



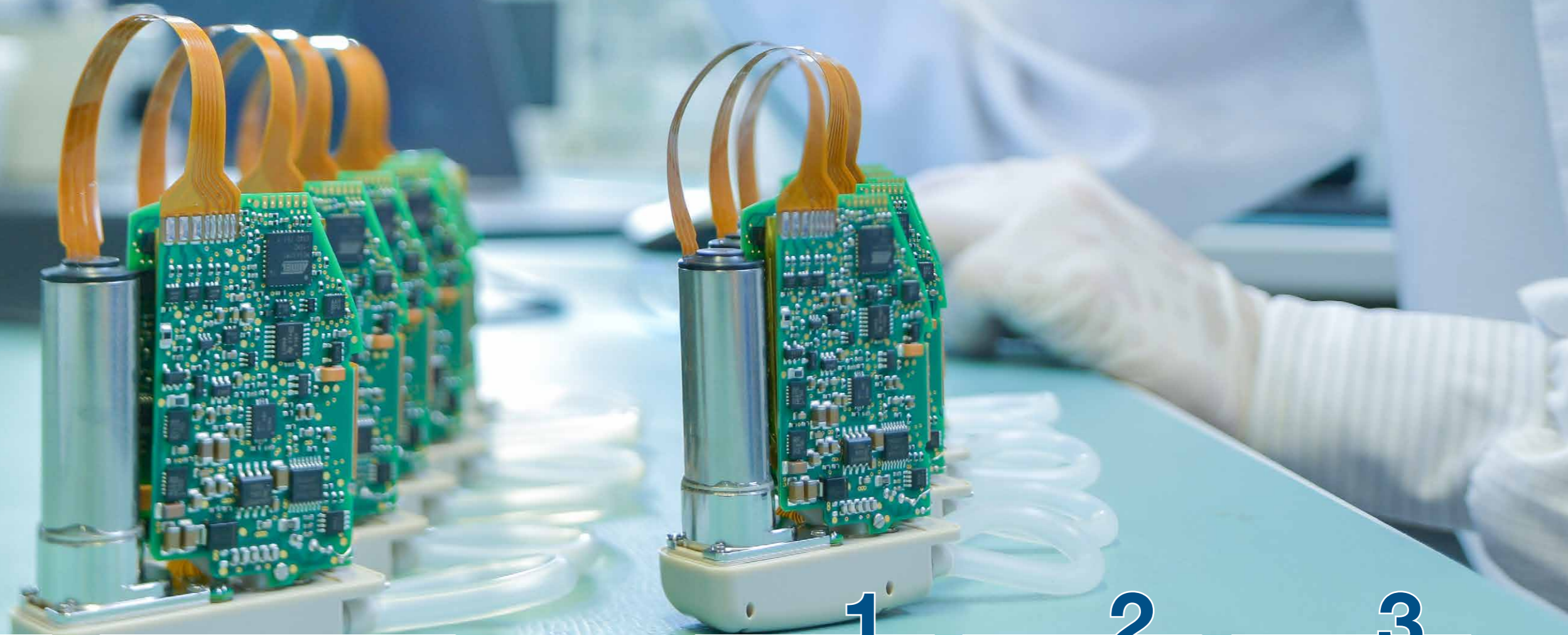
# sequanamedical

annual report 2019

## Our Strategy & Key Objectives

- 🔑 Obtain regulatory approval in North America for the **alfapump**<sup>®</sup> in the treatment of recurrent and refractory liver ascites and commercialise through establishing our own specialty salesforce
- 🔑 Advance clinical development of the **alfapump** DSR in the treatment of volume overload due to heart failure and establish a strategic partnership for development and commercialization
- 🔑 Explore the use of the **alfapump** DSR in further indications where diuretic-resistant volume overload is a key clinical complication, e.g., renal failure
- 🔑 Further develop monitoring capabilities of the **alfapump** to deliver patient management solutions

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# Sequana Medical at a glance

**We are a commercial stage medical device company developing the **alfapump**® platform for the management of fluid overload in liver disease, malignant ascites and heart failure.**

Our two pillars of growth are the commercialization of the **alfapump** in North America, a large market driven by non-alcoholic steatohepatitis (NASH)-related cirrhosis, and the clinical development of the **alfapump** DSR (Direct Sodium Removal), a potential chronic therapy for patients suffering from heart failure-induced volume overload. Both markets leverage our **alfapump**, 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.

Fluid overload is a key clinical challenge for many diseases when diuretic drugs are no longer effective. We estimate the U.S. market for the **alfapump** resulting from NASH-related cirrhosis to exceed €3 billion annually within the next 10-20 years<sup>1</sup> and the heart failure market for the **alfapump** DSR to be over €5 billion annually in the U.S. and EU5 by 2026<sup>2</sup>.

In the U.S., our key growth market, the **alfapump** 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 **alfapump** to bring a much-needed improvement to the effective treatment of this debilitating condition. Our North American pivotal POSEIDON study in recurrent and refractory ascites due to liver cirrhosis started in H2 2019, with the U.S. commercial launch previously planned for H1 2022 likely to be delayed due to the COVID-19 pandemic. In Europe, the **alfapump** 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 750 systems have been implanted. The **alfapump** has been endorsed by key independent third parties in Europe 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.

In addition, we have built on the proven **alfapump** platform to develop the **alfapump** DSR, a novel and proprietary approach to the treatment of volume overload in heart failure. Pre-clinical and clinical studies demonstrated that DSR can result in the removal of large quantities of sodium and fluid in a safe, tolerable and consistent manner. Data from these studies have been published in the high impact clinical journal *Circulation*, indicating the potential of this therapeutic approach. A repeated dose proof-of-concept **alfapump** DSR study in diuretic-resistant heart failure patients (RED DESERT), combining DSR therapy with our proven **alfapump** platform, is ongoing although the results originally expected in Q2 and Q3 2020, are likely to be delayed given the COVID-19 pandemic.

We are headquartered in Ghent, Belgium and raised €27.5 million in an IPO on Euronext Brussels in February 2019 and €19.0 million in an equity private

placement in January 2020, supported by existing and new experienced life science investors and industry experts. We are led by an experienced management team and a Board of Directors with significant industry

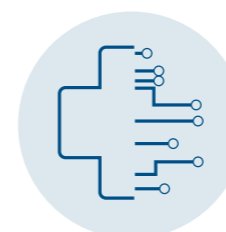
experience. We have strong endorsement for our technology and clinical approach from international Key Opinion Leaders (KOLs).



