sequanamedical

annual report 2021

Our Strategy & Key Objectives

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

- Commercialise **alfa**pump® in North America for the treatment of recurrent and refractory liver ascites through our own specialty salesforce.

- Develop DSR® (Direct Sodium Removal) therapy using our proprietary DSR Infusate for the treatment of persistent congestion due to heart failure and establish a strategic partnership for further clinical development and commercialisation.

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

Annual Report 2021

Sequana Medical at a glance

We are a commercial stage medical device company developing innovative treatments for patients with fluid overload where diuretics are no longer effective. Fluid overload is a frequent complication of many large diseases, including liver disease, cancer, heart failure and renal failure. Diuretics are generally standard of care but diuretic resistance is common and results in serious clinical complications. This large and growing market has been long ignored, resulting in poor clinical outcomes and significant costs for payors.

We have developed two innovative and elegant treatment approaches, protected by our strong intellectual property (IP) portfolio: (i) the **alfa**pump, a fully implanted system for the removal of localized fluid overload (e.g. ascites due to liver cirrhosis), and (ii) Direct Sodium Removal (DSR), a novel therapy in development for fluid overload throughout the body (e.g. congestion due to heart failure).

We are uniquely positioned in two large markets, (i) recurrent or refractory ascites due to liver cirrhosis in North America, a large market driven by NASH-related cirrhosis with an estimated market opportunity of over €3 billion annually in the U.S. within the next 10-20 years[1], and (ii) congestive heart failure, with an estimated market opportunity of over €5 billion annually in the U.S. and EU5 by 2026[2].

Our **alfa**pump is a unique, fully implanted system that automatically pumps fluid from the abdominal cavity into the bladder, where it is naturally eliminated through urination. More than 900 **alfa**pump systems have been implanted to date. The **alfa**pump is approved in Europe for refractory ascites due to liver cirrhosis and malignant ascites and has been included in key European treatment guidelines. In the U.S., 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 liver ascites. Our pivotal POSEIDON study to support the approval of the **alfa**pump in North America has completed **alfa**pump implantations in all patients and the primary endpoint is due to be reported in Q4 2022, with Pre-Market Approval filing to the U.S. FDA planned for mid-2023. Interim results have shown strong safety and efficacy, with over 90% reduction in mean therapeutic paracentesis frequency (the current standard of care), as well as a rapid and persistent clinically important improvement in patient quality of life.

Our DSR therapy uses a sodium-free infusate 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. We have combined our DSR therapy with the **alfa**pump to deliver an automated and fully implanted system for repeated DSR therapy. Clinical proof-of-concept data indicated that **alfa**pump DSR therapy is able to safely, rapidly and effectively remove persistent congestion in decompensated diuretic-resistant heart failure patients, our target population, as well as restoring diuretic response and improving cardio-renal status. This simultaneous normalization of diuretic response and improvement in cardio-renal status is a never seen before treatment effect and holds great potential. In parallel, we have made strong progress in the development of our proprietary DSR Infusate 2.0, a second generation infusate with an improved therapeutic profile, a favourable safety profile and Intellectual Property (IP) protection that will drive a high margin recurring revenue stream. We expect to commence MOJAVE DESERT, our first U.S. study using DSR Infusate 2.0 for short-term DSR in H2 2022. Following this U.S. efficacy study, we plan to establish a strategic partnership for further clinical development and commercialisation of our DSR therapy.

We are headquartered in Ghent, Belgium and listed on Euronext Brussels since February 2019, 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).

Founded in 2006

Proprietary **alfa**pump & DSR technologies for diuretic-resistant fluid overload

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

Over 60 employees

Over 900 **alfa**pump systems implanted to date

Clinical proof-of-concept of DSR therapy

Headquarters in Ghent, Belgium

Manufacturing in Zurich, Switzerland

Focus on two products with multi € billion opportunities

93 patents granted across 16 patent families

Listed on Euronext Brussels since February 2019

Cash runway into Q2 2023

Message from the Chairman and the CEO

Dear Shareholders, Colleagues and Business Partners,

We are very pleased to report on the significant achievements Sequana Medical has made during 2021, which demonstrate our progress towards our goal of developing innovative treatments for diuretic-resistant fluid overload in liver disease, cancer and heart failure. 2022 promises to be another busy year for us with a number of exciting milestones coming up, as we continue to demonstrate the power and versatility of our proprietary **alfa**pump and DSR technology platforms, and move closer to market launch.

Sequana Medical remains focussed on two strategic programmes in liver disease and heart failure. Our first is the commercialisation of the **alfa**pump in North America, our key growth market. During 2021, we made important progress in POSEIDON, our North American pivotal study of the **alfa**pump in recurrent and refractory ascites due to liver cirrhosis, which is the last clinical step in bringing the **alfa**pump to market in the U.S. and Canada. In mid-year, we reported strong data from the second interim analysis, which reaffirmed the previous positive efficacy results and provided longer-term evidence that the **alfa**pump dramatically improves the quality of life for patients. In December, we completed patient enrolment and more recently, completed **alfa**pump implantations, an important milestone that confirms our timing for reporting the primary endpoint by the end of this year. The **alfa**pump comes with a strong package of evidence, including a European market approval for refractory ascites due to liver cirrhosis, more than 900 systems already implanted to date, Breakthrough Device designation granted by the U.S. FDA, and strong interim data reported in North America. We look forward to submission of our Pre-Market Approval to the U.S. FDA in mid-2023 and moving another step closer to launch in the U.S.

Our second strategic focus is the clinical development of DSR therapy for congestive heart failure in North America and Europe, which was bolstered by further strong clinical results in 2021. Our RED DESERT study showed that **alfa**pump DSR is highly effective at not only safely managing the fluid and sodium balance in diuretic-resistant heart failure patients, but also dramatically improving their diuretic response and cardio-renal function, a treatment effect not seen before and one that holds great potential. With this initial strong clinical evidence, we progressed into heart failure patients with fluid overload (decompensated patients) with our phase 2a SAHARA DESERT study. We reported positive interim results from this study in December 2021, demonstrating the ability to safely, effectively and rapidly remove the fluid overload in these patients, as well as again improving their cardio-renal function and restoring the diuretic response of their kidneys. We look forward to reporting top-line data in all patients from this study in the second half of this year.

A key element and value driver of our DSR platform is our proprietary DSR Infusate 2.0, and this is progressing well through pre-clinical and CMC development. It is due to enter the clinic in the second half of this year in MOJAVE DESERT, a phase 1b/2a trial in the U.S. evaluating short-term DSR therapy in decompensated heart failure patients. The objective of DSR Infusate 2.0 is to develop a proprietary drug with a superior therapeutic and safety profile, that can deliver a high margin recurring revenue stream to accompany **alfa**pump DSR sales.

The outstanding clinical data Sequana Medical delivered throughout 2021 helped us secure our latest round of financing to cover our next stage of development, including the POSEIDON and SAHARA DESERT readouts, the start of the MOJAVE DESERT trial, and the preparations for the submission of the **alfa**pump for Pre-Market Approval in the U.S.

The tremendous developments in 2021 reinforce our belief in the potential of our proprietary **alfa**pump and DSR technology platforms to offer better treatment solutions for the clinically and commercially important market of diuretic-resistant fluid overload. Our employees are the bedrock of our success, and we are deeply grateful for all their hard work and commitment. We would also like to thank our shareholders, clinical investigators and other partners for their continued support.

Pierre Chauvineau **Ian Crosbie**

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Our Business

Our Business

Annual Report 2021

Achievements

2021

Liver programme

POSEIDON – Strong progress & derisking of North American pivotal study of the **alfa**pump in recurrent and refractory ascites due to liver cirrhosis

- We completed patient enrolment in *December 2021*, with 71 patients enrolled in the Pivotal Cohort.
- We reported a second interim analysis in *July 2021* on 26 patients from the Roll-In Cohort, reaffirming the previous positive efficacy results and providing longer-term evidence of the reduction in therapeutic paracentesis and continued improvements in quality of life. Data from this Roll-In Cohort substantially exceeded the primary endpoints as defined for the Pivotal Cohort in the study[I], demonstrating:
  - over 90% reduction in mean frequency of therapeutic paracentesis (TP) versus baseline (versus primary endpoint of at least 50% reduction)
  - all patients having at least a 50% reduction in mean frequency of TP per month versus baseline (versus primary endpoint of at least 50% of patients)
  - clinically important improvement in quality of life maintained even up to 12 months post-implantation
  - safety profile in line with expectations.

Key Opinion Leader (KOL) event endorsed **alfa**pump market potential

- We hosted a *Key Opinion Leader event* with two leading KOLs from the Mayo Clinic Arizona, Hugo E. Vargas, M.D. and Grace Knuttinen, M.D., Ph.D., who discussed the impact of ascites on patients' quality of life and the limitations of current treatment options, along with their experience of **alfa**pump implantation.

Heart failure programme

RED DESERT – Clinical proof-of-concept of repeated dose **alfa**pump DSR study in diuretic-resistant heart failure patients

- We reported strong top-line results in *May 2021* in 8 euvolemic heart failure patients on high dose diuretics, demonstrating that our **alfa**pump DSR (i) is highly effective at replacing high-dose loop diuretics, (ii) dramatically improved diuretic response and the benefit was maintained in long-term follow-up and (iii) significantly improved the cardio-renal function.
- Following the six-week study, patients continued to be followed for up to 19 months.[II] All patients had a reduction in their oral loop diuretic dose ranging from 40% to 96% at their last visit within the follow-up period (9-19 months after last DSR treatment in the study), showing significant durability to the improvement in diuretic responsiveness following **alfa**pump DSR therapy.
- Dr. Testani presented these results as a late-breaker at the European Society of Cardiology's Heart Failure 2021 Online Congress and they were selected as one of the highlights of the Congress.

SAHARA DESERT – Strong interim results of ongoing safety and feasibility study of **alfa**pump DSR in decompensated heart failure patients with persistent congestion

- We reported positive interim results from 6 patients in *December 2021*. This analysis showed that our **alfa**pump DSR can (i) safely, effectively and rapidly eliminate persistent congestion and restore euvolemia in diuretic-resistant heart failure patients, (ii) considerably benefit their cardio-renal status, and (iii) dramatically improve their diuretic responsiveness for months post-treatment.

Key DSR & **alfa**pump DSR patents granted in the U.S. and Europe

- Key patents were granted in the U.S. and European Union in *January 2021*, covering the **alfa**pump DSR and its method of operation.

DSR development programme on track

- Strong progress in the Chemistry, Manufacturing and Controls (CMC) and pre-clinical development work of our proprietary DSR Infusate 2.0, a second generation infusate with a superior therapeutic and safety profile as well as robust IP protection to drive a high margin recurring revenue stream to accompany **alfa**pump DSR sales.
- We expanded our DSR development programme with short-term DSR therapy (without the **alfa**pump) to derisk the regulatory process, support faster adoption of our DSR therapy in the clinical community, expand potential market opportunity and target earlier entry into the U.S. market.

Corporate

Medical Device Single Audit Program (MDSAP) certification

- We received MDSAP certification from our auditing organisation British Standards Institution (BSI) in *November 2021*, thereby expanding our Quality Management System (QMS) towards the U.S. and Canada within the scope of design, development, production and distribution of active implantable pump systems to transport fluids within the body.

Jackie Fielding appointed as independent Non-Executive Director

- We appointed *Jackie Fielding* as independent Non-Executive Director of the Company, a former Vice President of medical technology company Medtronic and ex-head of their UK & Ireland business, effective as of 1 September 2021.

€22.5 million raised in an equity placement

- In *February 2021*, we raised €22.5 million in an equity placement via an accelerated book building offering from existing investors and new local and international life sciences investors and industry experts.

(I) Pre- and post-implant periods for this analysis of the Roll-In Cohort differ from those that will be used for the Pivotal Cohort analysis
(II) One patient died 9 months after the end of the study (unrelated to DSR therapy).

2022 year-to-date

European Medical Device Regulation (MDR) certification

- We 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 be certified.

€28.4 million raised in an equity placement, cash runway extended into Q2 2023

- In *March 2022*, we raised €28.4 million in an equity placement via an accelerated book building offering from a new investor, Partners in Equity V B.V. and existing shareholders, extending our cash runway into Q2 2023.

Completion of **alfa**pump implantations in POSEIDON and encouraging survival data at 12 months vs. published literature

- In *April 2022*, we announced that all patients from the POSEIDON pivotal study have been implanted with the **alfa**pump, enabling us to report the primary endpoint data before the end of this year as planned.
- We also reported a preliminary interim analysis of patient survival in the Roll-In cohort indicating a 70% survival rate at one year post-implantation, comparing favourably to published literature of only 50% survival for refractory ascites patients after one year[3].

Outlook for 2022

2022 is on track to be a landmark year for Sequana Medical with the primary endpoint read-out of POSEIDON, our North American pivotal study of the **alfa**pump expected in Q4 2022 and the start of MOJAVE DESERT, our first U.S. study with our proprietary DSR Infusate 2.0 in decompensated heart failure patients, as well as other key value drivers throughout the year.

POSEIDON – North American pivotal study of the **alfa**pump in recurrent and refractory ascites due to liver cirrhosis:

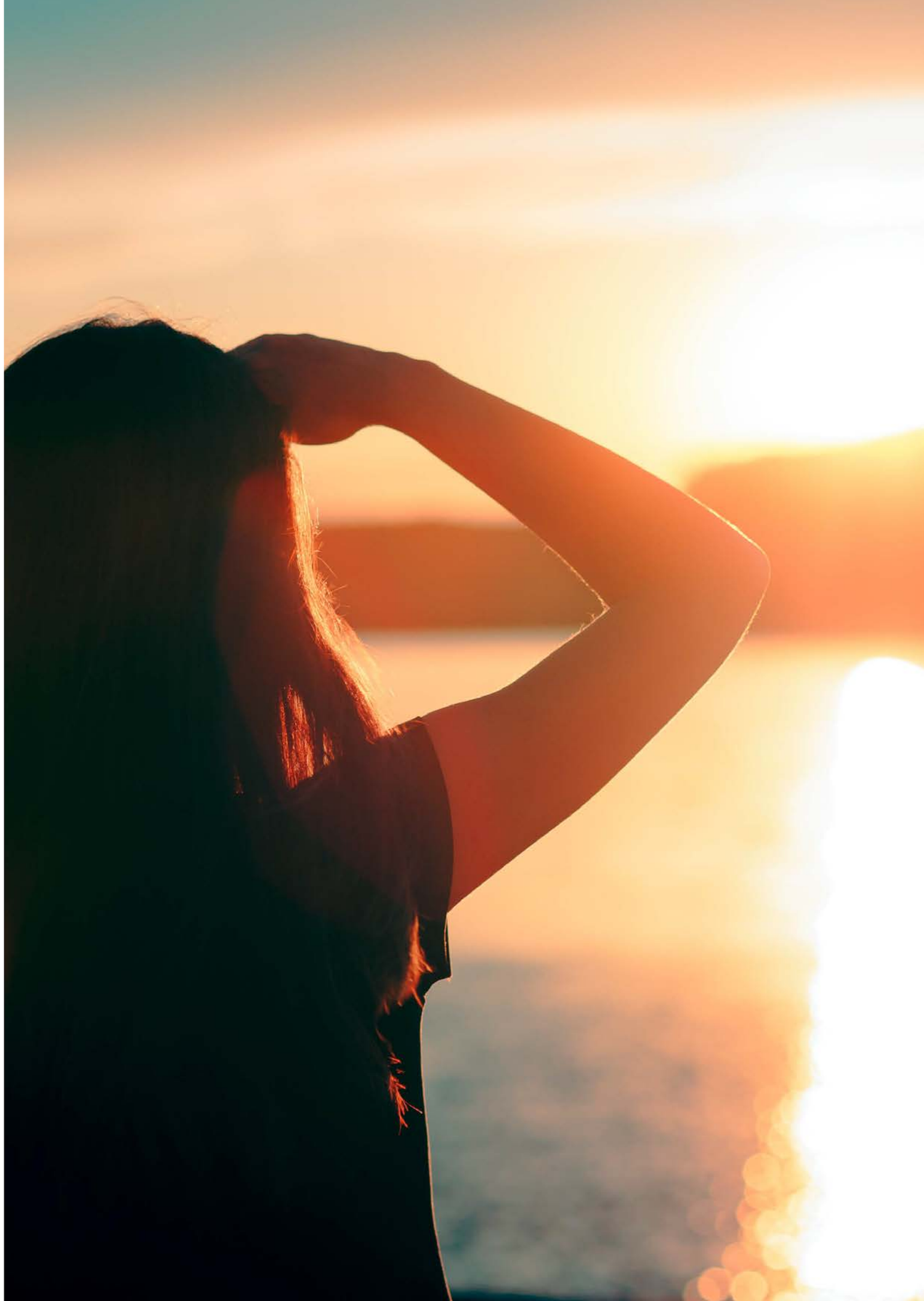
- reporting of primary endpoint planned for Q4 2022
- FDA regulatory submission expected in mid-2023

SAHARA DESERT – safety and feasibility study of **alfa**pump DSR in decompensated heart failure patients:

- reporting of top-line data expected in H2 2022

MOJAVE DESERT – safety and feasibility study of proprietary DSR Infusate 2.0 in decompensated heart failure patients in the U.S.:

- study due to commence before end of year

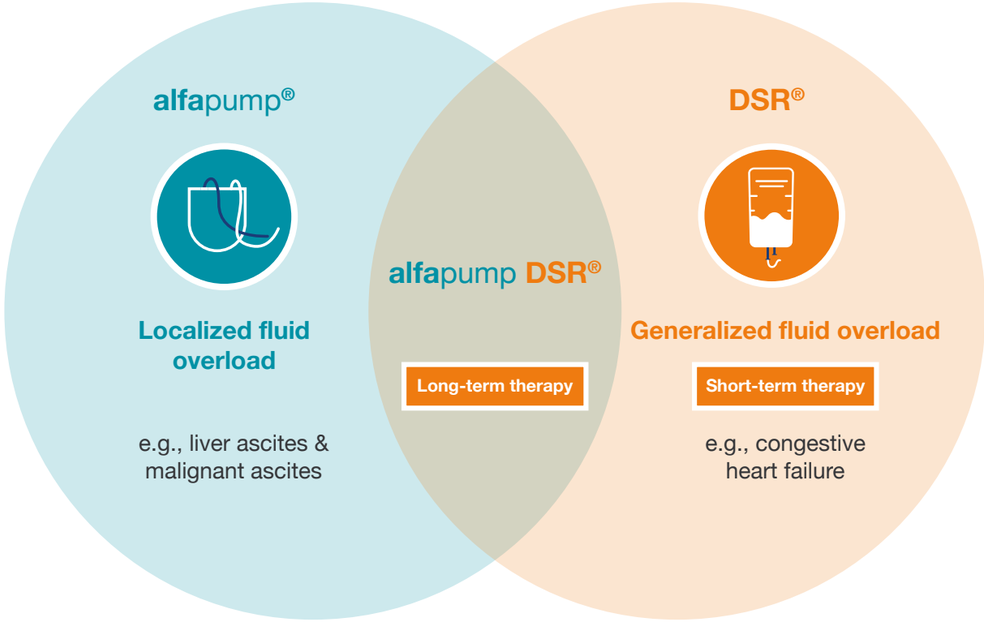


Proprietary alfapump & DSR platforms for diuretic-resistant fluid overload

We are using our proprietary **alfa**pump and DSR platforms to develop innovative treatments for patients with fluid overload where diuretics are no longer effective. Fluid overload is a key clinical problem of many large diseases, including liver disease, cancer, heart failure and renal failure. Diuretic resistance is widespread and results in serious clinical complications. This large and growing market has been long ignored resulting in limited treatment options for patients and significant costs for payors.

Complementary approaches to diuretic-resistant fluid overload

Our **alfa**pump is a fully implanted system for the removal of localized fluid overload (eg ascites due to liver cirrhosis), whilst Direct Sodium Removal (DSR) is a novel therapy in development for managing generalized fluid overload (eg congestion due to heart failure). Combining DSR therapy with the **alfa**pump creates a fully implanted and automated system for long-term therapy of generalized fluid overload. We are developing these treatment solutions to deliver improved clinical outcomes, better quality of life for patients and cost savings to healthcare systems.



alfapump®

Breakthrough Device Designation

Liver Disease (NASH) in N. America

> €3 Bn / year
market opportunity in US

POSEIDON pivotal study implantations completed

Sequana Medical salesforce

alfapump DSR®

Congestion due to Heart Failure

> €5 Bn / year
market opportunity in EU & US

SAHARA DESERT study ongoing

Partnering after US efficacy study

Built upon proven European clinical & commercial experience

Focus on two products - € billion opportunities

Our two pillars of growth are i) the direct commercialisation of the **alfa**pump in North America for recurrent and refractory liver ascites, a large market driven by NASH-related cirrhosis, and ii) the clinical development of DSR and **alfa**pump DSR for congestive heart failure, using our proprietary DSR Infusate.

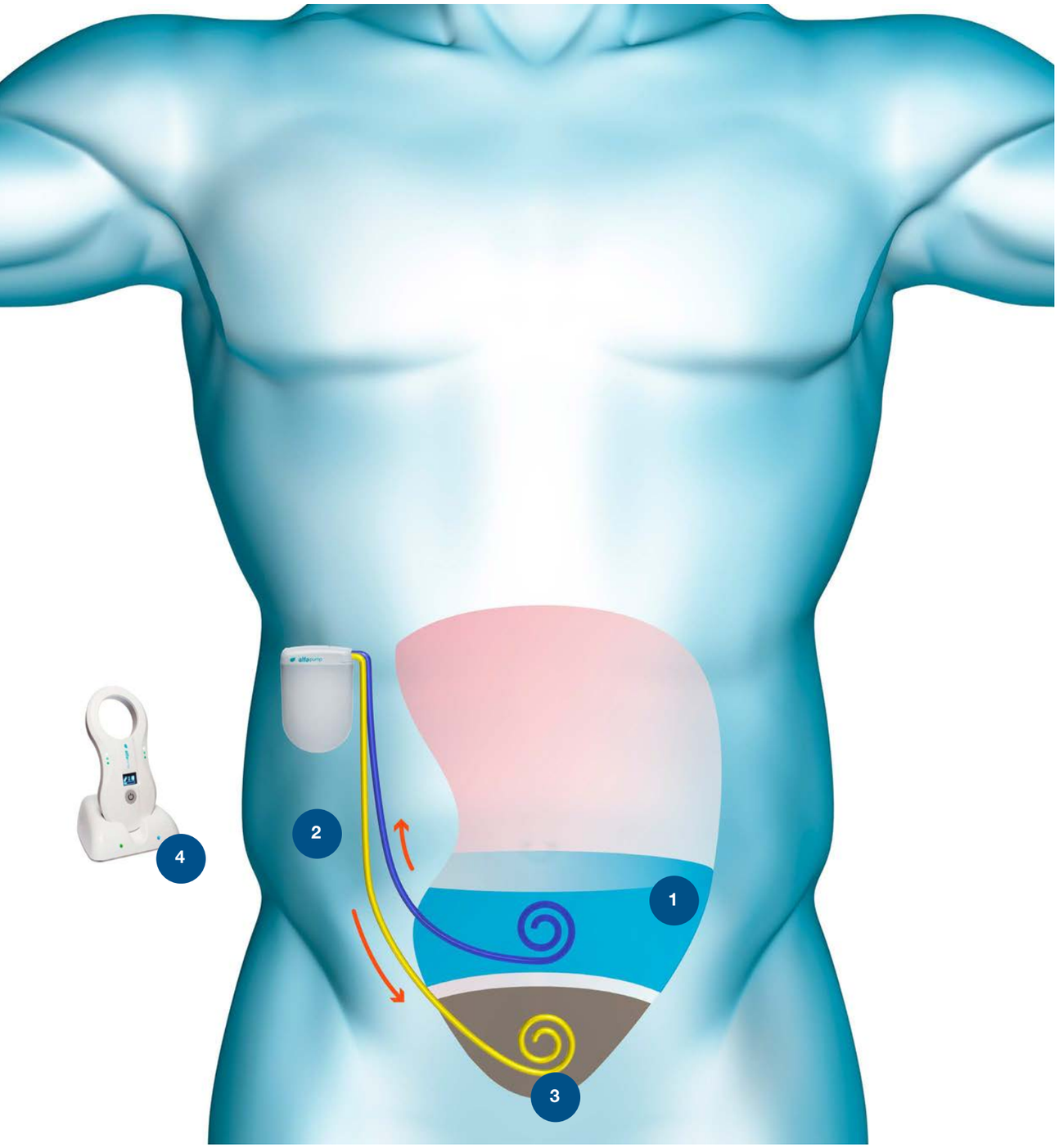
We estimate the **alfa**pump market stemming from NASH-related cirrhosis will exceed €3 billion per year within the next 10-20 years[1] in the U.S. alone and the heart failure market for the **alfa**pump DSR will reach over €5 billion per year in the U.S. and EU5 by 2026[2]. Both markets leverage our clinical and commercial experience of the **alfa**pump in Europe where it is CE-marked for treatment of refractory liver ascites and malignant ascites.

