sequanamedical

annual report 2020

Our Strategy & Key Objectives

Develop and commercialise innovative treatment options for diuretic-resistant fluid overload - improve clinical outcomes & patient quality of life, and reduce healthcare costs.

- Commercialise **alfa**pump in North America for the treatment of recurrent and refractory liver ascites through our own specialty salesforce.
- Advance the clinical development of DSR (Direct Sodium Removal) therapy and **alfa**pump DSR in the treatment of heart failure patients with diuretic-resistant fluid overload. Establish a strategic partnership for further clinical development and commercialisation.
- Explore the use of DSR therapy and **alfa**pump DSR in other indications where diuretic-resistant fluid overload is a key clinical challenge, such as chronic kidney disease.

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Sequana Medical at a glance

We are a commercial stage medical device company developing the **alfa**pump platform for the treatment of diuretic-resistant fluid overload in liver disease, malignant ascites and heart failure. Fluid overload is a complication of many large diseases and diuretics are generally standard of care. However, diuretic resistance is common and alternative treatment options are generally limited. We are developing the **alfa**pump platform as a safe and effective chronic treatment solution for these patients.

Our two pillars of growth are the direct commercialisation of the **alfa**pump in North America, a large market driven by non-alcoholic steatohepatitis (NASH)-related cirrhosis, and the clinical development of **alfa**pump DSR (Direct Sodium Removal), a potential chronic therapy for heart failure patients suffering from fluid overload. Both markets leverage our **alfa**pump, a unique, fully implanted wirelessly charged and controlled system that automatically pumps fluid from the abdomen into the bladder, where it is eliminated via urination. We estimate the U.S. market for the **alfa**pump resulting from NASH-related cirrhosis to exceed €3 billion annually within the next 10-20 years[1] and the heart failure market for the **alfa**pump DSR to be over €5 billion annually in the U.S. and EU5 by 2026[2].

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, which demonstrates the potential of the **alfa**pump to bring a much-needed improvement to the effective treatment of this debilitating condition. In November 2020, we reported positive interim data from POSEIDON, our ongoing North American pivotal study in recurrent and refractory ascites due to liver cirrhosis showing positive outcomes against all primary endpoints of the study. This study is intended to support the marketing application of the **alfa**pump in the U.S. and Canada, with primary endpoint read-out expected in Q2 2022. In Europe, the **alfa**pump is CE-marked for the treatment of refractory liver ascites and malignant ascites and has shown safety, efficacy and quality of life benefits in multiple clinical studies. To date, over 850 **alfa**pump systems have been implanted.

alfapump DSR combines our proven **alfa**pump platform with our proprietary DSR therapy, a unique approach that works in partnership with the body to treat fluid overload due to heart failure. Diuretics are the most common treatments, but in many cases they stop being effective. Studies have demonstrated that DSR therapy is capable of removing large quantities of sodium and fluid in a safe, tolerable and consistent manner and results were published in the high impact cardiovascular journal, *Circulation*. In October 2020, we reported strong interim safety and efficacy data from RED DESERT, our ongoing **alfa**pump DSR study, the first time our proprietary DSR therapy has been used repeatedly to treat patients with diuretic-resistant fluid overload due to heart failure.

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

Over 50 employees

Unique **alfa**pump platform addressing diuretic-resistant fluid overload in liver disease, malignant ascites and heart failure

Headquarters in Ghent, Belgium

Over 850 **alfa**pumps implanted to date

Manufacturing in Zurich, Switzerland

Two pillars of growth:

- Commercialisation of the **alfa**pump in North America in liver disease/ NASH
- Clinical development of the **alfa**pump DSR in heart failure

Listed on Euronext Brussels since February 2019

Extensive intellectual property portfolio & know-how

Supported by local and international life science investors and industry experts

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

Cash runway into Q2 2022

Message from the Chairman and the CEO

Dear Shareholders, Colleagues and Business Partners,

2020 was another very positive year for Sequana Medical where, despite the impact of COVID, we delivered outstanding clinical progress in both our focus areas, liver disease/non-alcoholic steatohepatitis (NASH) in North America and heart failure in North America and Europe. This growing body of clinical evidence supports our strategy of concentrating on these two large and growing markets where we intend to bring the unique benefits of our **alfa**pump-based therapies to address the clear unmet needs of patients, physicians and healthcare systems.

We have a clear focus on innovative treatments for diuretic-resistant fluid overload. Excess fluid in the body is a major problem in many large diseases, such as chronic heart, kidney and liver failure as well as cancer. In most cases, the fluid overload is treated with diuretics but for many patients these drugs stop becoming effective. When this happens, there are often limited alternative treatments available. We believe the novel treatment options we are developing will improve clinical outcomes and quality of life for these patients, and reduce the costs and burdens on healthcare systems and payers.

We were delighted to present the strong interim efficacy and safety data from POSEIDON, our ongoing North American pivotal study of the **alfa**pump in patients with recurrent or refractory ascites due to liver cirrhosis. In the first 13 patients from the Roll-In Cohort, we achieved a reduction of more than 90% in the average number of therapeutic paracenteses (TP) post-**alfa**pump implant versus pre-implant, with all patients having at least a 50% reduction in the average frequency of TP per month. In addition, we were able to show clinically relevant improvements in quality of life and we believe this clear benefit will be crucial in driving physician and patient acceptance. We look forward to presenting data from a larger group of Roll-In patients in Q2 of this year, ahead of the planned reporting of the primary endpoint data in Q2 2022, with the PMA (premarket approval) filing to the FDA scheduled for H2 2022.

Heart failure has advanced in two key areas this year and this has significantly strengthened the programme. First, we reported impressive interim results from our RED DESERT study where, for the first time, we evaluated repeated use of **alfa**pump DSR therapy in patients with diuretic-resistant heart failure. Data from the first five patients showed that **alfa**pump DSR therapy was safe and effective, maintaining the sodium and fluid balance in these patients without the need for any loop diuretics. Following the six-week study, the diuretic response of these patients was restored to near normal levels, with them requiring substantially lower diuretic doses even months after completion of DSR therapy. This indicates that DSR therapy is more than just a means to remove sodium and water but also has the potential to restore normal kidney response.

This key finding will be further explored in both heart failure and other disease areas where diuretic-resistance is a problem, such as renal failure. In Q2 2021, we plan to report top-line data from all the RED DESERT patients and start SAHARA DESERT, in which we intend to evaluate the dosing and frequency of **alfa**pump DSR therapy in decompensated heart failure patients with residual congestion. Secondly, the key **alfa**pump DSR patents were granted in U.S. and Europe providing a strong intellectual property platform that establishes Sequana Medical as a leader in the treatment of diuretic-resistant fluid overload. Following receipt of these patents, we have commenced development of our own DSR infusate that we expect to deliver an improved therapeutic profile as well as the potential for a high value recurring revenue stream.

We would like to take this opportunity to thank all our employees for their commitment and dedication to make Sequana Medical a success, and our shareholders and partners for their continued support. Despite the challenging circumstances over the past year, we can look back on our successes with pride. Together, we have enhanced the position of Sequana Medical and significantly strengthened the development of our ground-breaking treatments. We look forward to keeping you up to date on the exciting times ahead.

Pierre Chauvineau,
Chairman

Ian Crosbie,
CEO

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Our Business

Our Business

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Achievements

2020

POSEIDON (North American pivotal study of the **alfa**pump in recurrent and refractory ascites due to liver cirrhosis) reported *positive interim results* from the first 13 patients in the Roll-In Cohort. The interim data showed positive outcomes against all primary endpoints of the study[1], as well as indications of clinically relevant improvements in quality of life measures. The mean reduction in frequency of therapeutic parenthesis (TP) post-**alfa**pump implant versus pre-implant was over 90%. All patients had at least a 50% reduction in the average frequency of TP per month and the safety profile was in line with expectations. The study is designed to demonstrate in Pivotal Cohort patients 1) a 50% reduction in average monthly frequency of TP post-**alfa**pump implant versus pre-implant and 2) at least 50% of patients to achieve a 50% reduction in the requirement for TP post-**alfa**pump implant versus pre-implant.

RED DESERT (repeated dose proof-of-concept study of the **alfa**pump DSR in diuretic-resistant heart failure patients) reported *positive interim results* from the first five patients. The results showed that during the course of the six-week therapy, no loop diuretics were required, demonstrating the ability of the **alfa**pump DSR system to remove sodium and fluid from these patients, and there were no clinically significant changes in serum sodium levels or progressive hyponatremia. Following the six-week study, the diuretic response of these patients was restored to near normal levels with the majority of patients requiring low or no diuretics for months after completion of DSR therapy.

We hosted a *Key Opinion Leader (KOL) event* on the challenge of diuretic resistance in the management of heart failure patients and the potential for **alfa**pump DSR therapy, featuring a presentation by Dr. Testani, MD, MTR (Yale University School of Medicine).

Positive data from preclinical and clinical DSR proof-of-concept studies were *published in Circulation, a top-tier peer-reviewed cardiovascular journal*.

Positive results from MOSAIC (North American feasibility study of the **alfa**pump in recurrent and refractory ascites due to liver cirrhosis) were *published in the leading peer-reviewed journal Liver Transplantation*.

Dr. Oliver Gödje was appointed Chief Medical Officer; Dr. Gijs Klarenbeek remains as our Senior Medical Advisor.

Dr. Michael Felker and Dr. James Udelson were appointed as *new Heart Failure Scientific Advisors*.

Raised €19.0 million in an equity placement via an accelerated book building offering from existing investors and new experienced life sciences investors and industry experts.

Entered into subordinated loan agreements with several shareholders (including PMV/z-Leningen) for an aggregate principal amount of €7.3 million, of which €1.4 million can be converted by the lenders into new shares of the Company in the event of a future equity financing or sale of the Company.

2021 year-to-date

Key DSR (Direct Sodium Removal) patents were granted in the U.S. and Europe.

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, extending cash runway into Q2 2022.

(1) 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

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Outlook for 2021

Publication of additional data from POSEIDON and RED DESERT

Enrolment of the Roll-In and Pivotal Cohorts of POSEIDON, the North American pivotal study of the **alfa**pump, is continuing and we are confident of maintaining the strong clinical results that were reported in the Roll-In patients in Q4 2020. Full enrolment of the study is now expected in Q2 2021 due to delays related to the ongoing COVID-19 pandemic, including restrictions on non-essential hospital procedures in some centres in the U.S. and Canada, as well as travel restrictions. This will in turn delay the planned reporting of the primary endpoint from Q1 2022 to Q2 2022. Interim data from the larger Roll-In Cohort remains on track to be reported in Q2 2021. 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 targeted for H2 2022.

The RED DESERT repeated dose study of the **alfa**pump DSR in diuretic-resistant heart failure patients is expected to report top-line data in Q2 2021. Based on the highly encouraging interim safety and efficacy data from the first five RED DESERT patients, we are preparing SAHARA DESERT, a study to evaluate the dosing and frequency of **alfa**pump DSR therapy in decompensated heart failure patients with residual congestion. SAHARA DESERT is expected to start in Q2 2021 with interim data expected before year-end. We will continue developing our proprietary next generation DSR infusate which is intended to deliver an improved therapeutic profile, further strengthen our position as a leader in the treatment of diuretic-resistant fluid overload and generate a recurrent high-value revenue stream.

Q&A with Ian Crosbie, CEO

Sequana Medical reported positive interim results from the POSEIDON study in 2020. Why are these so encouraging?

The interim POSEIDON data are really important because they give the first potential insight into the study outcome and specifically the endpoints that the FDA and Health Canada will use to decide on approval of the **alfa**pump. In these first 13 patients from the POSEIDON Roll-In Cohort, we reduced the need for therapeutic paracentesis by more than 90% compared to baseline and indicated a clinically relevant improvement in quality of life. The FDA and Health Canada have set a 50% reduction in therapeutic paracentesis as one of the primary efficacy endpoints for the study so you can see why more than 90% is so exciting for us. We hope to continue the positive results seen in these first POSEIDON patients and deliver a positive outcome to this study so that we can bring the benefits of the **alfa**pump to patients in the U.S. and Canada as soon as possible.

“The FDA and Health Canada have set a 50% reduction in therapeutic paracentesis as one of the primary efficacy endpoints for the study so you can see why more than 90% is so exciting for us.”

Why is therapeutic paracentesis such a problem to treat?

Therapeutic paracentesis is the mainstay in chronic clinical management of refractory liver ascites - it has been used since the time of the ancient Egyptians and has not changed much! It is a painful and invasive procedure in which a large-bore needle is inserted into the abdomen to drain the fluid. It has to be done in hospital under medical supervision and can take five to seven hours. Unfortunately this does not stop the accumulation of the fluid and the drainage needs to be repeated every couple of weeks, so it has a severe impact on patients’ quality of life and creates a huge burden on already stretched healthcare systems. An equally important problem is the huge impact of the ascites accumulation on these patients in the days leading up to the drainage. Imagine trying to eat, sleep, breath, move, use the bathroom or in fact do anything when you have 10 – 15 litres of fluid in your belly! We estimate that half of the patient’s remaining life is “lost” due to the burden of this terrible condition and we believe that we can give these patients their life back and enable them to do the things that they want to do – maybe visit friends or family, travel, work in the garden or dance. With our **alfa**pump, we provide a 21st century solution for this debilitating condition and help these patients live a higher quality life.

Sequana Medical is developing a second product, alfapump **DSR. What does it address and how does it work?**

The **alfa**pump DSR is built upon the proven **alfa**pump platform, to deliver a fully implanted system for our proprietary Direct Sodium Removal (DSR) therapy. The intention is that heart failure patients suffering from fluid overload will have the system implanted for years and will be able to manage their fluid overload without the need for hospital visits.

DSR is a simple and elegant therapy that works in partnership with the body to reduce fluid overload. We extract sodium from the body using the DSR infusate and then the brain and kidneys work to quickly and accurately remove exactly the right amount of water from the body to maintain the correct concentration of sodium in the bloodstream. The fluid that the body removes is how we reduce the fluid overload.

You also reported impressive interim data from the RED DESERT study in 2020. Why is this trial important and what is so encouraging about the results?

First of all, it’s worth noting RED DESERT is a bold trial design, as we have set out to demonstrate for the first time that repeated dosing of DSR therapy using our **alfa**pump DSR system is both safe and effective. In five heart failure patients who were all on high doses of loop diuretic drugs, we stopped these drugs and were able to maintain their sodium and fluid balance just using DSR therapy. These results support our fundamental DSR hypothesis: our DSR therapy removes sodium from the body and then the kidneys step in and eliminate free water to maintain the correct sodium concentration in the blood. Moreover, by replacing their high dose loop diuretics with repeated dose **alfa**pump DSR therapy, we could restore the patients’ response to much lower doses of diuretic therapy – and this effect lasted many months after the DSR therapy ended.

“By replacing their high dose loop diuretics with repeated dose alfapump DSR therapy, we could restore the patients’ response to much lower doses of diuretic therapy.”

Can you tell me more about this restoration of the diuretic response in the patients treated so far in the RED DESERT study?

Over time, the kidneys of these patients stop responding effectively to diuretics, requiring higher and higher doses – which exacerbates the problem. These data have shown that by giving the kidneys a diuretic “holiday”, their response to diuretics can be restored. Diuretic resistance, in other words a poor response to diuretic drugs, is a common problem of heart failure patients and leads to fluid overload, also known as congestion, which is the most common cause of hospitalisation for these patients. These first five RED DESERT patients had an objectively poor response to diuretics at the start of the study but after six weeks of treatment with **alfa**pump DSR their diuretic response was restored to near normal levels. This is a really exciting aspect that we will be exploring further both in heart failure and other disease areas.

Beyond heart failure, what other indications are you looking at?

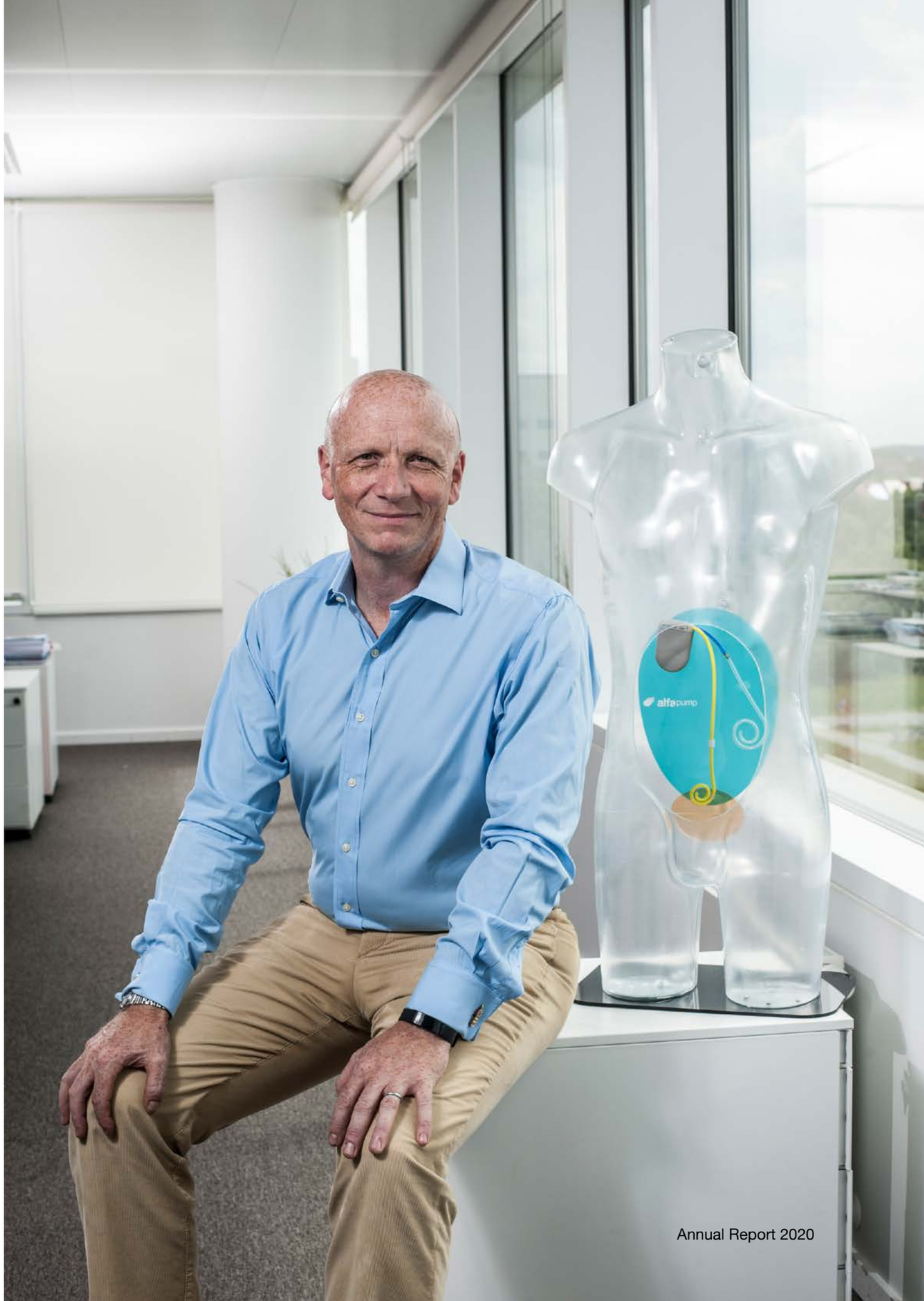
We are looking at new indications such as kidney disease / renal failure. For example, in hemodialysis the hemodialysis machine is doing two things – first it is removing the uremic toxins from the blood, but also it is seeking to control the fluid and sodium balance in the body. While hemodialysis is very good for removing toxins, in some patients it is less effective in maintaining the fluid and sodium balance or it may require very long sessions to remove sufficient fluid or sodium. We are supporting a study that evaluates **alfa**pump DSR in hemodialysis patients as a first step toward expanding the use of **alfa**pump DSR in hemodialysis.

In the longer term, we believe there could be the possibility to reduce kidney failure caused by high doses of loop diuretics – often when they are trying to maintain a damaged heart. If we could reduce the use of loop diuretics through regular DSR therapy, we may be able to delay or even avoid the need for hemodialysis and all the associated cost and quality of life impact on patients that it involves.

How important was the year 2020 for Sequana Medical? What feedback did you receive from investors?

We have taken very important steps in our journey to revolutionise the management of fluid overload when diuretic drugs are no longer effective and raised our profile with both local and international high-quality investors. There is a growing understanding and excitement for the commercial opportunity in both liver disease and heart failure as we explain the size of the potential markets, the clear clinical need and the limitation of the other treatment options. Investors have been impressed by our track record of delivering on our commitments and by the growing body of clinical data.

“Investors have been impressed by our track record of delivering on our commitments and by the growing body of clinical data.”



alfapump platform

One alfapump platform – two products, each with multi-billion euro opportunities

alfapump®

proven step change in liver refractory ascites and malignant ascites

over **850** devices implanted

Liver Disease (NASH)

POSEIDON

pivotal study ongoing

self-commercialisation

> €3 Bn / year
market opportunity

alfapump DSR®

breakthrough approach to fluid overload in heart failure

clinical proof-of-concept of Direct Sodium Removal (DSR)

Heart Failure

RED DESERT

repeated dose study ongoing

partnering after US efficacy study

> €5 Bn / year
market opportunity

Built upon proven European clinical & commercial experience

Our **alfa**pump is one of the first medical devices designed to treat fluid overload in patients when diuretics are no longer effective. Fluid overload is a frequent complication of many large diseases including advanced liver disease driven by NASH-related cirrhosis and heart failure, with diuretic resistance being widespread.