Founded in 2006



45 employees



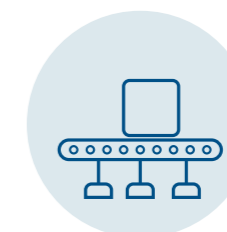
Groundbreaking, proprietary **alfapump** platform addressing fluid overload in liver disease, malignant ascites and heart failure



Headquarters in Ghent, Belgium



Over 750 **alfapumps** implanted to date



Manufacturing in Zurich, Switzerland



Two pillars of growth leveraging **alfapump** platform:

- Commercialization of the **alfapump** in North America, a large market driven by NASH-related cirrhosis
- Clinical development of the **alfapump** DSR, a potential chronic therapy for patients suffering from heart failure-induced volume overload



Raised €27.5 million in an Initial Public Offering on Euronext Brussels in 2019 and €19.0 million in an equity private placement in 2020 extending the cash runway into H1 2021



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



Supported by renowned specialist life science investors and industry experts

# Message from the Chairman and the CEO

Dear Shareholders, Colleagues and Business Partners,

Welcome to our 2019 Annual Report, a truly notable year for the Company as we made significant advances in bringing the **alfapump**® platform closer to market for a broader group of patients, laying the foundations for 2020 to be an exciting year.

Our **alfapump** is one of the first fully implantable devices designed to manage fluid overload, a key clinical challenge in many diseases. It is a fast-growing complication of advanced liver disease driven by NASH (Non-Alcoholic SteatoHepatitis)-related cirrhosis and a major problem for heart failure patients. For these patients, there are limited treatment options when diuretic drugs are no longer effective, which may lead to severe clinical complications, major impact on quality of life and large healthcare costs.

U.S. NASH-related cirrhosis and heart failure are our two growth pillars, building on our proven European clinical and commercial experience to exploit the significant market opportunities. We estimate the U.S. market for the **alfapump** in NASH-related cirrhosis will exceed €3 billion annually within the next 10-20 years and the heart failure market for the **alfapump** DSR to be over €5 billion annually in the U.S. and five biggest EU markets by 2026. In addition, we believe there are substantial additional opportunities for the **alfapump** in further indications where volume overload is a key clinical challenge.

Our aim remains to commercialise the **alfapump** ourselves in the U.S., and to seek a strategic partnership for the development and commercialization of the **alfapump** DSR in heart failure following the feasibility study, which we plan to start after the currently ongoing RED DESERT study.

## Clinical and financial progress

We have made significant clinical progress to prepare the introduction of the **alfapump** in the North American market. This includes obtaining Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA) for recurrent or refractory liver ascites and the initiation of POSEIDON, the North American pivotal study to support the marketing approval and reimbursement of the **alfapump** in the U.S. and Canada. As a result of the optimised clinical trial design, we moved forward the forecast U.S. launch date by nine months.

The **alfapump** DSR is also progressing well in heart failure, with the clinical proof-of-concept in the first-in-human single dose direct sodium removal (DSR) study and the initiation of the RED DESERT repeated dose study for the treatment of diuretic-resistant heart failure patients.

In February 2019, we raised €27.5 million in our Initial Public Offering (IPO) and a €19.0 million private equity placement in January 2020 further reinforces our financial position. Our cash runway now extends into H1 2021, enabling us to continue to deliver on our clinical development plan. We are grateful for the support and confidence of our investors as we continue this exciting journey.



## COVID-19 and clinical timelines

The spread of COVID-19 is creating significant uncertainties for all of us. The priority is protecting the safety and health of the patients and healthcare resources, and as such we expect there will be delays to our ongoing and planned trials. The POSEIDON pivotal study was expected to complete enrolment by mid-2020, with interim results in the second half of the year and primary endpoint results in mid-2021. These results will provide the basis for regulatory submission which was foreseen in 2021, with anticipated U.S. launch in the first half of 2022. These timings will likely be delayed. The results of the RED DESERT study expected in Q2 and Q3 2020, and the initiation of a larger feasibility study of the **alfapump** DSR planned before year-end, will also likely be delayed due to the current global health situation.

We thank all our stakeholders for their continued support: to our employees, for their hard work and dedication to transforming patients' lives; to our new and existing investors for their continued support and confidence in our strategy; to our clinical and business partners for the important collaborations and valuable advice; and to the patients in our clinical programs, for taking part in our efforts to bring treatments to market that will provide much-needed benefits to so many.

It is an honour for us to lead an organization with such an important mission, and we look forward to keeping you all up to date on Sequana Medical's exciting progress.

Pierre Chauvineau,  
Chairman

Ian Crosbie,  
CEO



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Our  
Business




## Our Business


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# Achievements


## 2019


-  Received Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA) for the **alfapump** for the treatment of recurrent and refractory liver ascites, recognising the high unmet medical need in this important medical condition and the potential for **alfapump** to improve the lives of these patients.


 First patient enrolled in the **alfapump** POSEIDON pivotal study which is planned to support approval and reimbursement in the U.S. and Canada for the treatment of recurrent or refractory liver ascites.

 Positive Direct Sodium Removal (DSR) clinical proof-of-concept data from the first-in-human single dose study, presented at world-leading conferences in the field including Heart Failure 2019, HFSA Annual Scientific Meeting and TCT 2019, demonstrated that single dose DSR therapy was safe and well-tolerated and resulted in a clinically relevant removal of sodium with consistent results across all treated patients.
-  First patient enrolled in the **alfapump** DSR RED DESERT study. The RED DESERT study is a repeated dose proof-of-concept study with **alfapump** DSR in diuretic-resistant heart failure patients.


 Appointed Dr. Butler, Dr. Costanzo, Dr. Tang and Dr. Testani as Heart Failure Scientific Advisors to support the **alfapump** DSR development programme.

 **alfapump** included in the German treatment guidelines (DGVS) for complications of liver cirrhosis, positioning **alfapump** as a good and safe alternative to repeated large volume paracentesis (LVP), the current standard of care.

 Appointed experienced Medtech executive, Jason Hannon, as Independent Non-Executive Director.

 Raised €27.5 million in an Initial Public Offering (IPO) on Euronext Brussels.

## 2020 year-to-date

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

 Publication in leading peer-reviewed journal, *Liver Transplantation* of positive results from the **alfapump** North American feasibility study (MOSAIC) in recurrent and refractory liver ascites.

 Raised €19.0 million in a successful private placement via an accelerated bookbuilding offering from existing investors and new experienced life science investors and industry experts, extending the Company's cash runway into H1 2021.



## Outlook for 2020

As a result of the strong progress in 2019, and the large commercial potential of the U.S. NASH-related cirrhosis market (estimated annual €3 billion **alfapump** market within the next 10-20 years) and U.S. / European heart failure market (estimated annual €5 billion **alfapump** DSR market by 2026), we have decided to prioritise development programmes in these areas.

The **alfapump** POSEIDON North American pivotal study in recurrent and refractory ascites due to liver cirrhosis was scheduled to complete enrolment by mid-2020 with interim results in H2 2020 and primary outcome read-out by mid-2021.

Results from the **alfapump** DSR RED DESERT study were initially expected in Q2 and Q3 2020. This study aims to evaluate the safety and efficacy of the **alfapump** DSR to remove excess sodium and fluid, and explore the potential impact of DSR therapy to restore patients' responsiveness to diuretics. A larger feasibility study of the **alfapump** DSR was planned to be initiated before year-end.