We believe the rising prevalence of NASH-related cirrhosis in the U.S. makes this market increasingly attractive, creating a much larger and more dynamic opportunity for the **alfa**pump compared to Europe, where alcoholic liver disease and viral hepatitis are still the key drivers.

alfapump market potential: > €3 Bn / year

Underlying disease: NASH

Patient characteristic: mainstream



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

Our **alfa**pump is one of the first medical devices designed to treat localized fluid overload in patients when diuretics are no longer effective. It is a battery-powered pump that is implanted just under the skin for the controlled and continuous removal of fluid from the abdominal cavity into the bladder where it is simply urinated away. The **alfa**pump system provides an automated system for the removal of fluid without the need for repeated needle punctures, needles or external tubes.

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**

Unique capabilities

- Fully implanted
- Automatic operation
- Battery charged 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 4 litres of fluid per day
- Virtually non-clogging
- No significant heating during charging and operation
- Strong IP barriers through extensive patent portfolio & know-how

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

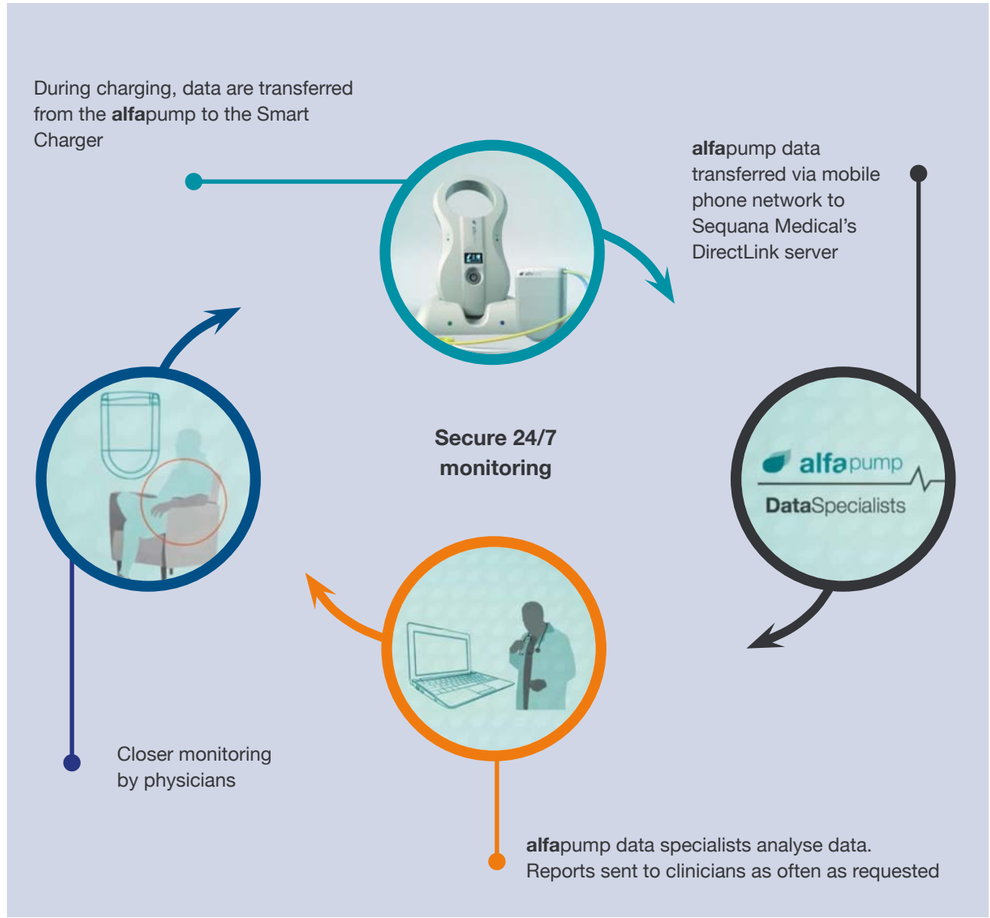
The only patient interaction is the need to recharge the battery each day with a wireless charger (the Smart Charger) through the skin for approximately 20 minutes (depending on the amount of fluid extracted each day).

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.

DirectLink technology

Using DirectLink technology, **alfa**pump performance data are continuously collected via the mobile phone network and transferred 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.



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.

*alfa*pump

The **alfa**pump is an automatic and programmable pump implanted under the skin and can pump up to 4 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.

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 and are not visible from the outside.

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.

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.

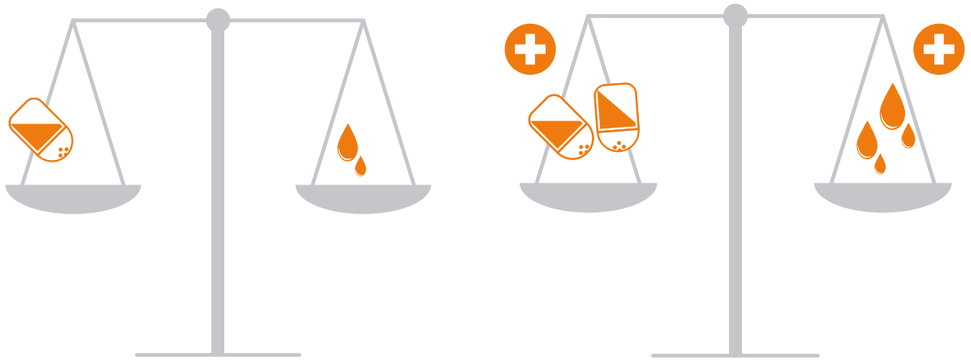
Programmer

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 that is specific to each individual patient.

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

DSR or Direct Sodium Removal is a 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 and 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 approach

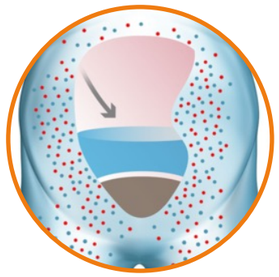
DSR removes excess sodium in patients with residual renal function leading to lower sodium concentration in the body.

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.

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.

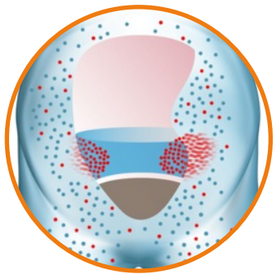
How DSR works

water
sodium



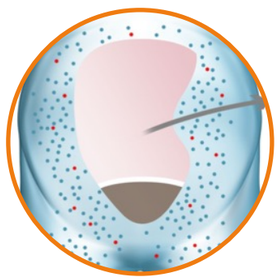
1 Sodium-free DSR Infusate administered to peritoneal cavity

In DSR, the objective is to remove sodium instead of toxins. To do this, we administer a sodium-free infusate (the “DSR Infusate”) to the peritoneal cavity and allow it to dwell for a pre-defined period.



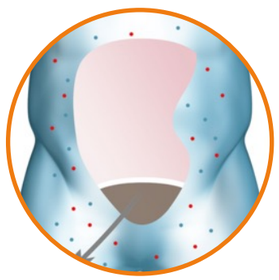
2 Sodium diffuses from body into DSR Infusate

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



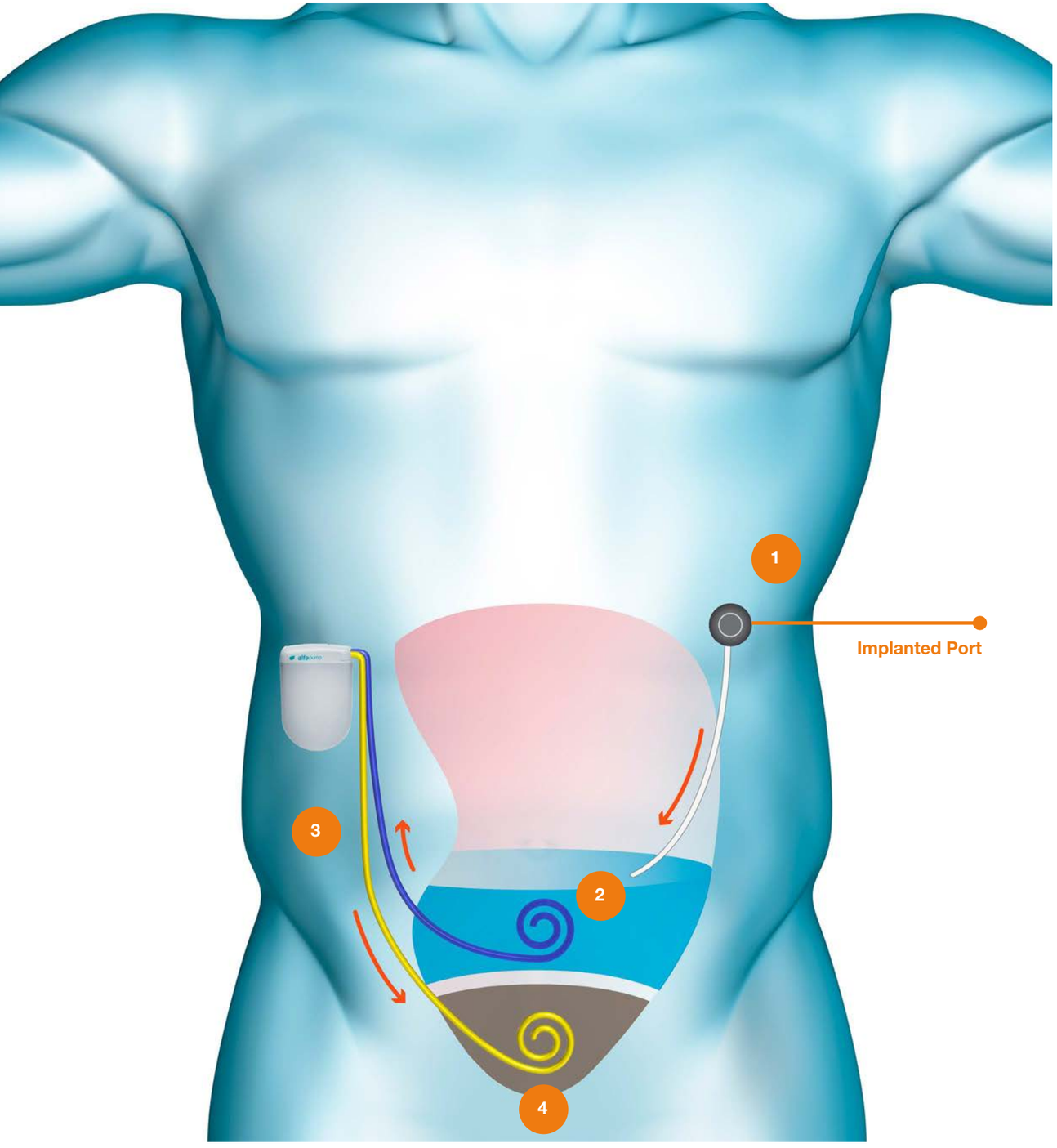
3 DSR Infusate + extracted sodium removed from the body

The DSR Infusate 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 the associated fluid via osmotic ultrafiltration (the movement of water, together with sodium, from the bloodstream to the peritoneal cavity) and/or urination.



1. **Sodium-free DSR Infusate administered to peritoneal cavity via implanted subcutaneous port**
2. **Sodium diffuses into DSR Infusate**
3. **alfa**pump **pumps sodium-rich DSR Infusate into the bladder**
4. **Body eliminates excess fluid through osmotic ultrafiltration and urination**

alfapump DSR:

- directly tackles fundamental problem of fluid overload
- leverages natural processes for fluid removal
- leverages proven elements: DSR, **alfa**pump, implanted port
- allows flexible dosing of DSR Infusate and adapting to patient's disease status

alfapump DSR

The **alfa**pump DSR is built upon the proven **alfa**pump platform, to deliver an automated and fully implanted system for repeated dose DSR therapy.

The sodium-free DSR Infusate is administered to the peritoneal cavity via an implanted subcutaneous port. The DSR Infusate remains in the peritoneal cavity for a pre-determined time before the DSR Infusate and the extracted sodium is pumped to the bladder by the **alfa**pump where it is eliminated via urination.

We believe that our accumulated experience of over 900 implanted **alfa**pump systems and the clinical proof-of-concept of DSR therapy potentially derisks the technical and clinical development of **alfa**pump DSR.

Extensive Intellectual Property Portfolio

Our patent portfolio consists of 93 patents being granted across 16 patent families and a further 18 patent applications pending for our **alfa**pump, DSR and **alfa**pump DSR. In addition to patents, we also rely on a combination of trade secrets, design rights, copyright laws, non-disclosure agreements and other contractual provisions and technical measures that help maintain and develop our competitive position with respect to intellectual property.

alfapump in liver disease and malignant ascites

Proven step change for treatment of refractory liver ascites and malignant ascites

The **alfa**pump provides an innovative treatment solution for the management of refractory liver ascites 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.

In the U.S., the **alfa**pump has been granted breakthrough device designation by the FDA for treatment of recurrent and refractory ascites due to liver cirrhosis. Interim data from the ongoing North American pivotal study (POSEIDON) showed positive outcomes against all primary endpoints of the study(l), as well as indications of clinically relevant improvements in quality of life measures. This study is intended to support a future marketing application of the **alfa**pump in the U.S. and Canada and its primary endpoint read-out is expected in Q4 2022.

In Europe, the **alfa**pump is CE-marked for the management 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 U.K. National Institute for Health and Care Excellence (NICE) interventional procedure guidance for treatment of refractory ascites caused by cirrhosis.

To date, over 900 **alfa**pump systems have been implanted.

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

Market opportunities 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 U.S. adults aged 18 and older were diagnosed with chronic liver disease[4].

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.

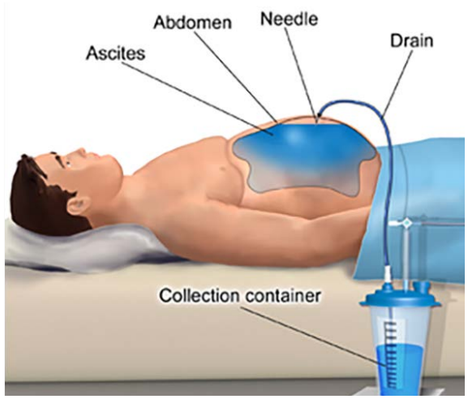
Approximately one-third of the U.S. population is affected by NAFLD[5] and approximately a quarter to one-third of NAFLD cases are classified as NASH[6]. NASH is a silent disease due to the difficulty in diagnosing it, making early-stage intervention challenging. Currently, there are no drugs approved for treatment of NASH and data from recently developed drugs have failed to demonstrate 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 U.S. 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.

Based on an analysis of 2019 Medicare Standard Analytic Files, we estimate that there are ca. 30 to 50 thousand patients with recurrent or refractory ascites per year currently in the U.S. We believe that this market is forecast to grow to approximately 150,000 patients annually in the U.S. in the next 10-20 years, driven by the dramatic increase of NASH-related cirrhosis[5].

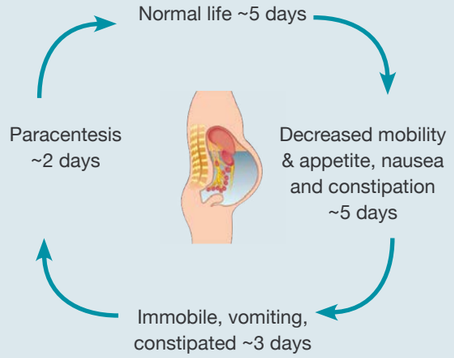
When drug therapy and dietary restriction are no longer effective, the common treatment of ascites is drainage (“paracentesis”).



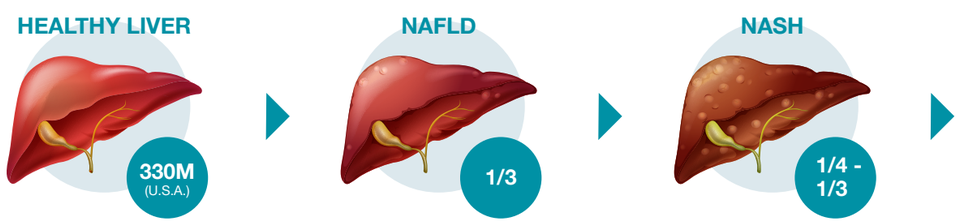
Paracentesis is a bedside or clinic procedure in which a needle is inserted into the peritoneal cavity to remove the ascitic fluid.

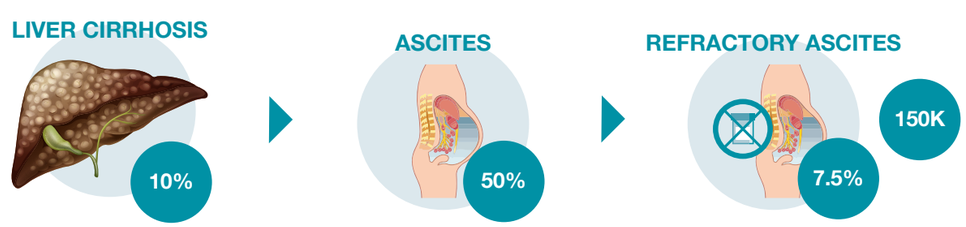
Large Volume Paracentesis treatment cycle

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.

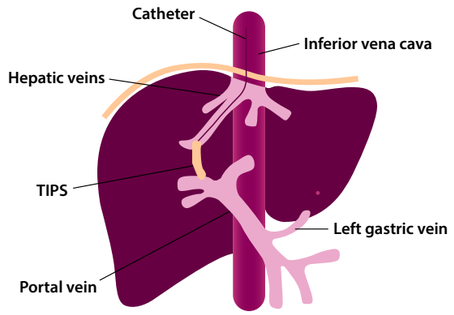


Source: Dr. Rajiv Jalan





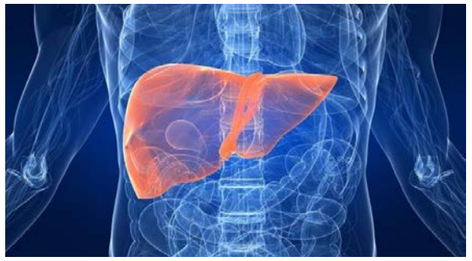
In selected patients with refractory ascites, a therapeutic alternative to repeated LVPs is the use of a transjugular intrahepatic portosystemic shunt (TIPS).



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.

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 U.S. and EU5 and an estimated 24,000 and 26,000 new cases of ovarian cancer diagnosed in the U.S. and EU5, respectively[13]. The estimated prevalence of malignant ascites due to ovarian and breast cancer is approximately 16,000 cases in the U.S. 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.

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, U.S.

"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 story

“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.”

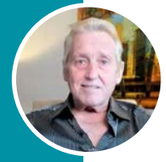
“My approach to life totally changed since the alfapump, I look at it as a second chance in life.”

63-year old patient, Canada

Living with refractory ascites, before and after implantation of the alfapump

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.

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 their 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.

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.

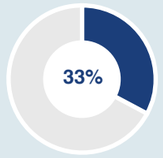
If left untreated, NASH can lead to serious complications such as cirrhosis, liver failure and ultimately death. It is now the second-leading cause of liver transplants and will soon become the leading cause in the U.S. Although diet measures and increased physical activity are key components of NASH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

(I) The NASH education program
(II) Younossi et al., Journal of Hepatology, 2016

- $292 bn -

In the U.S., the current economic burden of NAFLD is estimated at $292 billion per year, a tremendous and growing burden(2)

NAFLD

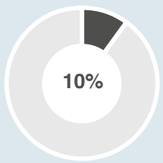


1/3 of US citizens has NAFLD, the hepatic manifestation associated with type-2 diabetes and obesity

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

“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.

Clinical development

Completed clinical studies

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[(I)]
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		
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:

- ~ 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; and
- 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.

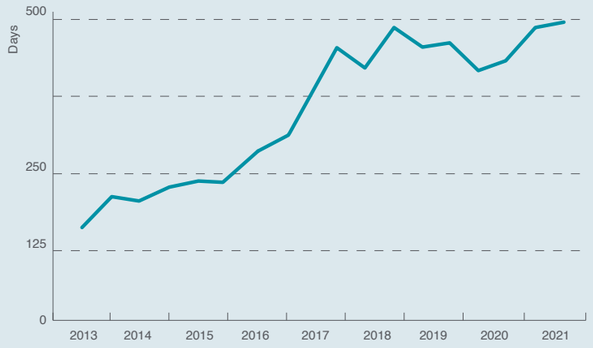
(I) Data on initial 56 patients have been published. Data on all 100 patients have been submitted for publication.

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, nine 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/alfa**pump* therapy duration

Ongoing clinical studies

We are currently running additional clinical studies in patients with recurrent or refractory liver ascites, 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.

The timings presented in the table below are subject to further developments related to the COVID-19 pandemic.

Name of Study	Description[I]	2021	2022	2023
POSEIDON (NCT 03973866)	North American pivotal study enrolling 71 Pivotal patients and 40 Roll-In patients with recurrent or refractory liver ascites to demonstrate the safety and efficacy of the **alfa**pump and support approval in U.S. and Canada.		*Primary endpoint*	
ARIA Pump Study[II] (NCT 03506893)	Randomised, 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 2023.

