liquidity risks. The Board of Directors is responsible for overseeing the Group's internal control system, which addresses risks to which the Group is exposed. These systems provide appropriate security against significant inaccuracies and material losses. Management is responsible for identifying and assessing risks that are of significance for the respective country.

3.1. Market risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. The market risks consist primarily of foreign currency risks and, to a lesser degree, interest rate risks. Main currency exposures are the Swiss franc and the Euro. The Group is not hedging any of these risks.

3.1.1. FOREIGN CURRENCY RISKS

Foreign currency risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate due to changes in foreign exchange rates. The group identifies two main types of foreign currency risk: foreign currency transaction risk and foreign currency translation risk.

The Group incurs foreign currency transaction risk on accounts receivable, accounts payable and other monetary items that are denominated in a currency other than the Company's functional currency. Foreign currency transaction risk in the Group's operations also arises from the variability of cash flows in respect of forecasted transactions. The foreign currency transaction risk is not significant.

Foreign operations which do not have the Euro as their functional currency give rise to a translation risk. The Group operates internationally and is exposed to foreign exchange risks arising from currency exposures, primarily with respect to the Swiss Franc (CHF).

The carrying amounts of the Group's main foreign currency denominated assets and liabilities in CHF at the end of the reporting period are as follows:

CHF	31 December 2022	31 December 2021
Assets		
Inventory	2,581,381	2,617,495
Cash and cash equivalents	1,462,972	1,308,155
Liabilities		
Long term debt	-	-
Short term debt	-	-

The Group has exposures to the Swiss Franc (CHF) and the US dollar (USD) due to their net investments in foreign operations.

Foreign exchange exposures are currently not hedged.

The following table shows the sensitivity to foreign exchange rate changes (CHF / EUR and USD / EUR), with all other variables held constant, of the Group's income statement and equity:

As at 31 December 2022

EUR	Impact on income statement
5% decrease of average foreign exchange rate	-725,845
5% increase of average foreign exchange rate	+725,651

As at 31 December 2021

EUR	Impact on income statement
5% decrease of average foreign exchange rate	-559,564
5% increase of average foreign exchange rate	+560,700

As of 31 December 2022, if the EUR had weakened 5% against the CHF and against the USD with all other variables held constant, the loss for the period would have been EUR 725,845 higher (2021: EUR 559,564). Conversely, if the EUR had strengthened 5% against the CHF and the USD with all other variables held constant, the loss of the period would have been EUR 725,651 lower (2021: EUR 560,700).

As at 31 December 2022

EUR	Impact on equity
5% decrease of average foreign exchange rate	+36,338
5% increase of average foreign exchange rate	-36,338

As at 31 December 2021

EUR	Impact on equity
5% decrease of average foreign exchange rate	-12,792
5% increase of average foreign exchange rate	+12,792

As of 31 December 2022, if the EUR had weakened 5% against the CHF and against the USD with all other variables held constant, the equity for the period would have been EUR 36,338 lower (2021: EUR -12,792). Conversely, if the EUR had strengthened 5% against the CHF and the USD with all other variables held constant, the equity of the period would have been EUR 36,338 higher (2021: EUR 12,792).

3.1.2. INTEREST RATE RISKS

Interest rate risks arise from changes in interest rates, which have negative repercussions on the Group's asset and earnings situation. Interest rate fluctuations lead to changes in interest income and interest expense on interest-bearing assets and liabilities.

The following table shows the sensitivity to interest rate changes, with all other variables held constant, of the Group's income statement and equity:

As at 31 December 2022	
EUR	Impact on income statement and equity
50 basis points increase / decrease	-/+ 9,822

As at 31 December 2021	
EUR	Impact on income statement and equity
50 basis points increase / decrease	-/+ 5,768

As at 31 December 2022 and 31 December 2021, the Group interest rates applied on material interest-bearing assets and liabilities are contractually fixed and therefore the above sensitivity is highly unlikely to materialise.

3.2. Liquidity risk

The Group's objective is to maintain sufficient cash and the availability of funding through an adequate amount of committed credit facilities to meet obligations when due. Sequana Medical defines Liquidity risk, a risk of being unable to raise funds to meet payment obligations when they fall due.

		Cash outflows		
EUR	Carrying amount			
	31 December 2022	Up to 1 year	1 to 3 years	More than 3 years
Trade payables	3,391,783	3,391,783	-	-
Other payables	2,728,350	2,118,892	300,485	308,973
Financial debt at amortized cost	15,740,964	4,282,914	11,458,050	-
Financial debt at FVTPL	934,779	200,000	734,779	-
Total	**22,795,876**	**9,993,588**	**12,493,314**	**308,973**

				Cash outflows
EUR	Carrying amount			
	31 December 2021	Up to 1 year	1 to 3 years	More than 3 years
Trade payables	2,367,110	2,367,110	-	-
Other payables	2,684,918	2,207,606	473,053	4,259
Financial debt at amortized costs	6,448,708	-	4,425,000	2,023,708
Financial debt at FVTPL	876,126	-	600,000	276,126
Total	**12,376,863**	**4,574,717**	**5,498,053**	**2,304,094**

3.3. Capital management

Management presently monitors its capital structure based on its legal, statutory requirements for stand-alone entities and, in particular, for the holding company. The Group's policy is to maintain sufficient capital to continue as a going concern, and sustain the future development of the business (see note 4 regarding the assessment of the going concern).

Management monitors rolling forecasts of the Group's liquidity reserve and cash and cash equivalents on the basis of expected cash flows for the next 12 months. This is carried out in accordance with practice and limits set by management and in accordance with the statutory capital requirements of the holding company. In addition, the Group's liquidity management policy involves projecting cash flows in EUR, CHF and GBP and considering the level of liquid assets necessary to meet these, monitoring balance sheet liquidity ratios against internal requirements and maintaining debt-financing plans.

No changes were made in the objectives, policies or processes for managing capital during the years ended 31 December 2022 and 2021.

3.4. General business risks

Over the years 2022 and 2021 the macroeconomic environment have been affecting businesses globally, including Sequana Medical. We refer to the risk factors defined in our Report of the Board of Directors (1.1.3 Information regarding major risks and uncertainties).

In view of the geopolitical situation between Russia and Ukraine, the Group does not have any operations in Russia or Ukraine, although it has conducted its SAHARA clinical study in Georgia, which borders Russia. The conflict could have an adverse impact on global macroeconomic conditions generally, including due to the increase in oil and gas prices resulting from the conflict. This could in turn result in suppressed demand for the **alfa**pump® and/or any future products. Finally, the conflict may in the longer term result in issues for Sequana Medical in procuring sub-components for the **alfa**pump®, particularly since neon and palladium are often sourced from Ukraine.

In view of climate related matters, the Groups operations are not likely to be impacted by extreme weather conditions such as droughts, earthquakes or floods. Consequently, the Group does not expect any significant indicators for impairment of any assets nor understatement of any liabilities.

4. Going concern

The Company is still in its development phase for its **alfa**pump® and DSR® products, and is conducting clinical trials in order to achieve regulatory marketing approvals for these products. This entails various risks and uncertainties, including but not limited to the uncertainty of the development process and the timing of achieving profitability. The Company's ability to continue operations also depends on its ability to raise additional capital and to refinance existing debt, in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows.

The impact of macroeconomic conditions and the geopolitical situation on the Company's ability to secure additional financing rounds or undertake capital market transactions remains unclear at this point in time and will remain under review by the Executive Management and the Board of Directors.

The Consolidated Statement of Financial Position as at 31 December 2022 shows a negative equity in the amount of EUR 2.2 million and ending cash balance of EUR 18.9 million. Reference is also made to section 14 "Events after the Reporting Period" below.

Equity placement

The Company envisions to conclude a capital increase by means of a private placement through an accelerated book building procedure in the coming days. We refer to the press release available on the Company's

website dated 24 April 2023. The Company will regularly provide an update on the envisioned equity placement via its website.

The above conditions indicate the existence of material uncertainties, which may also cast significant doubt about the Company's ability to continue as a going concern.

The Executive Management and the Board of Directors made an assessment of the Company's ability to continue as a going concern. Several measures have already been carried out in order to reduce costs and expenditures, and the Company intends to carry out further savings.These measures include:

- Heart Failure / DSR: Slowing down the further progression of the MOJAVE clinical study. The Board of Directors notes that (i) the Company still targets results from the first 3 patients by Q4 2023 for the safety cohort, (ii) the first patients are most important as the Company is looking for confirmation that DSR 2.0 in US patients has same dramatic treatment effect as DSR 1.0 in the patients from Republic of Georgia (cfr. SAHARA and RED DESERT studies).
- US **alfa**pump program: Delaying the establishment of a new production facility.
- EU **alfa**pump commercial strategy: Reducing the Company's European commercial team by moving to a "reactive" rather than "proactive" commercial stance (i.e., ready to act on clinician interest and maintaining dialogue with key centres, instead of actively promoting the therapy). The Board of Directors notes that (i) the platform for training US clinicians and implanting teams remains available, and (ii) it intends to scale-up the European commercial teams in the future (when additional financing has been attracted).

The Company is also assessing to what extent partnerships or licensing arrangements could be entered into regarding its **alfa**pump® and DSR® products in order to support the further development, regulatory approval process, and subsequent marketing. While on the date hereof no concrete plans are on the table, the Company continuously engages with potential partners, which could also provide further funding to the Company's business.