However, the COVID-19 pandemic will impact these programmes and likely delay the key milestones. We are in dialogue with our partners to assess the impact and adapt our operations as necessary. We have put in place plans to minimise any delays and be ready to reinstate recruitment and complete our studies as expeditiously as possible once the situation allows, while at the same time preserving the safety of patients and of our team. We will update our guidance on the expected impact and any material change in our operations and outlook when the situation is clarified.

Following the focus on our core commercial markets and the growing evidence of the benefits of the **alfapump** in patients with refractory liver ascites, we observed steady growth in sales from Germany in 2019 offset by a decline in non-core markets. We had originally expected this growth in core markets to continue in 2020, leading sales to increase from the 2019 level. However, the current restrictions on non-essential medical procedures and hospital visits, will impact sales in 2020.



# alfapump platform

## 1 platform, 2 products

### alfapump®

proven step change in liver refractory ascites and malignant ascites

over 750 devices implanted



### Liver Disease (NASH)



~145K

patients / year with refractory ascites due to NASH within next 10-20 yr

> €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



~400K

patients hospitalised / year for volume overload due to heart failure by 2026

> €5 Bn / year market opportunity

The **alfapump** is one of the first medical devices for automatic and continuous removal of fluid from the abdomen into the bladder, which is applicable across multiple life-threatening disorders. Fluid overload is a fast-growing complication of advanced liver disease driven by NASH-related cirrhosis and a common complication in heart failure.

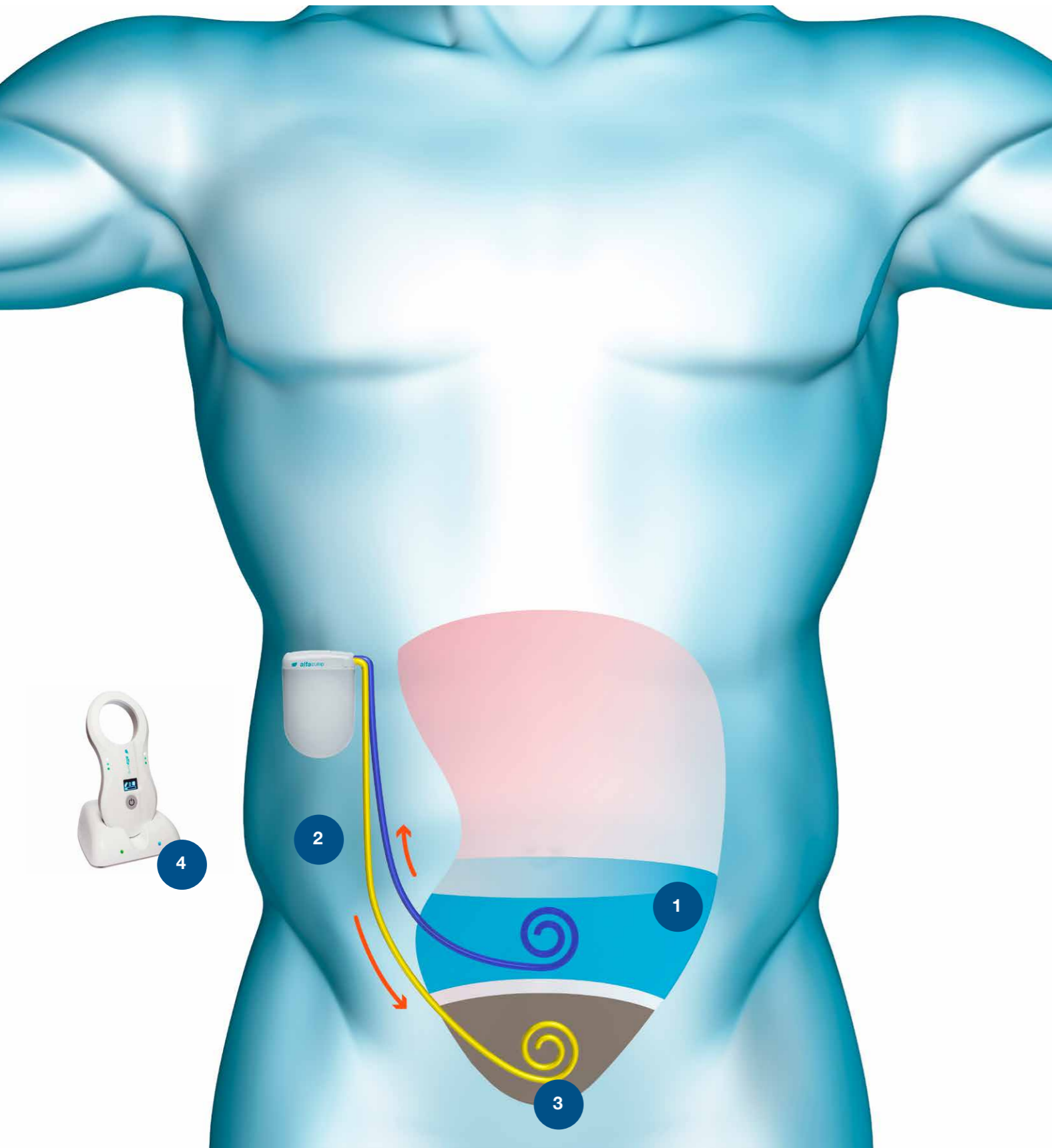
We estimate the U.S. market for the **alfapump** resulting from NASH-related cirrhosis to exceed €3 billion annually within the next 10-20 years<sup>1</sup> and the heart failure market for the **alfapump** DSR at over €5 billion annually in the U.S. and EU5 by 2026<sup>2</sup>. Both markets leverage our clinical and commercial experience of the **alfapump** in Europe where it is CE-marked for treatment of refractory liver ascites and malignant ascites.

The attractiveness of the U.S. market for the **alfapump** is driven by the increasing prevalence of NASH-related cirrhosis, creating a much larger and more dynamic market opportunity for the **alfapump** than the traditional cirrhosis markets due to alcoholic liver disease and hepatitis. We believe the **alfapump** will have

an enhanced adoption and a 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<sup>3,4</sup>) 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<sup>5</sup>). The designation of breakthrough device status for the **alfapump** by the U.S. FDA is a further recognition of the high unmet medical need for improved treatment options for patients with recurrent or refractory ascites, and the potential for the **alfapump** to improve the lives of these patients.

	U.S. Market Potential	EU5 Market Potential
<b>alfapump market potential</b>	~€0.4 Bn / year <sup>6</sup>	> €3 Bn / year
Underlying disease	Alcoholic Liver Disease, Hepatitis	NASH
Patient characteristic	Outside Mainstream	Mainstream
Average age	40-50 yrs	70 yrs+
<b>alfapump competitive positioning</b>	✓	✓✓





## alfapump platform - using the bladder to manage fluid overload

The **alfapump** 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 eliminated through urination. The **alfapump** system provides an automated system for the removal of fluid without the need for repeated needle punctures, needles or external tubes.