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

Pursuing approval of the alfapump in the U.S. and Canada

Breakthrough Device Designation by the U.S. FDA

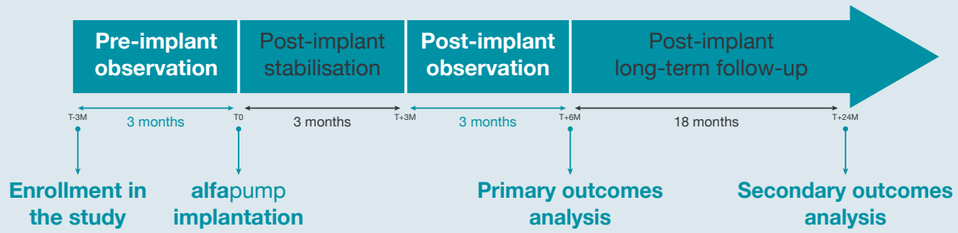
In January 2019, we received breakthrough device designation from the U.S. FDA for the **alfa**pump for the treatment of recurrent or refractory ascites due to liver cirrhosis. This program is designed to facilitate the development and expedite the review of devices that provide more effective treatment 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 and are eligible for prioritized review of the submission package to obtain regulatory approval in the U.S. In addition, breakthrough devices will also benefit from the reimbursement initiatives launched by CMS (Centers for Medicare and Medicaid Services).

POSEIDON – North American pivotal study to support approval of the alfapump in the U.S. and Canada

STUDY DESIGN

As a result of the **alfa**pump breakthrough device designation, we were able to interact frequently with the U.S. FDA who provided us with invaluable advice on the design of the POSEIDON study. The final study design allows for a reduced number of study patients to be enrolled and a shorter follow-up time for primary endpoint analysis. Following a positive interactive review process with the FDA, we received unconditional investigational device exemption (IDE) approval to start POSEIDON in a timely manner, using an optimised clinical trial design. We enrolled the first patient in September 2019 and the study completed enrolment in December 2021.

POSEIDON is a single-arm, open-label, within-subject crossover study of the **alfa**pump in patients with recurrent or refractory ascites due to liver cirrhosis in approximately 20 centres across the U.S. and Canada. The study includes a Pivotal Cohort with 71 patients enrolled, allowing for an expected 40 patients to be implanted with the **alfa**pump for primary endpoint analysis and an additional Roll-In Cohort with 29 patients implanted with the **alfa**pump to ensure new centres are familiarized with the implantation procedure before they enrol patients in the Pivotal Cohort.



Pivotal Cohort patients enter into a 3-month pre-implant observation period in which they receive standard of care therapy (consisting of paracentesis) before the **alfa**pump is implanted. Upon implementation of the inclusion/exclusion criteria, 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 50% reduction in average monthly frequency of therapeutic paracentesis (TP) post-**alfa**pump implant (month four to month six) versus pre-implant observation period and that 2) at least 50% of patients will achieve a 50% reduction in the requirement for TP post-implant versus pre-implant. The primary safety endpoint is the rate of **alfa**pump related re-interventions adjudicated by the Clinical Events Committee. 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. For more information about the study, please visit clinicaltrials.gov (NCT03973866).

STRONG INTERIM RESULTS REPORTED FROM 26 PATIENTS IN THE ROLL-IN COHORT

Patients from the Roll-In Cohort must fulfil the same inclusion and exclusion criteria as patients enrolled into the Pivotal Cohort, which allowed us to report interim data without compromising the primary endpoint analysis of the study. The only difference with the Pivotal Cohort patients is that patients from the Roll-In Cohort don't enter a pre-implant observation period first and therefore the patients' historical medical records are used as baseline.

Looking at the underlying cirrhosis etiology of these 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 cirrhosis market. The mean MELD (Model for End-stage Liver Disease) score in these patients was 10.3 (± 3.9) indicating that physicians in North America are willing to treat patients at an earlier stage of their disease than in Europe. Before enrolment, these patients required on average 3.8 TP per month, indicating that North American patients appear to have more TP per month than European patients.

Age (mean)	**63 y**
MELD score (mean ± SD)	**10.3 ± 3.9**
Cirrhosis etiology	
- Alcohol	50.0%
- NASH	**23.1%**
- NASH / Alcohol	**3.8%**
- Alcohol / Hepatitis	11.5%
- Alcohol / Primary Sclerosing Cholangitis	3.8%
- Hepatitis C	3.8%
- Budd Chiari Syndrome	3.8%
TP per month prior to study (mean ± SD)	**3.8 ± 1.4**

MELD: Model for End-stage Liver Disease; SD: Standard Deviation; NASH: Non-Alcoholic Steatohepatitis; TP: Therapeutic Paracentesis

The interim data demonstrated a **mean reduction in the frequency of TP post-implant versus pre-implant of over 90%, with all patients having at least a 50% reduction in the average frequency of TP per month(I).**

Mean values	Primary efficacy endpoint Pivotal Cohort	Interim data Roll-In Cohort (N=26)
% reduction in monthly frequency of TP	> 50%(II)	**> 90%(III)**
% patients with > 50% reduction in TP	> 50%(II)	**100%(III)**

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 alfapump on patient's quality of life**. Both, the mean physical component score of SF36 and the mean score

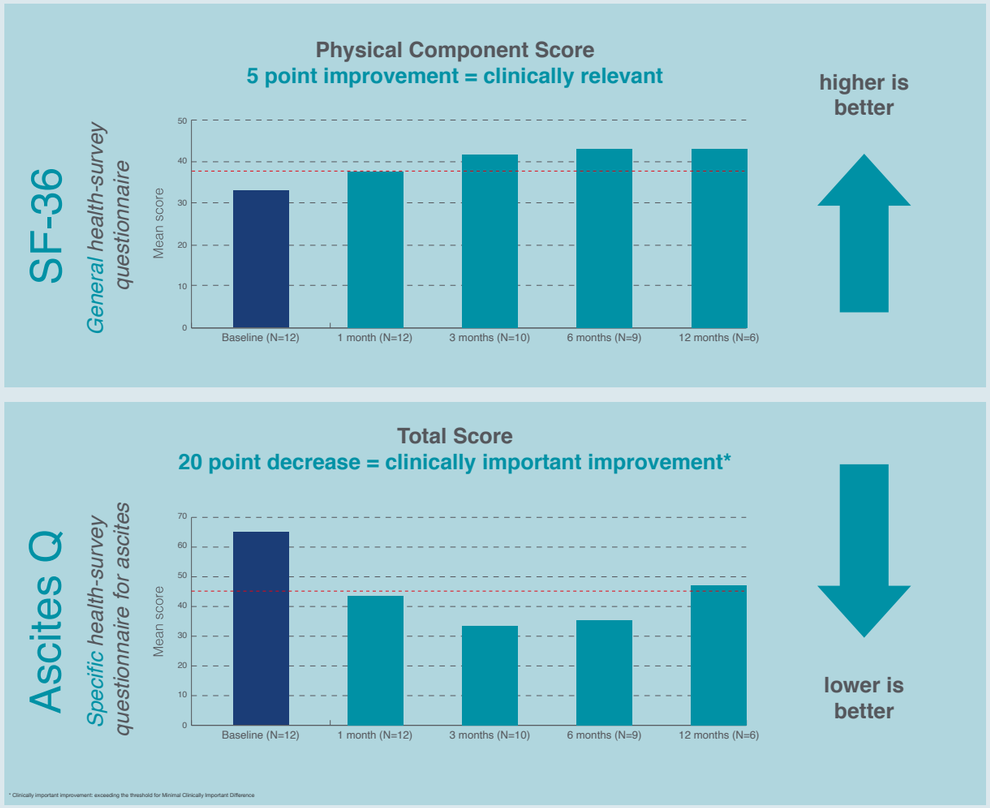
(I) Pre- and post-implant periods for this analysis of the Roll-In Cohort differ from those that will be used for the Pivotal Cohort analysis
(II) Monthly frequency of TP during 3-month post-implant observation periode (month 4 to 6) vs 3-month pre-implant observation period
(III) Monthly frequency of TP during period up to 12 months post-implant vs one month prior to implant (medical history)

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 (UADE[l]) 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.

The substantial reduction in the need for therapeutic paracentesis, good safety profile and clinically relevant improvement in quality of life reported in this study so far is very encouraging. These data further validate the great potential of **alfa**pump to become a key treatment option for this underserved patient population.

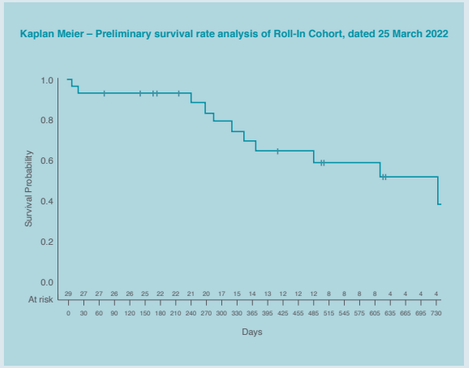
Furthermore, it is an important milestone towards achieving a future marketing application in the U.S. and Canada.



(l) 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)

ENCOURAGING SURVIVAL DATA AT 12 MONTHS VS. PUBLISHED LITERATURE

A preliminary interim analysis 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[3].

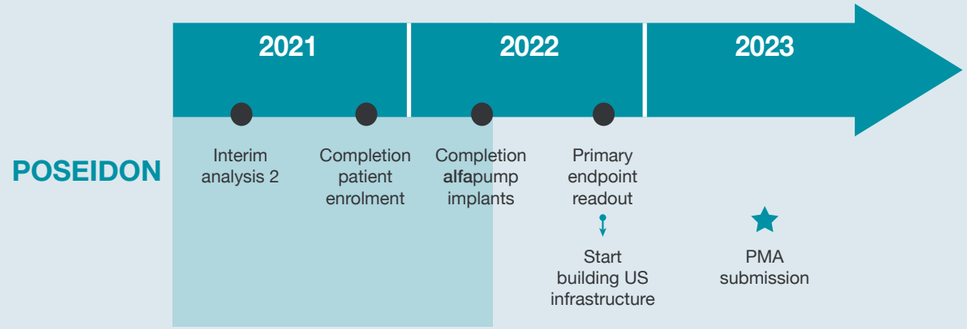


UPCOMING MILESTONES TOWARDS ALFAPUMP U.S. APPROVAL

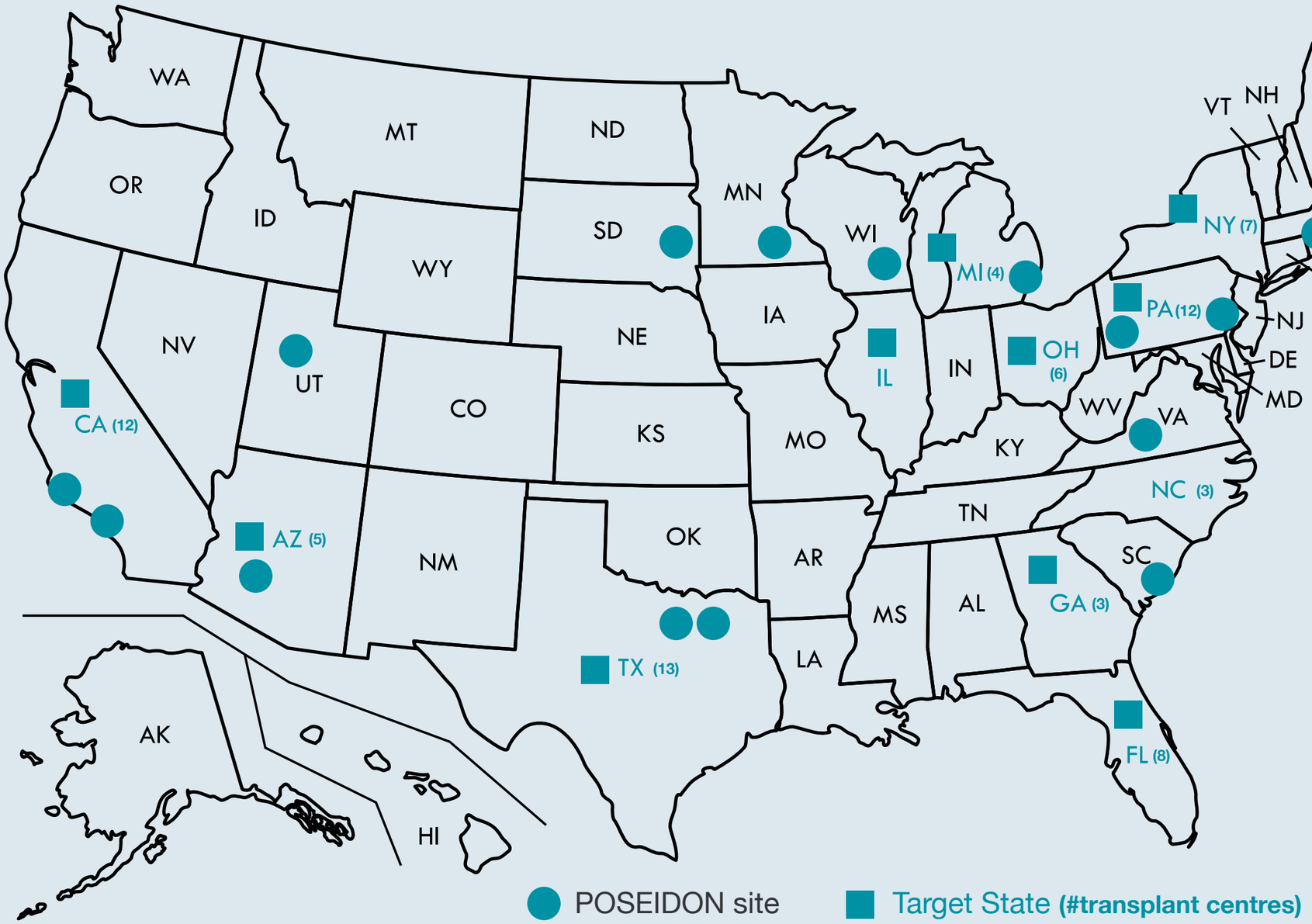
The recruitment of the POSEIDON study was completed in December 2021 and the primary endpoint read-out of the Pivotal Cohort is expected in Q4 2022. The POSEIDON study is intended to support a future marketing application of the **alfa**pump in the U.S. and Canada, with an FDA submission expected in mid-2023.

"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, Canada and Principal Investigator for POSEIDON



U.S. COMMERCIALISATION THROUGH OWN DEDICATED SPECIALTY SALESFORCE



We plan to directly commercialise the **alfa**pump in the U.S. by establishing our own specialty sales force, leveraging our experience from Europe and the North American studies. We will take advantage of the fact that virtually all refractory ascites patients in the U.S. are referred to one of the 140 U.S. liver transplant centres(I). We will initially focus on these specialist centres allowing coverage of the market with a lean commercial U.S. team of an estimated 35 sales representatives, 10 clinical support specialists and 5 corporate functions.

In the U.S., the **alfa**pump will be reimbursed through Current Procedural Terminology (CPT) codes for physician services and bundled Diagnosis Related Group (DRG) payments for hospital services. 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 (Centers for Medicare and Medicaid Services). This will allow Medicare beneficiaries, who will be our principal patient population, to have timely access to the **alfa**pump while real-world evidence continues to emerge.

(I) https://www.medtechdive.com/news/cms-eases-breakthrough-device-path-to-reimbursement-in-final-rule/560174/

The impact of Refractory or Recurrent Liver Ascites on Patients and Healthcare systems and the potential for alfapump therapy in NASH-related Ascites

KOL Event with Hugo E. Vargas, M.D. and Grace Knuttinen, M.D., Ph.D. from Mayo Clinic

— Thursday, July 15th, 2021

38
Live attendees
- 16 Equity analysts
- 10 Investors
- 6 Peers

29
Replays

1h
Duration

We hosted a total of 67 overall attendees, including institutional investors, sell-side analysts, bankers, high net worth individuals, and strategics.

Key Takeaways from KOL webinar with Dr. Vargas and Dr. Knuttinen from Mayo Clinic, Arizona

- **High Burden**
  Ascites has a significant negative impact on patients and may lead to serious complications.
- **Increasing prevalence**
  Net effect of NASH becoming very prevalent is that we will see an increased incidence of cirrhosis with the complication of ascites
- **Patient support**
  alfapump is very well accepted with strong interest from the patient community
- **Solid benefit on patients**
  Reported outcomes of POSEIDON are solid and shows that **alfa**pump has a positive impact on patients
- **Easy implantation**
  Implantation of **alfa**pump is a minimally invasive procedure under local anaesthesia / moderate sedation and recommends the use of ultrasound for ascites localisation and catheter placement

Replay available on our *website*

“The reported improvement in quality of life is extremely important to us since this is a very advanced and difficult disease process.”

- Dr. Hugo E. Vargas, M.D.

Hugo E. Vargas, M.D.
Dr. Vargas is a Mayo Clinic Consultant in the Department of Gastroenterology and Hepatology and the Mayo Clinic Transplantation Center. His current clinical and research interests include management of cirrhosis complications, acute chronic liver disease and alcohol related liver disease. Dr. Vargas is the Medical Director for the Office of Clinical Research – Arizona and a Professor of Medicine in the Mayo Clinic Alix School of Medicine and is the Chair of the Clinical Research Subcommittee, and the Vice Chair of the Arizona Research Operations Management Team. Dr. Vargas received his M.D. from Hahnemann University Graduate School of Medicine, has authored or coauthored more than 125 peer-reviewed articles and is a Fellow of the AASLD, AGA, ACG, ASGE and ACP.

“The alfapump implantation is a straightforward procedure using standard techniques, catheters and wires that we are already using on a daily basis.”

- Dr. Grace Knuttinen, M.D., Ph.D.

Grace Knuttinen, M.D., Ph.D.
Dr. Knuttinen is a Mayo Clinic Consultant and Professor in the Department of Radiology. She is an interventional radiologist with Mayo Clinic in Phoenix, with clinical and research interests in hepatobiliary disease, the management of post liver transplant complications, and vascular disease. Dr. Knuttinen has more than 20 years’ experience in interventional radiology and is a member of the Leadership Academy of the Society of Interventional Radiology and an Invited ABR Board Examiner for International Radiology at the American Board of Radiology. She is the Director for the Mayo Alix School of Medicine Dual Degree program, and the Director for the Barretts ASU- Mayo Alix School of Medicine Premedical Scholars program. Dr. Knuttinen received her M.D. and Ph.D. from Northwestern University, has coauthored over 95 peer-reviewed articles and written 13 book chapters. She is a Fellow of the Society of Interventional Radiology (SIR) and is the chair of a national SIR committee and currently the principal investigator of an ongoing national prospective funded clinical trial.

Commercial operations in Europe

Sales and marketing

Our European commercial team consists of 12 people and the **alfa**pump European commercial activities are concentrated on Germany and France, as part of our focused strategy and continued market penetration in these territories. We continuously evaluate the opportunity to enter into other markets based on the commercial potential and the likelihood to receive reimbursement. In those markets, we will either establish a direct commercial presence or work with distributors.

To raise awareness of the **alfa**pump amongst clinicians, patients and their relatives, we have invested and will continue to invest in promotional activities using both conventional and social media, such as LinkedIn, Facebook, Twitter and YouTube. We also raise awareness amongst clinicians through participation in specialist conferences and supporting clinical studies and amongst international patient advocacy groups. Our websites (www.sequanamedical.com and www.**alfa**pump.com) provide relevant information to patients, their families and clinicians. Our YouTube videos on the **alfa**pump have received more than 470,000 views.

Approval and reimbursement

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 U.S. 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.

In markets such as Denmark and Israel where we are working with distributors, we are seeking alternative funding sources including innovation funds, hospital budgets, arrangements with insurance funds, and direct payment by patients.

Customers

The **alfa**pump is primarily targeted at the specialist clinician treating the patient. In the case of refractory or recurrent liver ascites, the primary target is usually the hepatologist, whereas for malignant ascites it is the oncologist. This focus on specialist clinicians enables our commercial organisation to target a limited number of hospitals.

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 Europe and 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. In North America, 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.

DSR and **alfa**pump DSR in heart failure

Breakthrough approach to persistent congestion in heart failure leveraging proven alfapump platform

Direct Sodium Removal or DSR is a simple and elegant therapy to reduce fluid overload that is spread across the body. Via DSR, we remove the excess sodium from the body, causing the kidneys to step in and eliminate the right amount of free water to maintain the correct sodium concentration in the body. The **alfa**pump DSR is built upon the proven **alfa**pump platform to deliver a fully implanted system for DSR therapy. DSR and **alfa**pump DSR are in clinical development to manage fluid overload in the many heart failure patients who have become resistant to diuretic drugs. The **alfa**pump DSR is designed to provide a long-term therapy, whilst use of DSR without the **alfa**pump is being developed as a short-term therapy, to support faster adoption of DSR in the clinical community, support **alfa**pump DSR market entry, expand potential market opportunity and target earlier entry into the U.S. market. Key patents for the **alfa**pump DSR, DSR Infusate and method of operation have been granted in the U.S. and Europe. 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, thereby reducing the clinical burden on their weakened heart.

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 the RED DESERT study, a repeated dose **alfa**pump DSR proof-of-concept study in diuretic-resistant heart failure patients were reported in May 2021. Eight patients diagnosed with stable chronic heart failure on high dose oral diuretics (mean furosemide equivalent dose of 323 mg/day) were implanted with the **alfa**pump DSR system and underwent up to six weeks of DSR therapy whilst their loop diuretic treatment was withheld. The study demonstrated that **alfa**pump DSR therapy was safe and effective at maintaining the fluid and sodium balance of these patients without the need of any loop diuretics. Moreover, a significant improvement in patients' cardio-renal function and a dramatic and sustained improvement in their diuretic response were reported following the six-week **alfa**pump DSR therapy.

Based on the success of RED DESERT, we initiated the SAHARA DESERT study, evaluating the dosing and frequency of **alfa**pump DSR therapy in decompensated heart failure patients with persistent congestion, our target population. Interim data from six patients were reported

in December 2021 and indicated that **alfa**pump DSR could safely, effectively and rapidly eliminate persistent congestion and restore euvolemia without the need of any loop diuretics, as well as deliver a considerable benefit in patients' cardio-renal status and a dramatic improvement in their diuretic responsiveness. Recruitment in SAHARA DESERT continues and is on track to report top-line data in H2 2022.

In parallel, we have made strong progress in the development of our proprietary DSR Infusate 2.0, a second generation infusate with an improved therapeutic profile, a favourable safety profile and IP protection that will drive a high margin recurring revenue stream. We expect to commence MOJAVE DESERT, our first U.S. study using DSR Infusate 2.0 without the **alfa**pump in H2 2022, followed by SONORAN DESERT, a phase 2a study using DSR Infusate 2.0 with the **alfa**pump, planned to start in H2 2023. Following these U.S. efficacy studies, we plan to establish a strategic partnership for further clinical development and commercialisation 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 6.5 million adults in the U.S. aged 20 and over are affected by heart failure and that number is expected to rise to 8 million adults by 2030[14].