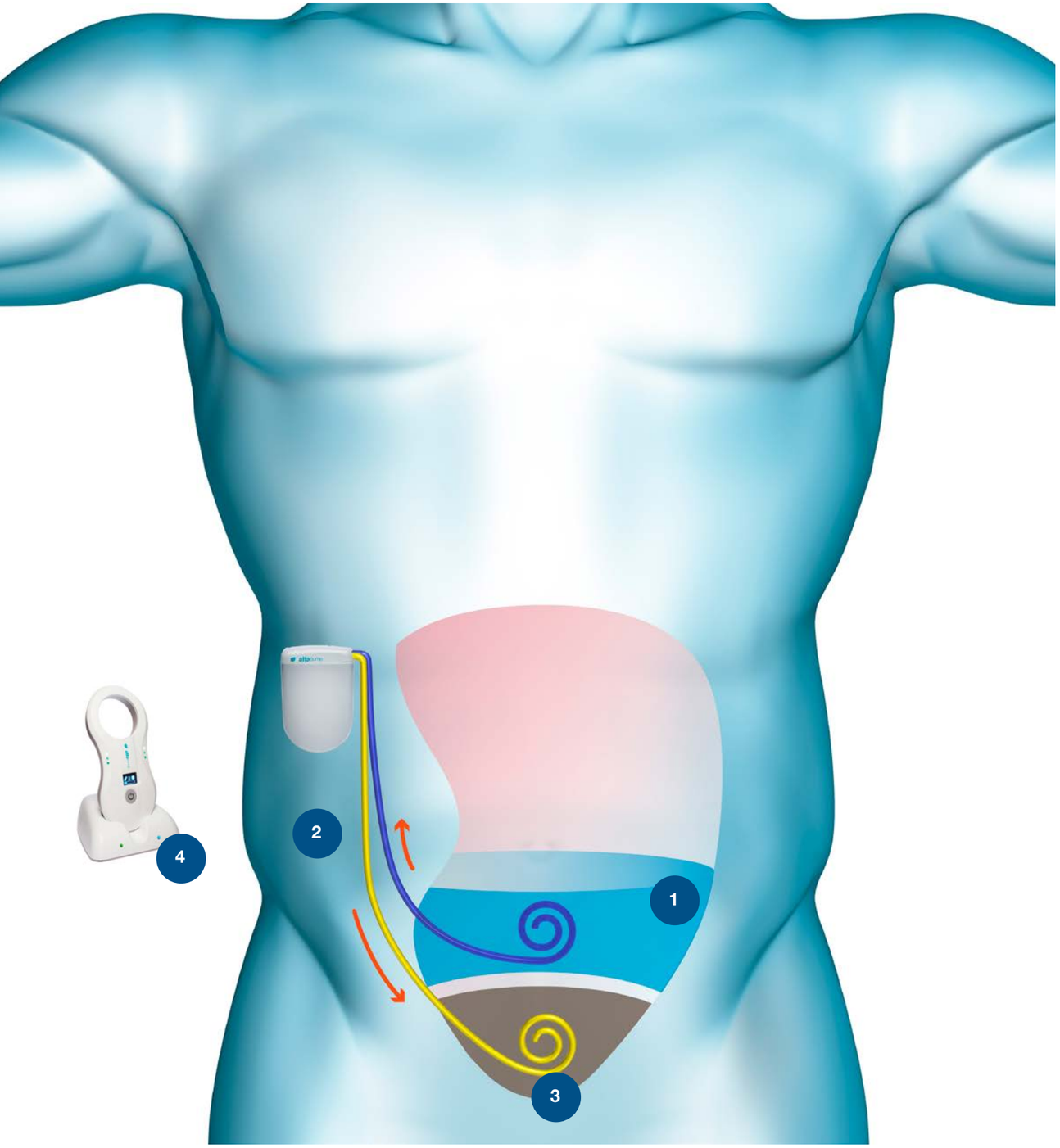
We estimate the **alfa**pump market stemming from NASH-related cirrhosis will exceed €3 billion per year within the next 10-20 years[1] in the U.S. alone and the heart failure market for the **alfa**pump DSR will reach over €5 billion per year in the U.S. and EU5 by 2026[2]. Both markets leverage our 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 compared with the traditional alcoholic liver disease and hepatitis cirrhosis markets in Europe, creating a much larger and more dynamic opportunity for the **alfa**pump.

We forecast the **alfa**pump will have an enhanced adoption and stronger competitive position in the U.S. NASH-related cirrhosis market versus the European market given the different patient characteristics (obesity vs. alcohol or hepatitis, 70+ vs. 40-50 years old[3,4]) and limited treatment options (e.g., use of a Transjugular Intrahepatic Portosystemic Shunt (TIPS) involves increased risk of dementia-like symptoms for patients above the age of 65 and is contraindicated for patients with heart failure[5]).

We view the designation of breakthrough device status by the U.S. FDA as a strong recognition of the high unmet medical need for improved treatment options for patients with recurrent or refractory ascites and the potential for the **alfa**pump to improve the lives of these patients.

		
alfapump market potential	**~€0.4 Bn / year[6]**	**> €3 Bn / year**
Underlying disease	Alcoholic Liver Disease, Hepatitis	**NASH**
Patient characteristic	Outside Mainstream	**Mainstream**
Average age	40-50 yrs	**70 yrs+**
alfapump competitive positioning	✓	✓✓



alfapump platform - using the bladder to manage fluid overload

The **alfa**pump is a subcutaneously implanted battery-powered pump that ensures 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.

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 and is usually performed under general anaesthesia but can also be performed under local anaesthesia with sedation. Placement of the **alfa**pump is performed by a general surgeon or by an interventional radiologist. 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.

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

Wirelessly charged through the skin

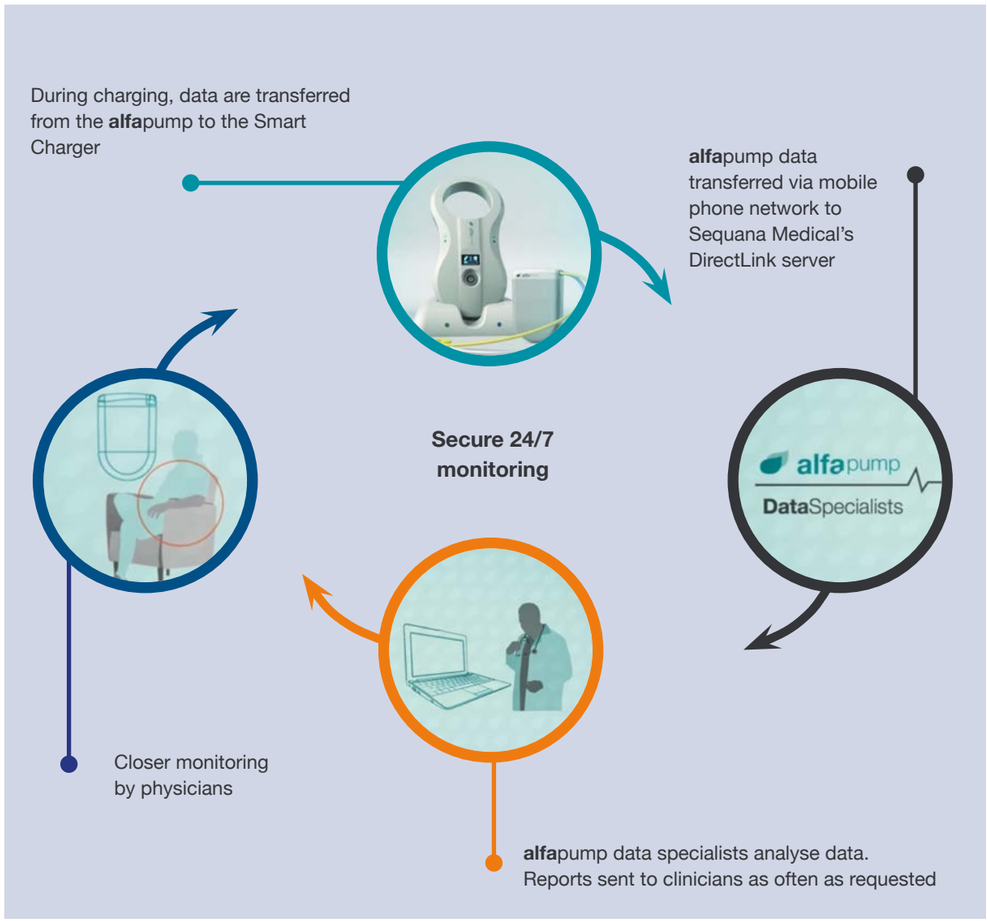
The only patient interaction is the need to recharge the battery each day with a wireless charger (the Smart Charger) through the skin for approximately 20 minutes (depending on the amount of fluid extracted each day).

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 built into the **alfa**pump system.

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.

Smart Charger

The Smart Charger is a hand-held charging device that charges the **alfa**pump through the skin. While charging, performance 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.

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Extensive Intellectual Property Portfolio & Established Supply Chain

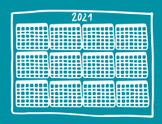
Our patent portfolio consists of 92 patents being granted across 14 patent families and a further 16 patent applications pending. In addition to patents, we also rely on a combination of trade secrets, design rights, copyright laws, non-disclosure agreements and other contractual provisions and technical measures that help maintain and develop our competitive position with respect to intellectual property.

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

Extensive alfapump experience

> 850
implantations

> 125,000 liters
of ascites removed



> 590 years
cumulative
pumping time

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

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 constant 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.

"It was absolutely horrendous, a horrible time, I couldn't do a thing. Honestly, ascites stops you short, that's why the alfapump saved my life."

67-year old alfapump patient, France

"The alfapump changes everything - it changes your look, your character and your well-being. I can tell everybody who needs a pump - go for it."

21-year old alfapump patient, Germany

alfapump for 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 or 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[1], 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.

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 850 **alfa**pump systems have been implanted.

(1) 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

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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.[7]

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 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.

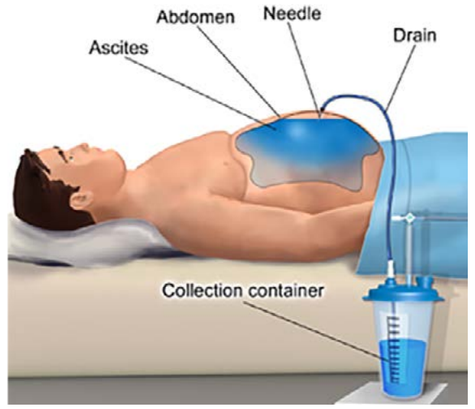
Approximately one-third of the U.S. population is affected by NAFLD[8] and approximately a quarter to one-third of NAFLD cases are classified as NASH[9]. NASH is a silent disease due to the difficulty in diagnosing it, making early stage intervention challenging. Currently, there are no drugs approved for treatment of NASH and recent data from drugs in development have failed to demonstrate efficacy in the later stages of the disease. It is estimated that about 10% of the NASH population will progress to liver cirrhosis in the near-to medium-term[10], 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.[11] 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,[12] 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.

It is estimated that there are approximately 18,000 patients with refractory liver ascites in the U.S. and 17,000 in EU5 (U.K., France, Germany, Italy and Spain).[13] By 2030, this number is expected to grow to approximately 151,000 in the U.S. and 89,000 in EU5.[8] We believe the recurrent ascites market further increases the market potential for the **alfa**pump.

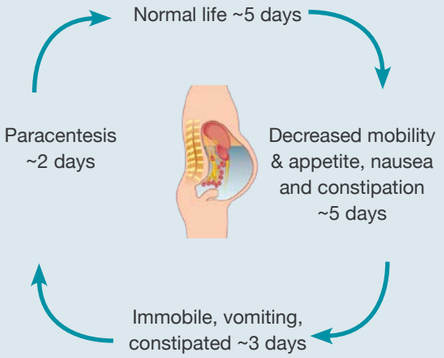
When drug therapy and dietary restriction are no longer effective, the common treatment of ascites is drainage (“paracentesis”).



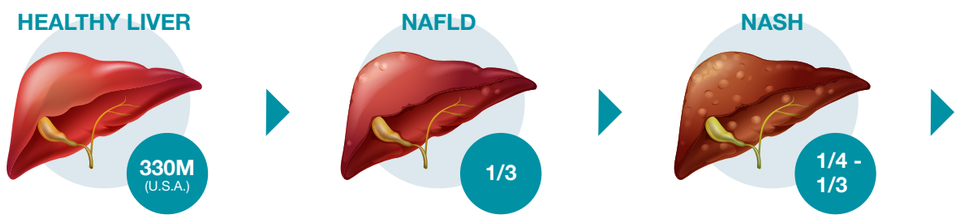
Paracentesis is a bedside or clinic procedure in which a needle is inserted into the peritoneal cavity to remove the ascitic fluid.

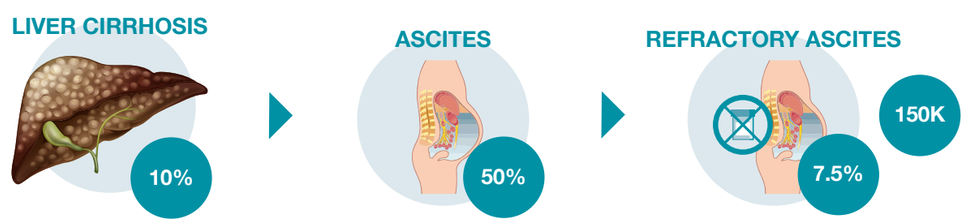
Large Volume Paracentesis treatment cycle

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

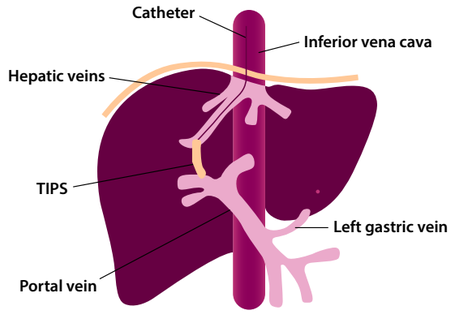




Ascites is a condition where excess fluid builds up in your abdomen, making your belly swell and stick out.

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.



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

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

There are a wide variety of complications that can be encountered with TIPS, such as haemorrhage, hepatic encephalopathy (up to 50% of patients),[15] heart failure, 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,[16] 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.

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[17] 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.[18] 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[17, 18].

As with liver ascites, paracentesis is often used to eliminate the ascites that accumulates when drugs are not effective. The impact of ascites on 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

"One of the major advantages of the alfapump over large volume paracentesis is that the quality of life of the patient improves dramatically. And this extends to the family because it allows for this particular patient to be free, mobile and self-caring."

Prof. Rajiv Jalan, Royal Free Hospital London

"I see a permanent increase in quality of life, in strength and also the courage to live with the disease. So I can say that this pump has completely improved my patient's life."

Dr. Heike Buhmann, Onkologische Praxis Herrsching

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[1]
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

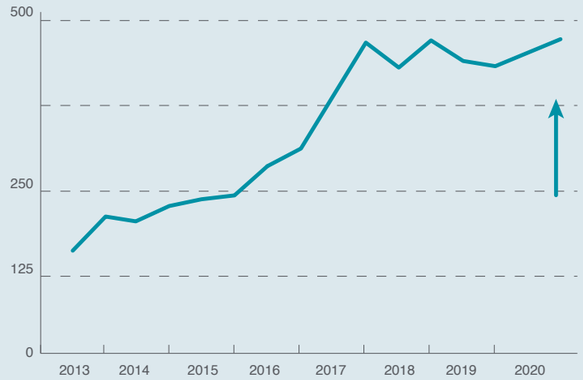
The key findings from clinical studies in recurrent or refractory liver ascites include:

- ~ 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
- 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

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

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/alfapump therapy duration

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.

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[1].

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.

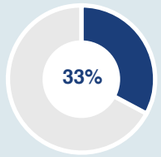
(1) The NASH education program

(2) 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

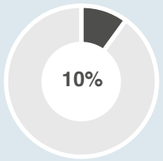


1/3 of US citizens has NAFLD, the hepatic manifestation associated with type-2 diabetes and obesity

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.

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 ongoing COVID-19 pandemic.

Name of Study	Description[1]	2019	2020	2021	2022
POSEIDON (NCT 03973866)	North American pivotal study in up to 50 patients with recurrent or refractory liver ascites implanted with the **alfa**pump to demonstrate the safety and efficacy of the **alfa**pump to support approval in U.S. and Canada.				*Primary endpoint*
ARIA Pump Study[2] (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.				

(1) 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 2022.

(2) 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 and they 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.

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 up to 60 patients to be enrolled, allowing for up to 50 patients to be implanted with the **alfa**pump for primary endpoint analysis and an additional Roll-In Cohort with up to 30 patients to be enrolled to ensure new centres are familiarized with the **alfa**pump system 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).

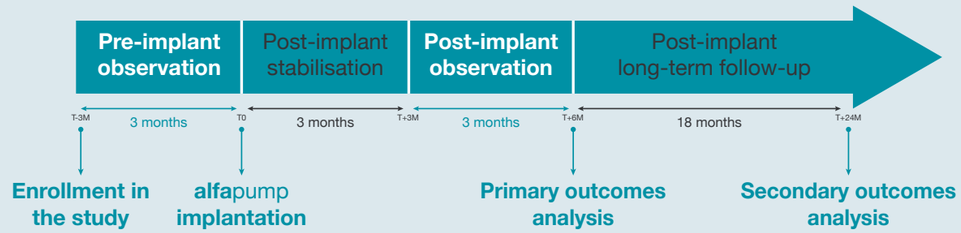
STRONG INTERIM RESULTS REPORTED FROM FIRST 13 PATIENTS IN THE ROLL-IN COHORT

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.

Age (mean)	**65 y**
MELD score (mean ± SD)	**10.5 ± 4.6**
Cirrhosis etiology	
- Alcohol	61.5%
- NASH	23.1%
- Hepatitis C	7.7%
- Alcohol, Hepatitis C, and Hepatitis B	7.7%
TP per month prior to study (mean ± SD)	**3.4 ± 1.8**

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

Looking at the underlying cirrhosis etiology of these first 13 Roll-In patients (61% alcohol, 23% NASH, 8% hepatitis C and 8% 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 10.5 (± 4.6) 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 3.4 TP per month, indicating that North American patients appear to have more TP per month than European patients.

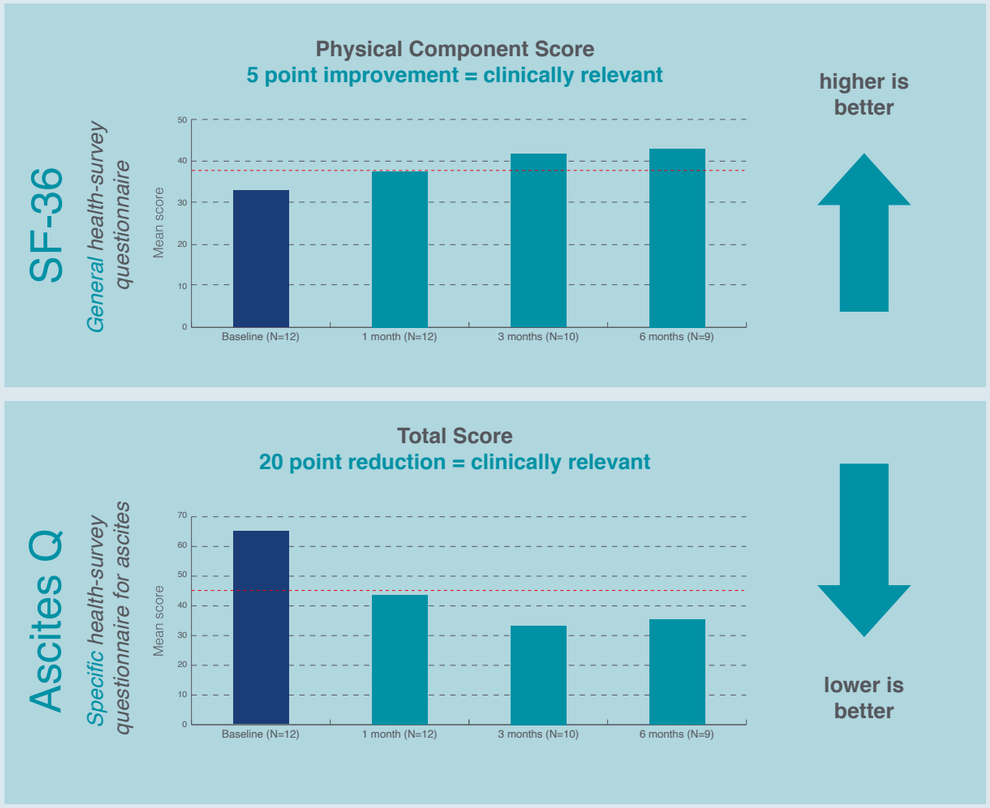


The interim data demonstrated a mean reduction in the frequency of TP post-implant versus pre-implant of over 90%, with all patients having at least a 50% reduction in the average frequency of TP per month[1].

Based on these interim data, the safety profile of the **alfa**pump is consistent with previously reported data.

"The adverse events were as expected in this population of patients and easily controlled with the standard of care treatments"

- Prof Wong, Hepatologist at Toronto General Hospital, Canada and Principal Investigator for POSEIDON



(1) 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

Patients' quality of life was assessed via established health-survey questionnaires. Results from SF36 (a general health quality survey) indicated clinically relevant improvements in the physical component score and improvement was seen in all SF36 subscales. Ascites Q, a questionnaire developed for patients with ascites, also indicated clinically relevant improvement in their quality of life and the improvement was seen in all subdomains of the survey. In both cases, the improvement was seen rapidly (within one month from implantation) and was persistent (6 months after implantation).

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.

"I am delighted to see the first, positive, results of these Roll-In patients. The dramatic reduction in the need for therapeutic paracentesis and improvement in quality of life is consistent with my long experience with the alfapump."

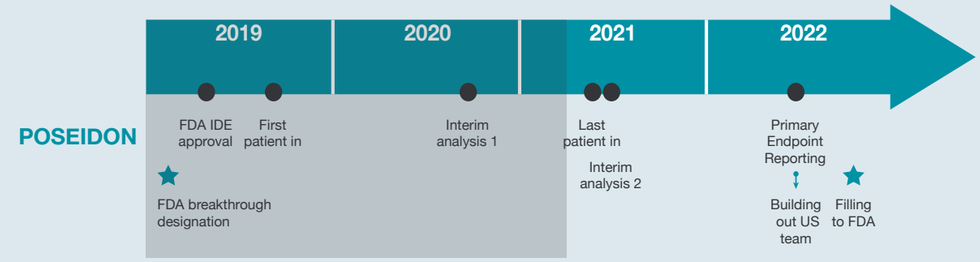
- Prof Wong, Hepatologist at Toronto General Hospital, Canada and Principal Investigator for POSEIDON

UPCOMING MILESTONES TOWARDS ALFAPUMP U.S. APPROVAL

Interim data of the larger Roll-In Cohort are expected in Q2 2021 and primary endpoint read-out of the Pivotal Cohort is expected in Q2 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 H2 2022.

Following positive interactions between the U.S. FDA and CMS (Centers for Medicare and Medicaid Services), patients may have access to new and innovative technologies sooner once approved by the FDA. In that respect, the U.S. Medicare agency issued an MCIT (Medicare Coverage of Innovative Technology) rule[1] allowing instant national Medicare coverage for FDA breakthrough devices such as the **alfa**pump, lasting for four years from as early as the date of FDA market authorization. In addition, FDA-designated and authorized breakthrough devices that meet certain cost criteria are eligible for the add-on payment under the alternative new technology add-on payment (NTAP) model[2]. We embrace these positive developments which makes us confident that the **alfa**pump will benefit from early reimbursement in the U.S. This will allow Medicare beneficiaries, who will be our principle patient population, to have timely access to the **alfa**pump while real-world evidence continues to emerge.