The Board of Directors believes that a combination of one or more of the foregoing measures will help in addressing the Company's liquidity and funding structure. It also believes that these may further help in finding additional equity and/or debt financing from existing and/or new investors, as well as to renegotiate and/or refinance existing debt financing arrangements. Efforts in that respect are ongoing continuously. The Company has also control over its spendings, and management can timely and adequately reduce budgeted expenditures should this be necessary in the context of the Company's going concern and/or should it be necessary to have more time to obtain additional financing.

We also refer to note 14 Events after the reporting period in the Notes to Consolidated Financial Statements.

With the existing cash resources, the current cash runway is sufficient into mid-2023.

The Executive Management and the Board of Directors remain confident about the strategic plan, which comprises additional financing measures including equity and/or other financing sources, and therefore consider the preparation of the present Consolidated Financial Statements on a going concern basis as appropriate.

5. Revenues from customers

The Group generates sales solely from the sale of **alfa**pump®, with the revenue recognized at a point in time, coinciding with the time the device is implanted in a patient. In case an advance payment is received prior to implant, a contract liability is booked, which is reversed only at the time revenue is recognized.

An overview of the receivables and contract liabilities from contracts with customers is as follows:

EUR	2022	2021
Trade receivables	113,871	81,882
Contract liabilities (relating to customers' advance payments)	164,492	174,207

No significant financing component is included in the amount of advance payments received from customers.

Contract liabilities refer to advances received from customers, for which revenue is recognized only upon implant to the final customer. An overview of the changes in the contract liabilities from contracts with customers is as follows:

EUR	2022	2021
Revenue recognized in the period (included in contract liability at the beginning of the period)	-	-
Increases due to cash received as advance payment	-	-
Effect of currency translation	4,263	3,782

In the period, there was no revenue recognized from performance obligations satisfied or partially satisfied in the previous period.

The Group applies the practical expedient of IFRS 15 (paragraph 121), and does not disclose information about the aggregate transaction price of remaining performance obligations that have original expected durations of one year or less. The Group also applies the practical expedient in paragraph 94 of IFRS 15, whereby the incremental costs of obtaining contracts are expensed as incurred if the amortization period of the assets that the Group would otherwise have recognized is one year or less.

6. Segment information

Operating segments required to be reported are determined on the basis of the management approach. Accordingly, external segment reporting reflects the internal organizational and management structure used within the Group as well as the internal financial reporting to the Chief Operating Decision Maker (CODM), which has been identified as the Executive Management Board (EMB). The EMB is responsible for the operational management of the Group, in line with the instructions issued by the Board of Directors.

Based on the Group's structure Sequana Medical's only entity (branch), which performs production and procurement of its only product, **alfa**pump is located in Switzerland. All other entities are either administration or distribution entities and are not able to operate on a stand-alone basis. Therefore, Sequana Medical constitutes only one reportable segment, which is represented by the whole Group.

Nevertheless, the EMB monitors all revenues on a country-by-country basis.

An overview of revenue by primary geographic market for the Group's reportable segment is included below:

EUR	2022	2021
Germany	692,650	315,000
France	114,375	38,000
Switzerland	85,662	17,500
Rest of the world	30,000	-

EUR	2022	2021
Total revenue	**922,687**	**370,500**

Revenue increased from EUR 0.37 million in 2021 to EUR 0.92 million in 2022 as a result of resumed commercial activity in Europe as the impact of COVID declines.

All revenue is recognized at a point in time, being when the device has been implanted into the patient.

The Swiss branch is the sole operating entity within the Group, 24% of the assets are located in Switzerland compared to 39% last year. There are no significant concentrations of credit risk through exposure to individual customers.

7. Detailed information on profit or loss items

7.1. Breakdown of expenses by nature

EUR	2022	2021
Personnel costs	10,078,399	8,833,964
Clinical studies	7,706,860	6,140,218
External consultancy	3,485,913	2,884,383
External accounting & legal services	849,405	809,177
Travel & lodging	703,274	387,963
Rent & infrastructure expenses	289,312	349,016
Intellectual property	295,671	310,295
Insurance & IT	834,986	526,835
Marketing	95,743	100,698
Depreciation and amortization(I)	812,483	408,535
Quality audits / Regulatory fees	1,435,554	1,390,152
Other	2,755,150	1,971,241
Total operating expenses	**29,342,749**	**24,112,476**

7.2. Operating Expenses – general and administration

EUR	2022	2021
Capital increase related expenses	343,778	210,941

The total amount of known and accrued capital raise related expenditure for 2022 is EUR 1,078,568, of which EUR 343,779 has been recognized in the Consolidated Income Statement as G&A expenses and EUR 734,789 has been reported under equity. The capital raise expenditure accounted for in equity relate to the issuance of equity instruments and represent the incremental costs attributed to new shares. They mainly consist of lawyer fees, audit fees, consulting fees and notary fees.

In 2021, the total amount of known and accrued capital raise related expenses was EUR 1,261,444, of which EUR 210,941 has been recognized in the Consolidated Income Statement as G&A expenses and EUR 1,050,503 has been reported under equity. The capital raise expenses accounted for in equity relate to the issuance of equity instruments and represent the incremental costs attributable to new shares.

(I) The amount relating to amortization is not material, therefore depreciation and amortization are presented in a single position in the table above.

7.3. Other Income

EUR	2022	2021
R&D Incentives	510,222	582,447
Other	19,952	622,549
Total Other income	**530,174**	**1,204,996**

Other income decreased from EUR 1.21 million in 2021 to EUR 0.53 million in 2022 largely driven by the one-off termination of a distribution agreement in mutual agreement in 2021.

The R&D incentives income was predominantly composed of:

- Income from Belgian R&D incentives (tax credit) with regard to incurred R&D expenses amounting to EUR 442,390 in 2022 (2021: EUR 463,860).
- Reduction on payroll withholding taxes of R&D qualified employees in Belgium amounting to EUR 67,832 in 2022 (2021: EUR 118,587).

7.4. Financial result

The financial result is split into the following categories:

EUR	2022	2021
Finance income	**450,553**	**246,384**
Interest income	131	94
Foreign exchange gains	274,292	246,290
Remeasurement at FVTPL on subscription rights	176,129	-
Finance cost	**(2,732,522)**	**(854,549)**
Interest costs	(816,348)	(523,493)
Interest costs leasing	(63,608)	(36,323)
Remeasurement at FVTPL on convertible loans	(58,653)	(12,693)
Remeasurement at FVTPL on subscription rights	(1,103,277)	-
FV correction tax credit receivable	(124,043)	-
Foreign exchange losses	(566,593)	(282,040)
Net financial result	**(2,281,970)**	**(608,165)**

The remeasurement at FVTPL on subscription rights is relating to the Bootstrap Warrant and Kreos subscriptions rights as further disclosed in note 8.8.

The increase in interest costs is mainly relating to the Secured loan facility agreement with Kreos as further disclosed in note 8.7.2.

7.5. Income taxes

Income tax expense

EUR	2022	2021
Current income taxes	(386,629)	(393,272)
Total income tax expense	**(386,629)**	**(393,272)**

The following elements explain the difference between the income tax expense at the applicable Group tax rate and the effective income tax expense:

EUR	2022	2021
Loss before tax	**(30,376,454)**	**(23,221,809)**
Tax rate	25.00%	25.00%
Income tax expense at the calculated tax rate	**(7,594,114)**	**(5,805,452)**
Effect of non-recognition of tax losses in current year	(7,207,485)	(5,412,180)
Effective income tax expense	**(386,629)**	**(393,272)**

The tax rate is the domestic rate of tax in Belgium. No income tax was applicable for any items recorded directly in equity or OCI.

Taxes on unremitted earnings

At 31 December 2022 and 2021, there was no recognized deferred tax liability for taxes that would be payable on the unremitted earnings of certain of the Group's subsidiaries. The Group does not expect any distribution of retained earnings to the parent company within the next twelve months.

Deductible temporary differences and available tax loss carry – forwards

Deductible temporary differences and unused tax losses for which no deferred tax asset has been recognized:

EUR	31 December 2022	31 December 2021
Deductible temporary differences for which no deferred tax asset has been recognised	-	-
Belgium	75,003,294	50,537,141
Switzerland	-	-
USA	983,723	717,013
Total unused tax losses	**75,987,017**	**51,254,154**

As of 2019, the unused tax losses are mainly incurred by the Belgian company. As the Company did not generate any taxable profits in the past and due to the fact that there is an uncertainty about the realization of future taxable profits the Company has decided to not recognize a deferred tax asset on the tax losses carried forward. The unused tax losses have no expiration date.

The Group obtained a tax ruling with the Swiss tax authorities. In this tax ruling, it has been agreed that the Swiss branch will be taxable on a cost-plus basis. The cost-plus percentage is 10%. The 2022 estimated tax amount, amounting to CHF 354,416 or EUR 360,104 has been accrued for in the statement of financial position, Other payables.

7.6. Loss per share

The calculation of the basic earnings per share is based on the loss/profit attributable to the holders of ordinary shares and the weighted average number of ordinary shares outstanding during the period.

The Group offers its employee's share-based compensation benefits (see note 9), which may have a dilutive effect on the basic earning per share.

For the purpose of calculating diluted earning per share, the number of ordinary shares shall be the weighted average number of ordinary shares plus the weighted average number of ordinary shares that would be issued in case of conversion into ordinary shares of all instruments that can be converted into ordinary shares.