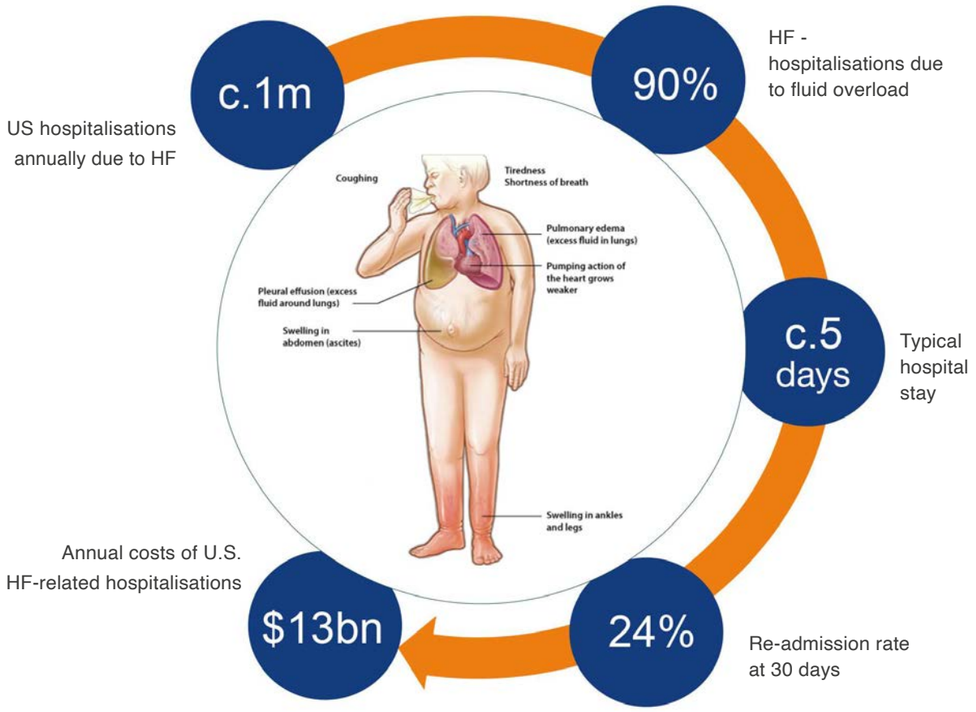
It is estimated that at least 26 million people are living with heart failure worldwide[15]. Total direct medical costs for the U.S. heart failure market are projected to reach $53 billion in 2030[16].

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 results 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 hospitalisations, poor quality of life and high healthcare costs.

There are approximately one million hospitalisations for heart failure annually in the U.S.[17], costing approximately $13 billion each year[18]. Of these admissions, 90% are due to symptoms of fluid overload[19], with an average 5 days length of stay[20]. 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 resultapproximately one in four patients are being readmitted to hospital within 30-days[21]. An estimated 40% of heart failure patients on intravenous loop diuretics experience diuretic resistance or intolerance[22] and nearly 50% of hospitalised patients with heart failure are discharged with residual fluid excess[17].

One other therapy that is used in patients resistant or intolerant to diuretics is extracorporeal ultrafiltration. Ultrafiltration 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[23].

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 anymore, reducing the number of hospitalisations and improving patient quality of life. This is the opportunity for our DSR and **alfa**pump DSR treatment solutions.



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 alfapump 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 (DR) 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 DR
- 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.

$13bn

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[24]

Pre-clinical and Clinical development

Completed studies

The impact of administering a single dose DSR Infusate to the peritoneal cavity, and the resulting sodium and fluid removal, was evaluated in pre-clinical and clinical studies. These studies used a first generation DSR Infusate, a sodium-free dextrose 10% (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.	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 via tamponade.	5
First-in-human 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 (without **alfa**pump) in patients who underwent peritoneal dialysis.	10
Repeated Dose study of alfapump DSR (RED DESERT)	Study in diuretic-resistant heart failure patients to demonstrate the safety, tolerability and efficacy of the **alfa**pump DSR using repeated dose DSR therapy over a 6-week period.	8

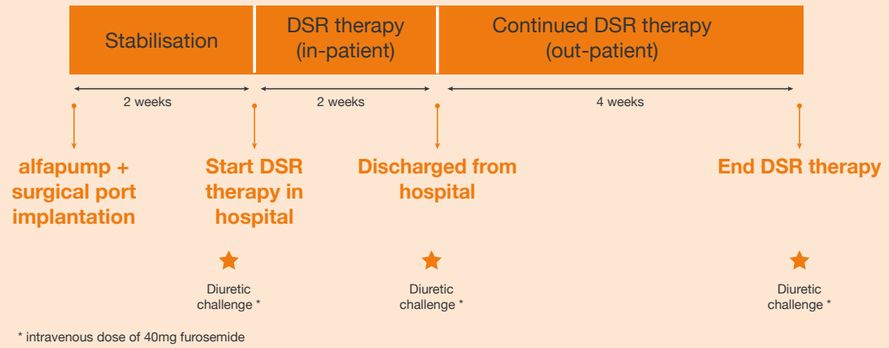
RED DESERT – repeated dose alfapump DSR proof-of-concept study in euvolemic heart failure patients on high dose diuretics

STUDY DESIGN

RED DESERT is our multi-centre, prospective, single-arm, first-in-human study to evaluate the safety and feasibility of **alfa**pump DSR. Eight patients diagnosed with stable chronic heart failure on high dose oral diuretics were implanted with the **alfa**pump DSR system (**alfa**pump system and implanted subcutaneous port).

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 **alfa**pump DSR system implantation, 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 sodium-free D10% infusate on Monday, Wednesday and Friday, administered through the implanted surgical port into the peritoneal cavity. The DSR Infusate 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 **alfa**pump DSR to maintain a neutral sodium balance in the absence of diuretic therapy and the sustained effect of DSR to maintain euvolemia through week 6. Additional exploratory endpoints evaluated the potential impact of DSR to restore response to diuretics following DSR therapy. For more information about the study, please visit clinicaltrials.gov (NCT04116034).



STRONG RESULTS REPORTED FROM 8 PATIENTS

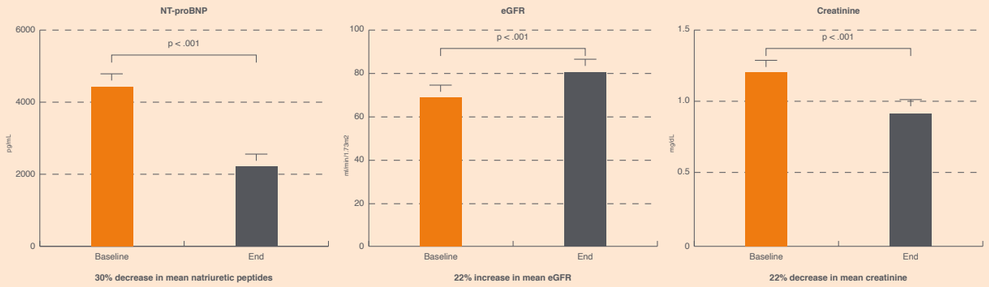
Eight euvolemic heart failure patients on high dose oral diuretics (mean furosemide equivalent dose of 323 mg/day) were implanted with the **alfa**pump DSR system and underwent up to six weeks of DSR therapy whilst their loop diuretic treatment was withheld. The heart failure patients enrolled in the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

	N=8
Ejection Fraction — % (Mean ± SD)	24.4 ± 3.1
NT-proBNP — pg/mL(I) (Mean ± SD)	4,589 ± 2,945
Furosemide equivalents — mg/day (Mean ± SD)	323 ± 263

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

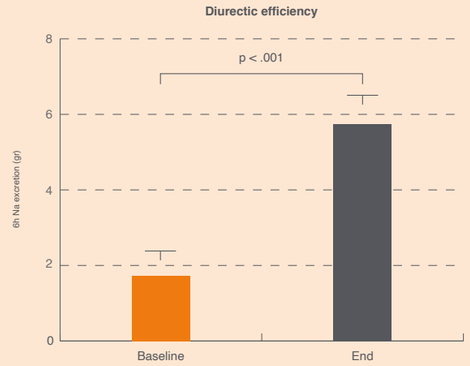
The **alfa**pump DSR implant procedure and repeated dosing of DSR therapy were **well tolerated** in all patients. There were **no clinically relevant changes in serum sodium levels** or progressive hyponatremia in any of the implanted patients. There were two serious adverse events in two of the last three patients, both having advanced heart failure. There was one transient ischemic attack (fully recovered) and one sudden cardiac death. The Data Monitoring Committee (DMC) 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 cardio-renal function** of these patients with a mean 30% reduction in NT-proBNP ($p<0.001$ vs baseline, N=7), mean 22% improvement in estimated glomerular filtration 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 cardio-renal function, whilst RED DESERT showed that both of these functions were improved following repeated **alfa**pump DSR therapy.



(I) NT-proBNP: N-terminal-pro hormone B-type Natriuretic Peptide — analysed in local lab

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 19 months. One patient died nine months after the end of the study (unrelated to DSR therapy). All patients had a reduction in their oral loop diuretic dose ranging from 40% to 96% at their last visit within the follow-up period (9-19 months after last DSR treatment in the study), showing a **significant durability to the improvement in diuretic responsiveness following alfapump DSR therapy.**

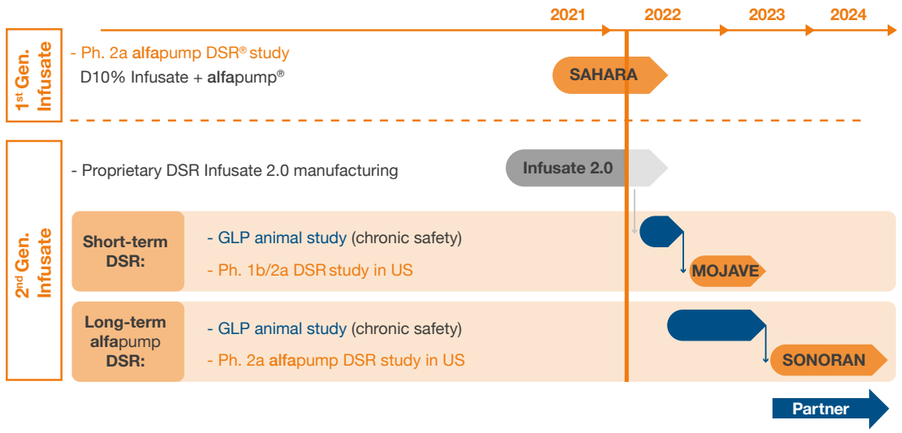
“The simultaneous normalisation of diuretic response and improvement in cardio-renal status of the RED DESERT patients is a never before seen treatment effect and could translate into important long-term clinical benefits in heart failure patients.”

- Dr. Jeffrey Testani, Associate Professor at Yale University

Ongoing and planned clinical studies

Following the success of the RED DESERT study, we initiated the SAHARA DESERT study in decompensated heart failure patients with persistent congestion, our target population for DSR therapy. This study uses the first generation DSR Infusate (sodium-free D10%) whilst we are developing our proprietary second generation DSR Infusate, a sodium-free dextrose/icodextrin solution. Following appropriate Good Laboratory Practice (GLP) animal testing, we plan to start human studies in the U.S. using our proprietary DSR Infusate 2.0. MOJAVE DESERT is planned to start in H2 2022 using short-term DSR therapy (without the **alfa**pump) followed by SONORAN DESERT which is planned to start in H2 2023 using **alfa**pump DSR long-term therapy. Once we have completed the U.S. MOJAVE DESERT study, we plan to establish a strategic partnership for further clinical development and commercialisation of our DSR therapy.

The timings presented below are subject to further developments related to the COVID-19 pandemic.(I)



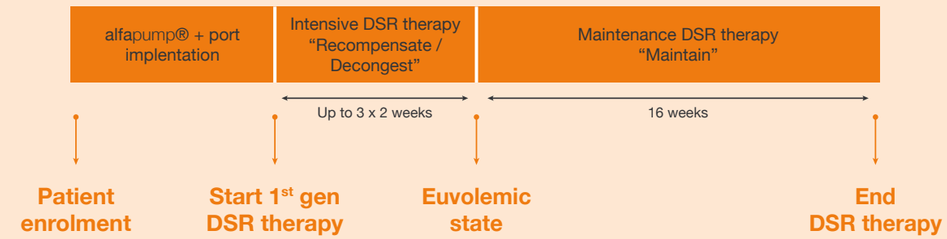
(I) The descriptions and timing of these studies are based on circumstances that may or may not occur in the future and remain subject to change and/or feedback from applicable regulatory authorities.

SAHARA DESERT – Phase 2a study in decompensated heart failure patients with persistent congestion

STUDY DESIGN

SAHARA DESERT is a multi-centre, prospective, randomised, open-label study to evaluate the safety and feasibility of **alfa**pump DSR therapy in heart failure patients with persistent congestion and resistance to loop diuretic treatment. Up to 20 patients will be implanted with the **alfa**pump DSR system. Following **alfa**pump DSR implantation, patients undergo a diuretic challenge to quantify their response to diuretics, which is repeated at specific time points throughout the study. At the start of the study treatment period, loop diuretics are withheld, and patients are randomised 1:1 to DSR therapy with or without SGLT2-inhibitor to evaluate their impact on DSR therapy. Patients undergo intensive DSR therapy with sodium-free D10% infusate for two weeks (phase 1) which can be 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 enter 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. Additional exploratory endpoints will evaluate the potential impact of SGLT-2 inhibitors on DSR therapy. The study is being conducted in up to three clinical centres in the Republic of Georgia. For more information about the study, please visit clinicaltrials.gov (NCT04882358).



STRONG INTERIM RESULTS REPORTED FROM FIRST 6 PATIENTS

All six patients evaluated for the interim analysis had severe heart failure at baseline (mean left ventricle ejection fraction percentage in low 20's and mean NT-proBNP of > 6,000 pg/ml), with persistent congestion despite being on high dose loop diuretics (mean furosemide equivalent dose of approx. 250 mg per day). Out of the six patients in the interim analysis, one patient had completed phase 2 of the study, three patients were in phase 2 and two patients were in phase 1.

Mean values at baseline of 6 patients in interim analysis

Left ventricular ejection fraction:	low 20%
NT-proBNP:	>6,000 pg/mL
Furosemide equivalent dose: (standard of care)	~250 mg/day

NT-proBNP: N-terminal-pro hormone B-type Natriuretic Peptide; analysed in local lab

Study status of 6 patients in interim analysis

Phase 1:	n = 2 (1 complete, 1 ongoing)
Phase 2:	n = 4 (1 complete, 3 ongoing)

After intensive **alfa**pump DSR therapy in phase 1, patients had a **mean weight loss of approx. 6kg or 7% of their body weight vs. baseline and all patients achieved euvolemia without the need of any loop diuretics**.

These interim data also showed a **near normalisation of diuretic response** with six-hour excretion of sodium more than doubling vs. baseline, as well as an **improvement in NT-proBNP,** a key cardiac function parameter, with a mean reduction of more than 30% vs. baseline. The **mean eGFR** (estimated Glomerular Filtration Rate) **and creatinine** after completion of phase 1 (active fluid removal) was **similar to baseline**, which is remarkable since worsening in kidney function during significant volume removal is the expectation in severely ill diuretic-resistant patients such as these. Patients who completed phase 1 are at **less than 10% of their baseline loop diuretic dose** (n=4, mean time post end of phase 1 is three months).

Serial **alfa**pump DSR therapy was **safe and well tolerated** with few adverse events and there were **no clinically significant changes in serum sodium levels or other electrolytes observed** in these six patients after intensive DSR therapy.

The recruitment of the SAHARA DESERT continues and is on track to report top-line data in H2 2022.

"These interim results are highly encouraging and could potentially provide a course of therapy for severely ill diuretic-resistant heart failure patients with persistent congestion where alternative treatment options are currently exceedingly limited."

- Dr. Jeffrey Testani, Associate Professor at Yale University

Proprietary DSR Infusate 2.0 drug development

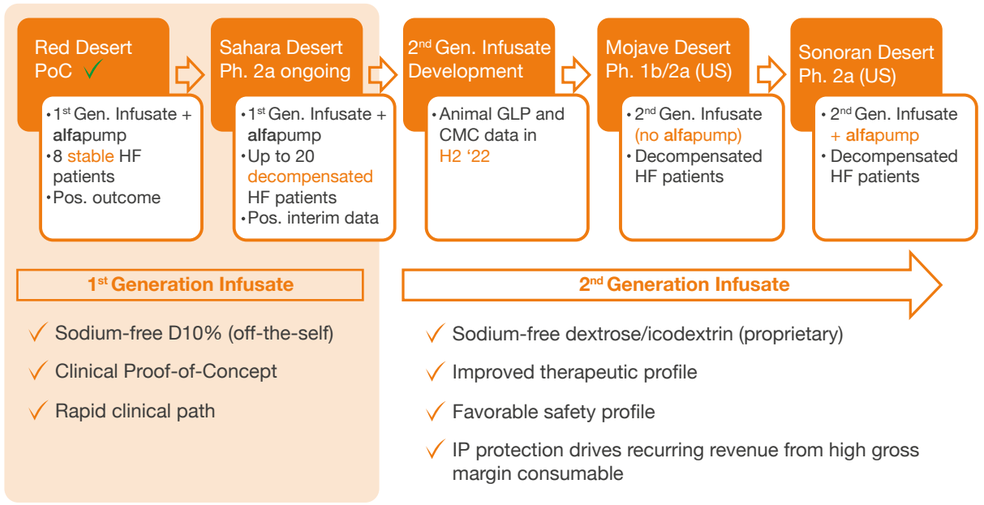
Following clinical proof-of-concept of our DSR therapy using a first generation DSR Infusate (sodium-free D10%), we started the development of our proprietary second generation DSR Infusate 2.0, a sodium-free dextrose/icodextrin solution for which the fundamental patents have been granted in the U.S. and Europe, and which are under review elsewhere in the world. The intention is to deliver an infusate with a superior therapeutic profile and a favourable safety profile with high margin recurring revenues. Pre-clinical development work and Chemistry, Manufacturing and Controls (CMC) activities on DSR Infusate 2.0 are ongoing with reporting of pre-clinical safety data expected in H2 2022.

The development strategy will allow DSR Infusate 2.0 to be used for short-term DSR therapy with a peritoneal catheter instead of the **alfa**pump, as well as long-term DSR therapy in combination with the **alfa**pump. Short-term DSR therapy is being developed to simplify the regulatory approval process, accelerate time to market, support faster adoption of DSR in the clinical community and expand the potential market opportunity.

MOJAVE DESERT, the U.S. phase 1b/2a study of short-term DSR therapy in decompensated heart failure patients will leverage the learnings from SAHARA DESERT as well as the anticipated improved therapeutic profile of DSR Infusate 2.0.

SONORAN DESERT is a U.S. phase 2a study of Long-Term **alfa**pump DSR therapy in decompensated heart failure patients, using DSR Infusate 2.0 in combination with our **alfa**pump.

Proprietary heart failure drug development programme



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 2021

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 2021, the share capital of the Company amounted to €1,924,931.96 represented by 18,577,078 shares.

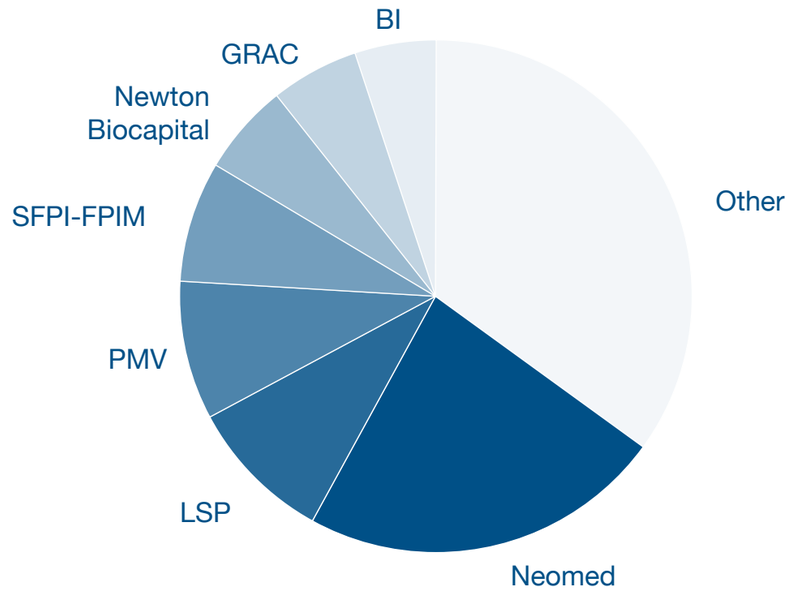
In addition to the outstanding shares, the total number of outstanding subscription rights on 31 December 2021 amounted to 2,248,427, entitling their holders (if exercised) to subscribe to 2,723,767 new shares with voting rights in total.

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

Trading volume in 2021	
Average daily volume	14,040
Average daily value	€119,660
Total traded volume	3,622,446
Total traded value	€30,872,280

Major Shareholders

Sequana Medical has an international shareholders 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 2021 and the transparency notifications received until that date, the shareholder structure of the Company as per 31 December 2021 was as follows:



23.0%	Neomed	Norway
9.2%	LSP	the Netherlands
8.4%	PMV	Belgium
7.9%	SFPI-FPIM	Belgium
5.9%	Newton Biocapital	Belgium
5.4%	GRAC	Belgium
4.9%	Belfius Insurance	Belgium

Analyst coverage

Sequana Medical was covered by seven analysts at the end of 2021.

Institution	Analyst
Degroof Petercam	Laura Roba, Kris Kippers
Edison Investment Research	Pooya Hemami
H.C. Wainwright	Yi Chen, Raghuram Selvaraju
KBC Securities	Jeroen Van den Bossche
Kempen	Christophe Beghin
Kepler Cheuvreux	Matthias Maenhaut
Mirabaud	Daniel Jelovcan

Financial calendar

27 May 2022	Annual General Meeting 2022
8 September 2022	Publication of Half Year Results 2022

Investor relations contact

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

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

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Corporate Governance

Corporate Governance

Annual Report 2021

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 2021.

1.1. Developments, results, risks and uncertainties

(Article 3:32, 1° BCAC)

1.1.1. Operational review

alfapump in liver disease

POSEIDON Strong progress and derisking of North American pivotal study of the **alfa**pump in recurrent and refractory ascites due to liver cirrhosis

- Completed patient enrolment in December 2021, with 71 patients enrolled in the Pivotal Cohort.
- Reported a second interim analysis in July 2021 on 26 patients from the Roll-In Cohort, reaffirming the previous positive efficacy results and providing longer-term evidence of the reduction in therapeutic paracentesis (TP) and continued improvements in quality of life. Data from this Roll-In Cohort substantially exceeded the primary endpoints as defined for the Pivotal Cohort in the study, demonstrating:
    - over 90% reduction in mean frequency of TP versus baseline (versus primary endpoint of at least 50% reduction),
    - all patients having at least a 50% reduction in mean frequency of TP per month versus baseline (versus primary endpoint of at least 50% of patients),
    - clinically important improvement in quality of life maintained even up to 12 months post-implantation, and
    - safety profile in line with expectations.

Key Opinion Leader (KOL) event endorsed **alfa**pump market potential

- Hosted a KOL event in July 2021 with two leading KOLs from the Mayo Clinic Arizona, Hugo E. Vargas, M.D. and Grace Knuttinen, M.D., Ph.D., who discussed the impact of ascites on patients' quality of life and the limitations of current treatment options, along with their experience of **alfa**pump implantation.

DSR in heart failure

RED DESERT Clinical proof-of-concept of repeated **alfa**pump DSR therapy in diuretic-resistant heart failure patients

- Reported strong top-line results in May 2021 in eight euvolemic heart failure patients on high dose diuretics, demonstrating that **alfa**pump DSR (i) is highly effective at safely managing fluid and sodium balance, (ii) dramatically improved diuretic response and the benefit was maintained in long-term follow-up, and (iii) significantly improved cardio-renal function.
- Following the six-week study, patients continued to be followed for up to 19 months. All patients had a reduction in their oral loop diuretic dose ranging from 40% to 96% at their last visit within the follow-up period (9-19 months after last DSR treatment in the study), showing significant durability to the improvement in diuretic responsiveness following **alfa**pump DSR therapy.
- Dr. Testani presented these results as a late-breaker at the European Society of Cardiology's Heart Failure 2021 Online Congress and they were selected as one of the highlights of the Congress.