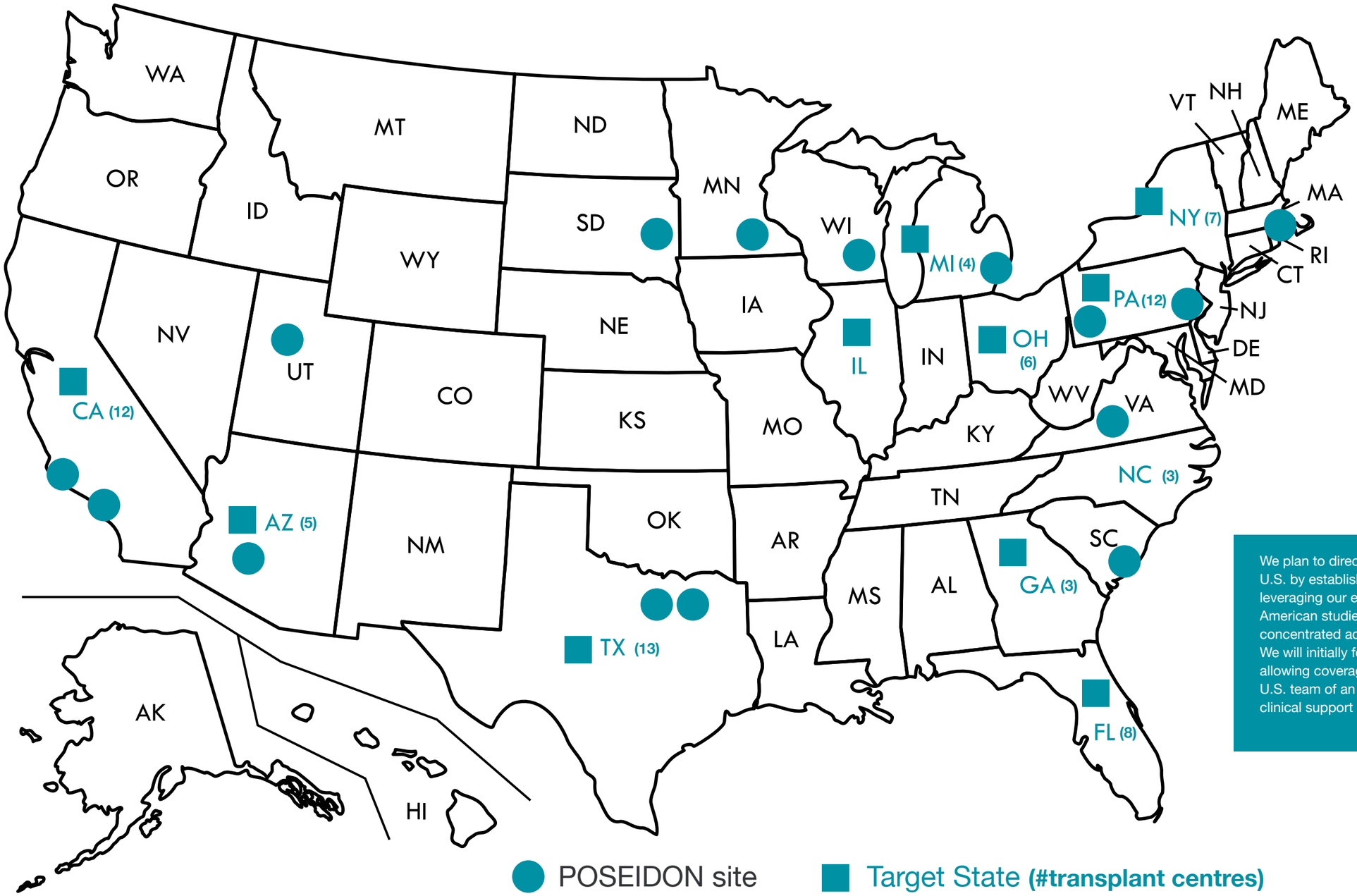
The timings presented below are subject to further developments related to the ongoing COVID-19 pandemic.



(1) https://www.cms.gov/newsroom/fact-sheets/medicare-coverage-innovative-technology-cms-3372-f

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

U.S. COMMERCIALISATION THROUGH OUR 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. The U.S. liver disease market is concentrated across 140 U.S. liver transplant centres[19]. We will initially focus on the key 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.

Commercial operations

Sales and marketing

Our European commercial team consists of 11 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. Upon approval of the **alfa**pump in North America, we intend to establish direct commercial activities in the U.S. 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 390,000 views.

Approval and reimbursement

The **alfa**pump has a CE-mark for the treatment of refractory ascites in patients with liver cirrhosis and for the treatment of malignant ascites and 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 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 the Netherlands, 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.

Annual Report 2020

alfapump DSR for heart failure

Potential chronic treatment for fluid overload in heart failure

The **alfa**pump DSR is built upon the proven **alfa**pump platform to deliver a fully implanted system for Direct Sodium Removal (DSR) to manage fluid overload in the many heart failure patients who have become resistant to diuretic drugs. DSR is a simple and elegant therapy that removes sodium from the body and then the kidneys step in and eliminate the right amount of free water to maintain the correct sodium concentration in the blood. We believe that our novel, proprietary approach could become a best-in-class treatment for diuretic-resistant heart failure patients. The **alfa**pump DSR is designed to be a chronic treatment for these patients, keeping them out of the hospital and with better control over their fluid balance, reducing the clinical burden on their weakened heart. The aim is to improve clinical outcomes, deliver a better quality of life for patients and reduce overall costs to the healthcare system.

Key patents for the **alfa**pump DSR, DSR infusate and method of operation have been granted in the U.S. and Europe over the past 12 months. Pre-clinical and clinical proof-of-concept data from single dose DSR therapy were published in the high impact cardiovascular journal, *Circulation.*

Interim data from the first five patients in RED DESERT, our ongoing repeated dose **alfa**pump DSR study in diuretic-resistant heart failure patients, indicated that **alfa**pump DSR therapy was safe and effective at maintaining the sodium and fluid balance. No patients required loop diuretic therapy during the six-week **alfa**pump DSR treatment. We were excited to see that following **alfa**pump DSR treatment, loop diuretic responsiveness was restored to near normal levels and the effect was durable for months post-treatment with the majority of patients requiring little or no oral diuretics post-study. In Q2 2021, we expect to report the top-line data from up to ten RED DESERT patients.

Based on the success of RED DESERT, by mid-year 2021 we plan to start SAHARA DESERT, our study to evaluate the dosing and frequency of **alfa**pump DSR therapy in decompensated heart failure patients with residual congestion, with interim data expected before year-end.

We have also started the development of a next generation proprietary DSR infusate with an improved therapeutic profile, which will further strengthen our position as leader in the treatment of diuretic-resistant fluid overload and provide us with a recurrent revenue stream.

We are delighted that Dr. Michael Felker and Dr. James Udelson have joined Dr. Javed Butler, Dr. Maria Rosa Costanzo, Dr. Wilson Tang & Dr. Jeffrey Testani as our Heart Failure Scientific Advisers and we are privileged to work with such pre-eminent figures in the heart failure clinical community.

Dr. Javed Butler

Dr. Butler is the Patrick H. Lehan Chair in Cardiovascular Research, and Professor and Chairman of the Department of Medicine at the University of Mississippi Medical Center. Dr. Butler's research focuses on clinical trials in patients with heart failure. He serves on several national committees including: the American College of Cardiology, American Heart Association, National Institutes of Health, and the Heart Failure Society of America. He is a recipient of the Simon Dack Award by the American College of Cardiology as well as the Time, Feeling, and Focus Award by the American Heart Association. Dr. Butler has authored more than 550 peer-reviewed publications. He serves on the editorial board of several peer-reviewed cardiovascular journals and has been cited in America's Best Doctors list.

Dr. Maria Rosa Costanzo

Dr. Costanzo is the Medical Director of the Edward Center for Advanced Heart Failure and Medical Director, Heart Failure Research for the Advocate Heart Institute. She is a Fellow of the American College of Cardiology, American Heart Association and European Society of Cardiology. Dr. Costanzo is also a member of the Ordine Dei Medici (The Italian National Medical Professional Association) and a member of the Board of Directors of the Heart Failure Society of America. Dr. Costanzo has led several multi-centre randomised clinical trials, has written more than 200 papers, abstracts and articles and has presented nationally and internationally on numerous topics related to heart failure and cardiac transplantation.

Dr. G. Michael Felker

G. Michael Felker, MD, MHS, FACC, FAHA, FHFSA is Professor of Medicine with tenure in the Division of Cardiology at Duke University School of Medicine. He is Director of Cardiovascular Research at the Duke Clinical Research Institute and Vice-Chief for Clinical Research in the Division of Cardiology. Dr. Felker's research focus is on clinical trials in acute and chronic heart failure and the use of biomarkers as diagnostics, prognostic, and therapeutic tools in heart failure. He has published over 320 peer reviewed articles and book chapters in the field of heart failure and has served on the executive and steering committees for multiple national and international clinical trials in heart failure. Previously, he was Chief of the Heart Failure Section at Duke University School of Medicine from 2013 to 2020.

Dr. W.H. Wilson Tang

Dr. Tang is Professor of Medicine at Cleveland Clinic Lerner College of Medicine at Case Western Reserve University. Dr. Tang is a practicing heart failure/transplant cardiologist specialising in specific cardiomyopathies, cardio-renal diseases, and cancer-related heart diseases. Dr. Tang is credited for unravelling the contemporary physiologic and molecular understanding of a subset of patients with cardio-renal syndrome, including the recognition of venous congestion, intra-abdominal pressure, and metabolic dysregulation as key determinants. Dr. Tang's NIH-funded translational research focuses on understanding the mechanisms through which nitrative stress and epigenetics contribute to disease progression in heart failure and cardiomyopathy in humans, with the goal of identifying preventive treatment strategies for heart failure. Dr. Tang has authored over 630 peer-reviewed scientific manu-scripts, editorials, and book chapters, which include the latest national heart failure guidelines.

Dr. Jeffrey Testani

Dr. Testani is Associate Professor of Medicine and Director of Heart Failure Research at Yale University School of Medicine. Dr. Testani's primary research interest is the mechanistic understanding of cardiac-renal interactions, fluid and sodium homeostasis, and diuretic resistance in heart failure. He has over 100 peer reviewed publications with the key focus of this work understanding cardio-renal interactions in heart failure. His laboratory utilises techniques of translational research using prospective human clinical trials and large animal models to better understand mechanism and develop new therapies and diagnostics. His lab is funded by the National Institutes of Health and industry sources totaling over $15 million, and is considered by many to be amongst the top laboratories in the world in this field of study.

Dr. James E. Udelson

James E. Udelson, MD is Chief of the Division of Cardiology at Tufts Medical Center and Professor of Medicine and Radiology at Tufts University School of Medicine. Dr. Udelson's research interests involve studying the effects of new therapeutic modalities in the setting of heart failure as well as acute and chronic coronary artery disease, and the development of imaging modalities to assess those effects. Dr. Udelson has directed and/or participated in numerous clinical trials on heart failure and cardiac imaging, focusing on the role of new therapies and how they affect remodeling, physiology, function, and outcomes. Dr. Udelson has served as a member of the FDA Medical Imaging Drugs Advisory Panel and has been invited as an ad hoc member of the FDA's Cardiovascular and Renal Drugs Advisory Panel and the Peripheral and Central Nervous System Advisory Panel.

Direct Sodium Removal

DSR, Direct Sodium Removal is a novel therapy that works in partnership with the body. Over thousands of years, our brains and kidneys have developed the capability to maintain the correct concentration of sodium in the blood. DSR therapy uses this to eliminate excess fluid from the body. Via DSR, we extract sodium from the body and then the brain and kidneys work to quickly and accurately remove the exact amount of water to maintain a correct concentration of sodium in the blood stream. In summary, we take out sodium and the body automatically restores the equilibrium by eliminating exactly the right amount of free water.

Key principle

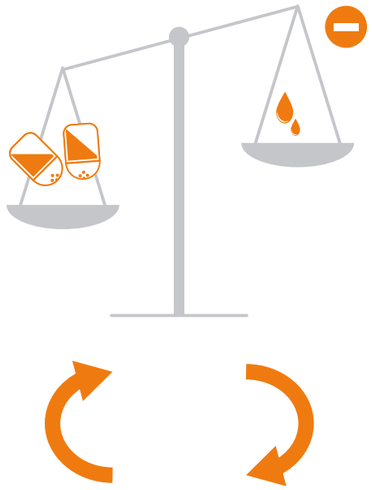
Maintaining a constant concentration of sodium in the body is a key physiological parameter that is vital to patient health ("homeostasis"). A concentration that is too high will result in hypernatremia and a concentration that is too low will result in hyponatremia, both of which are serious medical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

The body's response to heart failure causes sodium levels to increase.

To restore the balance, the body retains water, leading to fluid overload – resulting in an increased burden on the heart and further complications such as dyspnea.

Fluid overload in heart failure

The sodium concentration in patients with fluid overload is in balance but there is too much sodium and too much fluid in the body.



Key challenge

The key challenge in addressing fluid overload is that removal of water from the body without the removal of the associated amount of sodium only results in a temporary reduction in fluid volumes.

Traditional diuretic approaches primarily remove hypotonic urine (urine that has a lower concentration of sodium than the bloodstream), resulting in limited loss of sodium. As a result, the sodium concentration in the body increases and to restore this, the body either adds more fluid through eating or drinking or reduces fluid loss through limiting urination. In most cases, the body will retain its sodium reserves, as sodium is regarded by the body as a scarce resource.

Diuretics are known to cause patients to develop kidney failure and become less responsive to drugs over time. An estimated 40% of heart failure patients on intravenous loop diuretics experience diuretic resistance or intolerance.[23]

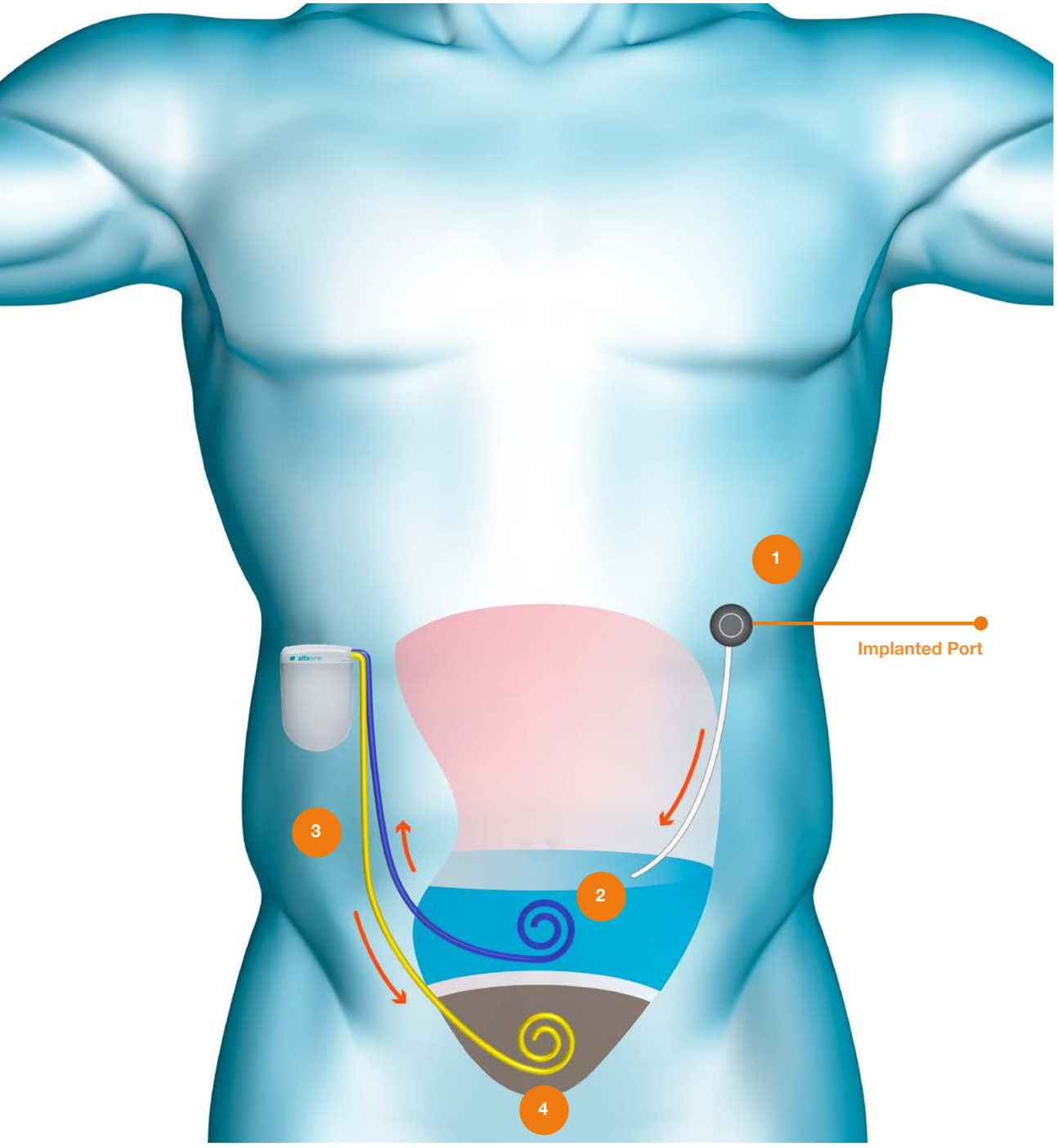
DSR approach

The DSR approach 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 uses the peritoneal cavity for the removal of sodium via diffusion. Just like your lungs, the peritoneal cavity has a 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.

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. During this time, sodium diffuses from the body down a steep diffusion gradient into the DSR infusate. The blood circulation keeps the effective sodium concentration high thereby preventing hyponatremia. The DSR infusate and the extracted sodium are then removed, resulting in a removal of sodium from the body. 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.



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 and is being developed as potential chronic therapy for diuretic-resistant heart failure patients with fluid overload.

The **alfa**pump DSR combines three proven elements:

- DSR
- the **alfa**pump system
- a surgically implanted port

The DSR infusate is administered to the peritoneal cavity via the surgically implanted 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 850 implanted **alfa**pump systems and the clinical proof-of-concept of DSR therapy potentially de-risks the technical and clinical development of **alfa**pump DSR.

Furthermore, the ability of the **alfa**pump to monitor changes in intra-abdominal pressure is believed to deliver important information to clinicians, potentially providing advance warning of decompensation. We believe the potential of this data monitoring by the **alfa**pump DSR may be of benefit to improving patient outcomes.

1. **Administration of DSR infusate to abdomen via Implanted Port**
2. **Sodium from systemic circulation diffuses into DSR infusate**
3. **alfa**pump **pumps sodium-rich fluid into the bladder where it is eliminated via urination**
4. **Body eliminates excess fluid through osmotic ultrafiltration & urination**

alfapump DSR:

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

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[20]. It is estimated that at least 26 million people are living with heart failure worldwide[21]. Total direct medical costs for the U.S. heart failure market are projected to reach $53 billion in 2030[22].

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 blood stream. 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 and often results in admissions to the emergency room. This fluid accumulation due to heart failure leads to frequent hospitalisations, poor quality of life and high healthcare costs.

40% of heart failure patients on IV loop diuretics have a poor response

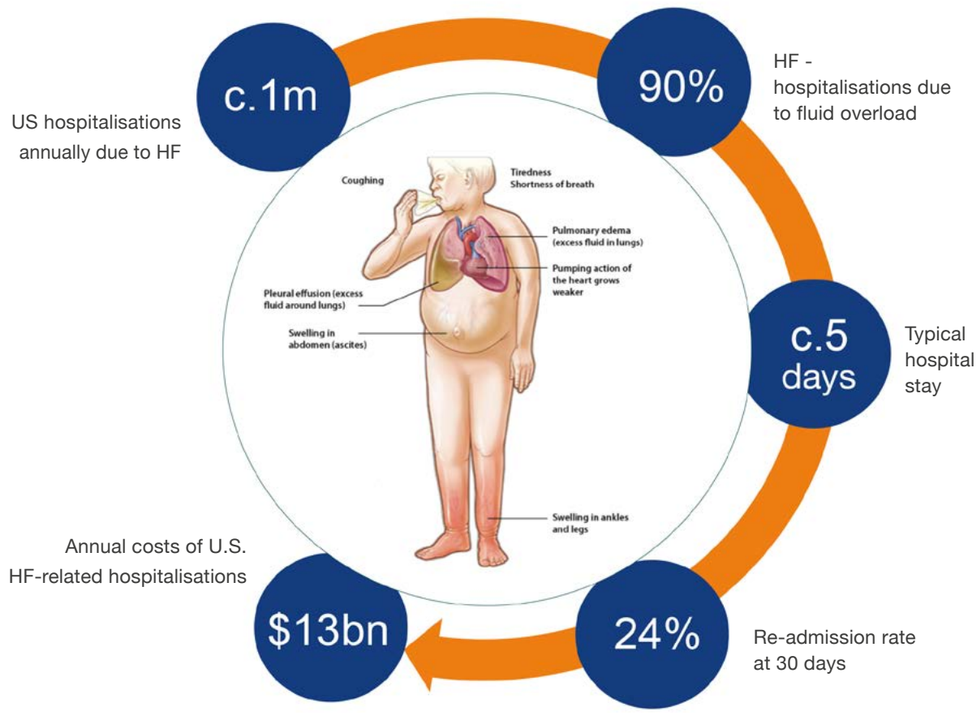
24% hospital re-admission within 30 days

There are approximately one million hospitalisations for heart failure annually in the U.S.[25], costing approximately $13 billion each year[26]. Of these admissions, 90% are due to symptoms of fluid overload[19], with an average 5 days length of stay[27]. By not truly addressing the fluid overload problem, approximately one in four patients are being readmitted to hospital within 30-days[28].

Fluid overload is generally treated with diuretics but they most often fail to address the underlying issue of sodium build-up as most diuretics remove hypotonic urine (urine that has a lower concentration of sodium than the bloodstream). This results in increased sodium concentrations in the body that triggers the thirst reflex and reduces urination to restore the fluid balance. In addition, diuretics have dose-dependent adverse effects and are known to cause patients to become less responsive over time. An estimated 40% of heart failure patients on intravenous loop diuretics experience diuretic resistance or intolerance[23] and nearly 50% of hospitalised patients with heart failure are discharged with residual excess fluid.[25] This suggests that there is a need for new options to help treat these poorly served patients. In addition to their limited benefit, chronic use of high dose diuretics can lead to even more advanced kidney failure which can result in the need for dialysis.

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[24].

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 the **alfa**pump DSR.