Once the **alfapump** has been implanted, it is programmed wirelessly by the physician to ensure that the optimal amount of fluid is removed each day and the schedule can be designed to suit each patient's individual daily routine.

In 2020, the **alfapump** 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.

### Fully implantable pump system

The **alfapump** is implanted under the patient's skin using minimally invasive surgery. This simple procedure usually takes approximately 60 minutes. The procedure is generally performed under general anaesthesia but can also be performed under local anaesthesia with sedation. Placement of the **alfapump** is normally performed by a general surgeon or by an interventional radiologist. Because the **alfapump** is fully implanted, patients are able to retain normal mobility and activity.

- 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 implantable
- 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
- Removing up to 4 litres of fluid / day
- Virtually non-clogging
- No significant heating during charging and operation
- Strong IP barriers through extensive patent portfolio & know-how

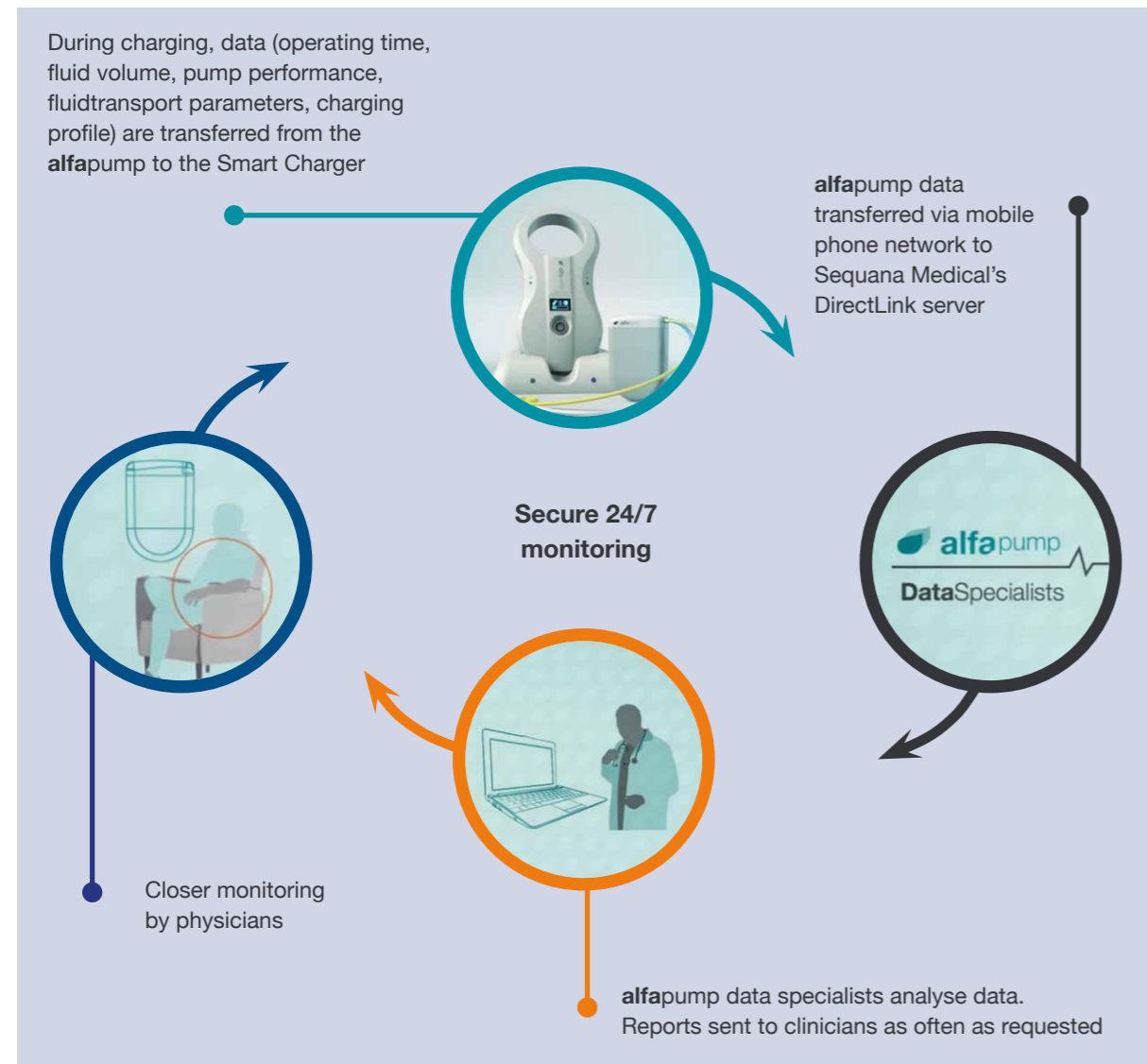
## Wirelessly charged through the skin

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 **alfapump** are transferred to the Smart Charger and transmitted wirelessly via the mobile phone network to secure servers using our DirectLink technology built into the **alfapump** system.

## DirectLink technology

DirectLink technology allows our data specialists to receive **alfapump** performance information (e.g., volume pumped and pump charging) 24 hours a day, 7 days a week, and report this information to clinicians to enable them to more effectively manage patients through closer monitoring and notification of changes in patients' condition.





## Components

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

### *alfapump*

The **alfapump** is an automatic and programmable pump implanted under the skin that can pump up to 4 litres of fluid per day. The **alfapump** monitors pressure in the bladder and 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 and transfer it to the bladder. These catheters are implanted inside the body and are not visible from the outside<sup>(1)</sup>.

<sup>(1)</sup> The catheter presented in the image is the one used in Europe



### **Smart Charger**

The Smart Charger is a hand-held charging device that charges the **alfapump** through the skin. While charging, data from the **alfapump** 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 **alfapump** programmer is a medical-grade notebook with proprietary FlowControl software that is used to change the **alfapump** settings. The FlowControl software enables the quick and easy adaption of a fluid-transport program that is specific to the individual patient.



## Extensive Intellectual Property Portfolio & Established Supply Chain

Our patent portfolio consists of 82 patents granted across 14 patent families and a further 20 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 **alfapump** and the **alfapump** DSR are sourced externally, from a total of approximately 70 external suppliers, including in our opinion, experienced and well-respected manufacturers for the critical components.

### 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 report feelings of isolation and depression because of their immobility and limitations in their daily activities. It also entails a huge burden for their family members because of the frequent hospital visits for paracentesis and the feeling of being housebound and constantly worrying when not around.