SAHARA DESERT Strong interim results of ongoing safety and feasibility study of **alfa**pump DSR in decompensated diuretic-resistant heart failure patients with persistent congestion

- Reported positive interim results from six patients in December 2021. This analysis showed that **alfa**pump DSR can (i) safely, effectively and rapidly eliminate persistent congestion and restore euvolemia in diuretic-resistant heart failure patients, (ii) considerably benefit their cardio-renal status, and (iii) dramatically improve their diuretic responsiveness for months post-treatment.

Key DSR and **alfa**pump DSR patents granted in U.S. and Europe

- Key patents were granted in the U.S. and European Union in January 2021, covering the **alfa**pump DSR and its method of operation.

DSR development programme on track

- Made strong progress in the Chemistry, Manufacturing and Controls (CMC) and pre-clinical development work of Sequana Medical's proprietary DSR Infusate 2.0, a second generation infusate with a superior therapeutic and safety profile as well as robust Intellectual Property (IP) protection to drive a high margin recurring revenue stream to accompany **alfa**pump DSR sales.
- Expanded the DSR development programme with short-term DSR therapy (without the **alfa**pump) to derisk the regulatory process, support faster adoption of the DSR therapy in the clinical community, expand potential market opportunity and target earlier entry into the U.S. market.

Corporate

Medical Device Single Audit Program (MDSAP) certification

- Received MDSAP certification from Sequana Medical's auditing organisation British Standards Institution (BSI) in November 2021, thereby expanding the Company's Quality Management System (QMS) towards the U.S. and Canada within the scope of design, development, production and distribution of active implantable pump systems to transport fluids within the body.

1.1.2. Commentary on the consolidated annual accounts

1.1.2.1. CONSOLIDATED STATEMENTS OF PROFIT AND LOSS

Revenue

Revenue decreased from €0.96 million in 2020 to €0.37 million in 2021 as a result of reduced supply of the **alfa**pump for the European commercial activities due to lower manufacturing yield and the prioritization of the product supply for the POSEIDON and RED DESERT clinical trials in H1 2021, as well as the impact of COVID-19 on **alfa**pump procedures in France and Germany.

Cost of goods sold

Cost of goods sold decreased from €0.20 million in 2020 to €0.08 million in 2021 which is in line with the decrease in revenue.

Operating expenses

Total operating expenses increased from €18.53 million in 2020 to €22.9 million in 2021 mainly due to i) the preparations for the submissions for marketing approval of the **alfa**pump in the U.S. and Canada, and ii) pre-clinical and clinical development work for Sequana Medical's proprietary DSR therapy.

Sales and marketing expenses decreased from €2.32 million in 2020 to €2.08 million in 2021 due to the reduced European commercial activities.

Clinical expenses increased from €6.11 million in 2020 to €7.79 million in 2021 mainly as a result of costs related to the North American pivotal POSEIDON study of the **alfa**pump, the RED DESERT and SAHARA DESERT feasibility studies of the **alfa**pump DSR and the pre-clinical development of the Company's proprietary DSR Infusate.

Quality and Regulatory expenses increased from €2.23 million in 2020 to €3.22 million in 2021, mainly driven by costs related to the new Medical Devices Regulation (Regulation 2017/145) and Medical Device Single Audit Program (MDSAP) certifications as well as external advice costs for the preparation of the submissions for marketing approval of the **alfa**pump in the U.S. and Canada.

Supply chain expenses increased from €1.64 million in 2020 to €2.72 million in 2021 largely driven by the additional staffing for the preparation for the submissions for marketing approval of the **alfa**pump in the U.S. and Canada.

Engineering expenses increased from €1.86 million in 2020 to €3.21 million in 2021, largely driven by external advice and staffing for the preparations for the submissions for marketing approval of the **alfa**pump in the U.S. and Canada.

General and administration expenses increased from €4.42 million in 2020 to € 5.10 million in 2021 mainly due to costs relating to the equity placement in H1 2021 and additional staffing.

Other income increased from €0.04 million in 2020 to €1.21 million in 2021 largely driven by i) the termination of a distribution agreement by mutual agreement and ii) recognized income from Belgian Research & Development (R&D) incentives with regards to incurred R&D expenses.

EBIT[I]

As a result of the above, earnings before interest and taxes (EBIT) evolved from a loss of €17.77 million in 2020 to a loss of €22.60 million in 2021.

Total net finance expenses

Net finance cost decreased from €1.18 million in 2020 to €0.61 million in 2021, mainly resulting from the repayment of the Bootstrap loan in 2020.

Income tax expense

Income tax expense increased from €0.16 million in 2020 to €0.39 million in 2021 largely caused by the increased activities in Switzerland.

Net loss for the period

As a result of the above, the net loss increased from €19.11 million in 2020 to €23.62 million in 2021.

Basic losses per share (LPS)

Basic losses per share increased from €1.25 in 2020 to €1.30 in 2021.

1.1.2.2. CONSOLIDATED STATEMENT OF FINANCIAL POSITION

Net debt

Net debt[II] at 31 December 2021 improved by €1.64 million mainly as a result of the proceeds from the February 2021 equity placement.

Working Capital

Working capital[III] improved by €0.33 million in 2021 compared to 2020, mainly as a result of an increase in accrued liabilities as well as other payables, partially compensated by an increase in inventory and other receivables and prepaid expenses.

1.1.2.3. CONSOLIDATED STATEMENTS OF CASH FLOWS

Net cash outflow from operating activities was €23.62 million in 2021 compared to €17.01 million in 2020. The outflow was mainly driven by higher net loss of the period.

(I) EBIT is defined as revenue less cost of goods sold and operating expenses.
(II) Net debt is calculated by adding short-term, long-term financial and lease debt and deducting cash and cash equivalents.
(III) The components of working capital are inventory + trade receivables + other receivables and prepaid expenses - trade payables - other payables - accrued liabilities and provisions.

Cash flow from investing activities resulted in a net outflow of €0.35 million in 2021, slightly higher than the net outflow of €0.14 million in 2020.

Cash flow from financing activities resulted in a net inflow of €22.44 million in 2021, mainly as a result of the proceeds from the February 2021 equity placement. In 2020, the net inflow of €22.63 million was mainly a result of the January 2020 equity placement and the new subordinated loan agreements concluded at the end of July 2020, partially offset by the repayment of the Bootstrap loan (on 16 July 2020).

The Company ended 2021 with a total liquidity position of €9.60 million (2020: €11.02 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 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 **alfa**pump DSR, the DSR Infusate and/or any future products.
- 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.

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 Infusate and the **alfa**pump DSR, 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 Infusate 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 Infusate 2.0, 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 Infusate
- 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 Infusate.
- 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 and/or the **alfa**pump DSR, the DSR Infusate 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 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,**alfa**pump DSR and DSR Infusate 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, **alfa**pump DSR and DSR Infusate, 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 and Gamida in Israel.

Risks relating to commercialization 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 **alfa**pump DSR, the DSR Infusate and/or any future products in target markets.
- The success of the **alfa**pump, the **alfa**pump DSR, the DSR Infusate 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 **alfa**pump DSR, the DSR Infusate 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, the **alfa**pump DSR 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 and Gamida, Sequana Medical may not be successful in commercialising the **alfa**pump, the **alfa**pump DSR 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 **alfa**pump DSR, the DSR Infusate and/or any future products, and/or reduce the margins for the **alfa**pump, the **alfa**pump DSR, the DSR Infusate 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 and the **alfa**pump DSR 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.

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 2021 with the objective to further develop the **alfa**pump:

- POSEIDON Strong progress and derisking of North American pivotal study of the **alfa**pump in recurrent and refractory ascites due to liver cirrhosis
    - Completed patient enrolment in December 2021, with 71 patients enrolled in the Pivotal Cohort.
    - Reported a second interim analysis in July 2021 on 26 patients from the Roll-In Cohort, reaffirming the previous positive efficacy results and providing longer-term evidence of the reduction in therapeutic paracentesis (TP) and continued improvements in quality of life. Data from this Roll-In Cohort substantially exceeded the primary endpoints as defined for the Pivotal Cohort in the study, demonstrating:
        - over 90% reduction in mean frequency of TP versus baseline (versus primary endpoint of at least 50% reduction),
        - all patients having at least a 50% reduction in mean frequency of TP per month versus baseline (versus primary endpoint of at least 50% of patients),
        - clinically important improvement in quality of life maintained even up to 12 months post-implantation, and
        - safety profile in line with expectations.
- RED DESERT Clinical proof-of-concept of repeated **alfa**pump DSR therapy in diuretic-resistant heart failure patients
    - Reported strong top-line results in May 2021 in eight euvolemic heart failure patients on high dose diuretics, demonstrating that **alfa**pump DSR (i) is highly effective at safely managing fluid and sodium balance, (ii) dramatically improved diuretic response and the benefit was maintained in long-term follow-up, and (iii) significantly improved cardio-renal function.
    - Following the six-week study, patients continued to be followed for up to 19 months. All patients had a reduction in their oral loop diuretic dose ranging from 40% to 96% at their last visit within the follow-up period (9-19 months after last DSR treatment in the study), showing significant durability to the improvement in diuretic responsiveness following **alfa**pump DSR therapy.
    - Dr. Testani presented these results as a late-breaker at the European Society of Cardiology's Heart Failure 2021 Online Congress and they were selected as one of the highlights of the Congress.
- SAHARA DESERT Strong interim results of ongoing safety and feasibility study of **alfa**pump DSR in decompensated diuretic-resistant heart failure patients with persistent congestion
    - Reported positive interim results from six patients in December 2021. This analysis showed that **alfa**pump DSR can (i) safely, effectively and rapidly eliminate persistent congestion and restore euvolemia in diuretic-resistant heart failure patients, (ii) considerably benefit their cardio-renal status, and (iii) dramatically improve their diuretic responsiveness for months post-treatment.

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 2.4 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.

1.8. Information that has an impact in case of public takeover bids

(Article 3:32, 8°/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 conducting clinical trials in order to achieve regulatory marketing approvals, which incurs various risks and uncertainties, including but not limited to the uncertainty of the development process and the timing of achieving profitability. The Companys 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 COVID-19 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 and will remain under review by the Executive Management and the Board of Directors.

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

The Consolidated Statement of Financial Position as at 31 December 2021 shows a negative equity in the amount of EUR 0.8 million and a cash balance of EUR 9.6 million. The Company will continue to require additional financing in the near future and in that respect already successfully raised EUR 28.4 million in March 2022 in a private equity placement via an accelerated book building offering disclosed in the note 15 Events after the reporting period in the Notes to Consolidated Financial Statements. Together with existing cash resources, the net proceeds from this financing round are expected to extend the current cash runway of the Company into Q2 2023. The Company continues to evaluate equity and other financing options, including discussions with existing as well as new investors.

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.

We refer for more details about the additional financing and Geopolitical situation in Ukraine to note 15 Events after the reporting period in the Notes to Consolidated Financial Statements.

1.11. Conflicts of interests procedure

(Article 7:96, §1 BCAC)

In 2021, no decision of the Board of Directors required the application of the conflicts of interests procedure as described in Article 7:96 of the Belgian Companies and Associations Code.

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 2021.

1.13. Transactions under the authorised capital

(Article 7:203 BCAC)

On 15 February 2021, 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 2,647,059 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 and 7:191 of the Belgian Companies and Associations Code in relation to the transaction, providing notably (i) a justification of the proposed issue price of the new shares, (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.

On 25 March 2021, two of the three convertible loans that were entered into with the Company in July 2020 have been converted 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 aforementioned convertible loans. In this context, the Board of Directors prepared a report in accordance with Article 7:198 juncto Article 7:179 and 7:197 of the Belgian Companies and Associations Code in relation to the contribution in kind, providing notably (i) a justification of the proposed issue price of the new shares, (ii) a description of the consequences of the transaction for the financial and shareholder rights of the shareholders of the Company, and (iii) a description of the contribution in kind, together with a justified valuation thereof. This board report must be read together with the relating reports 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 statutory accounts for the financial year ended on 31 December 2021 (21 April 2022) 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.
- 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	58	Chair, Independent Non-Executive Director	2021	2025
Mr. Ian Crosbie	54	CEO, Executive Director	2021	2025
Mr. Rudy Dekeyser	60	Non-Executive Director	2021	2025
Mr. Erik Amble	70	Non-Executive Director	2021	2025
Mr. Wim Ottevaere(IV)	65	Independent Non-Executive Director	2021	2025
Mrs. Jackie Fielding	57	Independent Non-Executive Director	2021	2022

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).

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.

Dr. Erik Amble is a non-executive director of the Company. Dr. Amble is the chairman and founder of NeoMed Management in 1997 and raised six NeoMed Innovation funds specializing in small and medium sized companies in the pharmaceutical, medical device and diagnostic industries. From 1993 to 1997, he co-managed two private equity investment companies, KS Nordic Healthcare Partners and Viking Medical Ventures Limited. Dr. Amble has served as a board member of Clavis Pharma AS, GenoVision AS/Qiagen AS, Thommen Medical AG, Vessix Vascular Inc., Sonendo Inc. and Axonics Modulation Technologies, and currently serves on the Board of Directors of JenaValve Technology Inc., CorFlow Therapeutics AG and Serca Pharmaceuticals AS. He is a founder and former Chairman of the Norwegian Venture Capital Association. He holds a Dr. scient. degree in organic chemistry from the University of Oslo and a Master of Science degree in Management from the Graduate School of Business, Stanford University, U.S.A.

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.

(IV) Acting as permanent representative of WIOT BV.

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.

The business address of each of the directors for the purpose of their mandate is the address of the Company's registered office: AA Tower, Technologiepark 122, 9052 Ghent, Belgium.

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	54	Chief Executive Officer
Mrs. Kirsten Van Bockstaele(V)	47	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.

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

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	57	Chief Medical Officer
Dr. Gijs Klarenbeek	45	Senior Medical Advisor
Mr. Timur Resch	40	Global Vice President QM/QA/RA
Dr. Andreas Wirth	53	Global Vice President Engineering
Mr. Martijn Blom	48	Chief Commercial Officer
Mr. Dragomir Lakic(VI)	39	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.

(VI) Mr. Dragomir Lakic joined Sequana Medical NV as of May 2021.

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. Mr. Resch has over 10 years of experience within quality management and regulatory affairs in the regulated medical device industry. In 2010, Mr. Resch 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, Mr. Resch 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. Mr. Resch 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. Mr. Wirth 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 developed metrology 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, he 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 he was Director International Marketing at 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. Mr. Blom studied economics at the MEAO in Breda and specialised at de Rooi Pannen in Marketing and Sales management.

Mr. Dragomir Lakic is the Global Vice President Manufacturing of the Company. Mr. Lakic 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 2024, at least one third of the members of the Board of Directors must be of the opposite gender.

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, Dr. 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 2021, 11 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 Dr. Erik Amble. 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 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 2021, 4 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. The following directors are the members of the remuneration and nomination committee: Dr. Rudy Dekeyser, Mr. Wim Ottevaere (WIOT BV) 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 2021, 2 meetings of the remuneration and nomination committee were held.

2.7. Activity report and attendance at Board and Committee meetings during 2021

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

Name	Board Meeting	Audit	Nomination and remuneration
Mr. Pierre Chauvineau	11 out of 11 meetings	4 out of 4 meetings	1 out of 2 meetings(VII)
Mr. Ian Crosbie	11 out of 11 meetings	N/A(x)	N/A(x)
Mr. Rudy Dekeyser(VIII)	11 out of 11 meetings	N/A(IX)	2 out of 2 meetings
Mr. Erik Amble	11 out of 11 meetings	4 out of 4 meetings	N/A(xii)
Mr. Wim Ottevaere(X),(XI)	11 out of 11 meetings	4 out of 4 meetings	2 out of 2 meetings
Mr. Jason Hannon	3 out of 11 meetings	N/A(x)	2 out of 2 meetings
Mrs. Jackie Fielding	2 out of 11 meetings	N/A(x)	0 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;

(VII) The board member attended the meeting as an observer
(VIII) The board member is chairman of the Nomination and Remuneration Committee
(IX) The board member is not a member of the specific committee
(X) Acting as permanent representative of WIOT BV
(XI) The board member is chairman of the Audit Committee

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) and Mrs. Jackie Fielding 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 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

2.13.2.1. 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.

2.13.2.2. 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.

2.13.2.3. 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.sequana-medical.com/investors/financial-information.

2.14. Principal shareholders

The Company has a wide shareholder base, mainly composed of institutional investors in Switzerland, Belgium and other European countries, but also comprising Belgian 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 2021. 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 below in relation to a shareholder is no longer up-to-date. The most recent update of principal shareholders is available on Sequana Medical's website (www.sequanamedical.com).

	Date of Notification	Number of Shares	% of the voting rights attached to Shares[XII]
Venture Incubator AG / VI Partners AG[XIII]	19 February 2021	N/A[XIV]	N/A[xvi]
LSP Health Economics Fund Management B.V.[XV]	19 February 2021	1,706,077	9.18%
NeoMed IV Extension L.P. / NeoMed Innovation V L.P[XVI]	19 February 2021	4,270,807	22.99%
Société Fédérale de Participations et d'Investissement SA – Federale Participatie- en Investeringsmaatschappij NV / Belfius Insurance SA[XVII]	18 February 2020	2,377,218	12.80%
Capricorn Partners NV[XVIII]	14 February 2020	N/A[XIX]	N/A[xxi]

(XII) The percentage of voting rights is calculated on the basis of 15,778,566 outstanding shares of the Company.

(XIII) VI Partners AG (acting as a person that notifies alone) informed the Company, by means of a notification dated 19 February 2021 that the shareholding of VI Partners AG crossed below the lowest threshold of 3% of the outstanding voting rights of the Company on 15 February 2021. The notification specifies furthermore that VI Partners AG is not a controlled entity within the meaning of Articles 1:14 and 1:16 of the Belgian Companies and Associations Code. The notification also states that VI Partners AG is a shareholder and management company of Venture Incubator AG, a multiinvestor investment company, and that it is authorised to exercise the voting rights associated with the shares held by Venture Incubator AG at its own discretion, in the absence of specific instructions.

(XIV) The transparency notification does not mention how many voting securities or voting rights are held or exercised by, respectively, VI Partners AG and Venture Incubator AG after the downward crossing of the lowest threshold of 3%.

(XV) LSP Management Group B.V., a parent undertaking or a controlling person of LSP Health Economics Fund Management B.V. ("LSP"), and LSP, informed the Company, by means of a notification dated 19 February 2021 that LSP's shareholding crossed below the threshold of 10% of the outstanding voting rights of the Company on 15 February 2021. The notification specifies furthermore that LSP is controlled by LSP Management Group B.V. within the meaning of Articles 1:14 and 1:16 of the Belgian Companies and Associations Code and that LSP Management Group B.V. is not a controlled entity. The notification also states that LSP is not an owner of the shares of the Company, but manages the funds which 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.

(XVI) A parent undertaking or the controlling persons of NeoMed IV Extension Limited ("NeoMed IV") and NeoMed Innovation V Limited ("NeoMed V"), informed the Company, by means of a notification dated 19 February 2021, that the aggregate shareholding of NeoMed IV and NeoMed V passively crossed below the threshold of 25% of the outstanding voting rights of the Company on 15 February 2021. The notification furthermore specifies 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 (Jersey) Limited (a private limited company incorporated in Jersey) and that NeoMed Management (Jersey) Limited is controlled by Erik Amble, Claudio Nessi, Dina Chaya and Pål Jensen. The notification also states that NeoMed IV and NeoMed V do not own the securities of the Company but manage partnershipsthat own the voting rights attached to the securities and that, as general partners to its partnerships, NeoMed IV and NeoMed V can exercise the voting rights attached to the securities at their discretion in the absence of specific instructions.

(XVII) A parent undertaking or a controlling person of Société Fédérale de Participations et d'Investissement SA / Federale Participatie- en Investeringsmaatschappij NV ("**SFPI-FPIM**"), Belfius Banque SA ("**Belfius Bank**") and Belfius Insurance SA ("**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. The joint notification specifies furthermore that SFPI-FPIM is the parent company of Belfius Bank (ex Dexia Banque SA), which in its turn is the parent company of Belfius Insurance. The notification also states 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 follows from the notification that Belfius Bank does not own any voting securities or voting rights in the Company.

(XVIII) Capricorn Partners NV ("**CP**") (acting as person that notifies alone), informed the Company, by means of a notification dated 14 February 2020, that the aggregate shareholding of the funds Capricorn Health-tech Fund NV and Quest for Growth NV, managed by CP, downward crossed the lowest threshold of 3% of the outstanding voting rights of the Company on 14 February 2020. The notification specifies furthermore that (a) CP is in itself no owner of shares in the Company but manages two funds (Capricorn Health-tech Fund NV and Quest for Growth NV) which are owner of shares of the Company, (b) CP exercises the voting rights in both funds as management company, and (c) CP is not controlled within the meaning of the articles 1:14 and 1:16 of the Belgian Companies and Associations Code. The notification also states that (a) the voting securities are owned by two funds managed by CP, and (b) CP can exercise the voting rights of the funds at its own discretion at the general meeting of shareholders of the Company.

(XIX) The transparency notification does not mention how many voting securities or voting rights are held by CP after downward crossing the lowest threshold of 3%.

	Date of Notification	Number of Shares	% of the voting rights attached to Shares[XII]
GRAC Société Simple[XX]	30 January 2020	1,008,333	5.43%
Newton Biocapital I Pricav Privée SA[XXI]	21 February 2019	1,102,529	5.93%
Participatiemaatschappij Vlaanderen NV[XXII]	18 February 2019	1,565,894	8.43%

No other shareholders, 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).

(XX) GRAC Société Simple ("**GRAC**") (acting as a person that notifies alone) informed the Company, by means of a notification dated 30 January 2020, that the shareholding of GRAC crossed the threshold of 5% of the outstanding voting rights of the Company. The notification specifies furthermore that GRAC is not controlled by another entity or holding.

(XXI) Newton Biocapital I Pricav Privée SA ("**NBC**"), a person that notifies alone, informed the Company, by means of a notification dated 21 February 2019 that, as a result of the completion of the IPO, on 11 February 2019, NBC's shareholding crossed the threshold of 5% of the outstanding voting rights of the Company. The notification specifies furthermore that NBC is not controlled within the meaning of the articles 5 and 7 of the Belgian Companies Code of 7 May 1999. The notification also states that (a) NBC acts as discretionary investment manager and holds voting rights attached to shares on behalf of its clients, and (b) NBC can exercise the voting rights at its own discretion without instructions of its clients.

(XXII) 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 IPO, on 11 February 2019, PMV's shareholding crossed the threshold of 5% of the outstanding voting rights of the Company. The notification specifies furthermore that PMV is controlled by Het Vlaams Gewest within the meaning of the articles 5 and 7 of the Belgian Companies Code of 7 May 1999 and that Het Vlaams Gewest is not controlled.