Due to the losses incurred by the Group, these instruments had an anti-dilutive effect on the loss per share. Instruments that can be converted into ordinary shares shall only be treated as when their conversion into ordinary shares would decrease earnings per share or increase loss per share from continuing operations.

EUR, except number of shares	2022	2021
Net loss attributable to shareholders	(30,763,083)	(23,615,081)
Weighted average number of shares - basic	22,769,576	18,212,944
Basic loss per share	**(1.35)**	**(1.30)**

8. Detailed information on statement on financial position items

8.1. Cash and cash equivalents

The Group held cash and cash equivalents of EUR 18,874,959 at 31 December 2022 (2021: EUR 9,600,412).

The cash is held with bank and financial institutions which are rated A as a minimum. All investments are highly liquid.

8.2. Trade receivables, other receivables and prepaid expenses

EUR	31 December 2022	31 December 2021
Trade receivables	113,871	81,882
Other receivables	292,330	301,244
Prepaid expenses	1,186,964	767,696

Other receivables mainly consist of VAT.

The total amount of Prepaid expenses in the statement of financial position amounts to EUR 1,186,964 (in 2021: EUR 767,696). For 2022 this is mainly related to prepayments for Clinical Research Organisations.

The following provides information about the exposure to credit risk and expected credit loss for trade receivables:

The counterparties are in most transactions hospitals in the public sector in Germany, Switzerland or France. Therefore, there were no credit losses in the past and the expected credit loss is close to nil.

The ageing of trade receivables at 31 December 2022 and 2021 past due, but not impaired, are as follows:

2022 (EUR)	Not past due	Total past due	0-90 days	90-180 days	180-360 days	More than 360 days
Trade receivables	68,931	44,940	44,940	-	-	-
Weighted average loss rate						

2021 (EUR)	Not past due	Total past due	0-90 days	90-180 days	180-360 days	More than 360 days
Trade receivables	24,075	57,807	57,807			
Weighted average loss rate						

8.3. Inventories

Inventories are categorized as follows:

EUR	31 December 2022	31 December 2021
Finished goods	500,634	499,698
Subassembly	174,671	161,722
Components	1,945,892	1,478,005
Total	**2,621,197**	**2,139,425**

No significant inventory write-down have been recorded nor any reversal of previous inventory write-downs. No write-downs of inventories to net realisable value have been recorded.

The increase in inventories is largely driven by the weakening of EUR compared to CHF.

8.4. Property, plant and equipment

Reconciliation of beginning and ending balance by classes of assets:

EUR				Fully owned
	Installation & machinery	Furniture, fixtures & vehicles	Other tangible fixed assets & AUC (I)	Total
Acquisition value				
1 January 2021	**126,671**	**539,346**	**23,151**	**689,168**
Additions	29,630	269,174	52,954	351,758
Disposals	-	-	-	-
Currency translation effects	(13,241)	(53,051)	(726)	(67,018)
31 December 2021	**143,060**	**755,469**	**75,379**	**973,909**
Additions	-	395,196	472,204	867,400
Disposals	-	-	-	-
Transfers	-	38,329	(38,329)	-
Currency translation effects	35,191	156,304	1,370	192,864
31 December 2022	**178,251**	**1,345,298**	**510,624**	**2,034,173**
Depreciations				
1 January 2021	**60,379**	**304,683**	**12,004**	**377,066**
Additions	11,690	125,792	11,147	148,629
Disposals	-	-	-	-
Currency translation effects	(6,480)	(38,896)	-	(45,376)
31 December 2021	**65,588**	**391,580**	**23,151**	**480,319**
Additions	13,496	262,681	31,704	307,882
Disposals	-	-	-	-
Currency translation effects	15,859	92,716	342	108,917
31 December 2022	**94,943**	**746,977**	**55,198**	**897,118**
Net book value 31 December 2021	**77,472**	**363,889**	**52,229**	**493,590**
Net book value 31 December 2022	**83,308**	**598,320**	**455,426**	**1,137,055**

The increase in fully owned P,P&E is largely driven by investments in offices and production area.

(I) Assets Under Construction

EUR	Land & building	Furniture, fixtures & vehicles	Right-of-use Total
Acquisition value			
1 January 2021	**484,592**	**284,961**	**769,553**
Additions	579,407	69,196	648,604
Disposals	-	-	-
Currency translation effects	-	-	-
31 December 2021	**1,064,000**	**354,157**	**1,418,157**
Additions	450,542	47,917	498,459
Disposals	-	(61,147)	(61,147)
Currency translation effects	-	-	-
31 December 2022	**1,514,542**	**340,927**	**1,855,469**
Depreciations			
1 January 2021	**298,747**	**78,189**	**376,937**
Additions	177,629	88,843	266,472
Disposals	-	-	-
Currency translation effects	-	-	-
31 December 2021	**476,376**	**167,032**	**643,409**
Additions	218,005	93,509	311,514
Disposals	-	(30,357)	(30,357)
Currency translation effects	-	-	-
31 December 2022	**694,381**	**230,184**	**924,565**
Net book value 31 December 2021	**587,623**	**187,125**	**774,748**
Net book value 31 December 2022	**820,161**	**110,743**	**930,904**

The increase in right-of-use assets is largely driven by new and renewed leasing contracts in office and production area.

8.5. Other non-current assets

Other non-current assets are composed of R&D incentives, which the Group has applied for starting in 2021. The R&D incentives receivables are future expected tax deductions or refunds resulting from tax incentives on research and development expenses in Belgium. The non-current R&D incentives receivables are discounted over the period until maturity date and therefore reported at net present value. The discount rate applied in 2022 embeds a Belgian OLO rate of 2.82% (2021: 0).

The table below provides an overview of the non-current R&D incentives receivables reported in the Consolidated Statement of Financial Position.

	31 December 2022			
	Maturity date			
EUR	**2026**	**2027**	**2028**	**Total**
Non-current R&D incentives receivables (discounted)	155,857	252,872	373,479	782,208
Total Other non-current assets	155,857	252,872	373,479	782,208

	31 December 2021		
	Maturity date		
EUR	**2025**	**2026**	**Total**
Non-current R&D incentives receivables (discounted)	174,478	289,382	463,860
Total Other non-current assets	174,478	289,382	463,860

8.6. Share capital and Share Premium

The share capital of the Company is EUR 2,460,487 and is represented by 23,746,528 ordinary shares. The share capital is fully paid-in. During 2022, several capital increases took place.

EUR, except number of shares	Shares	Share capital	Share premium	Total
31 December 2020	**15,778,566**	**1,635,006**	**119,332,864**	**120,967,870**
February 2021 Equity Placement	2,647,059	274,235	22,225,766	**22,500,002**
Capital increase ESOP 15/02/2021	12,810	1,327	94,235	**95,563**
Capital increase Convertible loan	97,084	10,058	608,859	**618,917**
Capital increase ESOP 30/04/2021	40,733	4,220	168,424	**172,644**
Capital increase ESOP 27/07/2021	826	86	2,567	**2,652**
31 December 2021	**18,577,078**	**1,924,932**	**142,432,715**	**144,357,647**
Capital increase ESOP 21/01/2022	2,182	226	6,779	**7,005**
March 2022 Equity Placement	5,167,268	535,329	27,884,645	**28,419,974**
31 December 2022	**23,746,528**	**2,460,487**	**170,324,139**	**172,784,626**

At 21 January 2022, the Company announced that a number of holders of share options (having the form of subscription rights), have exercised a total number of 756 Executive Share Options. As a result of this exercise of Executive Share Options, on 21 January 2022 the share capital of the Company has increased from EUR 1,924,932 to EUR 1,925,158 and the number of issued and outstanding shares has increased from 18,577,078 to 18,579,260 shares, through the issuance of a total of 2,182 new shares.

At 10 March 2022, the Company announced that in the context of the capital increase that was announced on 7 March 2022 and completed on 10 March 2022 by means of a private placement through an accelerated book building procedure of 5,167,268 new shares (being approximately 27.8% of the Company's outstanding shares) at an issue price of EUR 5.50 per share. Its share capital increased from EUR 1,925,158 to EUR 2,460,487 and the number of issued and outstanding shares has increased from 18,579,260 to 23,746,528 ordinary shares. Of the 5,167,268 new shares, 3,060,082 were immediately admitted to listing and trading on the regulated market of Euronext Brussels upon their issuance (on the basis of applicable listing prospectus exemptions), while 2,107,186 shares were not immediately admitted to listing and trading on the regulated market of Euronext Brussels upon their issuance (as their admission to listing and trading was subject to the approval of a listing prospectus). The remaining shares have been admitted to trading and listed on the regulated market of Euronext Brussels after the approval of a listing prospectus by the FSMA. As per 31 December 2022, there are no unlisted shares.

The new shares issued within the framework of the capital increases are common shares with the same rights and benefits, and in all respects a grade equivalent, including dividend rights, as the existing and outstanding shares of the Company at the time of their issue.

As of 31 December 2022 the Company does not hold any Treasury shares.

Authorised capital

The Extraordinary General Meeting decided on May 27, 2022 to grant the Board of Director's authorisation to increase the authorised share capital, such within the limits of the existing authorisation as set out in Article 8 of the Articles of Association, in one or more rounds by a maximum amount of EUR 2,460,487, such within a period of five years from the date of announcing such a decision in the Annexes of the Belgian Bulletin of Acts, Orders and Decrees.