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 the alfapump platform as a potential chronic treatment solution 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[30]

Clinical development

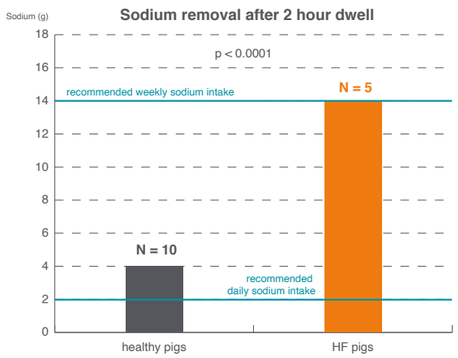
Completed studies

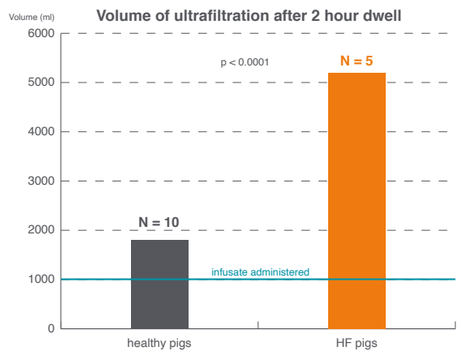
The impact of administering a single dose DSR infusate to the peritoneal cavity, and the resulting sodium and fluid removal, was evaluated in pre-clinical and clinical studies.

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 study		
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

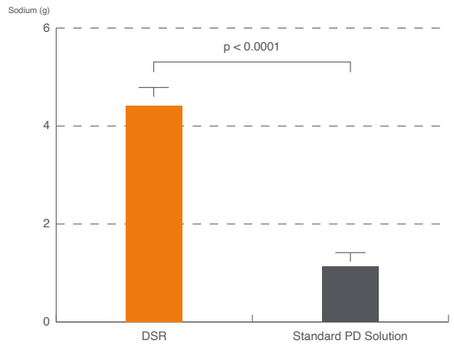
In the healthy pigs, administration of 1 litre of the DSR infusate and a 2-hour dwell period, resulted in removal of 4 grams of sodium which represents twice the recommended daily sodium intake for adults in the U.S[29], and approximately 2 litres of fluid from the peritoneal cavity (i.e., a net of 1 litre was removed).

In the pigs with experimentally induced heart failure (HF pigs), administration of 1 litre of DSR infusate and a 2-hour dwell period, resulted in removal of 14 grams of sodium, which represents the recommended weekly intake of sodium for adults in the U.S.[26], and approximately 5 litres of fluid from the peritoneal cavity (i.e., a net of 4 litres was removed).





Following the proof-of-concept studies in pigs, a single dose DSR study was conducted in 10 patients who underwent peritoneal dialysis (PD). One litre of either DSR infusate or standard PD solution was infused into the peritoneal cavity and left to dwell for two hours before being removed. The patient repeated the procedure with the alternate solution one week later.



Sodium removal with DSR was substantial, equating to approximately 4.5 grams (± 0.4 grams) removed with a single two hour treatment, and significantly higher than what was achieved with the standard PD solution (1.0 ± 0.3 grams, p<0.0001). Unlike what is typically seen with loop diuretics, the inter-patient variability was very low with DSR therapy. The fluid removal through ultrafiltration was also higher with DSR compared to standard PD solution (p<0.0001). As a result of the convincing positive and consistent results between patients, the study was halted after ten subjects (initially planned for up to 20 subjects).

With these studies, we have demonstrated that single dose DSR therapy is capable of removing large quantities of sodium and fluid in a safe, tolerable and consistent manner. The results were presented at key cardiac conferences, including Heart Failure 2019, HFSA Annual Scientific Meeting and TCT 2019, and published in the high impact cardiovascular journal, *Circulation*.

Ongoing and planned clinical studies

Following pre-clinical and clinical proof-of-concept of single dose DSR therapy, we are currently running a first-in-human study of **alfa**pump DSR (RED DESERT), combining repeated dose DSR therapy with our proven **alfa**pump platform, in patients with diuretic-resistant heart failure.

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

Name of Study	Description[1]	2020	2021	2022
Ongoing				
Repeated Dose study of alfapump **DSR (RED DESERT)**	Study in up to 10 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.	→	→	
Planned		2020	2021	2022
Dose-ranging feasibility study of alfapump **DSR (SAHARA DESERT)**	Feasibility study to evaluate the dosing and frequency of the **alfa**pump DSR therapy in 20 decompensated heart failure patients with residual congestion.		→	→

(1) 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.

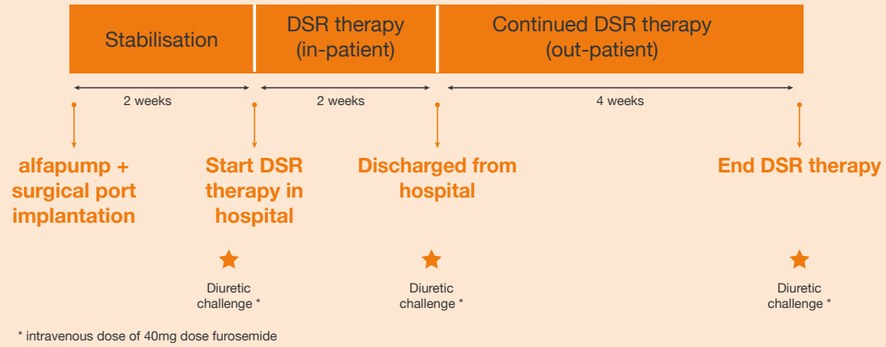
RED DESERT – our repeated dose alfapump DSR study for treatment of diuretic-resistant heart failure patients

STUDY DESIGN

RED DESERT is a multi-centre, prospective, single-arm, first-in-human study to evaluate the safety and feasibility of **alfa**pump DSR. Up to 10 patients diagnosed with stable chronic heart failure on high dose oral diuretics are implanted with the **alfa**pump DSR system (**alfa**pump and implanted surgical port).

Following **alfa**pump DSR system implantation, patients undergo a first diuretic challenge to evaluate their response to diuretics. This is determined by the six-hour excretion of fluid and sodium following intravenous administration of 40mg of furosemide. On day 14 post-implant (day 0), the patient is admitted for a 14-day in-patient period in which diuretics will be withheld and patients are put on a strict low-sodium diet. During the first 14 days, patients are treated with DSR D10% infusate on Monday, Wednesday and Friday, administered through the implanted surgical port into the peritoneal cavity. The DSR infusate remains in the peritoneal cavity for a two-hour dwell time, after which fluid is eliminated from the peritoneal cavity through the bladder using the **alfa**pump system. Following the 14-day in-patient period, patients undergo a second diuretic challenge. Thereafter, diuretics continue to be withheld and patients come into clinic for their DSR therapy over the subsequent four weeks. After completion of the study period, patients undergo a third diuretic challenge to quantify their response to diuretics.

The primary safety endpoints include 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 include 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 evaluate the potential impact of DSR to restore response to diuretics following DSR therapy. For more information about the study, please visit clinicaltrials.gov (NCT04116034).



* intravenous dose of 40mg dose furosemide

STRONG INTERIM RESULTS REPORTED FROM FIRST 5 PATIENTS

Five heart failure patients with mean left ventricle ejection fraction in mid-20%'s and mean NT-proBNP of 2,500 – 3,000 pg/mL were all on high dose diuretics with an average furosemide equivalent dose of 150 – 200mg per day and underwent up to six weeks of **alfa**pump DSR treatment.

The **alfa**pump DSR implant procedure and repeated dosing of DSR therapy were well tolerated in all patients with few adverse events. There were no clinically significant changes in serum sodium levels or progressive hyponatremia (low concentration of sodium in the blood) in these patients after repeated DSR dosing.

None of these patients required loop diuretics during the course of the six-week therapy, which demonstrates the ability of the **alfa**pump DSR system to effectively remove sodium and fluid from these patients. Moreover, in the majority of patients, reduced doses of DSR therapy could be utilised and / or some DSR doses could be omitted while maintaining stable to lower weight and natriuretic peptides compared to baseline.

Restoration of diuretic response is an exploratory endpoint of RED DESERT and evaluated serially throughout the study. All patients had an objectively poor diuretic response at baseline. After the six-week study, the diuretic response was restored to near normal levels with the six-hour sodium excretion more than doubled versus baseline. Furthermore, there was a significant durability to the improvement in diuretic responsiveness; in the majority of patients there was a dramatic reduction in loop diuretic requirements lasting months following the completion of **alfa**pump DSR therapy.

With these results, we believe it is the first time ever that fluid balance in heart failure patients has been managed using repeated dose DSR therapy without the need for diuretics. In addition, these data suggest that we can restore their response to diuretic drugs. This is a really exciting aspect that we will be exploring further both in heart failure and other disease areas.

"The durable improvement in diuretic responsiveness is particularly interesting. With additional confirmation of these encouraging results through continued study, I believe alfapump DSR has the potential to become a new therapy for the management of volume overload and diuretic resistance."

- Dr. Jeffrey Testani, Associate Professor at Yale University

NEXT STEPS

We will enrol up to 5 additional patients in RED DESERT and anticipate announcing top-line data in Q2 2021. Following the highly encouraging impact on diuretic responsiveness shown by the RED DESERT interim data, we plan to evaluate the dosing and frequency of **alfa**pump DSR therapy in decompensated heart failure patients with residual congestion in a first feasibility study (SAHARA DESERT), expected to start in Q2 2021.

We have also started development of our next-generation proprietary DSR infusate to replace the DSR D10% infusate used in pre-clinical and clinical studies to date. The benefits of developing our own DSR infusate are that it will have an improved therapeutic profile and provide us with a recurring revenue stream.

KOL event with Dr. Jeffrey Testani — Friday, December 11th, 2020

The challenge of diuretic resistance in the management of heart failure patients and the potential for alfapump DSR therapy

WE HOSTED A TOTAL OF 85 OVERALL ATTENDEES, INCLUDING INSTITUTIONAL INVESTORS, SELL-SIDE ANALYSTS, BANKERS, HIGH NET WORTH INDIVIDUALS, AND STRATEGICS

55 live attendees

30 replays

Duration of 1 hour

22 equity analysts

27 investors

15 peers

KEY OPINION LEADER - DR. JEFFREY TESTANI

Associate Professor of Medicine and Director of Heart Failure Research at Yale University School of Medicine.

KOL event with Dr. Jeffrey Testani — Friday, December 11th, 2020

KEY LEARNINGS, PRESENTED BY DR. TESTANI

Fluid overload is the primary cause of heart failure symptoms, hospitalisation, and quite possibly mortality
The majority of patients showing up to the hospital have too much fluid. Removal of fluid seems to be increasingly important to keep patients alive. Loop diuretics are the standard treatment for these patients but they have dose dependent adverse effects and patients rapidly develop resistance.

“Congestion is really a big part of the disease… and not just a nuisance symptom”

So why is there so much diuretic resistance?
The problem with diuretic resistance is that the kidneys are doing exactly what they were designed for, which is to keep the right amount of sodium and fluid in the body. In most patients, diuretics block sodium reabsorption locally but sodium is pumped back by the kidney downstream because it thinks the body is dehydrated. All novel therapies have failed because they are too distal in the sodium avidity pathway and the kidneys outsmart them.

“Diuretic resistance is nearly ubiquitous.”

Targeting sodium removal rather than fluid is key
The peritoneum is an alternative membrane that can be used for fluid and solute removal, just like in peritoneal dialysis. With Direct Sodium Removal or DSR, a sodium-free peritoneal solution is used to effectively remove the sodium. The **alfa**pump DSR combines this DSR concept with the **alfa**pump to use it in a chronic multi-dose setting.

“We talk about fluid overload, but it’s really all about the sodium.”

Replay available on our *website*

KOL event with Dr. Jeffrey Testani — Friday, December 11th, 2020

RED DESERT INTERIM RESULTS, PRESENTED BY DR. TESTANI

KEY OBJECTIVE
Demonstrate if repeated dose **alfa**pump DSR therapy can replace diuretics and maintain euvolemia in heart failure patients

MAIN FINDINGS FROM FIRST 5 PATIENTS WHO HAVE COMPLETED THE STUDY
- Repeated dose **alfa**pump DSR is well tolerated
- Majority of patients lost weight and had reduction in natriuretic peptide levels
  - *Despite volume loss all signs point toward improved renal function which is the opposite of what we see with diuretics*
- Loop diuretic response actually normalized in the majority of patients by the end of the study
- Improved global sodium avidity of the patient
  - *Most patients were not requiring full dose DSR by the end of therapy*
  - *Improvement in diuretic response durable for months in many patients*

Overall these preliminary findings provide optimism that alfapump DSR therapy is fundamentally improving the cardio-renal substrate of the patient.

“Use of alfapump DSR really reversed the diuretic resistance essentially to normal levels, giving a lot of optimism that this therapy could be a real game changer in the space.”

“Most patients were not requiring full dose DSR by end of therapy as the kidney had woken up and was doing a much better job of removing sodium on its own.”

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 platform to explore innovative treatment solutions for other indications complicated by fluid overload in order to maximise the potential of our innovative and patented technology. We may either undertake such development ourselves or seek to partner or out-license the **alfa**pump technology 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 **alfa**pump DSR therapy may be able to reverse such resistance leading to increased treatment options. This may lead to use of **alfa**pump therapy in conditions such as fluid overload related to chronic kidney disease.

Investor relations

The shares in 2020

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 2020, the share capital of the Company amounted to €1,635,006.12 represented by 15,778,566 shares.

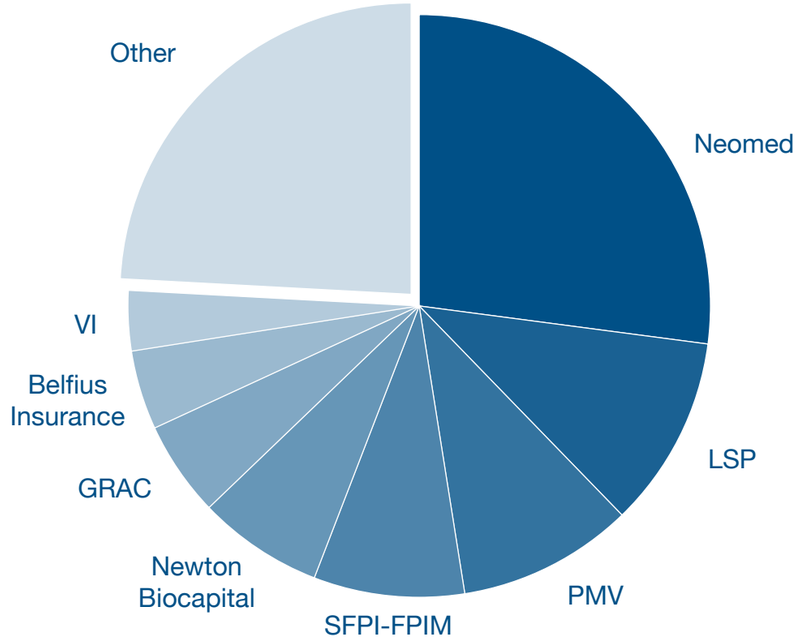
In addition to the outstanding shares, the total number of outstanding subscription rights on 31 December 2020 amounted to 1,308,733 entitling their holders (if exercised) to subscribe to 1,804,791 new shares with voting rights in total.

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

Trading volume in 2020	
Average daily volume	7,417
Average daily value	€51,743
Total traded volume	1,906,113
Total traded value	€13,297,919

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 2020 and the transparency notifications received until that date, the shareholder structure of the Company as per 31 December 2020 was as follows:



Neomed	Norway	27.1%
LSP	the Netherlands	10.8%
PMV	Belgium	9.8%
SFPI-FPIM	Belgium	8.2%
Newton Biocapital	Belgium	7.0%
GRAC	Belgium	5.3%
Belfius Insurance	Belgium	4.5%
VI Partners	Switzerland	3.3%

Analyst coverage

Sequana Medical was covered by four brokers at the end of 2020.

Broker	Analyst
KBC Securities	Lenny Van Steenhuyse
Kempen	Ingrid Gafanhão
Kepler Cheuvreux	Matthias Maenhaut
Mirabaud	Daniel Jelovcan

Financial calendar

27 May 2021	Annual General Meeting 2021
2 September 2021	Half year results 2021

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
Technologiepark 122
9052 Zwijnaarde, Belgium
T: +32 498 053579

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Corporate Governance

Corporate Governance

Annual Report 2020

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 2020.

1.1. Developments, results, risks and uncertainties

(Article 3:32, 1° BCAC)

1.1.1. Operational review

- POSEIDON (North American pivotal study of the **alfa**pump in recurrent and refractory ascites due to liver cirrhosis) reported positive interim results from the first 13 patients in the Roll-In Cohort. The interim data showed positive outcomes against all primary endpoints of the study(i), as well as indications of clinically relevant improvements in quality of life measures. The mean reduction in frequency of therapeutic parenthesis (TP) post-**alfa**pump implant versus pre-implant was over 90%. All patients had at least a 50% reduction in the average frequency of TP per month and the safety profile was in line with expectations. The study is designed to demonstrate in Pivotal Cohort patients 1) a 50% reduction in average monthly frequency of TP post-**alfa**pump implant versus pre-implant and that 2) at least 50% of patients to achieve a 50% reduction in the requirement for TP post-**alfa**pump implant versus pre-implant.
- RED DESERT (repeated dose proof-of-concept study of the **alfa**pump DSR in diuretic-resistant heart failure patients) reported positive interim results from the first five patients. The results showed that during the course of the six-week therapy, no loop diuretics were required, demonstrating the ability of the **alfa**pump DSR system to remove sodium and fluid from these patients, and there were no clinically significant changes in serum sodium levels or progressive hyponatremia. Following the six-week study, the diuretic response of these patients was restored to near normal levels with the majority of patients requiring low or no diuretics for months after completion of DSR therapy.
- Sequana Medical hosted a Key Opinion Leader (KOL) event on the challenge of diuretic resistance in the management of heart failure patients and the potential for **alfa**pump DSR therapy, featuring a presentation by Dr. Testani, MD, MTR (Yale University School of Medicine).
- Positive data from preclinical and clinical DSR proof-of-concept studies were published in *Circulation*, a top-tier peer-reviewed cardiovascular journal.
- Positive results from MOSAIC (North American feasibility study of the **alfa**pump in recurrent and refractory ascites due to liver cirrhosis) were published in the leading peer-reviewed journal *Liver Transplantation*.
- Dr. Oliver Gödje was appointed Chief Medical Officer; Gijs Klarenbeek remains with Sequana Medical as Senior Medical Advisor.
- Dr. Michael Felker and Dr. James Udelson were appointed as new Heart Failure Scientific Advisors.
- Refined the focus of European commercial activities on Germany and France, as part of the Company's focused strategy and continued penetration in these territories. In Q4 2020, there was a limited supply of the **alfa**pump to these markets due to manufacturing problems and the prioritisation of product supply to the POSEIDON and RED DESERT clinical studies. Despite this and the major disruption from COVID-19, revenues from European commercial activities in 2020 were maintained versus 2019.

(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

1.1.2. Commentary on the consolidated annual accounts

1.1.2.1. CONSOLIDATED STATEMENTS OF PROFIT AND LOSS

Revenue

Revenue (€0.96 million) remained at a similar level compared to the same period last year (€0.97 million).

Cost of goods sold

Cost of goods sold (€0.20 million) remained at the same level compared to last year (€0.20 million).

Operating expenses

Total operating expenses increased by 26% to €18.53 million compared to 2019 (€14.74 million).

Sales and marketing expenses decreased from €2.84 million to €2.32 million primarily as a result of reduced travel and marketing expenses due to COVID-19 restrictions and the focusing of our European commercial activities on Germany and France.

Clinical expenses increased from €3.92 million to €6.11 million mainly as a result of higher costs related to POSEIDON, the North American pivotal study of the **alfa**pump and RED DESERT, the repeated dose proof-of-concept study of the **alfa**pump DSR.

Quality and Regulatory expenses increased from €1.82 million to €2.23 million, mainly driven by costs for external advice for the POSEIDON study and the RED DESERT study, preparations for the new Medical Devices Regulation (Regulation 2017/745), as well as the preparation for the commercial marketing application of the **alfa**pump in the U.S. and Canada.

Supply chain expenses increased to €1.64 million (FY 2019: €0.93 million), mainly as a result of the increase in clinical expenses and production yield loss.

Engineering expenses increased from €0.98 million to €1.86 million largely driven by the preparation for the commercial marketing application of the **alfa**pump in the U.S. and Canada.

General and administration expenses (€4.42 million) remained at a similar level to last year (€4.26 million).

EBIT

Earnings before interest and taxes (EBIT) increased from a loss of €13.96 million in 2019 to a loss of €17.77 million in 2020 largely due to increased clinical activities, quality and regulatory expenses, engineering and supply chain expenses partially offset by lower expenses in sales and marketing.

Total net finance expenses

Net finance cost increased from €0.88 million in 2019 to €1.18 million in 2020 and consists mainly of charges related to the Bootstrap loan (repaid on 16 July 2020) and accrued interest on the new subordinated loan agreements concluded at the end of July 2020.

Income tax expense

Income tax expense (€0.16 million) remained at a similar level compared to 2019 (€0.14 million). These expenses largely reflect taxes payable in Switzerland.

Net loss for the period

As a result of the above, the net loss increased from €14.98 million in 2019 to €19.11 million in 2020.

Basic losses per share (LPS)

Basic losses per share for 2020 amounted to €1.25, compared to €1.22 in 2019.

1.1.2.2. CONSOLIDATED BALANCE SHEET

Net debt

Net debt[ii] at 31 December 2020 improved by €0.79 million, resulting in a positive net cash position of €3.16 million compared to €2.36 million at 31 December 2019, mainly as a result of the proceeds from the January 2020 Equity Placement.

Working Capital

Working capital[iii] improved from 2019 to 2020 by €1.56 million, mainly as a result of an increase in trade payables and accrued liabilities and a decrease in trade and other receivables and inventory.

Consolidated statements of cash flows

Net cash outflow from operating activities was €17.01 million compared to €18.48 million in 2019. The decrease was mainly driven by the normalization of the changes in trade and other payables (2019 was mainly impacted by the IPO expenses paid in 2019 and accrued in 2018) partially offset by a general increase in the net loss.

Cash flow from investing activities resulted in a net outflow of €0.14 million similar to the net outflow of €0.11 million in 2019.

Cash flow from financing activities resulted in a net inflow of €22.63 million in 2020, mainly as a result of the proceeds from the private equity placement in January 2020 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). In 2019, the net inflow of €22.99 million was mainly a result of the IPO proceeds.

The Company ended 2020 with a total liquidity position of €11.02 million (2019: €5.59 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 the COVID-19 outbreak

- 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 and/or the **alfa**pump DSR.

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.
- Sequana Medical has sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months as of this document but will require additional funds beyond this period in order to meet its capital and expenditure needs.
- 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 (i.e. physicians at clinical study centres that maintain overall responsibility for the conduct of a clinical study), obtaining necessary approvals from study sites or the enrolment of subjects in clinical studies, its receipt of necessary regulatory approvals could be delayed or prevented.
- Adverse events may result in delays to the completion of clinical studies regarding the **alfa**pump or the **alfa**pump DSR.