2.15. Share capital and shares

On 31 December 2021, the share capital of the Company amounts to EUR 1,924,931.96 and is fully paid-up. It is represented by 18,577,078 ordinary shares, each representing a fractional value of (rounded) EUR 0.1036 and representing one 18,577,078th 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 2,529,185, which entitles their holders (if exercised) to subscribe to 2,701,728 new shares with voting rights in total, namely:

- 302,804 new shares can be issued upon the exercise of one subscription right that was granted in 2016 to Bootstrap Europe S.C.SP. ("**Bootstrap**"), subject to the terms and conditions that are set out in the 'Warrant Agreement', dated 2 September 2016, between the Company and Bootstrap, as amended on 28 April 2017, 1 October 2018, and 20 December 2018 (the "**Bootstrap Subscription Right**");
- 264,077 new shares can be issued upon the exercise of 91,536 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
- 1,134,847 new shares can be issued upon the exercise of 1,134,847 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").

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 21 January 2020, the Board of Directors of the Company decided to increase the share capital of the Company in the framework of the authorised capital by the issuance of a maximum number of shares which still had to be determined, with dis-application of the preferential subscription right of the existing shareholders of the Company and, in so far as required, of the existing holders of subscription rights (stock options) of the Company, subject to, amongst other things, the condition that the new shares would be offered to a broad group of unidentified 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. On that basis, the Company decided to instruct a number of investment banks to organise, launch and close the offering of new shares via a private placement through an accelerated bookbuilding procedure. The transaction was launched on 22 January 2020, and later that same day the Company announced that it successfully raised an amount of approximately EUR 19.0 million in gross proceeds by means of a private placement via an accelerated bookbuilding procedure of 3,166,666 new shares at an issue price of EUR 6.00 per share. The settlement and payment of the 3,166,666 new shares took place on 27 January 2020. Of these new shares, 2,522,379 shares were immediately admitted to trading on the regulated market of Euronext Brussels upon their issuance, and 644,287 shares were not immediately admitted to trading on the regulated market of Euronext Brussels upon their issuance.

In this context, the Company prepared a listing prospectus to have the 644,287 unlisted shares admitted to trading on the regulated market of Euronext Brussels. The 644,287 shares were admitted to trading on the regulated market of Euronext Brussels on 25 June 2020.

On 31 December 2021, 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 that the Company has submitted for the first time to the general shareholders' meeting held on 27 May 2021, 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 in respect of the financial year ending 31 December 2021 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. 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'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, 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.

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 subordinated loan agreements entered into, at the end of July 2020, between the Company and several shareholders, including PMV/z (the "**Lenders**") (the "**Subordinated Loan Agreements**") provide that the Lenders may declare all outstanding amounts under the Subordinated Loan Agreements due and payable within 30 business days if a change of control occurs. For the purposes of the Subordinated Loan Agreements, "change of control" is to be understood as the holders of the shares at the date of the Subordinated Loan Agreements ceasing to directly or indirectly control the Company, whereby "control" means the power to (i) cast, or control the casting of, more than one-half of the maximum number of votes that might be cast at the shareholders' meeting; (ii) appoint or remove all, or the majority of, the directors; or (iii) give directions with respect to the operating and financial policies. These change of control provisions are subject to the approval of shareholders at the first annual general meeting to be held in May 2021.
- the exclusive distribution agreement between the Company and Gamida Ltd. provides that in case of a more than 50% change of ownership, or direct or indirect control of the Company occurs, both parties to the distribution agreement may terminate this agreement with immediate effect without curing procedures by written notice of termination. The agreement further provides that in such case, the Company shall use commercially reasonable efforts to convince the new owners of Sequana Medical of a new distribution agreement between Sequana Medical and Gamida Ltd. with terms that are similar to the terms of the current agreement.

(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.

Finally, the 'Warrant Agreement', dated 2 September 2016, between the Company and Bootstrap, as amended on 28 April 2017, 1 October 2018, and 20 December 2018, also contain take-over 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 three 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 obtain a gender diversity amongst its board members in accordance with the timeline set by 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 policy

3.1. Introduction

This remuneration policy has been prepared by the Board of Directors on recommendation of the remuneration and nomination committee in accordance with Article 7:89/1 of the Belgian Companies and Associations Code of 23 March 2019, as amended (the "**BCAC**") and the 2020 Belgian Code on Corporate Governance (the "**2020 Code**") and applies to the members of the Board of Directors and the Executive Management of Sequana Medical NV (the "**Company**" or "**Sequana Medical**").

This remuneration policy will be submitted for approval to the annual general shareholders' meeting of the Company to be held on 27 May 2022 and is aligned with the requirements of Article 7:89/1 BCAC. If a significant proportion of the votes were to be cast against this remuneration policy, the Company will take the necessary steps to address the concerns of those voting against it, and will consider adapting its remuneration policy. The present remuneration policy is intended to replace the previous remuneration policy that was approved by the annual general shareholders' meeting of the Company that was held on 27 May 2021. The main change against the previous remuneration policy is that the board of directors intends to have sufficient flexibility to grant share options or subscription rights also to non-executive independent directors.

3.2. Background and objectives

As a commercial stage medical devices company, Sequana Medical aims at achieving a strategy involving researching, developing, testing and eventually (after obtaining the necessary regulatory and other approvals) commercializing (potential) treatments for the management of diuretic-resistant fluid overload in liver disease, malignant ascites and heart failure. Successful implementation of the aforementioned strategy requires an intense long term effort of highly qualified experts. Therefore it is important that the Company is able to attract and retain Belgian and foreign directors and members of the Executive Management with the talent, knowledge, ability, experience, skills, values and behaviour to deliver on the Company's long-term strategy and goals, to support the Company's purpose and to promote continuous improvement in the Company's business.

This remuneration policy is based on meritocracy and a sense of ownership and is designed to reward performance in order to motivate members of the Board of Directors and the Executive Management of the Company in order to deliver increased shareholder value through superior business results. Levels of fixed and, as the case may be, variable, remuneration should be sufficient to attract, retain and motivate Belgian and foreign directors and members of the Executive Management who have the profile determined by the Board of Directors, to promote the achievements of strategic objectives in accordance with the Company's risk appetite and behavioural norms and to promote sustainable value creation and enhance patients' quality of life. Finally, it is also important that the remuneration policy of the Company is competitive in the (employment) markets in which the Company operates.

The Board of Directors determines the remuneration of the directors and the members of the Executive Management in accordance with the provisions of the BCAC and the 2020 Code, upon recommendation and proposal of the remuneration and nomination committee, while respecting the prerogatives of the general shareholders' meeting. The remuneration and nomination committee benchmarks (as the case may be with assistance of external advisors) the compensation of the members of the Board of Directors and the Executive Management against peer companies to ensure that it remains fair, competitive and in line with market practice. The remuneration of the members of the Board of Directors and the Executive Management are therefore market driven.

The specific powers and composition of the remuneration and nomination committee are set out in the Corporate Governance Charter of the Company (approved by the Board of Directors on 23 April 2020).

In accordance with Article 7:89/1, §5 of the BCAC, the Company may temporarily derogate from this remuneration policy in exceptional circumstances. These exceptional circumstances cover situations in which the derogation is necessary to serve the long term interests and sustainability of the Company as a whole or to assure its viability. Such derogation requires the approval of both the remuneration and nomination committee and the Board of Directors. The remuneration report relating to the relevant financial year will include information on any derogation, including its justification.

3.3. Components of the remuneration

3.3.1. Members of the Board of Directors

The level and structure of the remuneration of the members of the Board of Directors are determined based on their general and specific responsibilities and market practice. This remuneration includes a basic fixed yearly remuneration (irrespective of the number of board meetings that are held during the year). Directors are not entitled to any kind of performance cash bonus or other kind of variable remuneration. Directors are also not entitled to any kind of compensation when their mandate ends.

Furthermore, each director is in principle also entitled to receive share options or subscription rights. The aforementioned possibility to grant share options to non-executive directors is contrary to provision 7.6 of the 2020 Code, which provides that no share options should be granted to non-executive directors. The Company believes that this provision of the 2020 Code is not appropriate and does not take into account the realities of companies in the biotech and life sciences industry. Notably, the ability to remunerate non-executive directors with share options 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 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 Companys 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. For more information on the granting of share options to directors, see section 3.6 below.

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. The interests of the non-executive directors are however currently 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.

The directors who are also a member of the Executive Management are remunerated for the Executive Management mandate (see section 3.3.2 below), but not for their director mandate.

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.

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

As mentioned above, the Company may temporarily derogate from this remuneration policy in accordance with Article 7:89/1, §5 of the BCAC.

3.3.2. Members of the Executive Management

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.

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.

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 and 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. For more information on the criteria for the award of variable remuneration, see section 3.5 below.

Furthermore, each member of the Executive Management is in principle entitled to receive share options or subscription rights. For more information on the granting of share options to members of the Executive Management, see section 3.6 below.

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 members of the Executive Management are also reimbursed for certain costs and expenses made in the performance of their function.

Furthermore, as permitted by the Company's articles of association, the Company has entered into indemnification arrangements with the 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.

In accordance with provision 7.9 of the 2020 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.

As mentioned above, the Company may temporarily derogate from this remuneration policy in accordance with Article 7:89/1, §5 of the BCAC.

3.4. Consideration of pay and employment conditions of employees

The Company wants to attract talented employees who combine expertise and passion for the medical devices business and strive to make the business grow, taking into account the governance and working procedures the Company has put in place. Therefore the Company pays competitive salaries.

For employees of the Company, the remuneration package is composed of a competitive fixed remuneration, rewarding their skills, expertise and experience, and, for certain employees, to the Company's discretion and to the extent that the results of the Company allow it, and depending on individual performance and the market practice, a variable remuneration, rewarding specific quantitative and qualitative targets. A yearly target setting and appraisal cycle, defines the targets for each employee. An intermediate appraisal and final year end appraisal process assesses the targets and actual results for all employees, which may lead to a variable remuneration, based on this process.

The remuneration and nomination committee takes into account the compensation of the employees when preparing the remuneration policy applicable to the directors and the members of the Executive Management. Particularly, the remuneration and nomination committee discusses and assesses key areas of remuneration policy for the wider workforce throughout the year, the annual bonus pool and resulting pay outcomes for employees across the workforce and any material changes to the structure of workforce compensation.

3.5. Criteria for the award of variable remuneration

The criteria for the award of variable remuneration are either of quantitative nature, either of qualitative nature. Each year the Board of Directors, upon recommendation and proposal of the remuneration and nomination committee, determines the criteria and parameters to be applied on the variable remuneration.

The Company's objectives have been determined by the Board of Directors at the beginning of the year on the basis of the Company's strategy and long-term interests. The level of achievement of these pre-determined goals and objectives is reviewed in the beginning of the first subsequent year by the remuneration and nomination committee and finally established by the Board of Directors.

The company goals and objectives consist of Key Performance Indicators (KPIs) based on a range of business metrics that are composed of financial and non-financial KPIs which may be grouped into different KPI categories such as financial performance (sustainable growth in revenues, operate to budget and complete necessary financing rounds), execution and delivery on support projects for financial and commercial growth (feeding the pipeline of projects, clinical trial progression, delivering projects on time) and operational targets (quality and regulation as well as engineering and supply chain). The aforementioned criteria may change on a year-to-year basis. The criteria and the relative weight attributed to each of them are set by the Board of Directors annually. The Board of Directors is of the opinion that these KPIs contribute most to the realization of the Company's strategy, long-term interests and sustainable growth.

Each year, upon recommendation and proposal of the remuneration and nomination committee, the Board of Directors decides on the objectives of the Executive Management for the coming financial year and evaluates their performance for the period ending, in conformity with the procedure currently in place.

The individual performance of each member of the Executive Management is determined by an individual assessment between the member of the Executive Management and the Chief Executive Officer (or, for the Chief Executive Officer, between the Chief Executive Officer and the chairman of the Board of Directors). The assessment of the Chief Executive Officer is reviewed by the remuneration and nomination committee which makes a recommendation to the Board of Directors for final decision. The Chief Executive Officer does not participate to any decision regarding his own individual performance.

For the Chief Executive Officer, the variable remuneration is based on 100% of the Company performance. For the other members of the Executive Management, the variable remuneration is based on 80% of Company performance and 20% of individual performance. Those target percentages may be multiplied by a factor from 0% to 200%, depending on the overall performance.

The variable remuneration paid out to the members of the Executive Management is awarded unconditionally and is not subject to any vesting mechanisms.

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.

3.6. Share-based remuneration

The Company may from time to time award share options (in the form of subscription rights) to members of the Board of Directors and Executive Management, at the discretion of the Board of Directors. On the date of this remuneration policy, the Company has the following outstanding plans:

- 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, her or its share options; and
- 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, her or its share options.
- the "2021 Share Options" plan for members of the personnel of the Company, entitling the holder thereof to acquire one share when exercising one of his, her or its share options.

For more information about the abovementioned share option plans, reference is made to the latest version of the Company's remuneration report.

The number of share options offered to each of the beneficiaries is freely determined by the Board of Directors, acting upon the recommendation of the remuneration and nomination committee. The number of share options to be granted is based on a benchmarking exercise which is regularly performed, to ensure that the grants are competitive and in line with market practice.

The granting or vesting of share options does not depend on variable objectives or performance criteria. The share options are therefore considered not to qualify as variable remuneration. This has also been confirmed by the general shareholders' meeting.

Pursuant to Article 7:91 of the BCAC and provision 7.11 of the 2020 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 BCAC, for all persons who fall within the scope of these provisions (whether directly or pursuant to Articles 7:108 and 7:121 of the BCAC, 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.

The equity-linked remuneration intends to contribute to the Company's business strategy, long-term interests, and sustainability by incentivizing the beneficiaries to create shareholder value and enhance patients' quality of life.

3.7. Agreements with the members of the Board of Directors and the Executive Management

3.7.1. Non-executive directors

Each non-executive director exercises its mandates as self-employed workers. According to the articles of association of the Company, the term of a directors' mandate cannot exceed four (4) years, but may be renewed. The directors' mandates may be terminated "ad nutum" (at any time) without any form of compensation. There is no specific agreement between the Company and non-executive directors which waives or restrains this right of the Company to terminate "ad nutum" (at any time) the mandates of the directors.

3.7.2. Executive managers

In accordance with provision 7.12 of the 2020 Code, the Board of Directors approves, upon recommendation and proposal of the remuneration and nomination committee, the main terms and conditions of the contracts of the Chief Executive Officer and the other members of the Executive Management.

The employment or service agreements with the members of the Executive Management have been entered into for an indefinite term.

The employment agreement with the Chief Executive Officer of the Company 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.

3.7.3. Pension and early retirement schemes

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/fee of the Chief Executive Officer. See also section 3.3.2 above.

There is no specific early retirement scheme for the members of the Executive Management.

3.8. Decision-making process

The Board of Directors, upon recommendation and proposal of the remuneration and nomination committee, validates the remuneration policy and proposes the remuneration policy to the annual general shareholders' meeting for approval. The Board of Directors assesses, on a yearly basis, if the remuneration policy needs to adapt.

The remuneration and nomination committee assesses on a yearly basis if all elements of the remuneration policy are in line with the strategic objectives of the Company and proposes improvements to the Board of Directors, where deemed appropriate.

As mentioned in the Company's Corporate Governance Charter, the directors (thus members of the remuneration and nomination committee, or of any other concerned advisory committee) are deemed to avoid, to the extent possible, to perform any actions, to defend certain positions, and to pursue certain interests, if this would conflict, or would give the impression to conflict, with the interests of the Company. Each board member should, in particular, be attentive to conflicts of interests that may arise between the Company, its board members, its significant or controlling shareholder(s) and other shareholders. The board members who are proposed by significant or controlling shareholder(s) should also ensure that the interests and intentions of these shareholder(s) are sufficiently clear and communicated to the board in a timely manner.

4. Remuneration report

4.1. 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 statutory accounts for the financial year ended on 31 December 2021 (dated 21 April 2022) 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 27 May 2022 for approval.

4.2. 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 will be submitted for approval to the annual general shareholders' meeting held on 27 May 2022. The aforementioned remuneration policy can be consulted on the Company's website.

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.

4.3. Directors

4.3.1. 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.
  - The other independent non-executive directors receive an annual fixed fee of €25,000.
  - The members of the audit committee and the remuneration and nomination committee (other than the chair of such committees) receive an annual fixed fee of €10,000.
- Share based awards: Each non-executive director is in principle entitled to receive share options or subscription rights. Part of the 2018 Share Options and 2021 Share Options can be used for this purpose.

  The abovementioned possibility to grant share options to non-executive directors is contrary to provision 7.6 of the 2020 Code, which provides that no share options should be granted to non-executive directors. The Company believes that this provision of the 2020 Code is not appropriate and adapted to take into account the realities of companies in the biotech and life sciences industry. Notably, the ability to remunerate non-executive directors with share options allows the Company to limit the portion of remuneration in cash that the Company would otherwise need to pay to attract or retain renowned experts with the most relevant skills, knowledge and expertise. The Company is of

the opinion that granting non-independent non-executive directors the opportunity to be remunerated in part in share-based incentives rather than all in cash enables the non-independent 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.

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 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 currently considered to be sufficiently oriented to the creation of long-term value for the Company. The directors are also paid in cash, leaving it at their own initiative whether or not they wish to use such funds (in whole or in part) to acquire existing shares of the Company.

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.

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

4.3.2. Remuneration and compensation in 2021

During 2021, the non-executive directors received the following compensation, based on the approved fees in 4.3.1.

Name	Gross amount (in €)	Share options awarded
Pierre Chauvineau	70,000	-
Wim Ottevaere (WIOT BV)	50,000	-
Jason Hannon(XXIII)	26,521	-
Jackie Fielding(XXV)	11,667	-

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.

4.4. Executive Management

4.4.1. 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

(XXIII) The amounts are prorated the term that the director is appointed.

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 members of the Executive Management are also reimbursed for certain costs and expenses made in the performance of their function.

4.4.2. Remuneration and compensation in 2021

In 2021, 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[XXIV]	**%**	**Amount [XXV]**	**%**
Annual base salary	290,833	70%	285,600	83%
Pension plan[XXVI]	14,542	3%	N/A	N/A
Insurance plan[XXVII]	1,182	0%	N/A	N/A
Car lease/transport allowance	11,168	3%	N/A	N/A
Medical plan	4,536	1%	N/A	N/A
Bonus plan[XXVIII]	94,521	23%	59,146	17%
Total	**416,781**	**100%**	**344,746**	**100%**

In 2021, the Board of Directors has decided to establish the Company's performance at 65% (reflecting the level of achievement of the Company's 2020 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 2021 to the members of the Executive Management.

In 2021, 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 EUR 17,290.

(XXIV) The amount is paid in GBP to the CEO. The conversion applied to EUR is performed on the average GBP/EUR rate of 2021.
(XXV) Acting as permanent representative of Fin-2K BV
(XXVI) The pension plan amounts to 5% of the annual base salary of the CEO.
(XXVII) The Company pays a life insurance plan for the CEO.
(XXVIII) The bonus has been paid in cash.

4.4.3. Annual evolution in remuneration, performance and average annual remuneration of employees

Evolution of the remuneration of the directors and Executive Management on a full-time equivalent basis

	2017		2018		2019		2020		2021	
	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year
Directors and executive managers	422,470	95%	586,794	39%	834,090	42%	901,035	8%	919,714	2%

Note:

- 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 remuneration of the average remuneration on a full-time equivalent basis of employees other than directors and members of the Executive Management

	2017		2018		2019		2020		2021	
	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year
Employees	120,508	-19%	114,071	-5%	109,695	-4%	109,886	0%	112,481	2%

Note:

- The average remuneration on a full-time basis of 2017 and 2018 is less comparable to 2019, 2020 and 2021 as this was prior to the seat transfer to Belgium and the subsequent IPO (February 2019).
- In 2019, 2020 and 2021, some key positions were fulfilled by persons working via a consulting agreement. The consultancy fees of such positions are not reflected in the above average remuneration of employees.
- The remuneration is partially dependent on the fluctuation of the exchange rate of GBP/EUR and CHF/EUR.

Evolution of the performance of the Company

Performance Criteria	2017		2018		2019		2020		2021	
	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	-8,225,189	-41%	-13,983,224	70%	-14,977,445	7%	-19,106,205	28%	-23,615,081	24%
Total Equity	-4,610,672	-31%	-18,759,747	307%	925,932	-105%	112,761	-88%	-786,919	-798%
Paid dividends	-	-	-	-	-	-	-	-	-	-
Market capitalisation at 31 December	NA	NA	NA	NA	78,950,494	NA	186,305,079	136%	140,442,710	-25%

The ratio between the highest and lowest remuneration in 2021 was equal to 9 in the European Union and 7 outside the European Union.

4.4.4. 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.

4.4.5. 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.

4.5. 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.

4.6. Description of share option plans

The Company, as per 31 December 2021, has a number of outstanding options that are exercisable into ordinary shares, consisting of:

- 264,077 new shares can be issued upon the exercise of 91,536 share options (each share option having the form of a subscription right) 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
- 1,134,847 new shares can be issued upon the exercise of 1,134,847 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 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 and 2018 Share Options that are held by him or her on 31 December 2021.

	Number of Shares issuable	
Name	**Executive Share Options**	**2018 Share Options**
Ian Crosbie	216,442	112,839
Kirsten Van Bockstaele(XXIX)	6,226	56,419

In financial year 2021, 41,976 share options lapsed as a result of the termination of a number of employment contracts.

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

4.7. 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.
- Unless determined otherwise in a separate sub-plan or share option agreement with the beneficiary, 50% of the Share options granted vest upon the closing of the Offering, after which the balance of Share options will vest in equal parts on the last calendar date of each of the thirty-six months following the month in which the closing of the Offering falls, it being understood that any Share options that have not vested on the third anniversary of the date of grant shall immediately vest on that date. 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 Executive 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 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 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 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.

4.8. Shareholding and Share Options

As per 31 December 2021, 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 in 2020, nor in 2021.

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”.

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Financial Report

Financial Report

for the financial years ended 31 December 2021 and 2020

Annual Report 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 In EUR, unless noted otherwise.

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.

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 2021

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. 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 Company's consolidated accounts for 4 consecutive years.

2.1. Report on the consolidated accounts

2.1.1. 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 2021, 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 14,705,221 and a loss for the year of EUR 23,615,081.

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 2021, 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.

2.1.2. 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.

2.1.3. 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.

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

2.1.4. 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. We have determined there were no other matters to be considered as key audit matters to be communicated in our report, in addition to the matter described in the "Material Uncertainty Related to Going Concern" section.

2.1.5. 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.

2.1.6. 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 skepticism 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.

2.2. Other legal and regulatory requirements

2.2.1. 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.

2.2.2. 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.

2.2.3. 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.

2.2.4. 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.

Based on the work we have performed, we believe that the format of and marking of information in the official Dutch version of the digital consolidated financial statements included in the annual financial report of Sequana Medical NV per 31 December 2021 comply in all material respects with the ESEF requirements under the Delegated Regulation.

2.2.5. 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.