8.7. Financial debts / net debt

8.7.1. SUBORDINATED LOAN AGREEMENTS

In July 2020, the Company entered into subordinated loan agreements with PMV/z Leningen NV ("PMV/z"), Sensinnovat BV ("Sensinnovat") and Belfius Insurance NV ("Belfius Insurance"), for an aggregate principal amount of EUR 7.3 million, of which loans for a principal amount of EUR 1.4 million could be converted for new shares in the event of an equity financing or sale of the Company.

In March 2021, as a result of the equity raising by the Company that took place on 15 February 2021, Sensinnovat and Belfius Insurance converted their convertible loans for an aggregate amount of EUR 618,916.67 (representing principal and interests) into an aggregate of 97,084 new Shares in accordance with the terms of the convertible loans, thereby settling the convertible portion of their loans through a contribution in kind of their payables due by the Company under the relevant loans.

In December 2021, the Company entered into amendment agreements related to the outstanding subordinated loan agreements with the lenders, thereby (i) extending the duration of such loans, (ii) increasing the interest rates retroactively, and (iii) introducing payment by instalments. Consequently, the loans have a term of 60 months and are repayable in eight equal quarterly instalments between months 36 and 60. The loans bear an interest rate of 6.5% per annum, except that the convertible portion of the loan granted by PMV/z bears an interest rate of 5.5% per annum. The loans with PMV/z, Belfius Insurance and Sensinnovat allow the Company to prepay the relevant loans together with all accrued interest, provided that the Company pays a termination indemnity equal to six months of interest on the prepaid loan. The convertible portion of the loan granted by PMV/z can be converted in the event of an equity financing or sale of the Company, at a price per share that is equal to 75% of the price of the Company's shares as will be reflected in the relevant equity financing or sale.

All subordinated loan agreements described in this section have been concluded with similar terms and conditions on an at arm's length basis.

The Company considers no material changes have occurred in its own credit risk that would significantly impact the fair value of the convertible loans as at 31 December 2022.

8.7.2. SECURED LOAN FACILITY AGREEMENT KREOS

The Company entered into a secured loan facility agreement with Kreos (the "Kreos Loan Agreement") in the amount of EUR 10.0 million and pursuant to which the Company is permitted to request an increase of the facilities in the amount of a maximum of EUR 10.0 million on an uncommitted basis. The loan facility has been drawdown for an amount of EUR 10.0 million. During the initial period of six months from the first drawdown (extendable by mutual agreement), the Company only pays interest, with the loans amortising in equal monthly instalments of principal and interest until maturity. The loan matures on 30 September 2025.

The main elements of the Kreos Loan Agreement can be summarised as follows:

- *Interest*: The loans under the facility accrue interest at a fixed rate of 9.75% per annum.
- *Fees*: A number of fees will be payable to Kreos Capital, principally consisting of (i) a transaction fee equal to 1.25% of the total loan facility amount and (ii) an end of loan payment, payable upon final repayment of the loan, corresponding to 1.25% of the amount drawn.
- *Board observer*: Kreos Capital will be entitled to appoint a board observer to attend meetings of the Company's Board of Directors in a non-voting capacity.
- *Collateral*: The loans are secured by the Company's bank accounts, receivables and movable assets, including IP rights.
- *Change of control*: The Kreos Loan Agreement contains a change of control clause and requires such clause to be approved by the Company's general shareholders' meeting. The Extraordinary General Meeting, dated 10 February 2023 approved the related clause.
- *Contractual restrictions*: The Kreos Loan Agreement does not contain financial covenants, but does contain other customary restrictions on the business of the Company and its subsidiaries (such as limitations on future disposals, limitations on the incurrence of financial indebtedness, security and acquisitions, subject to certain carve-outs and limitations) and on the ability of the Company to distribute dividends as long as loans are outstanding.

In the framework of the Kreos Loan Agreement, the Company and Kreos Capital VII Aggregator SCSp entered into a subscription rights agreement in July 2022 (the "Kreos Subscription Rights Agreement") pursuant to which the Company agreed to issue and allocate subscription rights to Kreos Capital VII Aggregator SCSp (the "Kreos Subscription Rights") to subscribe to new shares of the Company. Refer to section 8.8.2. Kreos subscription rights for more information.

The table below contains an analysis of the net financial debt and the relevant movements for the periods presented. The amounts disclosed in the table are not substantially different to the undiscounted contractual cash flows.

EUR	2022	2021
Cash and cash equivalents	18,874,959	9,600,412
Borrowings - repayable within one year	(4,482,914)	-
Borrowings - repayable after one year	(12,192,829)	(7,324,835)
Net financial debt	**2,199,216**	**2,275,577**

EUR	Cash and cash equivalents	Borrowings due within 1 year	Borrowings due after 1 year	Total
Net financial debt as per 31 December 2020	**11,016,143**	**-**	**7,472,701**	**3,543,441**
Cash flows	(1,520,075)	-	-	(1,520,075)
Interest expenses accrued on non-convertible loans (non-cash item)	-	-	404,610	(404,610)
Transfer (non-cash item)	-	-	-	-
Converted to equity (non-cash item)	-	-	(618,917)	618,917
Remeasurement at FVTPL on convertible loans (non-cash item)	-	-	66,440	(66,440)
Foreign exchange impact (non-cash item)	104,344	-	-	104,344
Net financial debt as per 31 December 2021	**9,600,412**	**-**	**7,324,835**	**2,275,577**
Cash flows	9,189,389	-	9,626,085	(436,696)
Fair value adjustment at inception date (non-cash item)	-	-	(766,637)	766,637
Paid interest (cash item)	-	-	(314,516)	314,516
Interest expenses accrued on non-convertible loans (non-cash item)	-	-	747,324	(747,324)
Transfer (non-cash item)	-	4,482,914	(4,482,914)	-
Remeasurement at FVTPL on convertible loans (non-cash item)	-	-	58,653	(58,653)
Foreign exchange impact (non-cash item)	85,158	-	-	85,158
Net financial debt as per 31 December 2022	**18,874,959**	**4,482,914**	**12,192,829**	**2,199,216**

The loans are presented in the statement of financial position as follows:

EUR	31 December 2022	31 December 2021
Fair value of convertible loans issued at recognition date	800,000	1,400,000
Conversion convertible loan to shares	-	(618,917)
Cumulative remeasurement at FVTPL on convertible loans	134,779	95,043
Total convertible loans	934,779	**876,126**
Fair value of non-convertible loans	15,133,363	5,900,000
Subordinated loan agreements	5,900,000	5,900,000
Kreos loan agreement	9,233,363	-
Cumulative interest expenses accrued on non-convertible loans (amortized cost)	1,296,032	548,708
Paid interest Kreos loan agreement	(314,516)	
Advance payment Kreos loan agreement	(373,915)	
Total non-convertible loans	**15,740,964**	**6,448,708**
Total short term and long term financial debt	**16,675,743**	**7,324,835**

8.7.3. LEASES

The lease debts are presented in the statement of financial position as follows:

EUR	31 December 2022	31 December 2021
Long term lease debts	609,458	477,312
Short term lease debts	306,952	283,010
Total	**916,410**	**760,322**

The amounts recognized in the income statement related to depreciation of these right-of-use assets are as follows:

Leases	
Buildings	218,005
Vehicles	92,079
IT equipment	1,430
Total	**311,514**

The expenses related to low-value leases and variable lease payments not recognised as lease liability are considered not to be material.

8.8. Other current financial liabilities

8.8.1. BOOTSTRAP WARRANTS

The extraordinary general shareholders' meeting of the Company dd. 27 May 2022 approved the issuance of 10 new subscription rights for shares of the Company, named the "Bootstrap Warrants", to the benefit of Bootstrap Europe S.C.Sp. ("Bootstrap"), as initially stipulated in the Bootstrap Loan Agreement dd. 2 September 2016 (as amended over time).

The Bootstrap Warrants give Bootstrap the right to subscribe upon exercise of the 10 Bootstrap Warrants for an aggregate of up to 302,804 new shares of the Company at an issue price of EUR 3.21 per underlying new share, in whole or in part, at one or several occasions (the 'Cash Exercise'). The conditions also provide for a 'Cashless Exercise' and, in case of specific sale events, a 'Net Issuance Exercise' mechanism. The number of shares to be issued upon exercise of the Bootstrap is subject to certain adjustments in case of certain dilutive corporate actions, it being understood that transactions or operations approved by the general shareholders' meeting of the Company or which are implemented or occur on the basis of an authorization that was provided or approved by the general shareholders' meeting (such as, but not limited to, the authorized capital) shall not lead to such adjustments.

It is at the sole discretion of Bootstrap to apply for a Cash Exercise or a Cashless Exercise.

The exercise price of the Bootstrap Warrants depends on the applicable exercise mechanism:

- In the event of a Cash Exercise, the Bootstrap Warrants can be exercised at a price of EUR 3.21 per new share. This exercise price is subject to certain adjustments in case of certain dilutive corporate actions, it being understood that transactions or operations approved by the general shareholders' meeting of the Company or are implemented or occur on the basis of an authorisation that was provided or approved by the general shareholders' meeting (such as, but not limited to, the authorised capital) shall not lead to adjustments;
- In the event of a Cashless Exercise, the Bootstrap Warrants can be exercised at a price equal to the fractional value of the shares of the Company, i.e., currently rounded EUR 0.1036 per share; and
- In the event of a Net Exercise, no exercise price should be paid by Bootstrap.