Legal and regulatory risks

- Seeking and obtaining regulatory approval for medical devices 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 is and will be subject to certain post-approval regulatory obligations in relation to the **alfa**pump and **alfa**pump DSR.
- Sequana Medical intends to develop proprietary DSR Infusate 2.0 to be used in the U.S. feasibility study for the **alfa**pump DSR for the management of volume overload due to heart failure in 2022. DSR (Direct Sodium Removal) Infusate is Sequana Medical's proprietary formulation for use in the **alfa**pump. The DSR Infusate will likely be regulated as a drug in the United States, requiring approval by the FDA.
- 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 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. If Sequana Medical is found to have made false or misleading claims about the **alfa**pump and/or the **alfa**pump DSR 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.

(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 inventories plus trade receivables and other receivables minus trade payables (including contract liabilities) and other payables, and accrued liabilities.

Annual Report 2020

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

- Sequana Medical depends on third party suppliers for services and components used in the production and operation of the **alfa**pump and **alfa**pump DSR, and some of those services and components are supplied from a single source. Disruption of the supply chain, unavailability of third party services required for the production of the **alfa**pump and **alfa**pump DSR, 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 Fresenius in Belgium and the Netherlands, 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 and/or any future products in target markets.
- The success of the **alfa**pump, the **alfa**pump DSR 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 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 Fresenius, 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 and/or any future products, and/or reduce the margins for the **alfa**pump and/or the **alfa**pump DSR 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.

Risks relating to the shares of Sequana Medical

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

1.2. Information about important events after the closing of the financial year

(Article 3:32, 2° BCAC)

We refer to note 16 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 and 15 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 2020 with the objective to further develop the **alfa**pump:

- POSEIDON (North American pivotal study of the **alfa**pump in recurrent and refractory ascites due to liver cirrhosis) reported positive interim results from the first 13 patients in the Roll-In Cohort. The interim data showed positive outcomes against all primary endpoints of the study[(iv)], as well as indications of clinically relevant improvements in quality of life measures. The mean reduction in frequency of therapeutic parenthesis (TP) post-**alfa**pump implant versus pre-implant was over 90%. All patients had at least a 50% reduction in the average frequency of TP per month and the safety profile was in line with expectations. The study is designed to demonstrate in Pivotal Cohort patients 1) a 50% reduction in average monthly frequency of TP post-**alfa**pump implant versus pre-implant and that 2) at least 50% of patients to achieve a 50% reduction in the requirement for TP post-**alfa**pump implant versus pre-implant.
- RED DESERT (repeated dose proof-of-concept study of the **alfa**pump DSR in diuretic-resistant heart failure patients) reported positive interim results from the first five patients. The results showed that during the course of the six-week therapy, no loop diuretics were required, demonstrating the ability of the **alfa**pump DSR system to remove sodium and fluid from these patients, and there were no clinically significant changes in serum sodium levels or progressive hyponatremia. Following the six-week study, the diuretic response of these patients was restored to near normal levels with the majority of patients requiring low or no diuretics for months after completion of DSR therapy.

1.5. Use of financial instruments

(Article 3:32, 5° BCAC)

We refer to note 2.3.2.2 and 8.6 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 2.12 in the corporate governance statement.

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

(Article 3:32, 8° BCAC)

We refer to section 2.15 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.

(iv) 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

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 Company's ability to continue operations also depends on its ability to raise additional capital and to refinance existing debt, in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows.

The future impact of COVID-19 on the Company's ability to secure additional financing rounds or undertake capital market transactions remains unclear at this point in time and will remain under review by the Executive Management and the Board of Directors.

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

The consolidated statement of financial position as at 31 December 2020 shows a positive equity in the amount of EUR 0.1 million and ending cash balance of EUR 11.0 million. The Company will continue to require additional financing in the near future and in that respect already successfully raised EUR 22.5 million in February 2021 in a private equity placement via an accelerated book building offering disclosed in the note 16 Events after the reporting period in the Notes to consolidated financial statements. Together with existing cash resources, the net proceeds from these financing rounds are expected to extend the current cash runway of the Company into Q2 2022. The Company continues to evaluate equity and other financing options, including discussions with existing and/or new investors.

As a result, the Board of Directors remains confident that the liquidity requirements for the next twelve months can be secured based upon its current assessment of the COVID-19 situation and its impact on our ability to conduct clinical trials. 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 to note 16 Events after the reporting period in the Notes to consolidated financial statements.

1.11. Conflicts of interests procedure

(Article 7:96, §1 BCAC)

On 21 January 2020, the Board of Directors of the Company decided to approve (in principle) the increase of the share capital of the Company in the framework of the authorised capital by the issuance of new shares in the framework of a private placement through an accelerated bookbuilding procedure. On the same day, the Board of Directors of the Company decided, before a notary public and subject to a number of condition precedents, to increase the share capital of the Company in the framework of the authorised capital with the issuance of new shares to be offered via a private placement through an accelerated bookbuilding procedure. On 27 January 2020, 3,166,666 new shares were effectively issued.

The conflicts of interests procedure of Article 7:96 of the Belgian Companies and Associations Code was applied during each of the aforementioned board meetings. In accordance with the Articles 7:96 and 3:5 of the Belgian Companies and Associations Code, the sections below contain the relevant parts of the aforementioned board meetings.

1.11.1. Extract of the Minutes of the Private Meeting of the Board of Directors of 21 January 2020

"[…]

3.1. PRIOR DECLARATIONS BY RUDY DEKEYSER AND ERIK AMBLE

Prior to the deliberation and resolutions by the Board of Directors, Rudy Dekeyser, and Erik Amble, each a director of the Company and each being represented by one of the present directors, as aforementioned, made the following respective declarations as far as needed and applicable, in accordance with the provisions of the Belgian Companies and Associations Code:

- *Rudy Dekeyser informed the Board of Directors that he has an important interest in LSP HEF Sequana Holding B.V. ("LSP"), which company is an affiliate of the company that nominated him as a director of the Company.*
- *Erik Amble informed the Board of Directors that he has an important interest in NeoMed Innovation V L.P. ("NeoMed"), which company (together with Neomed IV Extension L.P.) nominated him as a director of the Company.*
- *Each of Rudy Dekeyser and Erik Amble informed the meeting that the agenda refers to a new fund raising via the proposed Transaction, that LSP and NeoMed, respectively, support the Transaction, and that LSP and NeoMed, respectively, are part of a number of investors (the "Participating Investors") that committed to submit an order (directly or indirectly) to the Underwriters (as defined below) to subscribe for new shares in the framework of the Transaction.*
- *Each of Rudy Dekeyser and Erik Amble noted that it is contemplated that the new shares shall need to be admitted to trading on the regulated market of Euronext Brussels. For this purpose, the Company is to make the necessary filings and applications, and, as the case may be, prepare a listing prospectus, all as required by applicable regulations, in order to permit an admission to trading following the issue of the new shares. Notably, in accordance with the Prospectus Regulation, up to 2,522,379 new shares can be immediately admitted to trading on Euronext Brussels upon this issuance, without listing prospectus, where the new shares in excess of such number can only be admitted to trading on Euronext Brussels after a listing prospectus has been prepared. Each of Rudy Dekeyser and Erik Amble noted LSP and NeoMed, respectively, have indicated that they would be willing to subscribe for new shares that are not immediately admitted to trading upon their issuance, but only after a listing prospectus has been prepared. LSP and NeoMed are also willing to make available existing shares that are admitted to trading. This could allow the Company to raise more funds via the Transaction than it would have been able to do if the maximum number of new shares issuable in the Transaction is limited to 2,522,379 new shares, and will enable the intervening Underwriters to deliver listed shares to the ultimate investors that will participate in the Transaction.*
- *Each of Rudy Dekeyser and Erik Amble hence informed the meeting that, as a result, he may have a conflict of interest within the meaning of Article 7:96 of the Belgian Companies and Associations Code in relation to the resolutions to be passed by the Board of Directors with respect to the Transaction. Rudy Dekeyser and Erik Amble will also inform the Company's statutory auditor of the foregoing, as far as needed and applicable in accordance with the provisions of Article 7:96 and/or 7:97 of the Belgian Companies and Associations Code. Despite this potential conflict, however, each of Rudy Dekeyser and Erik Amble stated that he believed that the proposed private placement is in the Company's interest, as it will allow the Company to complete the Transaction and raise new funds, which is in the Company's interest.*

3.2. PRIOR DECLARATIONS BY THE OTHER DIRECTORS

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

3.3. CONSIDERATIONS BY THE BOARD OF DIRECTORS IN RELATION TO THE PRIOR DECLARATIONS

- *The remaining members of the Board of Directors took note of the prior declarations by Rudy Dekeyser and Erik Amble.*
- *The Board of Directors considered that the report of the Board Report in accordance with Article 7:198 juncto Articles 7:179 and 7:191 of the Belgian Companies and Associations Code in relation to the Transaction and which is submitted for approval by the Board of Directors contains (a) a description of the nature of the Transaction, (b) a description of the consequences of the Transaction for the financial and shareholder rights of the shareholders of the Company, and (c) the justification for the Transaction. The Board Report contains further details and will be publicly available via (amongst others) the website of the Company and is hereby, as far as needed, incorporated by reference into the minutes of this meeting of the Board of Directors.*
- *The Board of Directors also specified that, subject to the launch of the Transaction, the Transaction will be open to institutional, qualified, professional and/or other investors as permitted under applicable private placement exceptions, as mentioned in the aforementioned report, and any final allocation to investors, as the case may be, will be made based on customary objective and pre-identified criteria. While the Company received already subscription commitments from a number of Participating Investors, the Board of Directors further confirmed that no guarantee will be given as to the final allocation to any of LSP, NeoMed, or any other Participating Investor, or any of their affiliates or other persons, that any allocation will be made to them, or as to the size of any such allocation."*

[…]

4. DELIBERATION AND RESOLUTIONS

[…]

After deliberation, it was unanimously:

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

(i) *The maximum number of shares to be issued will range range between maximum 2,522,379 and 6,305,950 new shares, which maximum number is still to be determined, at an issue price for the new shares that is still to be determined as a result of the accelerated bookbuilding procedure;*

(ii) *the new shares are to be offered by the Underwriters to a broad group of currently unidentified Belgian and foreign institutional, qualified, professional and/or other investors (including, subject to applicable securities law rules and regulations, natural persons, and it being understood that, with respect to investors other than qualified investors (as defined in the Prospectus Directive) in Belgium only, the minimum investment amount per investor will be at least EUR 100,000), in and outside of Belgium, on the basis of applicable private placement exemptions, with dis-application of the statutory preferential subscription right of the Company's existing shareholders and, in so far as required, of the Company's existing holders of subscription rights, and whereby (a) any final allocation of new shares to investors (as the case may be) must be made on the basis of customary objective and pre-identified criteria,*

and (b) no guarantee shall be given, by or on behalf of the Company or the Underwriters, as to any allocation of new shares to any party;

(iii) *an application will be made and all steps will be taken as shall be required (including, as the case may be, the preparation of a listing prospectus as required by the Prospectus Regulation) to admit the new shares to trading on Euronext Brussels in accordance with the applicable rules and regulations.*

(b) RESOLVED to approve, or, in so far as required, ratify, the following:

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

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

(c) RESOLVED to confirm the assignment to the statutory auditor to draw up a report in accordance with Article 7:198 juncto Articles 7:179 and 7:191 of the Belgian Companies and Associations Code with respect to the private placement and notes that, to the extent necessary and applicable, in accordance with Article 3:63, §5 of the Belgian Companies Code, the members of the audit committee agree that this assignment, in accordance with the rules and conditions necessary for such reports, is given to the statutory auditor of the Company.

(d) RESOLVED, subject to the finalisation of the Board Report and the report of the statutory auditor of the Company in relation thereto and subject to a final decision to be taken by the Placement Committee (as defined under section (e) below), to approve the passing of the Notarial Board Resolutions before a notary public.

[…]"

1.11.2. Extract of the Notarial Deed recording the Minutes of the Meeting of the Board of Directors of 21 January 2020

"[…]

PRIOR DECLARATIONS BY MR. DEKEYSER RUDY AND MR. AMBLE ERIK

Mr. DEKEYSER Rudy and Mr. AMBLE Erik, both as aforementioned, have indicated to have a conflict of interests within the meaning of article 7:96 of the Belgian Companies and Associations Code with respect to the proposed resolutions included in the agenda of this meeting of the Board of Directors.

Mr. DEKEYSER Rudy informed the Board of Directors that he has an important interest in LSP HEF Sequana Holding B.V. ("LSP"), which company is an affiliate of the company that nominated him as a director of the Company.

Mr. AMBLE Erik informed the Board of Directors that he has an important interest in NeoMed Innovation V L.P. ("NeoMed"), which company (together with NeoMed IV Extension L.P.) has nominated him as director of the Company.

Each of Mr. DEKEYSER Rudy and Mr. AMBLE Erik informed the meeting that the agenda refers to a new fund raising via the capital increase, that LSP and NeoMed, respectively, support the capital increase, and that LSP and NeoMed, respectively, are part of a number of investors that committed to submit an order (directly or indirectly) to the Underwriters to subscribe for new shares in the framework of the capital increase.

Each of Mr. DEKEYSER Rudy and Mr. AMBLE Erik noted that it is contemplated that the new shares shall need to be admitted to trading on the regulated market of Euronext Brussels. For this purpose, the Company is to make the necessary filings and applications, and, as the case may be, prepare a listing prospectus, all as required by applicable regulations, in order to permit an admission to trading following the issue of the new shares. Notably, in accordance with the Prospectus Regulation, up to 2,522,379 new shares can be immediately admitted to trading on Euronext Brussels upon this issuance, without listing prospectus, where the new shares in excess of such number can only be admitted to trading on Euronext Brussels after a listing prospectus has been prepared. Each of Mr. DEKEYSER Rudy and Mr. AMBLE Erik noted that LSP and NeoMed, respectively, have indicated that they would be willing to subscribe for new shares that are not immediately admitted to trading upon their issuance, but only after a listing prospectus has been prepared. LSP and NeoMed are also willing to make available existing shares that are admitted to trading. This could allow the Company to raise more funds via the capital increase than it would have been able to do if the maximum number of new shares issuable in the capital increase is limited to 2,522,379 new shares, and will enable the intervening Underwriters to deliver listed shares to the ultimate investors that will participate in the capital increase.

Each of Mr. DEKEYSER Rudy and Mr. AMBLE Erik hence informed the meeting that, as a result, he may have a conflict of interest within the meaning of Article 7:96 of the Belgian Companies and Associations Code in relation to the resolutions to be passed by the Board of Directors with respect to the Transaction. Mr. DEKEYSER Rudy and Mr. AMBLE Erik will also inform the Company's statutory auditor of the foregoing, as far as needed and applicable in accordance with the provisions of Article 7:96 and/or 7:97 of the Belgian Companies and Associations Code. Despite this potential conflict, however, each of Mr. Dekeyser Rudy and Mr. Amble Erik stated that he believed that the proposed private placement is in the Company's interest, as it will allow the Company to complete the capital increase and raise new funds, which is in the Company's interest.

Subsequently Mr. DEKEYSER Rudy and Mr. AMBLE Erik no longer took part of the further deliberations and resolutions of the Board of Directors with respect to the capital increase.

PRIOR DECLARATIONS BY THE OTHER DIRECTORS

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

CONSIDERATIONS BY THE BOARD OF DIRECTORS IN RELATION TO THE PRIOR DECLARATIONS

The remaining members of the Board of Directors took note of the prior declarations by Mr. DEKEYSER Rudy and Mr. AMBLE Erik.

The Board of Directors considered that the report of the Board of Directors referred to under item 1(a) of the agenda in relation to the capital increase and which is submitted for approval by the Board of Directors contains (a) a description of the nature of the capital increase, (b) a description of the consequences of the capital increase for the financial and shareholder rights of the shareholders of the Company, and (c) the justification for the capital increase. This report of the Board of Directors contains further details and will be

publicly available via (amongst others) the website of the Company and is hereby, as far as needed, incorporated by reference into the minutes of this meeting of the Board of Directors.

The Board of Directors also specified that, subject to the launch of the capital increase, the capital increase will be open to institutional, qualified, professional and/or other investors as permitted under applicable private placement exceptions, as mentioned in the aforementioned report, and any final allocation to investors, as the case may be, will be made based on customary objective and pre-identified criteria. While the Company received already subscription commitments from a number of participating investors, the Board of Directors further confirmed that no guarantee will be given as to the final allocation to any of LSP, NeoMed, or any other participating investor, or any of their affiliates or other persons, that any allocation will be made to them, or as to the size of any such allocation.

The Board of Directors has also clarified that the justification of the decision to increase the capital within the framework of the authorised capital and the financial consequences for the Company and its shareholders are described in the report of the Board of Directors referred to under item 1 (a) of the agenda."

[…]

DELIBERATION – DECISIONS

FIRST DECISION: Reports

The report of the Board of Directors of the Company in accordance with Articles 7:198 juncto Articles 7:179 and 7:191 of the Belgian Companies and Associations Code with respect to the proposal of the Board of Directors of the Company to dis-apply, in the interest of the Company, the statutory preferential subscription right of the Company's existing shareholders and, in so far as required, of the Company's existing holders of subscription rights, in connection with the proposed increase of the share capital of the Company in the framework of the authorised capital with a maximum amount ranging between EUR 261,318.46 and EUR 653,296.42 (without issue premium), through the issuance of new shares with a maximum ranging between 2,522,379 and 6,305,950 new shares, which maximum number is still to be determined, to be offered via a private placement, through an accelerated bookbuilding procedure, to a broad group of currently unidentified Belgian and foreign institutional, qualified, professional and/or other investors (including, subject to applicable securities law rules and regulations, natural persons, and it being understood that, with respect to investors other than qualified investors (as defined in the Prospectus Regulation) in Belgium only, the minimum investment amount per investor will be at least EUR 100,000), in and outside of Belgium, on the basis of applicable private placement exemptions, is submitted to the Board of Directors.

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

The Board of Directors approves this report again.

The Board of Directors subsequently takes note of the report of the statutory auditor of the Company in accordance with Articles 7:198 juncto Articles 7:179 and 7:191 of the Belgian Companies and Associations Code with respect to the proposal of the Board of Directors of the Company to dis-apply, in the interest of the Company, the statutory preferential subscription right of the Company's existing shareholders and, in so far as required, of the Company's existing holders of subscription rights, in connection with the proposed increase of the share capital of the Company in the framework of the authorised capital with a maximum amount ranging between EUR 261,318.46 and EUR 653,296.42 (without issue premium), through the issuance of new shares with a maximum ranging between 2,522,379 and 6,305,950 new shares, which maximum number is still to be determined.

The directors declare to have receive a draft of this report prior to the meeting, and declare to have taken note of it. They declare to not have any comments thereon.

[…]

SECOND DECISION: Increase of the share capital in the framework of the authorised capital

The Board of Directors decides to increase of the share capital of the Company in cash in the framework of the authorised capital as set out in Article 8 of the articles of association of the Company with a maximum amount ranging between EUR 261,318.46 and EUR 653,296.42 (without issue premium), through the issuance of new shares with a maximum ranging between 2,522,379 and 6,305,950 new shares, which maximum number is still 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 of the Company (in each case not in favour of one or more persons), subject to the following terms and conditions:

[…]"

1.12. Acquisition of own shares

(Article 7:220 BCAC)

Neither the Company nor any person acting in his own name but on behalf of the Company has acquired shares of the Company during the financial year 2020.

1.13. Transactions under the authorised capital

(Article 7:203 BCAC)

In 2020, the Board of Directors of the Company did not issue any convertible bonds or subscription rights in the framework of the authorised capital.

On 27 January 2020, 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 3,166,666 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 CVBA, a cooperative company with limited liability organised and existing under the laws of Belgium, with registered office at Woluwe Garden, Woluwedal 18, 1932 Sint-Stevens-Woluwe, Belgium, represented by Mr. Peter D'hondt, auditor.

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 Woluwe Garden, Woluwedal 18, 1932 Sint-Stevens-Woluwe, 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 Woluwe Garden, Woluwedal 18, 1932 Sint-Stevens-Woluwe, Belgium, represented by Mr. Peter Dhondt, 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 2020 (dated April 22, 2021) 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

In 2020, 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.

In 2020, 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 The Company's Board of Directors ishas been explicitly authorised to deviate from the provisionsrule 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.

2.3. Composition Board of Directors, Executive Management and Senior Management Team

2.3.1. 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	57	Chair, Independent Non-Executive Director	2019	2022
Mr Ian Crosbie	53	CEO, Executive Director	2019	2022
Mr Rudy Dekeyser	59	Non-Executive Director	2019	2022
Mr Erik Amble	69	Non-Executive Director	2019	2022
Mr Wim Ottevaere(v)	64	Independent Non-Executive Director	2019	2022
Mr Jason Hannon	49	Independent Non-Executive Director	2019	2022

Mr Pierre Chauvineau is an independent non-executive director and the chair of the Company's Board of Directors. Mr Chauvineau has over 29 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 living in Belgium, France, Switzerland, the U.K. and Ireland consistently demonstrating leadership in developing high performance teams and growing the business faster than the market. In 2010, Mr Chauvineau joined 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 for Boston Scientific. He is also an executive board member with U.K. based Creavo Medical Technologies and with London based Rhythm AI. 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 and the Company's Chief Executive Officer. 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. Before that, he 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, Mr Crosbie enjoyed a 20-year career in corporate finance, including Managing Director, Healthcare Investment

(v) Acting as permanent representative of WIOT BV.

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, Curetis, reMYND, Celyad 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. Prior to that, he has been Chairman and controlling shareholder of NeoMed AS, providing investment advisory services, specializing in small and medium sized companies in the pharmaceutical, medical device and diagnostic industries. From 1993 to 1997, NeoMed AS 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. and Sonendo Inc., and currently serves on the Board of Directors of JenaValve Technology Inc., CorFlow Therapeutics AG and Axonics Modulation Technologies Inc. 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 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.

Mr Jason Hannon is an independent non-executive director of the Company. Mr. Hannon has extensive experience in the medical devices industry and is currently Chief Executive Officer at Mainstay Medical International plc, a global medical device company focused on the development and commercialisation of an innovative implantable neurostimulation system designed to treat chronic low back pain. Mr Hannon previously served as President and Chief Operating Officer of NuVasive (NASDAQ:NUVA), a leading medical device company focused on transforming spine surgery with minimally disruptive, procedurally-integrated solutions. He helped grow NuVasive from a small U.S.-centric business with a handful of products into the third largest spine company in the world. During his 12 years at NuVasive, Jason led the international business, was responsible for business development and strategy, and also served as general counsel. Jason has a JD degree from Stanford University Law School and a BA degree from the University of California, Berkeley.

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.