2.2.6. 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, 26 April 2022

The statutory auditor
PwC Reviseurs d'Entreprises SRL / PwC Bedrijfsrevisoren BV
represented by

Peter D'hondt
Réviseur d'Entreprises / Bedrijfsrevisor

3.
Consolidated Income Statement for the years ended 31 December

In EUR	Notes	2021	2020
Revenue	5/6	**370,500**	**963,280**
Costs of goods sold		(76,663)	(202,411)
Gross margin		**293,837**	**760,869**
Sales & marketing		(2,079,049)	(2,321,754)
Clinical		(7,798,237)	(6,107,833)
Quality & regulatory		(3,214,729)	(2,232,323)
Supply chain		(2,716,090)	(1,635,729)
Engineering		(3,206,020)	(1,859,279)
General & administration	7.2	(5,098,351)	(4,416,535)
Other income	7.3	1,204,996	41,467
Total operating expenses	7.1	**(22,907,481)**	**(18,531,986)**
Earnings before interests and taxes (EBIT)		**(22,613,644)**	**(17,771,117)**
Finance income	7.4	246,384	169,547
Finance cost	7.4	(854,549)	(1,347,609)
Net finance cost		**(608,165)**	**(1,178,063)**
Income tax expense	7.5	(393,272)	(157,025)
Net loss for the period		**(23,615,081)**	**(19,106,205)**
Attributable to Sequana Medical shareholders		(23,615,081)	(19,106,205)
Basic loss per share	7.6	(1.30)	(1.25)

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

4.
Consolidated Statement of Comprehensive Income for the years ended 31 December

In EUR	Notes	2021	2020
Net loss for the period		**(23,615,081)**	**(19,106,205)**
Items that will not be reclassified to profit or loss:			
Remeasurements of defined benefit plans	8.8	95,572	(14,703)
Items that may be reclassified subsequently to profit or loss:			
Currency translation adjustments		(255,836)	(108,480)
Total other comprehensive income/(loss)-net of tax		**(160,263)**	**(123,183)**
Total comprehensive income		**(23,775,344)**	**(19,229,387)**
Attributable to Sequana Medical shareholders		(23,775,344)	(19,229,387)

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

5.
Consolidated Statement of Financial Position

In EUR	Notes	31 December 2021	31 December 2020
Property, plant and equipment	8.4	**1,268,338**	**704,718**
Financial assets		**82,363**	**67,305**
Other non-current assets	8.5	**463,860**	**-**
Total non-current assets		**1,814,560**	**772,023**
Trade receivables	8.2	**81,882**	**23,625**
Other receivables and prepaid expenses		**1,068,941**	**930,005**
Other receivables	8.2	301,244	313,598
Prepaid expenses	8.2	767,696	616,407
Inventory	8.3	**2,139,425**	**1,471,655**
Cash and cash equivalents	8.1	**9,600,412**	**11,016,143**
Total current assets		**12,890,660**	**13,441,429**
TOTAL ASSETS		**14,705,221**	**14,213,451**

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

In EUR	Notes	31 December 2021	31 December 2020
Share capital	8.6	1,924,932	1,635,006
Share premium	8.6	142,432,715	119,332,864
Reserves		(2,668,955)	(2,250,413)
Loss brought forward		(142,695,301)	(119,080,220)
Cumulative translation adjustment		219,689	475,525
Total equity		**(786,919)**	**112,761**
Long term financial debts	8.7	**7,324,835**	**7,472,701**
Long term lease debts	8.7	**477,312**	**122,942**
Retirement benefit obligation	8.8	**509,851**	**539,042**
Total non-current liabilities		**8,311,998**	**8,134,686**
Short term financial debts	8.7	**-**	**-**
Short term lease debts	8.7	**283,010**	**263,700**
Trade payables and contract liabilities		**2,367,110**	**2,802,488**
Trade payables	8.9	2,192,903	2,013,178
Contract liabilities	5	174,207	789,311
Other payables	8.9	**1,924,597**	**1,523,426**
Accrued liabilities and provisions		**2,605,426**	**1,376,390**
Provision warranty	8.9	83,361	77,545
Accrued liabilities	8.9	2,522,065	1,298,845
Total current liabilities		**7,180,142**	**5,966,004**
TOTAL EQUITY AND LIABILITIES		**14,705,221**	**14,213,451**

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

6. Consolidated Statement of Changes in Equity

In EUR	Notes	Share capital	Share premium	Reserves	Loss brought forward	Currency translation differences	Total shareholder equity
Balance at 1 January 2020		**1,306,940**	**100,660,934**	**(1,651,931)**	**(99,974,015)**	**584,005**	**925,932**
Net loss for the period					(19,106,205)		**(19,106,205)**
Other comprehensive income	8.8			(14,703)		(108,480)	**(123,183)**
January 2020 equity placement	8.6	328,067	18,671,929				**18,999,996**
Transaction costs for equity instruments	7.2			(839,639)			**(839,639)**
Share-based compensation	9			255,860			**255,860**
31 December 2020		**1,635,006**	**119,332,864**	**(2,250,413)**	**(119,080,220)**	**475,525**	**112,761**
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	8.8			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)**

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

7. Consolidated Statement of Cash Flows

In EUR	Notes	2021	2020
Net loss for the period		**(23,615,081)**	**(19,106,205)**
Income tax expense	7.5	393,272	157,025
Financial result	7.4	612,541	1,046,846
Depreciation	8.4	408,535	306,525
Change in defined benefit plan	8.8	(40,476)	(21,854)
Share-based compensation	9	536,389	255,860
Changes in trade and other receivables	8.2	(163,487)	383,873
Changes in inventories	8.3	(864,873)	125,968
Changes in trade and other payables / accrued liabilities	8.9	(662,243)	(116,862)
Taxes paid		(221,943)	(36,404)
Cash flow used for operating activities		**(23,617,366)**	**(17,005,228)**
Investments in tangible fixed assets	8.4	(325,782)	(138,017)
Investments in financial assets		(12,420)	(4,014)
Cash flow used for investing activities		**(338,201)**	**(142,031)**
Proceeds from capital increase	8.6	22,770,861	18,999,996
(Repayments) from leasing debts		(335,369)	(273,690)
(Repayments) from financial debts	8.7	-	(3,201,376)
Proceeds from financial debts	8.7	-	7,300,000
Interest paid	8.7	-	(194,395)
Cash flow generated from/used in (-) financing activities		**22,435,491**	**22,630,535**
Net change in cash and cash equivalents		**(1,520,075)**	**5,483,275**
Cash and cash equivalents at the beginning of the period		**11,016,143**	**5,586,470**
Net effect of currency translation on cash and cash equivalents		104,344	(53,602)
Cash and cash equivalents at the end of the period		**9,600,412**	**11,016,143**

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 is a commercial stage medical device company utilizing its proprietary **alfa**pump® and DSR® (Direct Sodium Removal) technologies to develop innovative treatments for fluid overload in liver disease, malignant ascites and heart failure where diuretics are no longer effective. Fluid overload is a frequent complication of many large diseases – including advanced liver disease driven by NASH (non-alcoholic steatohepatitis)-related cirrhosis and heart failure – with diuretic resistance being widespread. The U.S. market for the **alfa**pump resulting from NASH-related cirrhosis is forecast to exceed €3 billion annually within the next 10-20 years. The heart failure market for DSR and the **alfa**pump DSR® is estimated to be over €5 billion annually in the U.S. and EU5 by 2026.

The **alfa**pump is Sequana Medical's unique, fully implanted wireless device that automatically pumps fluid from the abdominal cavity into the bladder, where it is naturally eliminated through urination. DSR is Sequana Medical's proprietary approach to managing sodium and fluid overload through use of a sodium-free infusate administered into the abdominal cavity.

In the U.S., the Company's key growth market, the **alfa**pump has been granted breakthrough device designation by the FDA for recurrent or refractory ascites due to liver cirrhosis. Interim data from the ongoing North American pivotal study (POSEIDON) showed positive outcomes against all primary endpoints and a rapid and persistent clinically important improvement in quality of life. All patients have been enrolled in the study and primary endpoint reporting is planned for Q4 2022. This study is intended to support a future marketing application of the **alfa**pump in the U.S. and Canada. In Europe, the **alfa**pump is CE-marked for the management of refractory ascites due to liver cirrhosis and malignant ascites and is included in key clinical practice guidelines. Over 900 **alfa**pump systems have been implanted to date.

Sequana Medical has combined its proven **alfa**pump and proprietary DSR therapy, and is developing the **alfa**pump DSR, a breakthrough approach to fluid overload due to heart failure. RED DESERT demonstrated that repeated DSR therapy in diuretic-resistant heart failure patients is able to manage their fluid and sodium balance, improve their cardio-renal status and restore their diuretic response for months post-treatment. Interim results from the ongoing SAHARA DESERT study in decompensated heart failure patients indicated that repeated DSR therapy can safely, effectively and rapidly eliminate persistent congestion and restore euvolemia, together with considerable benefit in cardio-renal status and a dramatic improvement in diuretic responsiveness. Reporting of top-line data is planned for H2 2022.

1.1. Group information

1.1.1. Information about the subsidiaries

The Consolidated Financial Statements of Sequana Group include:

Company	Purpose	Share capital	Investment 2021	Investment 2020
Sequana Medical NV	Holding/Sales	EUR 1,924,932	**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.

1.1.2. 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.

1.1.3. Shareholder structure

The shareholder structure of the Company based on the transparency declarations, received in the period up to 31 December 2021, is as follows:

Shareholder	Shares	%
NeoMed IV Extension L.P. / NeoMed Innovation V L.P	4,270,807	23.0%
LSP Health Economics Fund Management B.V.	1,706,077	9.2%
Participatiemaatschappij Vlaanderen NV	1,565,894	8.4%
Société Fédérale de Participations et d'Investissement SA - Federale Participatie- en Investeringsmaatschappij NV	1,472,234	7.9%
Newton Biocapital I Pricav Privée SA	1,102,529	5.9%
GRAC Société Simple	1,008,333	5.4%
Belfius Insurance SA	904,984	4.9%
Total threshold	**12,030,858**	**64.8%**
Other	6,546,220	35.2%

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®, DSR® infusate and **alfa**pump DSR®.

The costs of obtaining and maintaining regulatory approval for the **alfa**pump, DSR infusate and the **alfa**pump DSR 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 and **alfa**pump DSR. 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 2022.

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 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 2021 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 2021 and the comparative periods to translate the following currencies into EUR, are as follows:

Currency	31 December 2021		31 December 2020	
	Year-end	Average Rate	Year-end	Average Rate
Swiss Franc (CHF)	1.0331	1.0811	1.0802	1.0705
US Dollar (USD)	1.1326	1.1827	1.2271	1.1422

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.

Re-measurements, 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 (NOTE 8.7)

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 (convertible loans)

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 2021 and 31 December 2020:

Discription	Note	Level	At 31 December 2021 in EUR	At 31 December 2020 in EUR
EUR denominated convertible loans at fair value through PL	8.7	3	876,126.33	1,428,602.74

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.

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.

Valuation inputs and relationships to fair value

Description/Financial statement	Liability component of convertible bond denominated in EUR including the conversion option
Class of subsequent measurement	Fair value through profit or loss
Fair value at 31 December 2021	876,126.33
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 – 23,068/+ 23,068

As the yield represents the only unobservable input, there are no inter-relationships between any unobservable inputs that affect fair values.

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 2021 and 2020 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 8.8.

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.

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 new standards and amendments to standards are mandatory for the first time for the financial year beginning 1 January 2021 and have been endorsed by the European Union and have no material impact on the Group's Consolidated Financial Statements:

- Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 Interest Rate Benchmark Reform – Phase 2 (effective 01/01/2021). These amendments address issues that might affect financial reporting after the reform of an interest rate benchmark, including its replacement with alternative benchmark rates. The amendments are effective for annual periods beginning on or after 1 January 2021, with earlier application permitted.
- Amendment to IFRS 16 Leases Covid 19-Related Rent Concessions (effective 01/06/2020, with early application permitted). If certain conditions are met, the Amendment would permit lessees, as a practical expedient, not to assess whether particular covid-19-related rent concessions are lease modifications. Instead, lessees that apply the practical expedient would account for those rent concessions as if they were not lease modifications.

The following new standards and amendments have been issued, are not mandatory for the first time for the financial year beginning 1 January 2021 but have been endorsed by the European Union and have no material impact on the Sequana Group Consolidated Financial Statements:

- 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).
- 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.
    - 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.
    - 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.
    - 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.

The following amendments have been issued, but are not mandatory for the first time for the financial year beginning 1 January 2021 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 1 January 2023), 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:
    - 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;
    - 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.
- 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 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 2021 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:

	31 December 2021 CHF	31 December 2020 CHF
Assets		
Inventory	2,617,495	1,664,476
Cash and cash equivalents	1,308,155	625,392
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:

	Impact on income statement	
In EUR	As at 31 December 2021	As at 31 December 2020
5% decrease of average foreign exchange rate	-559,564	-370,773
5% increase of average foreign exchange rate	+ 560,700	+370,714

As of 31 December 2021, 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 559,564 higher (2020: EUR 370,773). 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 560,700 lower (2020: EUR 370,714).

	Impact on equity	
In EUR	As at 31 December 2021	As at 31 December 2020
5% decrease of average foreign exchange rate	-12,792	-5,424
5% increase of average foreign exchange rate	+ 12,792	+5,424

As of 31 December 2021, 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 12,792 higher (2020: EUR 5,424). 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 12,792 lower (2020: EUR 5,424).

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:

	Impact on income statement and equity	
In EUR	As at 31 December 2021	As at 31 December 2020
50 basis points increase/decrease	-/+ 5,768	-/+ 2,860

As at 31 December 2021 and 31 December 2020, 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			
In EUR	Carrying amount 31 December 2021	Total	Up to 1 year	1 to 3 years	More than 3 years
Trade payables	2,162,903	2,162,903	2,162,903		
Other payables	2,684,918	2,684,918	2,207,606	473,053	4,259
Financial debt at amortized costs	6,448,708	6,448,708	0	4,425,000	2,023,708
Financial debt at FVTPL	876,126	876,126	0	600,000	276,126
Total	**12,376,863**	**12,376,863**	**4,574,717**	**5,498,053**	**2,304,094**

		Cash outflows			
In EUR	Carrying amount 31 December 2020	Total	Up to 1 year	1 to 3 years	More than 3 years
Trade payables	2,013,178	2,013,178	2,013,178		
Other payables	1,910,068	1,910,068	1,787,126	122,942	
Financial debt at amortized costs	6,044,099	6,044,099	0	6,044,099	
Financial debt at FVTPL	1,428,603	1,428,603	0	1,428,603	
Total	**12,185,258**	**12,185,258**	**4,589,614**	**7,595,643**	**0**

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 2021 and 2020.

4. Going concern

The Company is still in its development phase conducting clinical trials in order to achieve regulatory marketing approvals, which incurs various risks and uncertainties, including but not limited to the uncertainty of the development process and the timing of achieving profitability. The Companys 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 COVID-19 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 and will remain under review by the Executive Management and the Board of Directors.

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

The Consolidated Statement of Financial Position as at 31 December 2021 shows a negative equity in the amount of EUR 0.8 million and a cash balance of EUR 9.6 million. The Company will continue to require additional financing in the near future and in that respect already successfully raised EUR 28.4 million in March 2022 in a private equity placement via an accelerated book building offering disclosed in the note 15 Events after the reporting period in the Notes to Consolidated Financial Statements. Together with existing cash resources, the net proceeds from this financing round are expected to extend the current cash runway of the Company into Q2 2023. The Company continues to evaluate equity and other financing options, including discussions with existing as well as new investors.

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.

We refer for more details about the additional financing and Geopolitical situation in Ukraine to note 15 Events after the reporting period in the Notes to Consolidated Financial Statements.

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:

In EUR	2021	2020
Trade receivables	81,882	23,625
Contract liabilities (relating to customers' advance payments)	174,207	789,311

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:

In EUR	2021	2020
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	3,782	397

In the period, there was no revenue recognized from performance obligations satisfied or partially satisfied in the previous period.

The change in contract liabilities compared to prior year is largely driven by the termination of a distribution agreement in mutual agreement. Refer to note 7.3 Other Income.

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:

Geographical market in EUR	2021	2020
Germany	315,000	691,000
France	38,000	171,125
Switzerland	17,500	62,605
Rest of the world	-	38,550
Total revenue	370,500	963,280

Revenue decreased from €0.96 million in 2020 to €0.37 million in 2021 as a result of reduced supply of the **alfa**pump for the European commercial activities due to lower manufacturing yield and the prioritization of the product supply for the POSEIDON and RED DESERT clinical trials in H1 2021, as well as the impact of COVID-19 on **alfa**pump procedures in France and Germany.

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, 39% of the assets are located in Switzerland compared to 28% 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

In EUR	2021	2020
Personnel costs	8,833,964	6,934,950
Clinical studies	6,140,218	4,436,698
External consultancy	2,884,383	1,805,617
External accounting & legal services	809,177	979,192
Travel & lodging	387,963	341,305
Rent & infrastructure expenses	349,016	257,665
Intellectual property	310,295	328,842
Insurance & IT	526,835	455,786
Marketing	100,698	158,160
Depreciation and amortization(I)	408,535	306,525
Quality audits / regulatory fees	1,390,152	927,486
Other	766,245	1,599,761
Total operating expenses	22,907,481	18,531,986

7.2. Operating expenses – general and administration

In EUR	2021	2020
Capital increase related expenses	210,941	358,089

The total amount of known and accrued capital raise related expenditure for 2021 is 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 expenditure accounted for in equity relate to the issuance of equity instruments and represent the incremental costs attributed to new shares.

In 2020, the total amount of known and accrued capital raise related expenses was EUR 1,197,729, of which EUR 358,089 has been recognized in the Consolidated Income Statement as G&A expenses and EUR 839,639 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.

7.3. Other income

In EUR	2021	2020
R&D incentives	582,447	26,443
Other	622,549	15,024
Total Other income	1,204,996	41,467

Other income increased from EUR 0.04 million in 2020 to EUR 1.21 million in 2021 largely driven by i) the termination of a distribution agreement in mutual agreement and ii) recognized income from Belgian R&D incentives with regards to incurred R&D expenses.

The R&D incentives income was predominantly composed of:

- Income from Belgian R&D incentives with regard to incurred R&D expenses amounting to EUR 463,860 in 2021 (2020: EUR 0).
- Reduction on payroll withholding taxes of R&D qualified employees in Belgium amounting to EUR 118,587 in 2021 (2020: EUR 26,443).

(I) The amount relating to amortization is not material, therefore depreciation and amortization are presented in a single position in the table above.

7.4. Financial result

The financial result is split into the following categories:

In EUR	2021	2020
Finance income	**246,384**	**169,547**
Interest income	94	9,912
Foreign exchange gains	246,290	159,634
Finance cost	**(854,549)**	**(1,347,609)**
Interest costs	(536,186)	(1,022,742)
Interest costs leasing	(36,323)	(52,908)
Foreign exchange losses	(282,040)	(271,959)
Net financial result	**(608,165)**	**(1,178,063)**

7.5. Income taxes

7.5.1. Income tax expense

In EUR	2021	2020
Current income taxes	(393,272)	(157,025)
Total income tax expense	**(393,272)**	**(157,025)**

The following elements explain the difference between the income tax expense at the applicable Group tax rate and the effective income tax expense:

In EUR	2021	2020
Loss before tax	**(23,221,809)**	**(18,949,180)**
Tax rate	25%	25%
Income tax expense at the calculated tax rate	**(5,805,452)**	**(4,737,295)**
Effect of non-recognition of tax losses in current year	(5,412,180)	(4,580,270)
Effective income tax expense	**(393,272)**	**(157,025)**

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.

7.5.2. Taxes on unremitted earnings

At 31 December 2021 and 2020, 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.

7.5.3. 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:

In EUR	31 December 2021	31 December 2020
Deductible temporary differences for which no deferred tax asset has been recognized	-	-
Belgium	50,537,141	33,833,432
Switzerland	-	-
USA	717,013	704,672
Total unused tax losses	**51,254,154**	**34,538,103**

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 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 2021 estimated tax amount, amounting to CHF 327,770 or EUR 311,509 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.

In EUR, except number of shares	2021	2020
Net loss attributable to shareholders	(23,615,081)	(19,106,205)
Weighted average number of shares - basic	18,212,944	15,310,073
Basic loss per share	**(1.30)**	**(1.25)**

8. Detailed information on statement on financial position items

8.1. Cash and cash equivalents

The Group held cash and cash equivalents of EUR 9,600,412 at 31 December 2021 (2020: EUR 11,016,143).

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 and other receivables

In EUR	31 December 2021	31 December 2020
Trade receivables	81,882	23,625
Other receivables	301,244	313,598
Prepaid expenses	767,696	616,407

Other receivables mainly consist of VAT and import duties.

The total amount of Prepaid expenses in the statement of financial position amounts to EUR 767,696 (in 2020: EUR 616,407). For 2021 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 2021 and 2020 past due, but not impaired, are as follows:

2021 (In 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						

2020 (In EUR)	Not past due	Total past due	0-90 days	90-180 days	180-360 days	More than 360 days
Trade receivables	23,625					
Weighted average loss rate						

8.3. Inventories

Inventories are categorized as follows:

In EUR	31 December 2021	31 December 2020
Finished goods	499,698	288,502
Subassembly	161,722	195,429
Components	1,478,005	987,725
Total	**2,139,425**	**1,471,655**

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.

8.4. Property, plant and equipment

The company has decided to further fine tune the presentation of Property, plant and equipment and has revised the different categories within this type of assets to reflect the nature of the underlying assets.

Reconciliation of beginning and ending balance by classes of assets:

In EUR	Fully owned			
	Installation & machinery	Furniture, fixtures & vehicles	Other tangible fixed assets & AUC(I)	Total
Acquisition value				
1 January 2020	**122,246**	**393,462**	**23,151**	**538,859**
Additions	4,442	146,011	-	**150,452**
Disposals	-	-	-	**-**
Currency translation effects	(16)	(127)	-	**(143)**
31 December 2020	**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**

(I) AUC = Assets Under Construction

In EUR	Fully owned			
	Installation & machinery	Furniture, fixtures & vehicles	Other tangible fixed assets & AUC[1]	Total
Depreciations				
1 January 2020	**47,433**	**234,768**	**1,715**	**283,916**
Additions	12,955	69,973	10,289	**93,217**
Disposals	-	-	-	**-**
Currency translation effects	(9)	(58)	-	**(67)**
31 December 2020	**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**
Net book value 31 December 2020	**66,293**	**234,663**	**11,147**	**312,102**
Net book value 31 December 2021	**77,472**	**363,889**	**52,229**	**493,590**

In EUR	Right-of-use		
	Land & building	Furniture, fixtures & vehicles	Total
Acquisition value			
1 January 2020	**465,619**	**221,369**	**686,987**
Additions	18,974	133,258	**152,231**
Disposals	-	(69,666)	**(69,666)**
Currency translation effects	-	-	**-**
31 December 2020	**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**
Depreciations			
1 January 2020	**148,149**	**28,385**	**176,534**
Additions	150,598	62,777	**213,375**
Disposals	-	(12,972)	**(12,972)**
Currency translation effects	-	-	**-**
31 December 2020	**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**
Net book value 31 December 2020	**185,845**	**206,771**	**392,616**
Net book value 31 December 2021	**587,623**	**187,125**	**774,748**

Following the revision of the presentation of Property, plant & equipment compared to prior year the table below makes the reconciliation between the disclosed numbers in the Annual Report 2020 and the revised categories as disclosed in this annual report:

Categories	Net book value 31 December 2020	Category as disclosed in Annual Report 2020
Fully owned		
Installation & machinery	65,592	Laboratory
Furniture, fixtures & vehicles	234,663	IT
Installation & machinery	701	RD Tools
Other tangible fixed assets & AUC	11,147	Other tangible fixed assets
Other tangible fixed assets & AUC	-	Assets under construction
Right-of-use		
Land & building	185,845	Buildings
Furniture, fixtures & vehicles	206,771	Cars

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 2021 was 0% given the negative market rates (OLO).