The Bootstrap Warrants have a term commencing on 27 May 2022 and ending on 11:59 p.m. (Belgian time) on 2 September 2026.

Bootstrap shall be entitled to transfer or assign the Bootstrap Warrants, except to an entity that is a customer, competitor or supplier of the Company, or an entity that holds 20% or more of the Company's share capital of any such customer, competitor or supplier.

The Bootstrap Warrants are accounted for in accordance with 'IAS 32 - Financial Instruments: Presentation' (measurement category: derivative financial instruments at FVTPL) and are classified in the Condensed Consolidated Statement of Financial Position as 'Other current financial liabilities'. The fair value of the Bootstrap Warrants as at 31 December 2022 (EUR 1,103,277) has been reported as 'Finance cost' in the Condensed Consolidated Statement Income Statement.

The fair value of the Bootstrap Warrants as at 31 December 2022 has been calculated using the Black & Scholes model with parameters as described below.

	Bootstrap warrants
Number of warrants granted	10
Fair value / warrant (in EUR)	3.64
Share price (in EUR)	6.29
Exercise price (in EUR)	3.21
Expected volatility	40%
Lifetime (in years)	3.67
Risk-fee interest rate	2.76%
Expected dividends	0

The expected volatility is based on the volatility of the Company's shares.

The share price is calculated, in line with the terms and conditions of the Bootstrap Warrants, as the average of the closing price of the Company's shares on Euronext Brussels over the 30 calendar day period ending 3 days prior to the balance sheet date.

8.8.2. KREOS SUBSCRIPTION RIGHTS

In the framework of the Kreos Loan Agreement, the Company and Kreos Capital VII Aggregator SCSp entered into a subscription rights agreement in July 2022 (the "Kreos Subscription Rights Agreement") pursuant to which the Company agreed to issue and allocate subscription rights to Kreos Capital VII Aggregator SCSp (the "Kreos Subscription Rights") to subscribe to new shares of the Company. Notably, subject to approval by the Company's extraordinary general shareholders' meeting at the latest at the date of the annual shareholders' meeting of the Company to be held in 2023, Kreos Capital shall receive, free of charge, (a) subscription rights for new shares in an aggregate amount of EUR 650,000, at an exercise price per new Share equal EUR 5.31 (based on the arithmatic average of the daily volume weighted average price of the Shares traded on Euronext Brussels during the period of 30 consecutive tradings ending on (and including) the third trading days prior to the date of signing of the Kreos Loan Agreement), and (b) further subscription rights for new Shares for an aggregate amount of up to EUR 225,000 pro rata to the drawdowns under the initial facility, at an exercise price per new Share equal to the arithmatic average of the daily volume weighted average price of the Shares traded on Euronext Brussels during the period of 30 consecutive tradings ending on (and including) the third trading days prior to the date of the relevant drawdowns. The subscription rights have an initial term which expires five years after the date of the Kreos Loan Agreement or (if earlier) the completion of (i) a public takeover bid with respect to the Shares and other outstanding voting securities of the Company or securities granting access to voting rights, or (ii) a sale of the entire issued share capital of the Company to a bona fide third party on arm's length terms for cash consideration (a "Share Sale"). If at the end of the initial five-year period the subscription rights have not been fully exercised and no Share Sale has yet taken place, the Company will issue new subscription rights on similar terms for an additional period of two years (or until the completion of a Share Sale, if earlier).

The Extraordinary General Meeting, dated 10 February 2023 approved the related clause.

The Kreos subscription rights are accounted for in accordance with 'IAS 32 - Financial Instruments: Presentation' (measurement category: derivative financial instruments at FVTPL) and are classified in the Condensed Consolidated Statement of Financial Position as 'Other current financial liabilities'. The fair value of the Kreos subscription rights as at 31 December 2022 (EUR 465,508) has been reported as 'Finance income' in the Condensed Consolidated Statement Income Statement.

The fair value of the Kreos subscription rights as at 31 December 2022 has been calculated using the Black & Scholes model with parameters as described below.

	Kreos subscription rights
Number of subscription rights granted	161,405
Fair value / subscription right (in EUR)	2.77 - 2.92
Share price (in EUR)	6.00
Exercise price (in EUR)	5.31 - 5.77
Expected volatility	40%
Lifetime (in years)	6.55
Risk-fee interest rate	2.89%
Expected dividends	0

The expected volatility is based on the volatility of the Company's shares.

The share price is calculated, in line with the terms and conditions of the Kreos subscription rights, as the average of the closing price of the Company's shares on Euronext Brussels over the 30 calendar day period ending 3 days prior to the balance sheet date.

8.9. Post-employment benefits

The Group operates different employee benefit plans. The plans for all three countries, Switzerland, Germany and Belgium, remained unchanged compared to end of 2021.

8.9.1. PENSION PLAN IN SWITZERLAND

This pension plan is governed by the Swiss Federal Law on Occupational Retirement, Survivor's and Disability Pension Plans (BVG), which states that pension plans are to be managed by independent, separate legal entities. It also stipulates that a pension plan's most senior governing body (Board of Trustees) must be composed of equal numbers of employee and employer representatives.

Plan participants are insured against the financial consequences of old age, disability and death. The insurance benefits are subject to regulations, with the BVG specifying the minimum benefits that are to be provided. The employer and employees pay contributions to the pension plan. If a plan is underfunded, various measures can be taken, such as a reduction of the interests or compensation premiums by the employees.

The Group has entered into an agreement with PKG Joint Foundation. PKG is responsible for the governance of the plan; the Board is composed of an equal number of representatives from the employers and employees chosen from all affiliated companies. PKG has set up investment guidelines, defining in particular the strategic allocation with margins. PKG has taken out reinsurance for the pure risk benefits, like disability pension, spouse and orphans pension as well as lump sum in case of death.

Related plan assets are measured at fair value.

Reconciliation of the amount recognised in the statement of financial position at the end of period	2022	2021
Defined benefit obligation	2,644,813	3,327,469
Fair value of plan assets	2,440,244	2,835,694
Net defined benefit liability	**204,569**	**491,775**

The net defined benefit liability decreased from EUR 491,775 in 2021 to EUR 204,569 in 2022, mainly as a result of the increased discount rate.

Components of defined benefit cost in profit or loss	2022	2021
Current service cost (employer)	309,366	218,591
Plan amendment / Past Service Cost	-	-
Interest expense on defined benefit obligation	12,398	3,516
Interest income on plan assets	(10,629)	(2,740)
Administration cost excl. cost for managing plan assets	11,624	8,260
Defined benefit cost recognised in profit or loss	**322,760**	**227,628**
thereof service cost and administration cost	320,990	226,852
thereof net interest on the net defined benefit liability (asset)	1,770	776

The present value of the defined benefit obligation is determined annually by independent actuaries using the projected unit credit method.

Defined benefit obligation (DBO) (I)

The difference between the reconciliation and the valuated defined benefit obligation as of 31 December 2022 corresponds to an actuarial loss of EUR 237,540. The changes in financial assumptions led to an actuarial gain of EUR 569,062. The changes in demographic assumptions had no impact. The changes in experience adjustments led to an actuarial loss of EUR 6,519. These three components led to a total actuarial gain of EUR 562,543.

The plan assets are carried forward until 31 December 2022 taking into consideration employees' and employer's contributions as well as paid benefits and are compared with the assets of the pension fund. The difference between the carried forward plan assets and the plan assets as of 31 December 2022 corresponds to an actuarial loss of EUR 216,256.

The total actuarial gains of EUR 346,286 (gains on defined benefit obligations of EUR 562,543 and losses on plan assets of EUR 216,256) have been recognized in OCI.

Components of defined benefit cost in OCI	2022	2021
Actuarial (gain) / loss on defined benefit obligation	(627,485)	208,832
Return on plan assets excl. interest income	241,222	(300,310)
Defined benefit cost recognised in OCI	**(386,263)**	**(91,478)**

(I) Immaterial rounding differences are possible between the underlying actuarial tables and the statement of financial position information due to the foreign currency translation of the source actuarial tables, which are initially prepared in CHF, to EUR.

Components of actuarial gain/losses on obligations	2022	2021
Actuarial (gain) / loss arising from changes in financial assumptions	(634,757)	(84,145)
Actuarial (gain) / loss arising from changes in demogr. assumptions	-	(230,607)
Actuarial (gain) / loss arising from experience adjustments	(7,272)	523,584
Actuarial (gain) / loss on defined benefit obligation	**(627,485)**	**208,832**

Reconciliation in net defined benefit liability	2022	2021
Net defined benefit liability at 1 January	491,775	517,814
Defined benefit cost recognised in profit or loss	322,760	227,628
Defined benefit gain recognised in OCI	(386,263)	(91,478)
Contributions by the employer	(226,179)	(187,650)
Currency translation adjustments	26,092	25,462
Net defined benefit liability at 31 December	**228,185**	**491,775**

Reconciliation of defined benefit obligation	2022	2021
Defined benefit obligation at 1 January	3,327,469	2,271,652
Interest expense on defined benefit obligation	12,398	3,516
Current service cost (employer)	309,366	218,591
Contributions by plan participants	226,179	187,650
Plan amendment / Past Service Cost	-	-
Benefits (paid) / deposited	(474,420)	292,395
Administration cost (excl. cost for managing plan assets)	11,624	8,260
Actuarial (gain) / loss on defined benefit obligation	(627,485)	208,832
Currency translation adjustments	165,008	136,572
Defined benefit obligation at 31 December	**2,950,140**	**3,327,469**

Reconciliation of fair value of plan assets	2022	2021
Fair value of plan assets at 1 January	2,835,694	1,753,838
Interest income on plan assets	10,629	2,740
Contributions by the employer	226,179	187,650
Contributions by plan participants	226,179	187,650
Benefits (paid) / deposited	(474,420)	292,395
Return on plan assets excl. interest income	(241,222)	300,310
Currency translation adjustments	(167,760)	111,110
Fair value of plan assets at 31 December	**2,721,955**	**2,835,694**

Contributions are paid regularly to the pension funds. Furthermore, the investment strategy respects the need to guarantee the liquidity of the plan at all times. The Group does not make use of any assets held by the pension plan.