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

2.3.2. Executive Management and Senior Management Team

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

Name	Age	Position
Mr Ian Crosbie	53	Chief Executive Officer
Mrs Kirsten Van Bockstaele(vi)	46	Chief Financial Officer

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

Mrs Kirsten Van Bockstaele is the Chief Financial Officer of Sequana Medical. She is a seasoned finance executive with extensive international experience in the healthcare industry. Mrs Van Bockstaele joined Sequana Medical from Fagron (formerly Arseus), an international pharmaceutical compounding company. Within Fagron, she held a number of senior financial roles, most recently as Vice President of Finance, North America. In this role, Mrs Van Bockstaele was responsible for creating and overseeing the company's financial strategy and policy, positioning Fagron's North American companies for growth. She also played a pivotal role in building out the North American headquarters, supporting the financial integration of acquisitions and assisting in redirecting the company's strategy. Mrs Van Bockstaele previously served as Chief Financial Officer for Arseus Dental & Medical Solutions, where she was instrumental in the coordination, support and control of financial activities in

key European countries. Her previous roles include Financial Controller at Omega Pharma and Audit Manager at PwC. Kirsten Van Bockstaele has a degree in Business Economics from EHSAL and a degree in Financial and Fiscal Sciences from the University of Antwerp, Belgium.

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

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	56	Chief Medical Officer
Dr Gijs Klarenbeek	44	Senior Medical Advisor
Mr Timur Resch	39	Global Vice President QM/QA/RA
Dr Andreas Wirth[vii]	52	Vice President Engineering
Mr Martijn Blom	47	Chief Commercial Officer

Dr. Oliver Gödje is the Chief Medical Officer of the Company. Dr. Gödje has 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.

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 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.

(vii) Dr Andreas Wirth joined Sequana Medical NV as of 4 January 2021.

Dr Andreas Wirth is the 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 responsible for pharmaceutical primary packaging across 17 plants worldwide. Prior to this, he was head of R&D at medi Group managing seven small R&D groups in Germany, France and the US and project manager at Amaxa / Lonza Biologics of medical and laboratory devices. Andreas holds a PhD in applied science and studied physics at the University of Osnabrück, Germany.

Mr Martijn Blom is the Chief Commercial Officer of the Company. Mr Blom has over 15 years' experience in the life sciences industry. Most recently he was the Director of International Marketing at Myriad Genetics, responsible for the marketing development of genetic testing in the international markets. Previous to Myriad, 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.

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: AA Tower, Technologiepark 122, 9052 Ghent, Belgium.

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

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

During 2020, 17 meetings of the Board of Directors were held.

2.5. 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).

2.5.1. 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 statutory auditor, or at the request of the audit committee or of the Board of Directors, with the audit committee or with the Board of Directors, essential issues which are brought to light in the exercise of the statutory audit of the financial statements, which are included in the additional statement to the audit committee, as well as any meaningful shortcomings discovered in the internal financial control system of the Company.

During 2020, 4 meetings of the audit committee were held.

2.5.2. 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 Mr Jason Hannon.

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 2020, 2 meetings of the remuneration and nomination committee were held.

2.6. Activity Report and Attendance at Board and Committee Meetings during 2020

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	17 out of 17 meetings	4 out of 4 meetings	1 out of 2 meetings[viii]
Mr Ian Crosbie	16 out of 17 meetings	4 out of 4 meetings[ix]	2 out of 2 meetings[ix]
Mr Rudy Dekeyser	16 out of 17 meetings	N/A[x]	2 out of 2 meetings
Mr Erik Amble	16 out of 17 meetings	4 out of 4 meetings	N/A[xii]
Mr Wim Ottevaere[xi],[xii]	17 out of 17 meetings	4 out of 4 meetings	2 out of 2 meetings
Mr Jason Hannon[xiii]	15 out of 17 meetings	N/A[x]	2 out of 2 meetings

(viii) The board member attended the meeting as an observer.
(ix) The CEO is invited to the Audit Committee and Nomination and Remuneration Committee by the chair of the relating committee.
(x) The board member is not a member of the specific committee .
(xi) Acting as permanent representative of WIOT BV.
(xii) The board member is chairman of the Audit Committee
(xiii) The board member is chairman of the Nomination and Remuneration Committee

2.7. Independent Directors

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

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

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

Mr Pierre Chauvineau, Mr Wim Ottevaere (WIOT BV) and Mr Jason Hannon 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.

2.8. 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.

2.9. Executive Management and Chief Executive Officer

2.9.1. 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.

2.9.2. 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.

2.10. 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.

2.11. 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.

2.12. Internal Control and Risk Management

2.12.1. 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.

2.12.2. Control Environment

2.12.2.1. 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.

2.12.2.2. 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.

2.12.2.3. 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.

2.12.3. 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.

2.12.4. 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 balance sheet.

2.12.5. 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.

2.12.6. 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, 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 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 2.5.1. of this Corporate Governance Statement.

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

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

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

The accounting team is responsible for producing the accounting figures, whereas the controlling team checks the validity of these figures. These checks include coherence tests by comparison with historical and budget figures, as well as sample checks of transactions according to their materiality.

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

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

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

2.13. 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 below provides an overview of the shareholders that notified the Company, since the completion of the IPO, of their shareholding in the Company pursuant to applicable transparency disclosure rules, up to 31 December 2020. 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[xiv]
Société Fédérale de Participations et d'Investissement SA – Federale Participatie- en Investeringsmaatschappij NV / Belfius Insurance SA[xv]	18 February 2020	2,004,358	12.70%
Capricorn Partners NV[xvi]	14 February 2020	N/A[xvii]	N/A[xvii]
GRAC Société Simple[xviii]	30 January 2020	833,333	5.28%
NeoMed IV Extension L.P. / NeoMed Innovation V L.P[xix]	30 January 2020	4,270,807	27.07%

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

(xv) 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.

(xvi) 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.

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

(xviii) 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.

(xix) A parent undertaking or a controlling person of NeoMed IV Extension L.P. ("NeoMed IV") and NeoMed Innovation V L.P. ("NeoMed V"), informed the Company, by means of a notification dated 30 January 2020, that the aggregate shareholding of NeoMed IV and NeoMed V passively crossed below the threshold of 30% of the outstanding voting rights of the Company. The notification specifies furthermore 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 partnerships that own the voting rights attached to the securities and that, as general partners to its partnerships, NeoMed IV and NeoMed V exercise the voting rights attached to the securities at their discretion in the absence of specific instructions. The previous number of voting rights that was notified by NeoMed IV and NeoMed V amounted to, respectively, 2,853,673 and 1,342,968, being 4,196,641 in total.

	Date of Notification	Number of Shares	% of the voting rights attached to Shares[xiv]
Newton Biocapital I Pricav Privée SA[xx]	21 February 2019	1,102,529	6.99%
Venture Incubator AG / VI Partners AG[xxi]	21 February 2019	525,501	3.33%
LSP Health Economics Fund Management B.V.[xxii]	19 February 2019	1,539,407	9.76%
Participatiemaatschappij Vlaanderen NV[xxiii]	18 February 2019	1,223,906	7.76%

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) 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.

(xxi) VI Partners AG, 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, the joint shareholding of VI Partners AG and Venture Incubator AG crossed the threshold of 3% of the outstanding voting rights of the Company. The joint notification specifies furthermore that VI Partners AG is not a controlled entity within the meaning of article 5 and 7 of the Belgian Companies Code of 7 May 1999. The notification also states that (a) VI Partners AG is a shareholder and the management company of Venture Incubator AG, a multi-investor investment company, and (b) it is authorised to exercise the voting rights in the shares held by Venture Incubator AG at its free discretion, in the absence of specific instructions.

(xxii) A parent undertaking or a controlling person of LSP Health Economics Fund Management B.V. ("LSP"), informed the Company, by means of a notification dated 19 February 2019 that, as a result of the completion of the IPO, on 11 February 2019, LSP's shareholding crossed the threshold of 10% of the outstanding voting rights of the Company. The notification specifies furthermore that LSP is controlled by LSP Management Group BV within the meaning of the articles 5 and 7 of the Belgian Companies Code of 7 May 1999 and that LSP Management Group BV is no controlled undertaking. The notification also states that (a) LSP is not an owner of the shares of the Company, but manages the funds that own the shares of the Company, (b) LSP exercises the voting rights of the funds as management company, and (c) LSP can exercise the voting rights of the funds at its own discretion at the general meeting of shareholders of the Company.

(xxiii) 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.

2.14. Share Capital and Shares

On 31 December 2020, the share capital of the Company amounts to EUR 1,635,006.12 and is fully paid-up. It is represented by 15,778,566 ordinary shares, each representing a fractional value of (rounded) EUR 0.1036 and representing one 15,778,566th 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 amounted to 1,308,733, which entitles their holders (if exercised) to subscribe to 1,804,791 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"**);
- 295,782 new shares can be issued upon the exercise of 102,527 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
- 1,206,205 new shares can be issued upon the exercise of 1,206,205 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"**).

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. The loan has a term of 36 months, and is repayable in full upon expiry of the term. The loan bears an interest of 6% per annum, except that the convertible portion of the loan bears an interest of 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

2.14.1. 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 the date of this report, all of the Company's shares have been admitted to trading on the regulated market of Euronext Brussels.

2.14.2. 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.

2.14.3. 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 intends to submit for the first time to the general shareholders' meeting to be 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.

2.14.4. 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 2020 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 balance sheet, 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.

2.15. 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 1,920,626.45 and is fully paid-up. It is represented by 18,535,519 ordinary shares, each representing a fractional value of (rounded) EUR 0.1036 and representing one 18,535,519th 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 and the 2018 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.

2.16. Diversity & Inclusiveness

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

The Board of Directors is currently composed of only men. 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 2021 in order to align the current remuneration policy of the Company with the requirements of Article 7:89/1 BCAC. If a significant proportion of the votes were to be cast against this revised 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.

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 (other than, for now, the non-executive independent directors) is in principle also entitled to receive share options or subscription rights. The aforementioned possibility to grant share options to non-executive directors (other than to non-executive independent 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 (other than the non-executive independent 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-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. The Company is still considering whether share options or subscription rights will be granted to non-executive independent directors, but has not yet formally concluded on this matter. 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-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 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 (other than independent non-executive 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.

In addition, the Company will submit a new share option plan (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 or her share options. For approval by the extraordinary shareholders' meeting of 27 May 2021.

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 2020 (dated 22 April 2021) 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 2021 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 prepared a new remuneration policy that the Board of Directors intends to submit to the shareholders for approval at the occasion of the annual general shareholders' meeting to be held on 27 May 2021. The aforementioned remuneration policy can be consulted on the Company's website and has been included in the Section "Remuneration Policy" of the 2020 Annual Report.

No significant change to the remuneration policy is envisaged for 2021 or 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 (other than non-executive independent directors) is in principle entitled to receive share options or subscription rights. Part of the 2018 Share Options and 2021 Share Options (to be approved by the extraordinary shareholders' meeting of the Company of 27 May 2021) can be used for this purpose. The abovementioned possibility to grant share options to non-executive directors (other than to non-executive independent 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 that are still in a development phase. Notably, the ability to remunerate non-executive directors (other than the non-executive

independent 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. The Company is still considering whether share options or subscription rights will be granted to non-executive independent directors, but has not yet formally concluded on this matter.

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.

As mentioned, a revised (stand-alone) remuneration policy will be submitted for approval to the annual general shareholders' meeting of the Company to be held on 27 May 2021 in order to align the current remuneration policy of the Company with the requirements of Article 7:89/1 of the Belgian Companies and Associations Code.

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

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 2020

During 2020, 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	0
Wim Ottevaere (WIOT BV)	50,000	0
Jason Hannon	40,000	0

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 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.

As mentioned, a revised (stand-alone) remuneration policy will be submitted for approval to the annual general shareholders' meeting of the Company to be held on 27 May 2021 in order to align the current remuneration policy of the Company with the requirements of Article 7:89/1 of the Belgian Companies and Associations Code. The Company will continuously review the remuneration of members of the Executive Management against market practice.

4.4.2. Remuneration and compensation in 2020

In 2020, 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	280,993.59	62.91%	246,000.00	83.56%
Pension plan[xxvi]	14,049.68	3.15%	N/A	N/A
Insurance plan[xxvii]	1,130.40	0.25%	N/A	N/A
Car lease/transport allowance	10,790.15	2.42%	N/A	N/A
Medical plan	4,809.79	1.08%	N/A	N/A
Bonus plan[xxviii]	134,876.92	30.20%	48,384.00	16.44%
Total	**446,650.55**	**100.00%**	**294,384.00**	**100.00%**

In 2020, the Board of Directors has decided to establish the Company's performance at 80% (reflecting the level of achievement of the Company's 2019 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 2020 to the members of the Executive Management.

In 2020, 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 72,060.25.

(xxiv) The amount is paid in GBP to the CEO. The conversion applied to EUR is performed on the average GBP/EUR rate of 2020 of the ECB.
(xxv) Acting through 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

	2016	2017		2018		2019		2020	
	EUR	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year
Directors and Executive Management	216,514	422,470	95%	586,794	39%	834,090	42%	901,035	8%

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

	2016	2017		2018		2019		2020	
	EUR	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year
Employees	148,621	120,508	-19%	114,071	-5%	109,695	-4%	109,886	0%

Note:

- The average remuneration on a full-time basis of 2016, 2017 and 2018 is less comparable to 2019 and 2020 as this was prior to the seat transfer to Belgium and the subsequent IPO (February 2019).
- In 2019 and 2020, 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	2016	2017		2018		2019		2020	
	EUR	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year
Net loss for the period	-13,975,000	-8,225,189	-41%	-13,983,224	70%	-14,977,445	7%	-19,106,205	28%
Total Equity	-6,667,000	-4,610,672	-31%	-18,759,747	307%	925,932	-105%	112,761	-88%
Paid dividends	0	0	0	0	0	0	0	0	0
Market capitalisation at 31 December	NA	NA	NA	NA	NA	78,950,494	NA	186,305,079	136%

The ratio between the highest and lowest remuneration in 2020 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 2020, has a number of outstanding options that are exercisable into ordinary shares, consisting of:

- 295,782 new shares can be issued upon the exercise of 102,527 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
- 1,206,205 new shares can be issued upon the exercise of 1,206,205 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').

In addition, the Company will submit a new share option plan (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 or her share options. For approval by the extraordinary shareholders' meeting of 27 May 2021.

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 2020.

	Number of Shares issuable	
Name	**Executive Share Options**	**2018 Share Options**
Ian Crosbie	216,442	80,839
Kirsten Van Bockstaele[xxix]	6,226	40,419

In financial year 2020, 51,034 share options lapsed as a result of the termination of a number of employment contracts.

(xxix) Acting through 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 (to be submitted for approval to the extraordinary shareholders' meeting of the Company of 27 May 2021) 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 2020, with the exception of Mr Wim Ottevaere, who holds 15,200 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), Mr Pierre Chauvineau (10,192) and Mr Jason Hannon (10,192). No share options were granted to non-executive directors in 2020.

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

3

Financial Report

Financial Report

for the financial years ended december 31, 2020 and 2019

Annual Report 2020

1. Statement of the Board of Directors

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

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

The amounts in this document are represented in euros (EUR), unless noted otherwise.

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 2020

26 April 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. 1 October 2018, 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 2020. We have performed the statutory audit of the Company's consolidated accounts for 3 consecutive years.

2.1. Report on the consolidated accounts

2.1.1. Unqualified opinion

We have performed the statutory audit of the We have performed the statutory audit of the Group's consolidated accounts, which comprise the consolidated statement of financial position as at 31 December 2020, the consolidated statement of profit or loss and other 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 14,213,451 and a loss for the year of EUR 19,106,205.

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 2020, 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 and subject to various risks and uncertainties, including but not limited to the timing of achieving profitability and the substantial uncertainty of the development process. 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 judgment, 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 intend 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 Board of 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 judgment 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 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 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. 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.

2.2.5. 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 2021

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 December 31

In EUR	Notes	2020	2019
Revenue	5	**963,280**	**970,636**
Costs of goods sold		(202,411)	(197,756)
Gross Margin		**760,869**	**772,880**
Sales & Marketing		(2,321,754)	(2,838,080)
Clinical		(6,107,833)	(3,921,531)
Quality & Regulatory		(2,232,323)	(1,817,236)
Supply Chain		(1,635,729)	(930,654)
Engineering		(1,859,279)	(982,515)
General & administration	7.2	(4,416,535)	(4,264,188)
Other income		41,467	17,713
Total Operating Expenses		**(18,531,986)**	**(14,736,490)**
Earnings before interests and taxes (EBIT)		**(17,771,117)**	**(13,963,610)**
Finance income	7.4	169,547	52,755
Finance cost	7.4	(1,347,609)	(930,592)
Net Finance Cost		**(1,178,063)**	**(877,837)**
Income Tax Expense	7.5	(157,025)	(135,998)
Net loss for the period		**(19,106,205)**	**(14,977,445)**
Attributable to Sequana shareholders		(19,106,205)	(14,977,445)
Basic loss per share	7.6	(1.25)	(1.22)

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

4.
Consolidated statement of comprehensive income for the years ended December 31

In EUR	Notes	2020	2019
Net loss for the period		**(19,106,205)**	**(14,977,445)**
Components of other comprehensive income (OCI) items that will not be reclassified to profit or loss: Remeasurements of defined benefit plans	8.7	(14,703)	209,155
Items that may be reclassified subsequently to profit or loss: Currency translation adjustments		(108,480)	75,465
Total other comprehensive income/(loss)-net of tax		**(123,183)**	**284,620**
Total comprehensive income		**(19,229,387)**	**(14,692,825)**
Attributable to Sequana shareholders		(19,229,387)	(14,692,825)

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

5.
Consolidated statement of financial position

In EUR	Notes	Total December 31, 2020	Total December 31, 2019
Property, Plant and Equipment		**704,718**	**765,396**
Laboratory	8.4	65,592	70,684
Information Technology (IT)	8.4	234,663	158,694
RD Tools	8.4	701	4,129
Right-of-use assets	8.4	392,616	510,453
Other tangible Fixed Assets	8.4	11,147	21,436
Assets under construction	8.4	-	-
Financial assets		**67,305**	**63,149**
Financial assets - Rental deposit		67,305	63,149
Total non-current assets		**772,023**	**828,545**
Trade Receivables		**23,625**	**117,520**
Trade Receivables - Third parties	8.2	23,625	117,520
Other Receivables		**930,005**	**1,219,983**
Other Receivables - Third parties	8.2	313,598	507,130
Other Receivables - prepaid expenses	8.2	616,407	712,853
Inventory		**1,471,655**	**1,597,623**
Inventory	8.3	1,471,655	1,597,623
Cash and cash equivalents		**11,016,143**	**5,586,470**
Cash and cash equivalents	8.1	11,016,143	5,586,470
Total current assets		**13,441,429**	**8,521,597**
TOTAL ASSETS		**14,213,451**	**9,350,142**

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

In EUR	Notes	Total December 31, 2020	Total December 31, 2019
Total Equity		**112,761**	**925,932**
Share Capital	8.5	1,635,006	1,306,940
Share premium	8.5	119,332,864	100,660,934
Reserves		(2,250,413)	(1,651,931)
Loss brought forward		(119,080,220)	(99,974,015)
Cumulative Translation Adjustment		475,525	584,005
Long term financial debts		**7,472,701**	**2,260,905**
Long term financial debts	8.6	7,472,701	2,260,905
Long term lease debts		**122,942**	**305,046**
Long term lease debts	8.6	122,942	305,046
Retirement benefit obligation		**539,042**	**543,601**
Retirement benefit obligation	8.7	539,042	543,601
Total non-current liabilities		**8,134,686**	**3,109,553**
Short term financial debts		**-**	**459,495**
Short term financial debts	8.6	-	459,495
Short term lease debts		**263,700**	**199,158**
Short term lease debts	8.6	263,700	199,158
Trade Payables		**2,802,488**	**2,476,373**
Trade Payables - Third parties	8.8	2,013,178	1,687,460
Contract liabilities	5	789,311	788,913
Other payables		**1,523,426**	**1,269,415**
Other payables - Third parties	8.8	1,523,426	1,269,415
Accrued liabilities		**1,376,390**	**910,216**
Accrued liabilities - Provision warranty	8.8	77,545	70,268
Accrued liabilities - Third parties	8.8	1,298,845	839,947
Total current liabilities		**5,966,004**	**5,314,657**
TOTAL EQUITY AND LIABILITIES		**14,213,451**	**9,350,142**

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

6. Consolidated statement of changes in equity

IN EUR	Notes	Share capital	Other Equity	Share premium	Reserves	Loss brought forward	Currency translation differences	Total shareholder equity
Balance at 1 January 2019		**887,977**	**184,478**	**64,963,284**	**(451,652)**	**(85,003,302)**	**659,469**	**(18,759,746)**
Change in accounting policy						6,732		6,732
Restated total equity at 1 January 2019		**887,977**	**184,478**	**64,963,284**	**(451,652)**	**(84,996,571)**	**659,469**	**(18,753,014)**
Net loss for the period						(14,977,445)		(14,977,445)
Other comprehensive income	8.7				209,155		(75,465)	133,690
Capital increase IPO (convertible loans)	8.5	83,786		8,532,737				8,616,523
Capital increase IPO (contribution in cash)	8.5	318,902		25,845,840				26,164,743
Capital increase IPO (contribution in kind)	8.5	16,274		1,319,073				1,335,347
Transaction costs for equity instruments	7.2				(1,798,590)			(1,798,590)
Conversion rights on convertible loans	8.6		(184,478)					(184,478)
Share-based compensation	9				389,156			389,156
December 31, 2019		**1,306,940**	**-**	**100,660,934**	**(1,651,931)**	**(99,974,015)**	**584,005**	**925,932**
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	8.7				(14,703)		(108,480)	(123,183)
January 2020 Equity Placement	8.5	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
December 31, 2020		**1,635,006**	**-**	**119,332,864**	**(2,250,413)**	**(119,080,220)**	**475,525**	**112,761**

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

7. Consolidated statement of cash flows

In EUR	Notes	2020	2019
Net loss for the period		**(19,106,205)**	**(14,977,445)**
Income tax expense	7.5	157,025	135,998
Financial result	7.4	1,046,846	877,837
Depreciation		306,525	244,088
Change in defined benefit plan	8.7	(21,854)	(68,061)
Share-based compensation	9	255,860	389,156
Changes in trade and other receivables	8.2	383,873	(791,176)
Changes in inventories	8.3	125,968	(362,197)
Changes in trade and other payables / accrued liabilities	8.8	(116,862)	(3,921,680)
Taxes paid		(36,404)	(8,872)
Cash flow from operating activities		**(17,005,228)**	**(18,482,352)**
Investments in tangible fixed assets	8.4	(138,017)	(106,022)
Investments in financial assets		(4,014)	(4,000)
Cash flow used for investing activities		**(142,031)**	**(110,022)**
Proceeds from capital increase	8.5	18,999,996	26,164,837
(Repayments) from leasing debts		(273,690)	(227,002)
(Repayments) from financial debts	8.6	(3,201,376)	(1,667,495)
Proceeds from financial debts	8.6	7,300,000	
Interest paid	8.6	(194,395)	(1,279,416)
Cash flow from financing activities		**22,630,535**	**22,990,924**
Net change in cash and cash equivalents		**5,483,275**	**4,398,550**
Cash and cash equivalents at the beginning of the period		**5,586,470**	**1,317,697**
Net effect of currency translation on cash and cash equivalents		(53,602)	(129,776)
Cash and cash equivalents at the end of the period		**11,016,143**	**5,586,470**

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 October 1, 2018). As a result, Sequana Medical NV became a limited liability company organised under the laws of Belgium.