The table below provides an overview of the non-current R&D incentives receivables reported in the Consolidated Statement of Financial Position.

31 December 2021			
	Maturity date		
In 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 1,924,846 and is represented by 18,576,252 ordinary shares at 31 December 2021. The share capital is fully paid-in. During 2021, several capital increases took place.

In EUR, except number of shares	Shares	Share capital	Share premium	Total
31 December 2019	**12,611,900**	**1,306,940**	**100,660,934**	**101,967,874**
January 2020 equity placement	3,166,666	328,067	18,671,929	**18,999,996**
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**	**144,354,995**

At 15 February 2021 the Company completed a capital increase and successfully raised an amount of EUR 22.5 million in gross proceeds by means of a private placement via an accelerated bookbuild offering of 2,647,059 new shares (being approximately 16.78% of the Company's outstanding shares) at an issue price of EUR 8.50 per share. In addition, Sequana Medical announced that a number of holders of share options (having the form of subscription rights), in the context of the '2018 Share Option Plan' for directors, employees and other staff members of the Company and its subsidiaries (the "2018 Share Options"), have exercised a total number of 12,810 2018 Share Options.

At 25 March 2021, the Company announced that two of the three convertible loans that were entered into have been converted for an aggregate amount of EUR 618,917 (representing principal and interests) into an aggregate of 97,084 new shares in accordance with the terms of the convertible loans.

At 3 May 2021, the Company announced that a number of holders of share options (having the form of subscription rights), have exercised a total number of 10,705 Executive Share Options and 9,851 2018 Share Options. As a result of this exercise of Executive Share Options and 2018 Share Options, on 30 April 2021 the share capital of the Company has increased

to EUR 1,924,846 and the number of issued and outstanding shares has increased to 18,576,252 ordinary shares, through the issuance of a total of 40,733 new shares.

At 27 July 2021, the Company announced that a number of holders of share options (having the form of subscription rights), have exercised a total number of 286 Executive Share Options. As a result of this exercise of Executive Share Options, on 27 July 2021 the share capital of the Company has increased to EUR 1,924,932 and the number of issued and outstanding shares has increased to 18,577,078 ordinary shares, through the issuance of a total of 826 new 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 2021 the Company does not hold any Treasury shares.

Authorised capital

The Extraordinary General Meeting decided on May 27, 2021 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 1,924,846, 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. Loan agreement with Bootstrap

On 16 July 2020 the Company repaid the loan that previously had been granted to Sequana Medical by Bootstrap S.C.SP. in full for an amount of EUR 3.2 million or CHF 3.4 million. As a result hereof, the pledge on intellectual property and other assets of the Company has been released.

For more information, refer to the Annual Report 2020.

8.7.2. 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 618,917 (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. The impact of the modification has been recognized in the Consolidated Income Statement and was considered as not material.

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 2021.

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.

In EUR	2021	2020
Cash and cash equivalents	9,600,412	11,016,143
Borrowings - repayable within one year	-	-
Borrowings - repayable after one year	(7,324,835)	(7,472,701)
Net financial debt	**2,275,577**	**3,543,442**

In 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**	**0**	**7.472.701**	**3.543.441**
Cash flows	(1.520.075)	-	-	(1.520.075)
Interest expenses accrued on non-convertible loans in EUR (non-cash)			404.610	(404.610)
Transfer (non-cash)				-
Converted to equity (non-cash)			(618.917)	618.917
Cumulative remeasurement at FVTPL on convertible loans in EUR (non-cash)			66.440	(66.440)
Foreign exchange impact (non-cash)	104.344			104.344
Net financial debt as per 31 December 2021	**9.600.412**	**0**	**7.324.835**	**2.275.577**

The loans are presented in the statement of financial position as follows:

In EUR	31 December 2021	31 December 2020
Fair value of convertible loans issued in EUR at recognition date	1,400,000	1,400,000
Conversion convertible loan to shares	(618,917)	-
Cumulative remeasurement at FVTPL on convertible loans in EUR	95,043	28,603
Total convertible loans	**876,126**	**1,428,603**
Face value of non-convertible loans issued in EUR	5,900,000	5,900,000
Interest expenses accrued on non-convertible loans in EUR	548,708	144,099
Other loans	-	-
Total non-convertible loans	**6,448,708**	**6,044,099**
Total short term and long term debt	**7,324,835**	**7,472,701**

8.7.3. Leases

The lease debts are presented in the statement of financial position as follows:

In EUR	31 December 2021	31 December 2020
Long term lease debts	477,312	122,942
Short term lease debts	283,010	263,700
Total	**760,322**	**386,642**

The amounts recognized in the income statement related to depreciation of these right-of-use assets are as follows:

Buildings	177,629
Vehicles	88,843
Total	**266,472**

The expenses related to low-value leases and variable lease payments not recognised as lease liability are considered not to be material.

8.8. 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 2020.

8.8.1. 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	2021	2020
Defined benefit obligation	3,327,469	2,271,652
Fair value of plan assets	2,835,694	1,753,838
Net defined benefit liability	**491,775**	**517,814**

The net defined benefit liability is at a similar level of 2020.

Components of defined benefit cost in profit or loss	2021	2020
Current service cost (employer)	218,591	162,011
Plan amendment / Past service cost	-	(76,362)
Interest expense on defined benefit obligation	3,516	6,302
Interest income on plan assets	(2,740)	(4,670)
Administration cost excl. cost for managing plan assets	8,260	6,366
Defined benefit cost recognised in profit or loss	**227,628**	**93,648**
thereof service cost and administration cost	226,852	92,015
thereof net interest on the net defined benefit liability (asset)	776	1,633

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 2021 corresponds to an actuarial loss of EUR 208,832. The changes in financial assumptions led to an actuarial gain of EUR 84,145. The changes in demographic assumptions led to an actuarial gain of EUR 230,607. This is entirely offset by the change in experience adjustments, which led to an actuarial loss of EUR 523,584. These three components led to a total actuarial loss of EUR 208,832.

The plan assets are carried forward until 31 December 2021 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 2021 corresponds to an actuarial gain of EUR 310,238.

The total actuarial gains of EUR 91,478 (losses on defined benefit obligations of EUR 208,832 and gains on plan assets of EUR 300,310) have been recognized in OCI.

(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 defined benefit cost in OCI	2021	2020
Actuarial (gain) / loss on defined benefit obligation	208,832	34,820
Return on plan assets excl. interest income	(300,310)	(31,493)
Defined benefit cost recognised in OCI	**(91,478)**	**3,327**

Components of actuarial gain/losses on obligations	2021	2020
Actuarial (gain) / loss arising from changes in financial assumptions	(84,145)	44,438
Actuarial (gain) / loss arising from changes in demogr. assumptions	(230,607)	-
Actuarial (gain) / loss arising from experience adjustments	523,584	(9,618)
Actuarial (gain) / loss on defined benefit obligation	**208,832**	**34,820**

Reconciliation in net defined benefit liability	2021	2020
Net defined benefit liability at 1.1.	517,814	537,205
Defined benefit cost recognised in profit or loss	227,628	93,648
Defined benefit gain recognised in OCI	(91,478)	3,327
Contributions by the employer	(187,650)	(119,206)
Currency translation adjustments	25,462	2,839
Net defined benefit liability at 31 December	**491,775**	**517,814**

Reconciliation of defined benefit obligation	2021	2020
Defined benefit obligation at 1.1.	2,271,652	2,013,959
Interest expense on defined benefit obligation	3,516	6,302
Current service cost (employer)	218,591	162,011
Contributions by plan participants	187,650	119,206
Plan amendment / Past service cost	-	(76,362)
Benefits (paid) / deposited	292,395	(2,533)
Administration cost (excl. cost for managing plan assets)	8,260	6,366
Actuarial (gain) / loss on defined benefit obligation	208,832	34,820
Currency translation adjustments	136,572	7,883
Defined benefit obligation at 31 December	**3,327,469**	**2,271,652**

Reconciliation of fair value of plan assets	2021	2020
Fair value of plan assets at 1.1.	1,753,838	1,476,753
Interest income on plan assets	2,740	4,670
Contributions by the employer	187,650	119,206
Contributions by plan participants	187,650	119,206
Benefits (paid) / deposited	292,395	(2,533)
Return on plan assets excl. interest income	300,310	31,493
Currency translation adjustments	111,110	5,043
Fair value of plan assets at 31 December	**2,835,694**	**1,753,838**

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	2021	2020
Weighted average duration of DBO in years	19.5	20.9

There are no retired plan participants for the years 2021 and 2020.

For the reporting year 2022, employer contributions of EUR 216,593 are expected.

Significant actuarial assumptions:

Actuarial assumptions	2021	2020
Discount rate (DR) at 1.1.	0.15%	0.30%
Discount rate (DR) at 31.12.	0.35%	0.15%
Interest rate on retirement savings capital (IR) at 31.12.	0.15%	0.15%
Future salary increases (SI) at 31.12.	1.00%	1.00%
Future pension increases (PI) at 31.12.	0.00%	0.00%
Future inflation at 31.12.	~0.75%	~0.50%
Mortality tables	BVG 2020 GT	BVG 2015 GT
Date of last actuarial valuation	31/12/2021	31/12/2020

Sensitivities of significant actuarial assumptions

The following impacts on the defined benefit obligation would result from changes in actuarial assumptions:

Sensitivity	2021	2020
DBO = Defined benefit obligation, SC = Service cost (employer)		
DBO at 31.12. with DR -0.25%	3,497,820	2,396,425
DBO at 31.12. with DR +0.25%	3,170,231	2,157,205
DBO at 31.12. with IR -0.25%	3,267,169	2,229,062
DBO at 31.12. with IR +0.25%	3,389,745	2,316,083
DBO at 31.12. with SI -0.25%	3,368,867	2,244,080
DBO at 31.12. with SI +0.25%	3,287,340	2,300,526
DBO at 31.12. with life expectancy +1 year	3,377,033	2,314,320
DBO at 31.12. with life expectancy -1 year	3,381,573	2,318,017
SC of next year with DR +0.25%	264,042	203,812
SC of next year with IR +0.25%	295,744	228,006

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.

8.8.2. 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 2021, the Net Defined Benefit Liability equals to EUR 21,257.

As per 31 December 2021, there are 10 employees in the plan.

Funded status and recognised/unrecognised amounts	2021	2020
Defined Benefit Obligation at end of year	152,055,00	112,204,88
Fair value assets at end of year	133,958,54	90,948,37
Funded status: plan assets above/(below) DBO	-18,096,46	-21,256,51
Unrecognised net (gain)loss	0.00	0.00
Unrecognised past service costs	0.00	0.00
Unrecognised net transition obligation/(asset)	0.00	0.00
Unrecognised asset (because of limit)	0.00	0.00
Defined benefit Liability at end of year	**18,096,46**	**21,256,51**

The contributions recognised in 2021 for the defined contribution plan in Belgium amounted to EUR 48,146.

For the reporting year 2022, employer contributions of EUR 49,831 are expected.

In view of materiality, Sequana Medical decided not to disclose any additional information regarding the pension plan in Belgium.

8.8.3. Pension plan in Germany

The contributions paid to the defined contribution plan in Germany amounted to EUR 5,033 (2020: EUR 5,033).

8.9. Trade payables, other payables and accrued liabilities

In EUR	31 December 2021	31 December 2020
Trade payables	**2,192,903**	**2,013,178**
Other payables	**1,924,597**	**1,523,426**
Accrued liabilities	**2,605,426**	**1,376,390**
Provision warranty	83,361	77,545
Accrued liabilities	2,522,065	1,298,845

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 2,522,065 (in 2020: EUR 1,298,845) 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, the SAHARA DESERT feasibility study of the **alfa**pump DSR and the pre-clinical development of the Company's proprietary DSR infusate.

9. Share-based compensation

Subscription right plan	Grant date	Expiry date	Exercise price (€)[I]	Outstanding per 1 January 2021	Granted during the year	Exercised during the year	Forfeited during the year	Expired during the year	Outstanding per 31 December 2021	Exercisable per 31 December 2021
Executive share options - CEO[II]	27/09/2018	27/09/2028	0.92	75,025	-	-	-	-	75,025	75,025
Executive share options - other[2]	30/09/2018	30/09/2028	9.19	27,502	-	10,991	-	-	16,511	16,511
2018 Share Options	13/02/2019	13/02/2029	7.46	202,475	-	22,661	3,910	-	175,904	175,904
2018 Share Options	24/05/2019	13/02/2029	6.22	25,480	-	-	10,192	-	15,288	14,006
2018 Share Options	20/08/2019	13/02/2029	6.78	5,096	-	-	-	-	5,096	4,242
2018 Share Options	30/07/2020	13/02/2029	6.19	325,036	-	-	14,026	-	311,010	155,447
2018 Share Options	5/01/2021	13/02/2029	8.61	-	51,848	-	1,848	-	50,000	-
2018 Share Options	23/03/2021	13/02/2029	8.38	-	290,400	-	12,000	-	278,400	-
2018 Share Options	29/07/2021	13/02/2029	7.88	-	20,000	-	-	-	20,000	-
Subtotal Executive Share Options				**102,527**	**-**	**10,991**	**-**	**-**	**91,536**	**91,536**
Subtotal 2018 Share Options				**558,087**	**362,248**	**22,661**	**41,976**	**-**	**855,698**	**349,599**

The extraordinary shareholders' meeting of 27 May 2021 approved the 2021 Share Option plan containing 1,000,000 share options (1 share option gives right to 1 share). No share options from this plan have been granted yet as per 31 December 2021.

9.1. Executive Share Options

Early October 2018, Sequana Medical implemented a new 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.

(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

The effect of the share-based payment transactions on the 2021 Consolidated Income Statement of the Group is an expense of EUR 22,483. 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 (€)
Outstanding on 31 December 2019	**104,378**	**3.25**
Exercisable on 31 December 2019	71,025	9.19
Granted during the year	-	-
Forfeited during the year	1,851	9.19
Exercised during the year	-	-
Expired during the year	-	-
Outstanding on 31 December 2020	**102,527**	**3.14**
Exercisable on 31 December 2020	83,550	3.21
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

9.2. 2018 Share Option Plan

2018 Share Options	Subscription rights	Weighted average exercise price (€)
Outstanding on 31 December 2019	**278,745**	**7.29**
Exercisable on 31 December 2019	-	-
Granted during the year	325,036	6.19
Forfeited during the year	45,694	7.17
Exercised during the year	-	-
Expired during the year	-	-
Outstanding on 31 December 2020	**558,087**	**6.66**
Exercisable on 31 December 2020	127,186	7.32
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

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 2021 Consolidated Income Statement of the Group is an expense of EUR 513,906. 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.

The following table sets forth a summary of subscription rights outstanding and exercisable on 31 December 2021 per subscription right plan.

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
Number of options granted	51,848	290,400	20,000
Fair value of options (in €)	3.29	1.84	1.84
Share price (in €)	10.6	8.32	8.32
Exercise price (in €)	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	-	-	-

Below is an overview of the parameters used in relation to the determination of the fair value of the grants during 2020:

Stock options granted in	July 2020
Number of options granted	325,036
Fair value of options (in €)	1.45
Share price (in €)	6.28
Exercise price (in €)	6.19
Expected volatility	55%
Expected option life (in years)	8.55
Risk-fee interest rate	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 2021.

11.2. Asset pledges

The Company has no material assets pledged as per 31 December 2021.

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:

In EUR	2021	2020
Pierre Chauvineau	70,000	70,000
Wim Ottevaere	50,000	50,000
Jason Hannon(I)	26,521	40,000
Jackie Fielding(1)	11,667	0

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.

(I) The amounts are prorated the term that the director is appointed

12.5. Executive Management compensation

The compensation for the Executive Management is as follows:

2021 Executive Management compensation

In EUR (except number of share options)	Short-term employee benefits	Post-employment benefits	Number of share options
Ian Crosbie	402,239	14,542	32,000
Kirsten Van Bockstaele	344,746	-	16,000
Total	**746,985**	**14,542**	**48,000**

2020 Executive Management compensation

In EUR (except number of share options)	Short-term employee benefits	Post-employment benefits	Number of share options
Ian Crosbie	432,601	14,050	40,073
Kirsten Van Bockstaele	294,384	-	20,036
Total	**726,985**	**14,050**	**60,109**

13. Belgian GAAP disclosures

13.1. Subsidiaries included in or excluded from the consolidation scope, and associates

The Consolidated Financial Statements of Sequana Group include:

Company	Purpose	Share capital	Investment 2021	Investment 2020
Sequana Medical NV	Holding/Sales	EUR 1,924,932	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

	2021	2020
Average number of employees	52	40

13.3. Employee benefits and advances given to parent company directors by the parent company, subsidiaries and associates

In EUR (except number of share options)	2021	2020
Short term employee benefits	402,239	432,601
Post-employment benefits	14,542	14,050
Number of share options	48,000	60,109

14. COVID-19

The impact of COVID-19 has been described in note 4. Going concern.

15. Events after the reporting period

15.1. Geopolitical situation Russia - Ukraine

On 24 February 2022, Russia launched a full-scale invasion of Ukraine. The United States, the United Kingdom and the European Union (among others) imposed sanctions against Russia in response to these events targeting certain Russian banks and individuals. These sanctions included restrictions on such banks' access to the SWIFT international payment system as well as restrictions on reserves of the Russian Central Bank. In addition, Germany announced the freezing of the Nordstream pipeline project, which is being built to transport gas from Russia to the rest of Europe.

While the Group does not have any operations in Russia or Ukraine, it is conducting its SAHARA DESERT clinical study in Georgia, which borders Russia, and if the conflict were to spill over into neighbouring countries, this could have an adverse impact on the study and result in delays. Moreover, 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®, the **alfa**pump® DSR, the DSR Infusate 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.

15.2. Private equity placement

As announced in the press release dated 8 March 2022, the Company has successfully raised an amount of EUR 28.4 million in gross proceeds by means of a private placement via an accelerated bookbuild offering 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. For the impact on the current cash runway, refer to note 4. Going Concern.

16. Audit fees

In EUR	2021	2020
Fees of the independent auditor with the respect to the statutory audit mandate for the Company and the Group (Belgium)	75,000	63,700
Additional services rendered by the auditor's mandate:		
Audit related fees		
Tax advisory & compliance services		
Due diligence fees		
Other services	69,087	26,774
Subtotal	**144,087**	**90,474**
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	**144,087**	**90,474**

9. Condensed Statutory Financial Statements of Sequana Medical NV

9.1. Statutory income statement

In EUR	2021	2020
Operating income	8,944,795	6,133,007
Operating charges	(27,983,942)	(21,927,553)
Operating loss	**(19,039,147)**	**(15,794,546)**
Financial result	(556,823)	(864,988)
Loss for the period before taxes	**(19,595,971)**	**(16,659,533)**
Income taxes	(377,759)	(126,483)
Loss for the period	**(19,973,729)**	**(16,786,016)**

9.2. Statutory balance sheet

In EUR	2021	2020
Intangible assets	6,877,201	2,728,260
Tangible assets	522,991	312,102
Financial fixed assets	82,113	67,055
Participating interests	25,000	25,000
Fixed assets	**7,507,305**	**3,132,416**
Other non-current assets	**463,860**	**-**
Total non-current assets	**7,971,165**	**3,132,416**
Inventory	2,336,528	1,471,655
Amounts receivable within one year	812,175	661,565
Deferred charges and accrued income	767,696	616,407
Cash and cash equivalents	9,241,343	10,712,897
Current assets	**13,157,742**	**13,462,524**
TOTAL ASSETS	**21,128,907**	**16,594,940**
Capital	1,924,932	1,635,006
Share premium	142,432,715	119,332,864
Reserves	755,715	637,670
Accumulated losses	(138,518,432)	(118,544,703)
Total Equity	**6,594,930**	**3,060,837**
Provisions	**509,851**	**539,042**
Amounts payable after more than one year	7,312,142	7,472,701
Financial debt	7,312,142	7,472,701
Amounts payable within one year	4,148,754	4,203,715
Trade debts	2,363,630	2,816,275
Taxes, remuneration and social security	1,785,124	1,387,441
Accruals and deferred income	2,563,230	1,318,644
Amounts payable	**14,024,126**	**12,995,061**
TOTAL EQUITY AND LIABILITIES	**21,128,907**	**16,594,940**

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
CE	Conformité Européenne
CEC	Clinical Events Committee
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
DR	Diuretic Resistance
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
IDE	Investigational Device Exemption
IPO	Initial Public Offering
ISIN code	International Securities Identification Number
IV	IntraVenous
KOLs	Key Opinion Leaders
LVP	Large Volume Paracentesis
MELD	Model for End-stage Liver disease
MDR	Medical Device Regulation
MDSAP	Medical Device Single Audit Program
MOSAIC	North American IDE feasibility study of the alfapump
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 hormne B-type Natruiretic Peptide
PD	Peritoneal Dialysis
PMSR	Post Marketing Surveillance Registry

Abbreviation	Significance
POSEIDON	North American pivotal alfapump study
QMS	Quality Management System
RCT	Randomised Controlled Trial
RED DESERT	Repeated dose alfapump DSR study
SAHARA DESERT	Dose-ranging alfapump DSR feasibility study
SD	Standard Deviation
SF 36	Short Form 36
TCT	Transcatheter Cardiovascular Therapeutics
TIPS	Transjugular Intrahepatic Portosystemic Shunt
TP	Therapeutic Paracentesis
UADE	Unanticipated Adverse Device Effects
WHO	World Health Organisation

Disclaimer

This annual report may contain predictions, estimates or other information that might be considered forward-looking statements. Such forward-looking statements are not guarantees of future performance. These forward-looking statements represent the current judgment of Sequana Medical on what the future holds, and are subject to risks and uncertainties that could cause actual results to differ materially. Sequana Medical expressly disclaims any obligation or undertaking to release

any updates or revisions to any forward-looking statements in this annual report, except if specifically required to do so by law or regulation. You should not place undue reliance on forward-looking statements, which reflect the opinions of Sequana Medical only as of the date of this annual report. Certain monetary amounts and other figures included in this annual report have been subject to rounding adjustments. Accordingly, any discrepancies in any tables between the totals and the sums of amounts listed are due to rounding.

Regulatory Disclaimers

The **alfa**pump system is currently not approved in the United States or Canada. In the United States and Canada, the **alfa**pump system is currently under clinical investigation (POSEIDON Study) and is being studied in adult patients with refractory or recurrent ascites due to cirrhosis. For more information regarding the POSEIDON clinical study see www.poseidonstudy.com.

The DSR therapy is still in development and it should be noted that any statements regarding safety and efficacy arise from ongoing pre-clinical and clinical investigations which have yet to be completed. The DSR therapy is currently not approved for clinical research in the United States or Canada. There is no link between the DSR therapy and ongoing investigations with the **alfa**pump system in Europe, the United States or Canada.

Note: **alfa**pump® is a registered trademark. DSR® is a registered trademark in Australia, the Benelux, the EU, United Kingdom, Hong Kong, Israel, Norway, and Switzerland. **alfa**pump DSR® is a registered trademarks in Australia, the Benelux, China, the EU, United Kingdom, Hong Kong, Israel, New Zealand, and Norway.

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