Maturity profile of defined benefit obligation	2022	2021
Weighted average duration of DBO in years	17.3	19.5

There are no retired plan participants for the years 2022 and 2021.

For the reporting year 2023, employer contributions of EUR 228,167 are expected.

Significant actuarial assumptions:

Actuarial assumptions	2022	2021
Discount rate (DR) at 1 January	0.35%	0.15%
Discount rate (DR) at 31 December	2.30%	0.35%
Interest rate on retirement savings capital (IR) at 31 December	2.30%	0.15%
Future salary increases (SI) at 31 December	1.75%	1.00%
Future pension increases (PI) at 31 December	0.00%	0.00%
Future inflation at 31 December	~1.50%	~0.75%
Mortality tables	BVG 2020 GT	BVG 2020 GT
Date of last actuarial valuation	31/12/2022	31/12/2021

Sensitivities of significant actuarial assumptions

The following impacts on the defined benefit obligation would result from changes in actuarial assumptions:

Sensitivity	2022	2021
DBO = Defined benefit obligation, SC = Service cost (employer)		
DBO at 31 December with DR -0.25%	3,060,322	3,497,820
DBO at 31 December with DR +0.25%	2,806,593	3,170,231
DBO at 31 December with IR -0.25%	2,876,967	3,267,169
DBO at 31 December with IR +0.25%	2,982,434	3,389,745
DBO at 31 December with SI -0.25%	2,896,485	3,368,867
DBO at 31 December with SI +0.25%	2,962,206	3,287,340
DBO at 31 December with life expectancy +1 year	2,999,154	3,377,033
DBO at 31 December with life expectancy -1 year	3,003,533	3,381,573
SC of next year with DR +0.25%	215,892	264,042
SC of next year with IR +0.25%	258,087	295,744

The sensitivity analysis is based on reasonable possible changes as at the end of the reporting year. Each change in a significant actuarial assumption was analysed separately as part of the test. Interdependencies were not taken into account.

8.9.2. PENSION PLAN IN BELGIUM

According to IAS 19, Defined Contribution plans are those, which do not bear any financial or actuarial risks. All the plans, which do not meet this definition, are Defined Benefit Plans.

Article 24 of the Belgian WAP/LPC obliges employers to ensure that plan members receive, when leaving the plan, at least the amount of the contributions capitalized at the statutory guaranteed minimum rate. As a result, the Belgian Defined Contribution plans do not meet the definition of Defined Contribution plans as stated in IAS 19 and should, by default, be classified as Defined Benefit plans.

According to IAS 19, the net (i.e. before taxes and social security contributions) total pension obligation at valuation date is equal to the Defined Benefit Obligation (DBO). For a given participant, the DBO "retirement" is the maximum between the individual vested reserves at valuation date and the discounted value of future pension obligations, taking into account the assumptions made.

According to IAS 19, the net total obligation must be compared to the plan assets at the same date, namely the vested mathematical reserves of the participants increased by the assets of the financing fund at AXA if any.

The comparison of these amounts gives the amount of the net Defined Benefit Liability (DBL), which represents the net deficit at the valuation date, according to IAS 19:

Net DBL = - (DBO - Assets)

The gross Defined Benefit Liability is equal to the net Defined Liability increased by the Belgian tax of

4,40% and the Belgian social security contribution of 8,86%, namely a total of 13,26%.

Per 31 December 2022, the Net Defined Benefit Liability equals to EUR 0 (2021: EUR 18,096).

As per 31 December 2022, there are 9 employees in the plan.

Funded status and recognised/ unrecognised amounts	2022	2021
Defined Benefit Obligation at end of year	176,625	152,055
Fair value assets at end of year	176,625	133,959
Funded status: plan assets above/(below) DBO	-	(18,096)
Unrecognised net (gain) loss	-	-
Unrecognised past service costs	-	-
Unrecognised net transition obligation/(asset)	-	-
Unrecognised balance sheet asset (because of limit)	-	-
Defined benefit Liability at end of year	**-**	**18,096**

The contributions recognised in 2022 for the defined contribution plan in Belgium amounted to EUR 48,439.

For the reporting year 2023, employer contributions of EUR 51,502 are expected.

In view of materiality, Sequana Medical decided not to disclose any additional information regarding the pension plan in Belgium.

8.9.3. PENSION PLAN IN GERMANY

The contributions paid to the defined contribution plan in Germany amounted to EUR 5,033 (2021: EUR 5,033).

8.10. Trade payables, other payables and accrued liabilities

EUR	31 December 2022	31 December 2021
Trade payables	**3,227,290**	**2,192,903**
Other payables	**1,811,940**	**1,924,597**
Accrued liabilities	**3,585,631**	**2,605,426**
Provision warranty	71,088	83,361
Accrued liabilities	3,514,543	2,522,065

Other payables mainly consist of salary related provisions, VAT, income taxes payable, social security, employee insurances and other employee provisions (e.g. holiday pay and bonus).

The total amount of Accrued Liabilities in the Consolidated Statement of Financial Position amounts to EUR 3,514,543 (in 2021: EUR 2,522,065) and are mainly accruals related to clinical expenses and other liabilities. The accruals related to clinical expenses have increased compared to prior year mainly as a result of accruals related to the North American pivotal POSEIDON study of the **alfa**pump, and the pre-clinical development of the Company's proprietary DSR therapy.

9. *Share-based compensation*

The following table sets forth a summary of subscription rights outstanding and exercisable on 31 December 2022 per subscription right plan:

Subscription right plan	Grant date	Expiry date	Exercise price (EUR) [I]	Outstanding per 1 January 2022	Granted during the year	Exercised during the year	Forfeited during the year	Expired during the year	Outstanding per 31 December 2022	Exercisable per 31 December 2022
Executive share options - CEO[II]	27/09/2018	27/09/2028	0.92	75,025	-	-	-	-	75,025	75,025
Executive share options - other[II]	30/09/2018	30/09/2028	9.19	16,511	-	756	-	-	15,755	15,755
2018 Share Options	13/02/2019	13/02/2029	7.46	175,904	-	-	-	-	175,904	175,904
2018 Share Options	24/05/2019	13/02/2029	6.22	15,288	-	-	-	-	15,288	15,288
2018 Share Options	20/08/2019	13/02/2029	6.78	5,096	-	-	-	-	5,096	5,096
2018 Share Options	30/07/2020	13/02/2029	6.19	311,010	-	-	24,044	-	286,966	215,122
2018 Share Options	05/01/2021	13/02/2029	8.61	50,000	-	-	-	-	50,000	29,164
2018 Share Options	23/03/2021	13/02/2029	8.38	278,400	-	-	27,200	-	251,200	146,456
2018 Share Options	29/07/2021	13/02/2029	7.88	20,000	-	-	0	-	20,000	8,332
2018 Share Options	22/03/2022	13/02/2029	6.21	-	263,170	-	15,400.00	-	247,770	-
2021 Share Options	22/03/2022	27/05/2031	6.21	-	5,030	-	-	-	5,030	-
Subtotal Executive Share Options				**91,536**	**-**	**756**	**-**	**-**	**90,780**	**90,780**
Subtotal 2018 Share Options				**855,698**	**263,170**	**-**	**66,644**	**-**	**1,052,224**	**595,362**
Subtotal 2021 Share Options				**-**	**5,030**	**-**	**-**	**-**	**5,030**	**-**

(I) equals the market value of the underlying shares on the grant date

(II) one share option of the Executive share options plan entitles the holder thereof to acquire ca. 2.88 shares when exercising one of his or her share options

9.1. Executive Share Options

Early October 2018, Sequana Medical implemented an option plan for a certain group of employees and granted 111,177 share options, which each entitle the holder for a subscription of one share. The options are accounted for as equity-settled share-based payments.

The Group used the Black & Scholes model for share-based payment calculation purposes in order to determine the fair value of the Executive share-based option plan. The volatility parameter has been based on the volatility of relevant peer shares, listed on the STOXX Medtech stock exchange.

The share price considered per 31 December 2018 is EUR 9.25 and is the lowest based on the expected gross amount of IPO proceeds of EUR 30.0 million, whereas probability weighted scenarios between EUR 9.25 and EUR 10.50 per share have been applied.

The effect of the share-based payment transactions on the 2022 Consolidated Income Statement of the Group is an expense of EUR 3,747 . The same amount goes through reserves in equity so that the net effect on the Group's equity is zero.