Patients with refractory liver ascites who have been implanted with the **alfapump** experienced a significant improvement in quality of life as demonstrated in the various clinical studies and through extensive commercial experience. When we interviewed patients that had been implanted with the **alfapump**, they all indicated how it changed their lives in a positive way, by feeling better and being mobile and self-caring again. Patients indicated that they are eating, breathing and sleeping better; able to cook for their family again, go on vacation without worrying about getting back in time for the paracentesis; feeling strong enough to do anything they want to do. Also their family members experienced a big change and were able to enjoy life together again.



**“I chose the alfapump because everything is completely inside the body and all I learned about it was simply perfect.”**

alfapump patient, Germany



**“I can travel, I can go away and see friends, I can go away for 2 weeks or a month if I want. Everybody tells me I look absolutely 100% better than one year ago, and I feel different too.”**

67-year old alfapump patient, France



## alfapump products

# alfapump

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

### The alfapump system

The **alfapump** 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. It has been granted breakthrough device designation by the U.S. FDA for treatment of recurrent and refractory liver ascites. In Europe, the **alfapump** is CE-marked for the management of refractory ascites due to liver cirrhosis and malignant ascites and is included in key clinical practice guidelines. By automatically and continuously moving ascites from the abdomen to the bladder where it is eliminated via urination, the **alfapump** prevents fluid build-up and possible complications, improving patients' quality of life and nutrition, and potentially reducing hospital visits and healthcare costs. To date, over 750 **alfapump** systems have been implanted.



## 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 2015, more than 3.9 million U.S. adults were diagnosed with chronic liver disease.<sup>7</sup> 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).

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<sup>8</sup> and approximately a quarter to one-third of NAFLD cases are classified as NASH<sup>9</sup>. NASH is a silent disease due to the difficulty in diagnosing it, making early stage intervention clinically challenging. Currently, there are no drugs approved

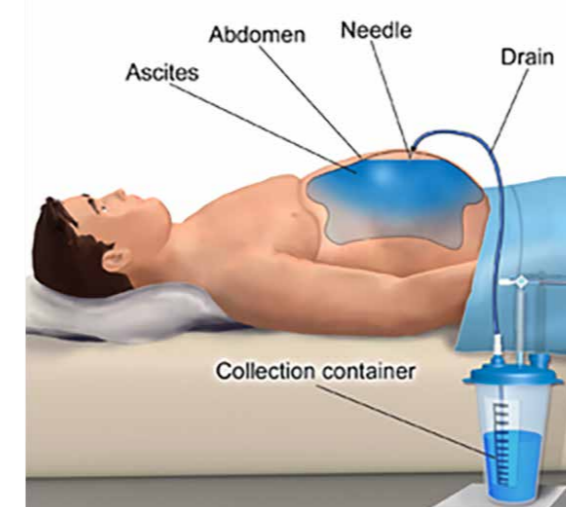
for treatment of NASH. It is estimated that about 10% of the NASH population will progress to liver cirrhosis in the near-to medium-term<sup>10</sup>, making the U.S. NASH-related cirrhosis market an important market for the **alfapump**.

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.<sup>11</sup> Management of ascites is based on a low-sodium diet and diuretic treatment. However, approximately 7.5% of patients with cirrhosis and ascites will develop refractory liver ascites,<sup>12</sup> 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).<sup>13</sup> By 2030, this number is expected to grow to approximately 151,000 in the U.S. and 89,000 in EU5, primarily due to the growth in NASH-related cirrhosis.<sup>14</sup> We believe the recurrent ascites market further increases the market potential for the **alfapump**.

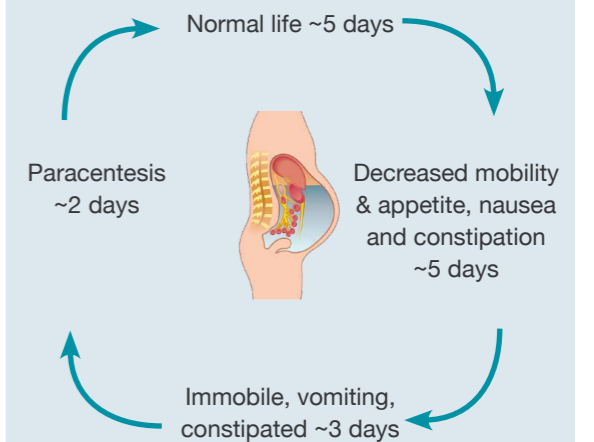
When drug therapy and dietary restriction are no longer effective, the common treatment of ascites is drainage (“paracentesis”).



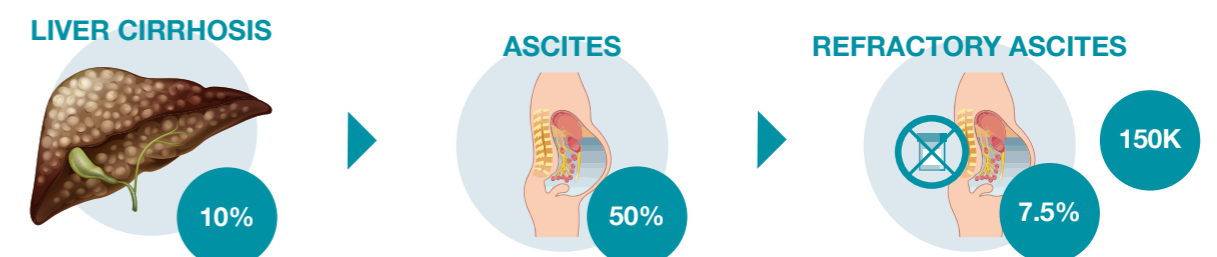
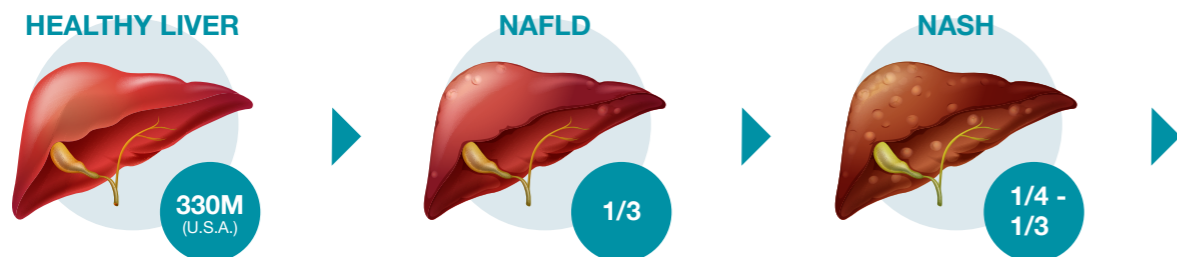
Paracentesis is a bedside or clinic procedure in which a needle is inserted into the peritoneal cavity to remove the ascitic fluid.