The registered office’s address is Technologiepark 122, AA Tower, 9052 Ghent, Belgium.

Sequana Medical is a commercial stage medical device company developing the **alfa**pump platform for the treatment of fluid overload in liver disease, malignant ascites and heart failure where diuretics are no longer effective. Fluid overload is a fast growing complication of advanced liver disease driven by NASH (non-alcoholic steatohepatitis) related cirrhosis and a common complication in heart failure. Both indications leverage Sequana Medical’s **alfa**pump, a unique, fully implanted wireless device that automatically pumps fluid from the abdomen into the bladder, where it is naturally eliminated through urination.

The **alfa**pump has been granted breakthrough device designation by the U.S. FDA for recurrent or refractory liver ascites with a pivotal study underway. It is also approved in Europe for refractory liver ascites and malignant ascites. Over 850 **alfa**pump systems have been implanted to date. The **alfa**pump DSR (Direct Sodium Removal) builds on this experience and is in clinical development to treat diuretic-resistant fluid overload in heart failure.

1.1. Group information

1.1.1. Information about the subsidiaries

The consolidated financial statements of Sequana Group include:

Company	Purpose	Share capital	Investment 2020	Investment 2019
Sequana Medical NV	Holding/Sales	EUR 1,635,006	**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 December 31, 2020, is as follows:

Shareholder	Shares	%
NeoMed IV Extension L.P. / NeoMed Innovation V L.P	4,270,807	27.1%
LSP Health Economics Fund Management B.V.	1,706,077	10.8%
Participatiemaatschappij Vlaanderen NV	1,540,572	9.8%
Société Fédérale de Participations et d'Investissement SA - Federale Participatie- en Investeringsmaatschappij NV	1,297,234	8.2%
Newton Biocapital I Pricav Privée SA	1,102,529	7.0%
GRAC Société Simple	833,333	5.3%
Belfius Insurance SA	707,124	4.5%
Venture Incubator AG / VI Partners AG	525,501	3.3%
Total threshold	**11,983,177**	**75.9%**
Other	3,795,389	24.1%

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 have been prepared on an historical cost basis, except for items measured at fair value. 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. Section 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 and Marketing, Clinical Affairs, Quality and Regulatory, Supply Chain, Engineering and General and Administration.

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

The costs of obtaining and maintaining regulatory approval for the **alfa**pump (and potentially in the future the **alfa**pump DSR) are included within quality and regulatory expenses. Employee related costs, such as salaries, benefits and travel expenses, of Sequana Medical employees are a key part of quality and 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, are also included within quality and regulatory expenses.

The consolidated financial statements were approved for issue by the Board of Directors on 22 April 2021.

2.2. Principles of consolidation

The consolidated financial statements of Sequana 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'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 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 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, 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 part of trade and other payables. 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.

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

2.3.1.2. 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.

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

2.3.1.3. CURRENT VERSUS NON-CURRENT CLASSIFICATION

In the Group's consolidated financial statements assets and liabilities are classified as current or non-current.

An **asset** is current when it is:

- expected to be realized or intended to be sold or consumed in the normal operating cycle
- held primarily for the purpose of trading
- expected to be realized within twelve months after the reporting period

Or

- cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least twelve months after the reporting period

All other assets are classified as non-current.

A **liability** is current when:

- it is expected to be settled in the normal operating cycle
- it is held primarily for the purpose of trading
- it is due to be settled within twelve months after the reporting period

Or

- there is no unconditional right to defer the settlement of the liability for at least twelve months after the reporting period

The Group classifies all other liabilities as non-current.

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 2020 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 balance sheet presented are translated at the closing rate at the date of that balance sheet
- 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 2020 and the comparative periods to translate the following currencies into EUR, are as follows:

Currency	December 31, 2020		December 31, 2019	
	Year-end	Average Rate	Year-end	Average Rate
Swiss Franc (CHF)	1.0802	1.0705	1.0854	1.1124
US Dollar (USD)	1.2271	1.1422	1.1234	1.1195

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 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
Laboratory	Straight-line	5 - 10 years
IT	Straight-line	3 - 10 years
RD Tools	Straight-line	10 years
Leased assets	Straight-line	Contract lease term

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 IAS 38, 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. 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.

2.3.1.10. CASH ON HAND

Cash on hand 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.

2.3.1.11. 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.

2.3.1.12. 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 balance sheet date. 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

2.3.1.13. 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 – Third parties' 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 balance sheet 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.

2.3.1.14. LOANS AND BORROWINGS

After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortized cost using the effective interest method. Gains and losses are recognized in profit or loss when the liabilities are derecognized as well as through the effective and 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 and interest method. The amortization is included as finance costs in the statement of profit or loss. This category generally applies to interest-bearing loans and borrowings.

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, these are the EUR denominated loans in particular.

Compound financial instruments include a liability component and an equity component whereby the convertible loan can only be settled by the issue of a fixed number of shares for a fixed amount of cash (i.e. no contractual obligation to deliver a variable number of the group's equity instruments). On initial recognition, the liability component is measured at its fair value. For compound instruments containing more than one non-equity derivative, the value of non-equity derivatives is included in the liability component. The value of the liability component is established by measuring a loan's fair value with similar terms, credit status and containing similar non equity derivative features (if any), but without the equity conversion feature. The equity component is measured as the residual amount that results from deducting the fair value of the liability component from the initial carrying amount of the instrument as a whole. Subsequent to initial recognition, the liability component (host debt contract) is measured based on its amortised cost, using the effective interest method. Non-equity derivatives (if any) that are not closely related to the host debt contract are accounted for separately and subsequently measured at fair value. Equity components are not remeasured subsequently.

Alternatively, 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.

Under method 2) the value of the derivative would correspond to the fair value of the conversion option while the initial carrying amount of the host instrument is the residual amount to the consideration received.

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).

In light of the facts and circumstances described above, the change in fair value from the re-measurement for the above convertible loans, shall be presented in profit or loss.

The Group has no other derivative financial instruments, in all material respect, to hedge interest rates and foreign currency risks.

2.3.1.15. 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.

2.3.1.16. SHARE-BASED COMPENSATION TRANSACTIONS

The Group has offered equity-settled, share-based compensation plans to its employees, Executive Management and 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.

2.3.1.17. LEASES

As from 2019, an accounting policy change took place where the group is the lessee as a result from the adoption of IFRS 16.

The new lease accounting policy is as follows:

The Group leases various company cars and buildings. Rental contracts for the cars are typically made for fixed periods of 4 years and the rental contracts for the offices are typically made for 2 to 3 years. The contracts have no 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.

Until the 2018 financial year, leases of property, plant and equipment were classified as operating lease. Payments made under operating leases (net of any incentives received from the lessor) were charged to profit or loss on a straight-line basis over the period of the lease.

From 1 January 2019, 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.

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.

2.3.1.18. 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 2020 and 2019 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'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 is subject to risks and uncertainties, which may lead to actual results differing from these estimates, both positively and negatively. Sequana'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 balance sheet 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 8.7.

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. 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 2020 and 31 December 2019:

Description	Note	Level	At 31 december 2020 in EUR	At 31 december 2019 in EUR
EUR denominated convertible loans at fair value through PL	8.6	3	1,428,602.74	0

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 interest rate of 5% in the most recent loan with related parties, which is deemed to be the best indicator of the market interest rate for loans without conversion features for Sequana.

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 Dec. 2020	1,428,602.74
Unobservable inputs	Discount rate / market rate
Input range (probability-weighted average)	5%
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 – 11,441/+ 11,441

As the discount rate / market interest rate 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.

2.3.2.3. 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 section 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 January, 18 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 section 9.2.

Employee turnover as a parameter for share-based payment calculations is considered to be limited.

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 2020 and have

been endorsed by the European Union and have no material impact on the Sequana Group consolidated financial statements:

- Amendments to References to the Conceptual Framework in IFRS Standards (effective 1 January 2020). The revised Conceptual Framework includes a new chapter on measurement; guidance on reporting financial performance; improved definitions and guidance—in particular the definition of a liability; and clarifications in important areas, such as the roles of stewardship, prudence and measurement uncertainty in financial reporting.
- Amendments to the definition of material in IAS 1 and IAS 8 (effective 1 January 2020). The amendments clarify the definition of material and make IFRSs more consistent. The amendment clarifies that the reference to obscuring information addresses situations in which the effect is similar to omitting or misstating that information. It also states that an entity assesses materiality in the context of the financial statements as a whole. The amendment also clarifies the meaning of 'primary users of general purpose financial statements' to whom those financial statements are directed, by defining them as 'existing and potential investors, lenders and other creditors' that must rely on general purpose financial statements for much of the financial information they need. The amendments are not expected to have a significant impact on the preparation of financial statements.
- Amendments to IFRS 9, IAS 39 and IFRS 7: Interest Rate Benchmark Reform (effective 1 January 2020). The amendments require qualitative and quantitative disclosures to enable users of financial statements to understand how an entity's hedging relationships are affected by the uncertainty arising from interest rate benchmark reform.

The following new amendments have been issued, is not mandatory for the first time for the financial year beginning 1 January 2020 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 (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, but are not mandatory for the first time for the financial year beginning 1 January 2020 and have not been endorsed by the European Union and are currently not expected to have a material impact on the Sequana Group consolidated financial statements:

- Amendments to IAS 1 'Presentation of Financial Statements: Classification of Liabilities as current or non-current' (effective 1 January 2022), 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. The IASB has issued an exposure draft to defer the effective date to 1 January 2023. 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 16 Property, Plant and Equipment; IAS 37 Provisions, Contingent Liabilities and Contingent Assets as well as Annual Improvements (effective 01/01/2022). 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 make minor amendments to IFRS 1 First-time Adoption of International Financial Reporting Standards, IFRS 9 Financial Instruments and the Illustrative Examples accompanying IFRS 16 Leases.
- 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.

The Group is continuously assessing the impact of the upcoming standards. The Group expects currently no material impact on the Sequana Group 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 2020 do not have any significant impact on the Sequana Group Consolidated Financial Statements.

3. Financial Instruments and Financial Risk Management

The nature of Sequana'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 2020 (CHF)	31 December 2019 (CHF)
Assets		
Inventory	1,664,476	1,801,841
Cash and cash equivalents	625,392	663,204
Liabilities		
Long term debt	0	2,453,987
Short term debt	0	498,736

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 and equity	
In EUR	As at 31 December 2020	As at 31 December 2019
5% decrease of average foreign exchange rate	-370,773	-321,532
5% increase of average foreign exchange rate	+370,714	+322,082

As of 31 December 2020, 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 370,773 higher (2019: EUR 321,532). 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 370,714 lower (2019: EUR 322,082).

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 2020	As at 31 December 2019
50 basis points increase/decrease	-/+ 2,860	-/+ 53,309

As at 31 December 2020 and 31 December 2019, 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 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 2020	Total	Up to 1 year	1 to 3 years	More than 3 years
Trade payable	2,802,488	2,802,488	2,802,488		
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**

		Cash outflows			
In EUR	Carrying amount 31 December 2019	Total	Up to 1 year	1 to 3 years	More than 3 years
Trade payable	2,476,373	2,476,373	2,476,373		
Other payables	1,773,619	1,838,161	1,533,115	305,046	
Financial debt at amortized costs	3,168,636	3,168,636	780,375	2,388,261	
Interest payment on financial debt	0	0			
Total	**7,418,628**	**7,483,170**	**4,789,864**	**2,693,307**	**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 2020 and 2019.

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 Company's ability to continue operations also depends on its ability to raise additional capital and to refinance existing debt, in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows.

The future impact of COVID-19 on the Company's ability to secure additional financing rounds or undertake capital market transactions remains unclear at this point in time and will remain under review by the Executive Management and the Board of Directors.

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

The consolidated statement of financial position as at 31 December 2020 shows a positive equity in the amount of EUR 0.1 million and ending cash balance of EUR 11.0 million. The Company will continue to require additional financing in the near future and in that respect already successfully raised EUR 22.5 million in February 2021 in a private equity placement via an accelerated book building offering disclosed in the note 16 Events after the reporting period in the Notes to consolidated financial statements. Together with existing cash resources, the net proceeds from these financing rounds are expected to extend the current cash runway of the Company into Q2 2022. The Company continues to evaluate equity and other financing options, including discussions with existing and/or new investors.

As a result, the Board of Directors remains confident that the liquidity requirements for the next twelve months can be secured based upon its current assessment of the COVID-19 situation and its impact on our ability to conduct clinical trials. 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 to note 16 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	2020	2019
Trade receivables	23,625	117,520
Contract liabilities (relating to customers' advance payments)	789,311	788,913

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	2020	2019
Revenue recognized in the period (included in contract liability at the beginning of the period)	0	(57,357)
Increases due to cash received as advance payment	-	-
Effect of currency translation	397	1,081

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

The Group applies the practical expedient of IFRS 15 (paragraph 121), and does not disclose information about the aggregate transaction price of remaining performance obligations that have original expected durations of one year or less. The Group also applies the practical expedient in paragraph 94 of IFRS 15, whereby the incremental costs of obtaining contracts are expensed as incurred if the amortization period of the assets that the Group would otherwise have recognized is one year or less.

6. Segment information

Operating segments required to be reported are determined on the basis of the management approach. Accordingly, external segment reporting reflects the internal organizational and management structure used within the Group as well as the internal financial reporting to the Chief Operating Decision Maker (CODM), which has been identified as the Executive Management Board (EMB). The EMB is responsible for the operational management of the Group, in line with the instructions issued by the Board of Directors.

Based on the Group's structure Sequana's only entity, 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 constitutes only one reportable segment, which is represented by the whole group.

Nevertheless, the EMB monitors all revenues on a country basis.

An overview of revenue by primary geographic market for the Group's reportable segment is included below:

Geographical market in EUR	2020	2019
Germany	691,000	761,875
France	171,125	57,125
Switzerland	62,605	107,659
Rest of the world	38,550	43,978
Total revenue	963,280	970,636

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, 28% of the assets are located in Switzerland compared to 46% 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	2020	2019
Personnel costs	6,934,950	6,098,516
Clinical Studies	4,436,698	2,520,685
External consultancy	1,805,617	1,266,069
External accounting & legal services	979,192	494,412
Travel & Lodging	341,305	869,096
Rent & infrastructure expenses	257,665	204,698
Intellectual Property	328,842	210,366
Insurance & IT	455,786	625,714
Marketing	158,160	263,653
Depreciation and amortization (1)	306,525	244,088
Quality Audits / Regulatory Fees	927,486	785,768
Other	1,599,761	1,153,424
Total operating expenses	**18,531,986**	**14,736,490**

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

7.2. Operating Expenses – General and Administration

Expenses in EUR	2020	2019
IPO and capital increase related expenses	358,089	548,824

The total amount of known and accrued capital raise related expenses for 2020 is 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 attributed to new shares.

In 2019, the total amount of known and accrued IPO related expenses was EUR 2,347,414, of which EUR 548,824 has been recognized in the Consolidated Income Statement as G&A expenses and EUR 1,798,590 has been reported under equity. The IPO expenses accounted for in equity relate to an anticipated issuance of equity instruments and represent the incremental costs attributable to new shares.

7.3. Leases

On adoption of IFRS 16 on 1 January 2019 the Group recognized leased assets and lease liabilities in relation to leases which had previously been classified as 'operating leases' under the principle of IAS 17.

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

In EUR	
Buildings	150,598
Cars	62,777
Total	**213,375**

Following the implementation of IFRS 16, the expenses related to low-value leases and variable lease payments not recognised as lease liability are considered not to be material.

7.4. Financial result

The financial result is split into the following categories:

In EUR	2020	2019
Finance income	**169,547**	**52,755**
Interest income	9,912	190
Foreign exchange gains	159,634	52,565
Finance cost	**(1,347,609)**	**(930,592)**
Interest costs	(1,022,742)	(724,964)
Interest costs IFRS 16	(52,908)	(45,623)
Foreign exchange losses	(271,959)	(160,005)
Net financial result	**(1,178,063)**	**(877,837)**

7.5. Income taxes

7.5.1. Income tax expense

In EUR	2020	2019
Current income taxes	(157,025)	(135,998)
Total income tax expense	**(157,025)**	**(135,998)**

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	2020	2019
Loss before tax	**(18,949,180)**	**(14,841,447)**
Current income taxes	25.00%	29.58%
Income tax income at the applicable tax rate	**(4,737,295)**	**(4,390,100)**
Effect of non-recognition of tax losses in current year	(4,580,270)	(4,254,102)
Effective income tax expense	**(157,025)**	**(135,998)**

The applicable 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 2020 and 2019, 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	December 31, 2020	December 31, 2019
Deferred tax assets not recognized on deductible temporary differences	-	-
Deductible temporary differences for which no deferred tax asset has been recognized	-	-
Belgium	33,833,432	13,054,511
Switzerland	-	-
USA	704,672	718,960
Total unused tax losses	**34,538,103**	**13,773,471**

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 2020 estimated tax amount, amounting to CHF 190,000 or EUR 175,893 has been accrued for in the statement of financial position, Accrued Liabilities-Third parties.

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	2020	2019
Net loss attributable to shareholders	(19,106,205)	(14,977,445)
Weighted average number of shares - basic	15,310,073	12,296,042
Basic loss per share	**(1.25)**	**(1.22)**

8. Detailed information on balance sheet items

8.1. Cash and cash equivalents

The Group held cash and cash equivalents of EUR 11,016,143 at 31 December 2020 (2019: EUR 5,586,470).

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	December 31, 2020	December 31, 2019
Trade receivables	23,625	117,520
Other receivables - Third parties	313,598	507,130
Other receivables - prepaid expenses	616,407	712,853

Other receivables – Third parties mainly consist of VAT.

The total amount of Other receivables – prepaid expenses in the Balance Sheet amounts to EUR 616,407 (in 2019: EUR 712,853). For 2020 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 2020 and 2019 past due, but not impaired, are as follows:

2019 (In EUR)	Not past due	Total past due	0-90 days	180 days	180-360 days	More than 360 days
Trade receivables	74,445	67,150	43,075		24,075	
Weighted average loss rate	0%					

Note that in 2019 there was a provision for bad debt, amounting to EUR 24,075.

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

8.3. Inventories

Inventories are categorized as follows:

In EUR	December 31, 2020	December 31, 2019
Finished goods	288,502	362,498
Subassembly	195,429	158,629
Components	987,725	1,076,496
Total	**1,471,655**	**1,597,623**

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

Reconciliation of beginning and ending balance by classes of assets:

				Leased Fixed Assets				
Cost (in EUR)	**Laboratory**	**IT**	**RD Tools**	**Buildings**	**Cars**	**Other tangible fixed assets**	**Assets under construction**	**Total**
December 31, 2018	**27,662**	**323,351**	**22,320**	**-**	**-**	**-**	**4,129**	**377,462**
Additions	74,084	74,459	-	465,619	221,369	23,151	(32,404)	826,277
Currency translation effects	(1,480)	(4,347)	(341)	-	-	-	28,275	22,107
December 31, 2019	**100,267**	**393,462**	**21,979**	**465,619**	**221,369**	**23,151**	**-**	**1,225,846**
Additions	4,442	146,011	-	18,974	133,258			302,684
Disposals					(69,666)			(69,666)
Currency translation effects	(16)	(127)	-					(143)
December 31, 2020	**104,692**	**539,346**	**21,979**	**484,592**	**284,961**	**23,151**	**-**	**1,458,721**

				Leased Fixed Assets				
Accumulated depreciation (in EUR)	**Laboratory**	**IT**	**RD Tools**	**Buildings**	**Cars**	**Other tangible fixed assets**	**Assets under construction**	**Total**
December 31, 2018	**21,895**	**185,117**	**14,899**	**-**	**-**	**-**	**-**	**221,910**
Additions	8,098	54,446	3,301	148,149	28,385	1,715	-	244,094
Currency translation effects	(410)	(4,795)	(350)			-	-	(5,554)
December 31, 2019	**29,583**	**234,768**	**17,850**	**148,149**	**28,385**	**1,715**	**-**	**460,450**
Additions	9,524	69,973	3,430	150,598	62,777	10,289		306,592
Disposals					(12,972)			12,972
Currency translation effects	(7)	(58)	(2)					(67)
December 31, 2020	**39,100**	**304,683**	**21,278**	**298,747**	**78,189**	**12,004**	**-**	**754,003**
Net book value December 31, 2019	**70,684**	**158,694**	**4,129**	**317,469**	**192,984**	**21,436**	**-**	**765,396**
Net book value December 31, 2020	**65,592**	**234,663**	**701**	**185,845**	**206,771**	**11,147**	**-**	**704,718**

8.5. Share capital and Share Premium

The share capital of the Company is EUR 1,635,006 and is represented by 15,778,566 common shares. The share capital is fully paid-in. During 2020, a capital increase took place as a result from the January 2020 Equity Placement.

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
December 31, 2020	**15,778,566**	**1,635,006**	**119,332,864**	**120,967,870**

At 31 December 2019, the share capital of the Company was EUR 1,306,940 represented by 12,611,900 shares.

At 27 January 2020 the Company completed a capital increase and successfully raised an amount of EUR 19.0 million in gross proceeds by means of a private placement via an accelerated bookbuild offering of 3,166,666 new shares (being approximately 25.11% of the Company's outstanding shares) at an issue price of EUR 6.00 per share.

The share capital has increased from EUR 1,303,940 to EUR 1,635,006 and the number of issued and outstanding shares has increased from 12,611,900 to 15,778,566 ordinary shares, through the issuance of a total of 3,166,666 new shares.

The new shares issued within the framework of the capital increase 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.

Of the 3,166,666 shares, 2,522,379 were immediately admitted to listing and trading on the regulated market of Euronext Brussels upon their issuance (on the basis of applicable listing prospectus exemptions), while 644,287 shares were not immediately admitted to listing and trading on the regulated market of Euronext Brussels upon their issuance (as their admission to listing and trading was subject to the approval of a listing prospectus).

A listing prospectus has been approved by the Belgian Financial Services and Markets Authority with respect to the 644,287 shares (the "Prospectus") and has been published the 25th of June 2020.

As of 31 December 2020, the Company does not hold any treasury shares.

8.5.1. Authorised capital

The Extraordinary General Meeting decided on 18 January 2019 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 1,306,939.52, 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.