One share option of the Executive Share Options plan entitles the holder thereof to acquire ca. 2.88 shares when exercising one of his or her share options.

Presented below is a summary of subscription right activities for the reported periods.

Executive Share Options

	Subscription rights	Weighted average exercise price (EUR)
Granted during the year	-	-
Forfeited during the year	-	-
Exercised during the year	10,991	9.19
Expired during the year	-	-
Outstanding on 31 December 2021	**91,536**	**2.41**
Exercisable on 31 December 2021	91,536	2.41
Granted during the year	-	-
Forfeited during the year	-	-
Exercised during the year	756	9.19
Expired during the year	-	-
Outstanding on 31 December 2022	**90,780**	**2.36**
Exercisable on 31 December 2022	90,780	2.36

9.2. 2018 Share Option Plan

The extraordinary shareholders meeting of 18th of January 2019 approved the new Share options for directors, employees and other staff members of Sequana Medical (the "2018 Share Options"). There was no obligation for the holders of the 2011 Share Options and Executive Share Options to exercise the Share options prior to the closing of the Offering. The number of options is equal to 10% of the total number of New Shares outstanding after the closing of the Offering and after the allocation of the over-allotment option.

The Group used the Black & Scholes model for share-based payment calculation purposes in order to determine the fair value of the Executive share-based option plan. The volatility parameter has been based on the volatility of relevant peer shares, listed on the STOXX Medtech stock exchange.

The effect of the share-based payment transactions on the 2022 Consolidated Income Statement of the Group is an expense of EUR 555,980. The same amount goes through reserves in equity so that the net effect on the Group's equity is zero.

Presented below is a summary of subscription right activities for the reported periods.

2018 Share Options

	Subscription rights	Weighted average exercise price (EUR)
Granted during the year	362,248	7.46
Forfeited during the year	41,976	7.46
Exercised during the year	22,661	7.46
Expired during the year	-	-
Outstanding on 31 December 2021	**855,698**	**7.46**
Exercisable on 31 December 2021	349,599	6.84
Granted during the year	263,170	6.21
Forfeited during the year	66,644	7.09
Exercised during the year	-	-
Expired during the year	-	-
Outstanding on 31 December 2022	**1,052,224**	**7.08**
Exercisable on 31 December 2022	595,362	7.25

9.3. 2021 Share Option Plan

The Extraordinary General Meeting of 27 May 2021 approved the new Share options for directors, employees and other staff members of Sequana Medical (the "2021 Share Options"). There was no obligation for the holders of the 2011 Share Options and Executive Share Options to exercise the Share options prior to the closing of the Offering. The number of options is equal to 10% of the total number of New Shares outstanding after the closing of the Offering and after the allocation of the over-allotment option.

The Group used the Black & Scholes model for share-based payment calculation purposes in order to determine the fair value of the Executive share-based option plan. The volatility parameter has been based on the Company's shares.

The effect of the share-based payment transactions on the 2022 Consolidated Income Statement of the Group is an expense of EUR 4,713. The same amount goes through reserves in equity so that the net effect on the Group's equity is zero.

Presented below is a summary of subscription right activities for the reported periods.

2021 Share Options

	Subscription rights	Weighted average exercise price (EUR)
Granted during the year	5,030	6.21
Forfeited during the year	-	-
Exercised during the year	-	-
Expired during the year	-	-
Outstanding on 31 December 2022	**5,030**	**6.21**
Exercisable on 31 December 2022	-	-

Below is an overview of the parameters used in relation to the determination of the fair value of the grants during 2022:

Stock options granted in	March 2022	March 2022
Subscription right plan	2018 Share Options	2021 Share Options
Number of options granted	263,170	5,030
Fair value of options (in EUR)	1.67	1.67
Share price (in EUR)	6.44	6.44
Exercise price (in EUR)	6.21	6.21
Expected volatility	48%	48%
Expected option life (in years)	6.90	9.19
Risk-fee interest rate	0.77%	0.77%
Expected dividends	-	-

Below is an overview of the parameters used in relation to the determination of the fair value of the grants during 2021:

Stock options granted in	January 2021	March 2021	July 2021
Subscription right plan	2018 Share Options	2018 Share Options	2018 Share Options
Number of options granted	51,848	290,400	20,000
Fair value of options (in EUR)	3.29	1.84	1.84
Share price (in EUR)	10.6	8.32	8.32
Exercise price (in EUR)	8.61	8.38	7.88
Expected volatility	51%	51%	51%
Expected option life (in years)	8.11	7.90	7.55
Risk-fee interest rate	0%	0%	0%
Expected dividends	-	-	-

10. Contingencies and arbitrations

At present there are no significant contingencies and arbitrations.

11. Commitments

11.1. Capital commitments

The Group has no material contracted expenditures for the acquisition of property, plant and equipment at 31 December 2022.

11.2. Asset pledges

The Kreos secured loan facility is secured by the Company's bank accounts, receivables and movable assets, including IP rights. The Company has no other meaningful pledges as per 31 December 2022.

12. Transactions with related parties

Related parties primarily comprise members of Executive Management, members of the Board of Directors and significant shareholders. There are no significant transactions with related parties except for:

1. the remuneration and reimbursement of expenses paid, if any, to the members of Board of Directors and Executive Management in fulfilling their responsibilities as disclosed in notes 12.3, 12.4 and 12.5.
2. the subordinated loan agreements concluded with amongst others PMV/z-Leningen as described in notes 8.7.2 and 12.2.

12.1. Consolidated companies

We refer to note 1 for the list of subsidiaries.

12.2. Relations with the shareholders

We refer to notes 8.6 Share Capital and Share Premium and 8.7 Financial debts / net debt for the changes in the relations with the shareholders.

There exist no other relations with the shareholders as those described in the sections above.

12.3. Relations with non-executive members of the Board of Directors

The non-executive directors earned the following compensation (gross), based on the approved fees:

EUR	2022	2021
Pierre Chauvineau	70,750	70,000
Wim Ottevaere	55,500	50,000
Jason Hannon	-	26,521
Jackie Fielding	43,750	11,667
Alexandra Clyde	18,331	-
Doug Kohrs	20,037	-

No remuneration or compensation was paid to the non-executive directors, other than the reimbursement of travel and hotel expenses incurred by the directors in connection with their attendance of meetings of the Board of Directors.

12.4. Relations with Executive Management

The Executive Management consists of the Chief Executive Officer and the Chief Financial Officer.

The Executive Management include those persons having authority and responsibility for planning, directing and controlling the activities of the Group.

12.5. Executive Management compensation

The compensation for the Executive Management is as follows:

2022	Executive Management compensation			
	EUR (except number of share options)	Short-term Employee benefits	Post-employment benefits	number of share options
	Ian Crosbie	448,938	14,658	357,281
	Kirsten Van Bockstaele	354,144	-	76,645

2021	Executive Management compensation			
	EUR (except number of share options)	Short-term Employee benefits	Post-employment benefits	number of share options
	Ian Crosbie	402,239	14,542	329,281
	Kirsten Van Bockstaele	344,746	-	62,645

13. Belgian GAAP disclosures

13.1. Subsidiaries included in or excluded from the consolidation scope, and associates

The Consolidated Financial Statements of Sequana Medical Group include:

Company	Purpose	Share capital	Investment 2022	Investment 2021
Sequana Medical NV	Holding/Sales	EUR 2,460,487	n/a	n/a
Sequana Medical branch (Switzerland)	Production and research	n/a	n/a	n/a
Sequana Medical GmbH (Germany)	Distribution	EUR 25,000	100%	100%
Sequana Medical Inc. (USA)	Administration	USD 0	100%	100%

There are no non-controlling interests or structured entities. All entities have been newly established by the Group, and included in the Consolidated Financial Statements as from their respective date of incorporation.

13.2. Average number of employees

	2022	2021
Average number of employees	60	52

13.3. Employee benefits and advances given to parent company directors by the parent company, subsidiaries and associates

EUR (except number of share options)	2022	2021
Short term employee benefits	448,938	402,239
Post-employment benefits	14,658	14,542
Number of share options	357,281	329,281

14. Events after the reporting period

Restructuring program

In April 2023, several measures have already been carried out in order to reduce costs and expenditures, and the Company intends to carry out further savings. These measures include:

- Heart Failure / DSR: Slowing down the further progression of the MOJAVE clinical study. The Board of Directors notes that (i) the Company still targets results from the first 3 patients by Q4 2023 for the safety cohort, (ii) the first patients are most important as the Company is looking for confirmation that DSR 2.0 in US patients has same dramatic treatment effect as DSR 1.0 in the patients from Republic of Georgia (cfr. SAHARA and RED DESERT studies).
- US **alfa**pump program: Delaying the establishment of a new production facility.
- EU **alfa**pump commercial strategy: Reducing the Company's European commercial team by moving to a "reactive" rather than "proactive" commercial stance (i.e., ready to act on clinician interest and maintaining dialogue with key centres, instead of actively promoting the therapy). The Board of Directors notes that (i) the platform for training US clinicians and implanting teams remains available, and (ii) it intends to scale-up the European commercial teams in the future (when additional financing has been attracted).