### LVP 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.

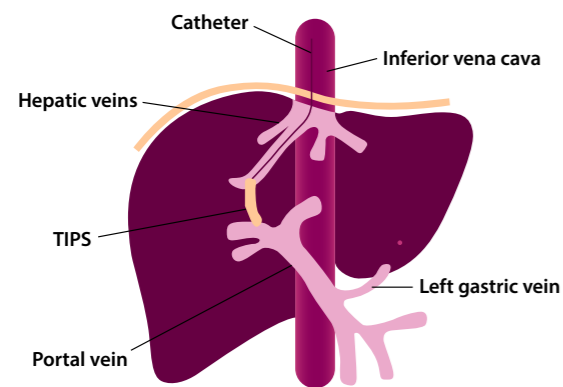
Ascitic fluid is a protein-containing fluid that leaks from the liver as a result of advanced cirrhosis. Due to the scarring of the liver, the pressure inside the liver's blood vessels increase, forcing fluid into the abdominal cavity.

Patients may accumulate as much as 10-15 litres of fluid within the abdomen every 15 days. This has a dramatic negative impact on a patient's quality of life due to the severe swelling of the abdomen, resulting in pain, difficulty in breathing, sleeping and eating, severe nausea and constipation as well as increased risk of severe infection including spontaneous bacterial peritonitis.

In selected patients with refractory ascites, a therapeutic alternative to repeated LVPs 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 (which develops in up to 30% to 50% of patients),<sup>15</sup> 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,<sup>16</sup> 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.

The only curative treatment for liver disease is liver transplantation. Liver transplants are very limited in availability and result in large healthcare costs. Lifelong use of immunosuppression drugs is required to reduce the risk that the recipient's body will reject the transplant.



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

The **alfapump** 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 **alfapump** 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.<sup>17</sup>

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.<sup>18</sup> 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<sup>17,18</sup>.

As with liver ascites, paracentesis is 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 reduce their quality of life.

The **alfapump** offers a new and much-needed treatment option for this patient population.

A further benefit of the **alfapump** in malignant ascites is that the physician is able to conduct 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



**“Patients are reporting they are suffering significantly less due to them not re-accumulating ascites or requiring further paracentesis.”**

Dr. Markus Schoenberg, Klinikum der Universität München



**“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

### Liver cirrhosis and refractory ascites

#### COMPLETED STUDIES

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

Name of Study	Description	Number of Patients
<b>PIONEER Study</b>	Prospective, multi-centre, open-label, uncontrolled study to assess the safety and performance of the <b>alfapump</b> in patients with refractory liver ascites and diuretic resistance (completed in 2013).	40
<b>Gines Study</b>	Prospective, single-centre, uncontrolled study to evaluate the effects of the <b>alfapump</b> on kidney and circulatory function in patients with liver cirrhosis and refractory ascites (completed in 2014).	10
<b>European Randomised Controlled Trial (RCT)</b>	6-month open-label, randomised and controlled study in Europe on the <b>alfapump</b> versus LVP for the treatment of refractory liver ascites (completed in 2016).	58
<b>Post Marketing Surveillance Registry (PMSR)</b>	Multi-centre, open-label observational study in Europe designed to follow patients implanted with an <b>alfapump</b> for up to 24 months (completed in 2018).	100 <sup>(1)</sup>
<b>Retrospective Study at Hannover Medical School</b>	Retrospective, single-centre study at Hannover Medical School to investigate the <b>alfapump</b> as an alternative for LVP in a real-world setting (published in 2018).	21
<b>MOSAIC (North American IDE feasibility) Study</b>	12-month open-label, single-arm study in the U.S. and Canada (North America) to assess the safety and efficacy of the <b>alfapump</b> in patients with recurrent or refractory liver ascites (completed in 2018).	30

The key findings from these studies include:

- an approximately 90% reduction in the mean number of LVPs per month for refractory liver ascites patients treated with the **alfapump** versus patients treated with LVP standard of care;
- a clinically significant improvement in quality of life for patients treated with the **alfapump** versus patients treated with LVP standard of care; and

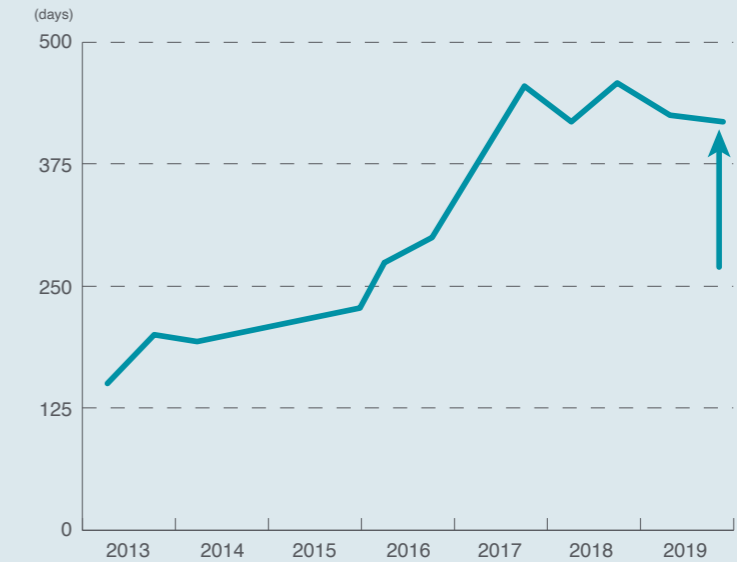
- refractory liver ascites patients treated with the **alfapump** demonstrated a clear nutritional benefit versus patients treated with LVP standard of care over 30-day and 90-day periods.

To date, nine publications on clinical study results have been issued in peer-reviewed journals, which we believe are essential to support the acceptance of the **alfapump**.

(1) Data on initial 56 patients has been published. Data on all 100 patients is intended to be submitted for publication in 2020.

## 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 **alfapump** therapy. Following these improvements, there has been a clear increase in clinical outcomes.



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

## NASH 101

Incidence of obesity has more than doubled world-wide 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<sup>(i)</sup>.

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

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

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

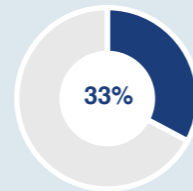
(i) The NASH education program

(ii) Younossi et al., Journal of Hepatology, 2016

- \$292 bn -

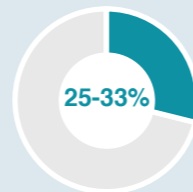
In the U.S., the current economic burden of NAFLD is estimated at \$292 billion per year, a tremendous and growing burden<sup>(ii)</sup>

### NAFLD



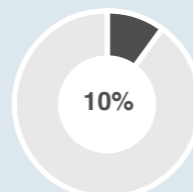
1/3 of US citizens has NAFLD, the hepatic manifestation associated with type-2 diabetes and obesity

### 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

“A Big, Fatty Opportunity for Big Pharma”

The Wallstreet Journal

“Nonalcoholic Steatohepatitis (NASH): An Overlooked Disease”

Int. J. Clin. Pharmacol. Pharmacother.