8.6. Financial debts / net debt

8.6.1. Loan agreement with Bootstrap

On October 1, 2018, the agreement for the Bootstrap Loan (CHF 5,000,000) was amended to provide that 5% of the proceeds of an Initial Public Offering must be used for a partial repayment of the principal outstanding under the facility, which would lead to a maximum partial repayment of the Bootstrap loan of EUR 1.5 million. The final amount repaid based on the gross proceeds of EUR 27,500,089 was EUR 1,375,004 (CHF 1,560,768).

In addition, Sequana Medical granted Bootstrap additional rights to subscribe to new shares in the Company. The New Shares in the Offering could also be subscribed for through a contribution in kind by Bootstrap of the payable due by the Company upon the closing of the Offering as "Exit Fee" pursuant to the Bootstrap Loan. The exit fee mentioned above amounts to CHF 663,996.83. Half of this (being CHF 331,998.41) is converted into shares. The applicable conversion price was CHF 1.1351 for EUR 1.00. Based on this, 34,409 new shares could be issued at EUR 8.50 (being EUR 292,476.50 in total). The remaining amount of CHF 663,996.83 minus EUR 292,476.50, being EUR 292,491.19 (based on the aforementioned exchange rate) has been paid in cash by the Issuer following the closing of the Offering.

Interest remains at the contractually agreed 12% per annum, with payments due on a monthly basis beginning in October 2018 through March 2021. In accordance with the revised contract, the unpaid interest from 1 January 2018 through 31 October 2018 amounting to EUR 0.41 million were due at the time of the Offering, including the balance of unpaid interest from 1 May 2017 to 31 December 2017 in the amount of EUR 0.44 million are paid in equal monthly instalments over the six-month period on the last day of each month following the completion of the Offering, starting 28 February 2019 to 31 July 2019.

As at 31 December 2019, an amount of EUR 2.7 million (discounted) was still outstanding under the loan that previously had been granted to Sequana Medical by Bootstrap S.C.SP. According to the terms of the loan (as amended), the loan would become repayable in four monthly instalments on 31 December 2020, 21 January 2021, 28 February 2021 and 31 March 2021. The loan could be prepaid in whole or in part at any time prior to its maturity without penalty, and on 16 July 2020 the Company repaid the loan 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.

8.6.2. Subordinated loan agreements

At the end of July 2020, the Company entered into subordinated loan agreements with several shareholders, including PMV/z-Leningen, for an aggregate principal amount of EUR 7.3 million, of which EUR 1.4 million can be converted by the lenders into new shares of the Company in the event of a future equity financing or sale of the Company.

The loans have a term of 36 months and are repayable in full upon expiry of the term. The loans bear an interest of 6% per annum, except that the convertible portion of the loans bear an interest of 5% per annum. The interest is payable only upon expiry of the term of the loans. The price per share at which the convertible portion of the loans can be converted 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 equity financing or sale.

The subordinated loan by PMV/z-Leningen is part of the action plan of the Flemish Region to support businesses as a result of the COVID-19 crisis.

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 2020.

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	2020	2019
Cash and cash equivalents	11,016,143	5,586,470
Borrowings - repayable within one year	-	(459,495)
Borrowings - repayable after one year	(7,472,701)	(2,260,905)
Net financial debt	**3,543,442**	**2,866,070**

in EUR	Cash and cash equivalents	Borrowings due within 1 year	Borrowings due after 1 year	Total
Net financial debt as per 31 December 2019	**5,586,470**	**459,495**	**2,260,905**	**2,866,069**
Cash flows	5,483,275	(3,201,376)	7,300,000	1,384,651
Accrued interest (non-cash)			172,701	(172,701)
Transfer (non-cash)		2,260,905	(2,260,905)	
Converted to equity (non-cash)				
Unwinding of discounted cash flows (non-cash)		419,311		(419,311)
Foreign exchange impact (non-cash)	(53,602)	61,665		(115,267)
Net financial debt as per 31 December 2020	**11,016,143**	**0**	**7,472,701**	**3,543,442**

The loans are presented in the balance sheet as follows:

in EUR	December 31, 2020	December 31, 2019
Fair value of convertible loans issued in EUR at recognition date	1,400,000	-
Remeasurement at FVTPL on convertible loans in EUR	28,603	-
Face value of non-convertible loans issued in EUR	5,900,000	-
Interest expenses accrued on non-convertible loans in EUR	144,099	
Other loans	-	2,720,401
Total short term and long term debt	**7,472,701**	**2,720,401**

8.6.3. Lease debts

On adoption of IFRS 16, the Group recognised lease liabilities in relation to leases which had previously been classified as 'operating leases' under the principle of IAS 17 Leases. The lease debts are presented in the balance sheet as follows:

in EUR	December 31, 2020	December 31, 2019
Long term lease debts	122,942	305,046
Short term lease debts	263,700	199,158
Total	**386,642**	**504,204**

8.7. 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 2019.

8.7.1. 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	2020	2019
Defined benefit obligation	2,271,652	2,013,959
Fair value of plan assets	1,753,838	1,476,753
Deficit	517,814	537,205
Net defined benefit liability	**517,814**	**537,205**

The decrease in net defined benefit liability is partially related to the plan amendment/ past service cost of EUR 76,362 which is recognized in P&L in 2020.

Components of defined benefit cost in profit or loss	2020	2019
Current service cost (employer)	162,011	140,831
Plan amendment / Past Service Cost	(76,362)	(114,149)
Interest expense on defined benefit obligation	6,302	22,207
Interest income on plan assets	(4,670)	(16,011)
Administration cost excl. cost for managing plan assets	6,366	5,915
Defined benefit cost recognised in profit or loss	**93,648**	**38,794**
thereof service cost and administration cost	92,015	32,598
thereof net interest on the net defined benefit liability (asset)	1,633	6,196

The present value of the defined benefit obligation is determined annually by independent actuaries using the projected unit credit method.

Defined benefit obligation (DBO)[1]

The difference between the reconciliation and the valuated defined benefit obligation as of 31 December 2020 corresponds to an actuarial loss of EUR 34,820. The changes in financial assumptions led to an actuarial loss of EUR 44,438. This is partially offset by the change in experience adjustments, which led to an actuarial gain of EUR 9,618. These two components led to a total actuarial loss of EUR 34,820.

The plan assets are carried forward until 31 December 2020 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 2020 corresponds to an actuarial gain of EUR 31,493.

The total actuarial losses of EUR 3,327 (losses on defined benefit obligations of EUR 34,820 and gains on plan assets of EUR 31,493) have been recognized in OCI.

(1) Immaterial rounding differences are possible between the underlying actuarial tables and the balance sheet 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	2020	2019
Actuarial (gain) / loss on defined benefit obligation	34,820	(35,272)
Return on plan assets excl. interest income	(31,493)	(180,279)
Defined benefit cost recognised in OCI	**3,327**	**(215,551)**

Components of actuarial gain/losses on obligations	2020	2019
Actuarial (gain) / loss arising from changes in financial assumptions	44,438	164,185
Actuarial (gain) / loss arising from changes in demogr. assumptions	-	-
Actuarial (gain) / loss arising from experience adjustments	(9,618)	(199,457)
Actuarial (gain) / loss on defined benefit obligation	**34,820**	**(35,272)**

Reconciliation in net defined benefit liability	2020	2019
Net defined benefit liability at 1 January	537,205	792,217
Defined benefit cost recognised in profit or loss	93,648	38,794
Defined benefit gain recognised in OCI	3,327	(215,551)
Contributions by the employer	(119,206)	(106,855)
Currency translation adjustments	2,839	28,601
Net defined benefit liability at 31 December	**517,814**	**537,205**

Reconciliation of defined benefit obligation	2020	2019
Defined benefit obligation at 1 January	2,013,959	2,478,405
Interest expense on defined benefit obligation	6,302	22,207
Current service cost (employer)	162,011	140,831
Contributions by plan participants	119,206	106,855
Plan amendment / Past Service Cost	(76,362)	(114,149)
Benefits (paid) / deposited	(2,533)	(672,905)
Administration cost (excl. cost for managing plan assets)	6,366	5,915
Actuarial (gain) / loss on defined benefit obligation	34,820	(35,272)
Currency translation adjustments	7,883	82,070
Defined benefit obligation at 31 December	**2,271,652**	**2,013,959**

Reconciliation of fair value of plan assets	2020	2019
Fair value of plan assets at 1 January	1,476,753	1,686,189
Interest income on plan assets	4,670	16,011
Contributions by the employer	119,206	106,855
Contributions by plan participants	119,206	106,855
Benefits (paid) / deposited	(2,533)	(672,905)
Return on plan assets excl. interest income	31,493	180,279
Currency translation adjustments	5,043	53,469
Fair value of plan assets at 31 December	**1,753,838**	**1,476,753**

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	2020	2019
Weighted average duration of DBO in years	20.9	22.8

There are no retired plan participants for the years 2020, 2019 and 2018.

For the reporting year 2021, employer contributions of EUR 132,664 are expected.

Significant actuarial assumptions:

Actuarial assumptions	2020	2019
Discount rate (DR) at 1.1.	0.30%	0.90%
Discount rate (DR) at 31.12.	0.15%	0.30%
Interest rate on retirement savings capital (IR) at 31.12.	0.15%	0.30%
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.	~0.50%	1.00%
Mortality tables	BVG 2015 GT	BVG 2015 GT
Date of last actuarial valuation	31/12/2020	31/12/2019

Sensitivities of significant actuarial assumptions

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

Sensitivity	2020	2019
DBO = Defined benefit obligation, SC = Service cost (employer)		
DBO at 31.12. with DR -0.25%	2,396,425	2,136,846
DBO at 31.12. with DR +0.25%	2,157,205	1,901,334
DBO at 31.12. with IR -0.25%	2,229,062	1,981,771
DBO at 31.12. with IR +0.25%	2,316,083	2,055,472
DBO at 31.12. with SI -0.25%	2,244,080	1,983,761
DBO at 31.12. with SI +0.25%	2,300,526	2,045,170
DBO at 31.12. with life expectancy +1 year	2,314,320	2,055,825
DBO at 31.12. with life expectancy -1 year	2,318,017	2,059,674
SC of next year with DR +0.25%	203,812	138,796
SC of next year with IR +0.25%	228,006	158,249

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.

8.7.2. 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 2020, the Net Defined Benefit Liability equals to EUR 21,257.

As per 31 December 2020, there are 9 employees in the plan.

Funded status and recognised/unrecognised amounts	2020	2019
Defined benefit obligation at 31 December	112,205	59,947
Fair value assets at 31 December	90,948	53,551
Funded status: plan assets above/(below) DBO	-21,257	-6,396
Unrecognised net (gain)loss		
Unrecognised past service costs		
Unrecognised net transition obligation/(asset)		
Unrecognised balance sheet asset (because of limit)		
Net benefit Liability at 31 December	**21,257**	**6,396**

The contributions recognised in 2020 for the new defined contribution plan in Belgium amounted to EUR 41,141.

For the reporting year 2021, employer contributions of EUR 41,881 are expected.

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

8.7.3. Pension plan in Germany

The contributions paid to the defined contribution plan in Germany amounted to EUR 5,033 (2019: EUR 6,903).

8.8. Trade payables, other payables and accrued liabilities

In EUR	December 31, 2020	December 31, 2019
Trade payables	**2,802,488**	**2,476,373**
Other payables	**1,523,426**	**1,269,415**
Accrued liabilities:	**1,376,390**	**910,216**
Provision warranty	77,545	70,268
Third Parties	1,298,845	839,947

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: Third parties in the Balance Sheet amounts to EUR 1,298,845 (in 2019: EUR 839,947) and are mainly accruals related to clinical expenses and other liabilities.

9. Share-based compensation

9.1. Executive Share Options

Early October 2018, Sequana 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.

Below table summarizes the main parameters.

Warrants	2020
Number of warrants granted	111,177
Number of warrants forfeited	(8,650)
Number of warrants not vested at 31 Dec 2020	18,977
Exercise price (in Euro)[1]	
CEO[1a]	0.92
Other	9.19
Expected dividend yield	0%
Expected stock price volatility[2]	49%
Risk-free interest rate[3]	0.76%
Expected duration in years	10
Fair value (in Euro) at grant date	
CEO	8.33
Other	1.00

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 peer shares, listed on the STOXX Medtech stock exchange.

The share price considered per 31 December 2018 is EUR 9.25 and is the lowest based on the expected gross amount of IPO proceeds of EUR 30.0 million, whereas probability weighted scenarios between EUR 9.25 and EUR 10.50 per share have been applied.

The effect of the share-based payment transactions on the 2020 profit & loss of the Group is an expense of 60,523 EUR. The same amount goes through reserves in equity so that the net effect on the Group's equity is zero.

9.2. 2018 Share Option Plan

The extraordinary shareholders meeting of 18th of January 2019 approved the new Share options for directors, employees and other staff members of Sequana Medical (the "2018 Share Options"). There was no obligation for the holders of the 2011 Share Options and Executive Share Options to exercise the Share options prior to the closing of the Offering. The number of options is equal to 10% of the total number of New Shares outstanding after the closing of the Offering and after the allocation of the over-allotment option.

Warrants	Granted in 2019
Number of warrants granted	290,601
Number of warrants forfeited	(57,550)
Number of warrants not vested at 31 Dec 2020	77,425
Exercise price (in EUR)[1]	
Grant date 13/02/2019	7.46
Grant date 24/05/2019	6.22
Grant date 20/08/2019	6.78
Expected dividend yield	0%
Expected stock price volatility[2]	49%
Risk-free interest rate[3]	0.07%
Expected duration in years	10
Fair value (in Euro) at grant date	
Grant date 13/02/2019	0.62
Grant date 24/05/2019	1.15
Grant date 20/08/2019	0.98

Warrants	Granted in 2020
Number of warrants granted	325,036
Number of warrants forfeited	-
Number of warrants not vested at 31 Dec 2020	325,036
Exercise price (in Euro)[1]:	
Grant date 30/07/2020	6.19
Expected dividend yield	0%
Expected stock price volatility[2]	55%
Risk-free interest rate[3]	0.00%
Expected duration in years	8.55
Fair value (in Euro) at grant date	
Grant date 30/07/2020	1.45

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 2020 profit & loss of the Group is an expense of EUR 195,337. The same amount goes through reserves in equity so that the net effect on the Group's equity is zero.

(1) equals the market value of the underlying shares on the grant date

(1a) The actual Market Value and Unrestricted Market Value per Preferred E-share of CHF 1.05 or EUR 0.92 for the purposes of granting EMI (Enterprise Management Incentives) options has been agreed upon and accepted by the HM Revenue & Customs in the UK on August 2, 2018

(2) based on peer companies listed on the STOXX Medtech stock exchange

(3) represents the interest rate on government bonds on 10 year

(1) equals the market value of the underlying shares on the grant date

(2) based on peer companies listed on the STOXX Medtech stock exchange

(3) represents the interest rate on government bonds on 10 year

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10. Contingencies and arbitrations

At present there are no 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 2020.

11.2. Asset pledges

As per 31.12.2019, a security for the fulfilment of the financial obligation existed. The Company had pledged Intellectual Property as well as the related assets to the venture debt provider Bootstrap Europe S.C.Sp. As per 16 July 2020, the Bootstrap loan has been repaid as described in section 8.6.1.

As a result hereof, the pledge on intellectual property and other assets of the Company has been released.

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 sections 12.3, 12.4 and 12.5.
2. the subordinated loan agreements concluded with amongst others PMV/z-Leningen as described in sections 8.6.2 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 sections 8.5 Share Capital and 8.6 Financial 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

During 2020, the non-executive directors received the following compensation (gross), based on the approved fees:

	Amount EUR
Pierre Chauvineau	70,000
Wim Ottevaere	50,000
Jason Hannon	40,000

During 2020, no remuneration or compensation was paid to the non-executive directors, other than the reimbursement of travel and hotel expenses incurred by the directors in connection with their attendance of meetings of the Board of Directors.

12.4. Relations with Executive Management

The Executive Management consists of the Chief Executive Officer and the Chief Financial Officer.

The Executive Management include those persons having authority and responsibility for planning, directing and controlling the activities of the Group.

12.5. Executive Management compensation

The compensation for the Executive Management is as follows:

In EUR (except number of share options)	Short-term Employee benefits	Post-employment benefits	Number of share options
Ian Crosbie	432,601	14,050	297,281
Kirsten Van Bockstaele	294,384	-	46,645
Total	**726,985**	**14,050**	**343,926**

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 2020	Investment 2019
Sequana Medical NV	Holding/Sales	EUR 1,635,006	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

	2020	2019
Average number of employees	40.5	33.8

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)	2020	2019
Short term employee benefits	432,601	441,794
Post-employment benefits	14,050	14,422
Number of share options	297,281	40,766

14. Brexit – business exposure

On 23 June 2016, the U.K. held a referendum pursuant to which voters approved an exit from the E.U., commonly referred to as “Brexit.” The British Prime Minister formally announced the country’s withdrawal in March 2017. Following a general election in December 2019, the British Parliament ratified the withdrawal agreement, and the U.K. left the E.U. on 31 January 2020. This began a transition period that is set to end on 31 December 2020, during which the U.K. and E.U. has negotiated the terms of their future relationship.

The transition period has ended on 31 December 2020. The impact of the Brexit on Sequana Medical is limited in Q1-2021, however at this moment there remain several items unclear regarding the agreements closed between the U.K. and E.U in December 2020. Therefore, the long-term impact of Brexit on medical device companies and Sequana Medical in particular is uncertain and has to be assessed in the coming months.

15. COVID-19

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

16. Events after the reporting period

As announced in the press release dated 9 February 2021, the Company has 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 (the "Offering"). The Offering was upsized from EUR 17.5 million to EUR 22.5 million due to strong demand from new and existing local and international investors. The capital increase has been completed on 15 February 2021. For the impact on the current cash runway, refer to section 4 Going Concern.

The Company announced, in the press release dated 16 February 2021, 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 an exercise price per 2018 Share Option of EUR 7.46. As a result of this exercise of the 2018 Share Options, on 15 February 2021 the share capital of the Company has increased to EUR 1,910,568.55 and the number of issued and outstanding shares has increased to 18,438,435 ordinary shares, through the issuance of a total of 12,810 new shares.

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 Woluwe Garden, Woluwedal 18, 1932 Sint-Stevens-Woluwe, Belgium, represented by Mr. Peter Dhondt, auditor.

17. Audit fees

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

9.
Condensed statutory financial statements of Sequana Medical NV

9.1. *Statutory Income Statement*

In EUR	2020	2019
Operating income	6,133,007	970,636
Operating loss	**(15,746,095)**	**(15,698,694)**
Financial result	(1,121,931)	(830,958)
Loss for the period before taxes	**(16,868,025)**	**(16,529,652)**
Income taxes	(126,483)	(131,848)
Loss for the period	**(16,994,508)**	**(16,661,500)**

9.2. *Statutory Balance Sheet*

In EUR	2020	2019
Assets	**16,594,940**	**8,955,576**
Fixed assets	**3,132,416**	**342,842**
Intangible assets	2,728,260	-
Tangible assets	312,102	254,943
Financial fixed assets	67,055	62,899
Participating interests	25,000	25,000
Current assets	**13,462,524**	**8,612,734**
Inventory	1,471,655	1,597,623
Equity and liabilities	**16,594,940**	**8,955,576**
Capital	1,635,006	1,306,940
Share premium	119,332,864	100,660,934
Reserves	637,670	817,559
Accumulated losses	(118,544,703)	(101,550,195)
Provisions	**539,042**	**543,601**
Amounts payable after more than one year	7,472,701	2,260,905
Long-term financial debt	7,472,701	2,260,905
Short-term financial debt	-	459,495
Trade debts	2,816,275	2,442,175
Taxes, remuneration and social security	1,387,441	1,157,852
Accruals and deferred income	1,318,644	856,310

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
CMS	Centers for Medicare and Medicaid Services
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
FDA	Food and Drug Administration
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
MCIT	Medicare Coverage of Innovative Technology
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
PD	Peritoneal Dialysis
PMSR	Post Marketing Surveillance Registry
POSEIDON	North American pivotal alfapump study
RCT	Randomised Controlled Trial
RED DESERT	Repeated dose alfapump DSR study
SAHARA DESERT	Dose-ranging alfapump DSR feasibility study
SF 36	Short Form 36
TCT	Transcatheter Cardiovascular Therapeutics
TIPS	Transjugular Intrahepatic Portosystemic Shunt
TP	Therapeutic Paracentesis
WHO	World Health Organisation

Sources

1 Management estimate that is inclusive of estimated growth in prevalence of NASH for the US based on Global Data Epidemiology Forecast to 2026

2 Management estimate based on Global Data Heart Failure Epidemiology Forecast to 2026; Costanzo et al. (2007); Kiglore et al (2017)

3 Ginès et al., Hepatology, 1987 (for age of alcohol/hepatitis related cirrhosis)

4 Bhala et al., Hepatology, 2011 (for age of NAFLD related cirrhosis vs hepatitis related cirrhosis; progress from NASH to cirrhosis)

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6 Management estimate using historical liver cirrhosis mortality rates based on Mokdad AA, Lopez AD, Shahraz S, Lozano R, Mokdad AH, Stanaway J, Murray CJ, Naghavi M. Liver cirrhosis mortality in 187 countries between 1980 and 2010: a systematic analysis. BMC Med. 2014;12:145 and the estimated percentage of cirrhosis patients that die each year per expert feedback.

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9 Estes et al. (2018).

10 GlobalData NASH Epidemiology Forecast to 2026.

11 Runyon et al. (2009).

12 Ginès et al. (2004) (stating refractory ascites occurs in 5 to 10 percent of patients with ascites).

13 Management estimate using historical liver cirrhosis mortality rates based on Mokdad AA, Lopez AD, Shahraz S, Lozano R, Mokdad AH, Stanaway J, Murray CJ, Naghavi M. Liver cirrhosis mortality in 187 countries between 1980 and 2010: a systematic analysis. BMC Med. 2014;12:145 and the estimated percentage of cirrhosis patients that die each year per expert feedback.

14 GlobalData NASH Epidemiology Forecast to 2026; Runyon et al. (2009); Ginès et al. (2004)

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16 Copelan A, Kapoor B, Sands M. Transjugular Intrahepatic Portosystemic Shunt: Indications, Contraindications, and Patient Work-Up. Seminars in Interventional Radiology. 2014;31(3):235-242. doi:10.1055/s-0034-1382790.

17 Ayantunde et al. (2007).

18 World Health Organization International Agency for Research on Cancer 2018 (http://gco.iarc.fr/today/home) (estimated number of new breast and ovarian cases in 2018 (crude rate))

19 Health Resources and Services Administration, U.S. Department of Health & Human Services.

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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 not currently 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 not currently 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® and **alfa**pump DSR® are registered trademarks in the Benelux.

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