Refinancing of subordinated debt agreements with PMV/z-leningen (currently known as PMV-Standaardleningen) Belfius Insurance en Sensinnovat BV

In March 2023, the Company has obtained an amendment to its subordinated debts with PMV/z-loans, Belfius Insurance and Sensinnovat BV whereby the repayment of the outstanding amount will not take place in 8 quarterly payments starting on 30 September 2023. Under the amended agreement, the outstanding amount is to be repaid in 4 quarterly payments starting on 30 September 2024. The nominal interest rate was retroactively increased by 0.5%. The result of this amended agreement is that in 2023 the repayment of this subordinated debt has decreased by EUR 1.7 million. A similar decrease will take place in the first half of 2024.

Refinancing of Senior debt agreements with Kreos Capital VII (UK) Limited

In April 2023, the Company has obtained an amendment to its debt financing with Kreos Capital VII (UK) Limited. The amended agreement is subject to a number of conditions. If the Company succeeds in securing equity financing, of at least EUR 15,000,000 and no later than 30 June 2023, capital repayments will be reduced by 75% until 31 December 2023. As far as relevant and applicable, in case the equity financing, before 30 June 2023, is at least EUR 25,000,000, the capital repayments will be reduced by 80% (instead of 75%) until 31 December 2023. The end date of the reduced capital repayments may be extended to 31 March 2024 if the company succeeds in starting up the first clinical site of its MOJAVE study no later than 31 December 2023.

If the Company succeeds in completing an additional equity financing (additional to the previously described equity financing no later than 30 June 2023) of at least EUR 20,000,000 no later than 31 December 2023, the capital repayments will be reduced by 50% for an additional period of 6 months.

The agreement is subject to a number of conditions as described before, including an increase of the end of loan payment from 1.25% to 1.75%.

Application of article 7:228 of the Belgian Companies and Associations Code

The Board of Directors notes that at the occasion of the preparation of the statutory (non-consolidated) financial statements of the Company for the financial year ended 31 December 2022, it determined that the Company's (non-consolidated) accounting net assets (as defined in the Belgian Companies and Associations Code) had fallen below the thresholds of the articles 7:228 and 7:229 of the Belgian Companies and Associations Code, and therefore has initiated the procedure set out in the article 7:228 of the Belgian Companies and Associations Code. For more information on the measures the Board of Directors has taken and proposes to take to redress the financial situation of the Company, and its proposal to continue the operations of the Company, reference is made to the relevant report of the Board of Directors submitted to the annual general shareholders' meeting to be held on Thursday, 25 May 2023.

Equity placement

The Company envisions to conclude a capital increase by means of a private placement through an accelerated book building procedure in the coming days. We refer to the press release available on the Company's website dated 24 April 2023. The Company will regularly provide an update on the envisioned equity placement via its website.

15. Audit fees

EUR		2022	2021
Fees of the independent auditor with the respect to the statutory audit mandate for the Company and the group (Belgium)		81,330	75,000
Additional Services rendered by the auditor's mandate:			
	Audit related fees		
	Tax advisory & compliance services		
	Due diligence fees		
	Other Services	35,000	69,087
Subtotal		**116,330**	**144,087**
Fees of independent auditor's network with respect to a statutory audit mandate at the level of the Group (foreign operations)			
Additional Services rendered by the auditor's mandate:			
	Audit related fees		
	Tax advisory & compliance services		
	Due diligence fees		
	Other Services		
Subtotal		-	-
Total		**116,330**	**144,087**

9 Condensed Statutory Financial Statements of Sequana Medical NV

1. Statutory income statement

EUR	2022	2021
Operating income	12,582,212	8,944,795
Operating charges	(35,722,507)	(27,983,942)
Operating loss	**(23,140,294)**	**(19,039,147)**
Financial result	(1,274,930)	(556,823)
Loss for the period before taxes	**(24,415,225)**	**(19,595,971)**
Income taxes	(369,938)	(377,759)
Loss for the period	**(24,785,163)**	**(19,973,729)**

2. Statutory balance sheet

EUR	2022	2021
Intangible assets	11,926,220	6,877,201
Tangible assets	1,077,518	522,991
Financial fixed assets	85,746	82,113
Participating interests	25,000	25,000
Non-current assets	**13,114,483**	**7,507,305**
Other non-current assets	**782,207**	**463,860**
Total non-current assets	**13,896,690**	**7,971,165**
Inventory	2,294,111	2,336,528
Amounts receivable within one year	1,212,434	812,175
Deferred charges and accrued income	1,186,964	767,696
Cash and cash equivalents	18,356,178	9,241,343
Current assets	**23,049,688**	**13,157,742**
TOTAL ASSETS	**36,946,378**	**21,128,907**
Capital	2,460,487	1,924,932
Share premium	170,324,139	142,432,715
Reserves	1,321,184	755,715
Accumulated losses	(163,303,595)	(138,518,432)
Total Equity	**10,802,215**	**6,594,930**
Provisions	228,194	509,851
Amounts payable after more than one year	12,807,500	7,312,142
Financial debt	*12,807,500*	*7,312,142*
Amounts payable within one year	9,588,189	4,148,754
Financial debt	*4,482,914*	
Trade debts	*3,375,796*	*2,363,630*
Taxes, remuneration and social security	*1,729,479*	*1,785,124*
Accruals and deferred income	3,520,281	2,563,230
Amounts payable	**25,915,969**	**14,024,126**
TOTAL EQUITY AND LIABILITIES	**36,946,378**	**21,128,907**

The full version of the accounts (including the auditor's report) is available on the company's website and can be obtained free of charge.

Glossary

Abbreviation	Significance
AASLD	Association for the Study of Liver Diseases
CAGR	Compound Annual Growth Rate
CE	Conformité Européenne
CEC	Clinical Events Committee
CHF	Congestive Heart Failure
CMS	Centers for Medicare and Medicaid Services
CMC	Chemistry, Manufacturing and Controls
CPT	Current Procedural Terminology
DGVS	German Society of Gastroenterology Digestive and Metabolic Diseases
DRG	Diagnosis-Related Group
DSR	Direct Sodium Removal
EASL	European Association for the Study of the Liver
eGFR	estimated Glomerular Filtration Rate
FDA	Food and Drug Administration
GLP	Good Laboratory Practices
HF	Heart Failure
HFSA	Heart Failure Society of America
IND	Investigational New Drug
IP	Intellectual property
IPO	Initial Public Offering
ISIN code	International Securities Identification Number
IV	IntraVeneous
KOLs	Key Opinion Leaders
LVP	Large Volume Paracentesis

Abbreviation	Significance
MDR	Medical Device Regulation
MDSAP	Medical Device Single Audit Program
NAFLD	Non-Alcoholic Fatty Liver Disease
NASH	Non-Alcoholic SteatoHepatitis
NICE	National Institute for Health and Care Excellence
NACSELD	"North American Consortium for the Study of End stage Liver Disease"
NTAP	New Technology Add-on Payment
NUB	Neue Untersuchungs- und Behandlungsmethode
NT-proBNP	N-Terminal -pro hormone B-type Natruiretic Peptide
NYHA	New York Heart Association
PD	Peritoneal Dialysis
PMSR	Post Marketing Surveillance Registry
QMS	Quality Management System
RCT	Randomised Controlled Trial
SD	Standard Deviation
SF 36	Short Form 36
TCET	Transitional Coverage for Emerging Technologies
TCT	Transcatheter Cardiovascular Therapeutics
TIPS	Transjugular Intrahepatic Portosystemic Shunt
TP	Therapeutic Paracentesis
UADE	Unanticipated Adverse Device Effects
WHO	World Health Organisation

Sources and notes

1 Based on US and Canada market assessment conducted by highly experienced international consulting group, estimating over 170,000 patients with recurrent or refractory ascites in North America by 2035, with estimated incidence of 60% and based on $25K for price of **alfa**pump

2 NYHA: New York Heart Association Classification stratifies severity of heart failure by patient-reported symptoms. Data collected outstide study protocols of RED DESERT and SAHARA

3 Predicted one-year survival analysis using Seattle Heart Failure Model of seven patients from RED DESERT and ten patients from SAHARA pre- and post-intensive DSR therapy. Analysis includes physician-assessed data collected post hoc.

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7 Global Data NASH Epidemiology Forecast to 2026.

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9 Ginès et al. (2004) (stating refractory ascites occurs in 5 to 10 percent of patients with ascites).

10 European Association for the Study of the Liver. EASL clinical practice guidelines on the management of ascites, spontane bacterial peritonitis, and hepatorenal syndrome in cirrhosis. Journal of Hepatology. 2010 vol. 53. 397-417. p. 402.

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23 Ravnan, Susan L et al. “Pharmacotherapy in congestive heart failure: diuretic resistance and strategies to overcome resistance in patients with congestive heart failure.” Congestive heart failure (Greenwich, Conn.) vol. 8,2 (2002): 80-5. doi:10.1111/j.1527-5299.2002.0758.x; Gupta, Richa et al. “Diuretic Resistance in Heart Failure.” Current heart failure reports vol. 16,2 (2019): 57-66.doi:10.1007/s11897-019-0424-1; Shah, Niel et al. “A perspective on diuretic resistance in chronic congestive heart failure.” Therapeutic advances in cardiovascular disease vol. 11,10 (2017): 271-278. doi:10.1177/1753944717718717; Richard E. Klabunde “Cardiovascular Pharmacology Concepts” https://www.cvpharmacology.com/diuretic/diuretics

Colophon

This is a publication of Sequana Medical
Concept and lay-out: Cantilis