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

The Nash Education Program

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

KBC Securities

“Non-alcoholic fatty liver disease: a pandemic disease with multisystem burden”

Hepatobiliary Surg. Nutr.

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

CNBC

“Prepare for ‘the coming tsunami’ of NAFLD”

The Hospitalist

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

The Telegraph

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

Gastroenterology



**ONGOING STUDIES**

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

The timings presented in the table below reflect pre-COVID-19 expectations and are likely to be delayed given the current global health situation.

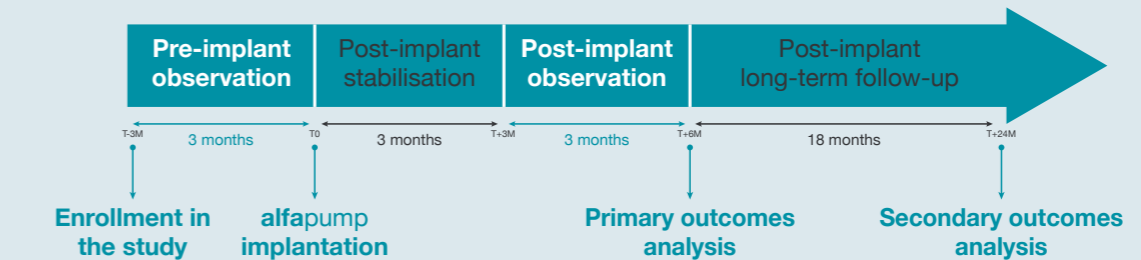
Name of Study	Description <sup>(1)</sup>	2019 2020 2021 2022			
<b>POSEIDON (North American pivotal) Study</b>	North American pivotal study in up to 50 patients with recurrent or refractory liver ascites implanted with the <b>alfapump</b> to demonstrate the efficacy and cost-effectiveness of the <b>alfapump</b> .				
<b>ARIA Pump Study<sup>(2)</sup></b>	Randomised, open-label health economic study in France in 90 patients with refractory liver ascites to evaluate the cost utility of the <b>alfapump</b> 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).				
<b>TOPMOST<sup>(3)</sup></b>	European registry study in cirrhosis patients that have been implanted with the <b>alfapump</b> .				
<b>Step Counter Study</b>	Quality of life study in 20 patients to measure the impact of the <b>alfapump</b> 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.

(2) Funded by the French government and conducted by leading French clinicians. Estimated study completed date Dec 2022 as per [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03506893) (NCT03506893).

(3) The dashed shading of the arrow indicates that the study is expected to extend beyond 2022.

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

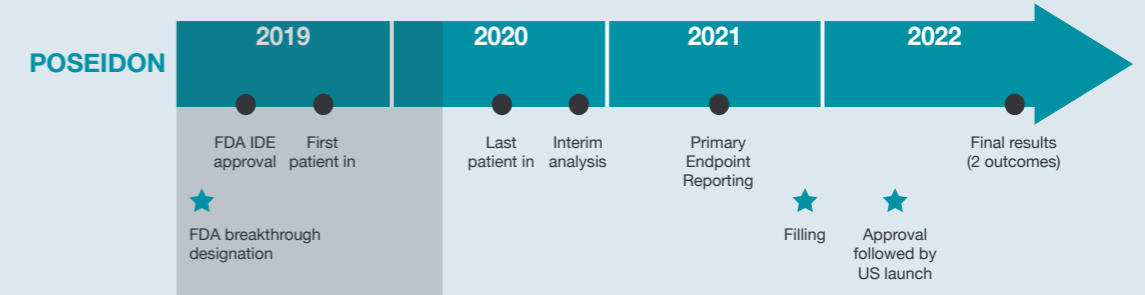


POSEIDON is a single-arm, open-label, within-subject crossover study of the **alfapump** in patients with recurrent or refractory ascites due to liver cirrhosis in centres across the U.S. and Canada. Up to 60 patients will be enrolled in the study, entering into the pre-implant observation period, allowing for up to 50 patients to be implanted with the **alfapump** for primary endpoint analysis. The study also allows for up to 30 patients to be enrolled in a roll-in cohort, to ensure centres are experienced with the **alfapump** prior to implanting patients in the pivotal study cohort.

Pivotal cohort patients will enter into a 3-month pre-implant observation period in which they will receive standard of care therapy (consisting of

paracentesis) before the **alfapump** is implanted. The primary effectiveness outcomes of the study include the proportion of patients with a 50% reduction in the overall average frequency of therapeutic paracentesis per month in the post-implant observation period (month four to month six after implantation) as compared to the pre-implant observation period. The primary safety endpoint is the rate of **alfapump** 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.

## Pursuing North American approval of the **alfapump** – POSEIDON study



The timings presented in the graph reflect pre-COVID-19 expectations and are likely to be delayed given the current global health situation.

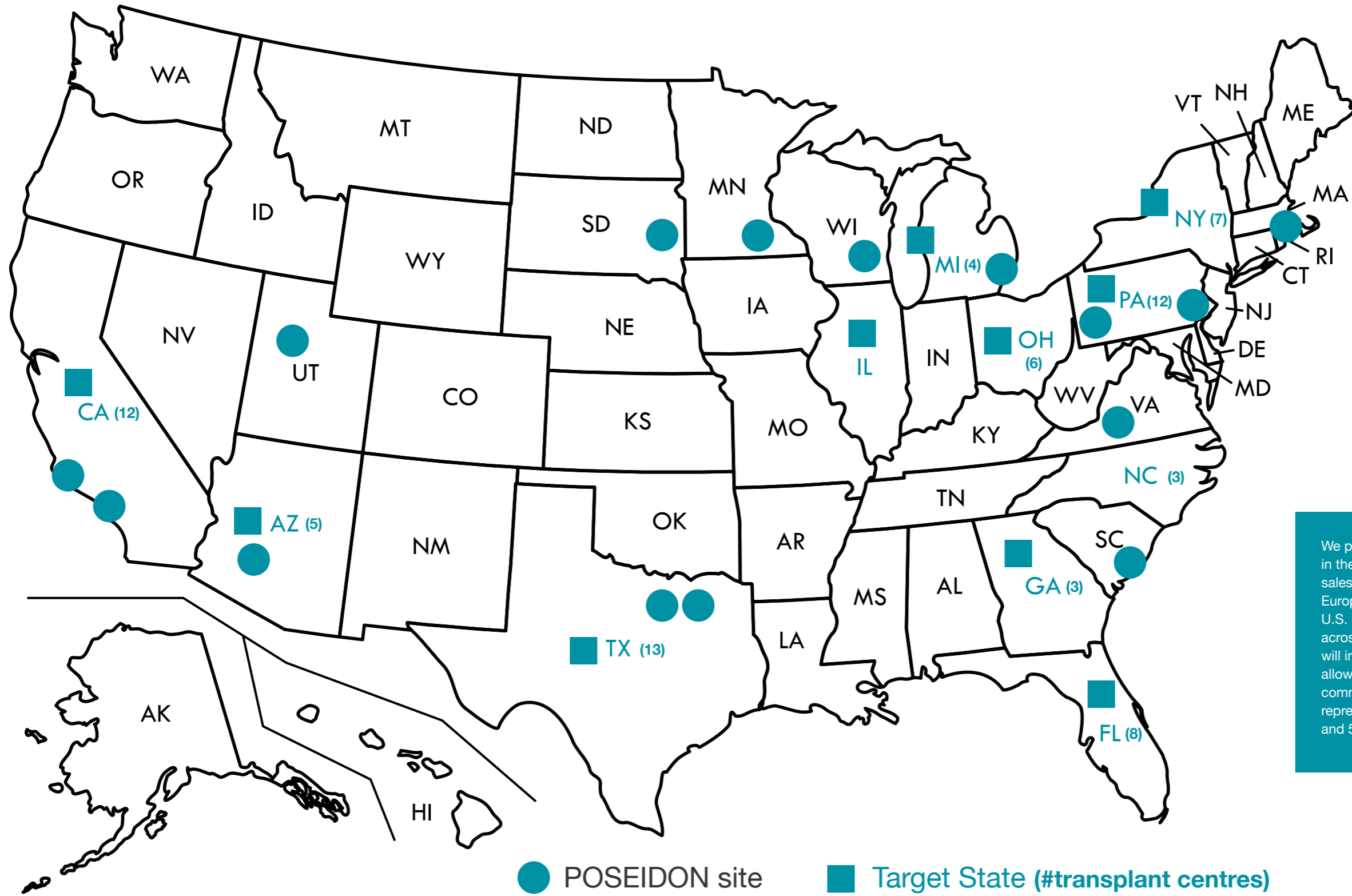
In January 2019, we received breakthrough device designation from the U.S. FDA for the **alfapump** for the treatment of recurrent or refractory ascites. This program is designed to facilitate the development and expedite the review of devices that provide more effective treatment or diagnosis of life-threatening 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.

As a result of the **alfapump** 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 and before the COVID-19 pandemic we expected all patients to be enrolled by mid-2020. Interim results from the roll-in cohort were forecast to be reported in H2 2020 and reporting of

the primary endpoint for the study cohort was expected by mid-2021. Reporting of secondary endpoints that was planned by end 2022, is intended to further support reimbursement of the **alfapump**. The planned U.S. launch of the **alfapump** was brought forward to H1 2022, as a result of the optimised clinical trial design and breakthrough device designation, taking into account prioritised FDA review of our regulatory filing package. However, all of these timings are subject to delay due to the COVID-19 pandemic.

Another benefit of the **alfapump** breakthrough device designation is an enhanced path to CMS (Centers for Medicare and Medicaid Services) reimbursement under an alternative new technology add-on payment (NTAP) model. This special status for breakthrough devices was recently defined in a final CMS ruling<sup>(1)</sup> and is expected to further support reimbursement and market adoption of the **alfapump** in the U.S. Pursuant to this ruling, FDA-designated and authorized breakthrough devices that meet certain cost criteria are eligible for the add-on payment without being required to meet the substantial clinical improvement standard required under the existing NTAP system. As a result, we believe the **alfapump** will be eligible for reimbursement at an earlier stage than would have been the case prior to the CMS ruling and Medicare beneficiaries will have timely access to the **alfapump** while real-world evidence continues to emerge.

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



We plan to directly commercialise the **alfapump** 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<sup>19</sup>. 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.



## Malignant ascites

### COMPLETED STUDIES

In addition to the clinical studies in patients with liver disease, we have also completed a clinical study in patients with malignant ascites:

Name of Study	Description	Number of Patients
<b>Retrospective Malignant Ascites Study</b>	Retrospective open-label study in Europe to assess the performance and safety of the <b>alfapump</b> for the treatment of malignant ascites (completed in 2017).	17

This retrospective study demonstrated that the **alfapump** 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. The results of this study were published in *BMC Palliative Care*.

### PLANNED STUDIES

Following positive results in the Retrospective Malignant Study, we plan to start PROMAS, a prospective, controlled study in selected European countries to confirm the efficacy and clinical impact of the **alfapump** in patients with malignant ascites. The study is expected to enrol up to 40 patients with malignant ascites due to various malignancies.

The timing presented in the table below reflect pre-COVID-19 expectations and is likely to be delayed given the current global health situation.

Name of Study	Description <sup>(1)</sup>	Timing			
		2019	2020	2021	2022
<b>ProMAS</b>	Controlled study in Europe to evaluate the efficacy and clinical impact of the <b>alfapump</b> vs. standard of care in up to 40 malignant ascites patients.				

(1) The description and timing of this study 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.

## Commercial operations

### Approval and reimbursement

The **alfapump** has a CE-Mark for the treatment of refractory ascites in patients with liver cirrhosis and malignant ascites and is currently reimbursed in Switzerland and Germany. In Switzerland, the **alfapump** is reimbursed for approximately CHF 30,000 through a Swiss DRG code, which covers both the pump and the implantation procedure. In Germany, the **alfapump** 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 completion of the study.

In the U.K., NICE issued a final recommendation in November 2018 for the use of the **alfapump** for the treatment of refractory ascites with special arrangements for clinical governance, consent, and audit or research.

In markets such as the Netherlands, Denmark, Belgium 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 **alfapump** 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 approach, 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 **alfapump**.

### Sales and marketing

We have a commercial team of 14 people focusing on our key European markets, including Germany, Switzerland, the U.K. and France (subject to the successful completion of the ARIA Pump Study). Outside of those markets, we have entered into exclusive distribution agreements with Fresenius Medical Care in Belgium and the Netherlands, Vingmed in Denmark and Gamida in Israel.

Upon approval of the **alfapump** in the U.S. and Canada, 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 get reimbursement. In those markets, we will either establish a direct commercial presence or work with distributors.

To raise awareness of the **alfapump** amongst clinicians, patients and their relatives, we invest in promotional activities using both conventional and social media, such as Facebook 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](http://www.sequanamedical.com) and [www.alfapump.com](http://www.alfapump.com)) provide information to patients, their families and clinicians on the **alfapump**. Our YouTube videos on the **alfapump** have received more than 340,000 views.

To date, over 750 **alfapump** systems have been implanted, of which 80% were commercial implants and 20% as part of a clinical study.

# alfapump DSR

Potential chronic treatment for heart failure-induced volume overload

## The alfapump DSR system

The **alfapump** DSR is built upon the proven **alfapump** platform, to deliver a fully implanted system for Direct Sodium Removal (DSR) therapy for the management of volume overload in heart failure. Clinical proof-of-concept data from the first-in-human single dose DSR study have been published in the high impact cardiovascular journal, *Circulation*. A repeated dose **alfapump** DSR study for the treatment of diuretic-resistant heart failure patients (RED DESERT) is ongoing.

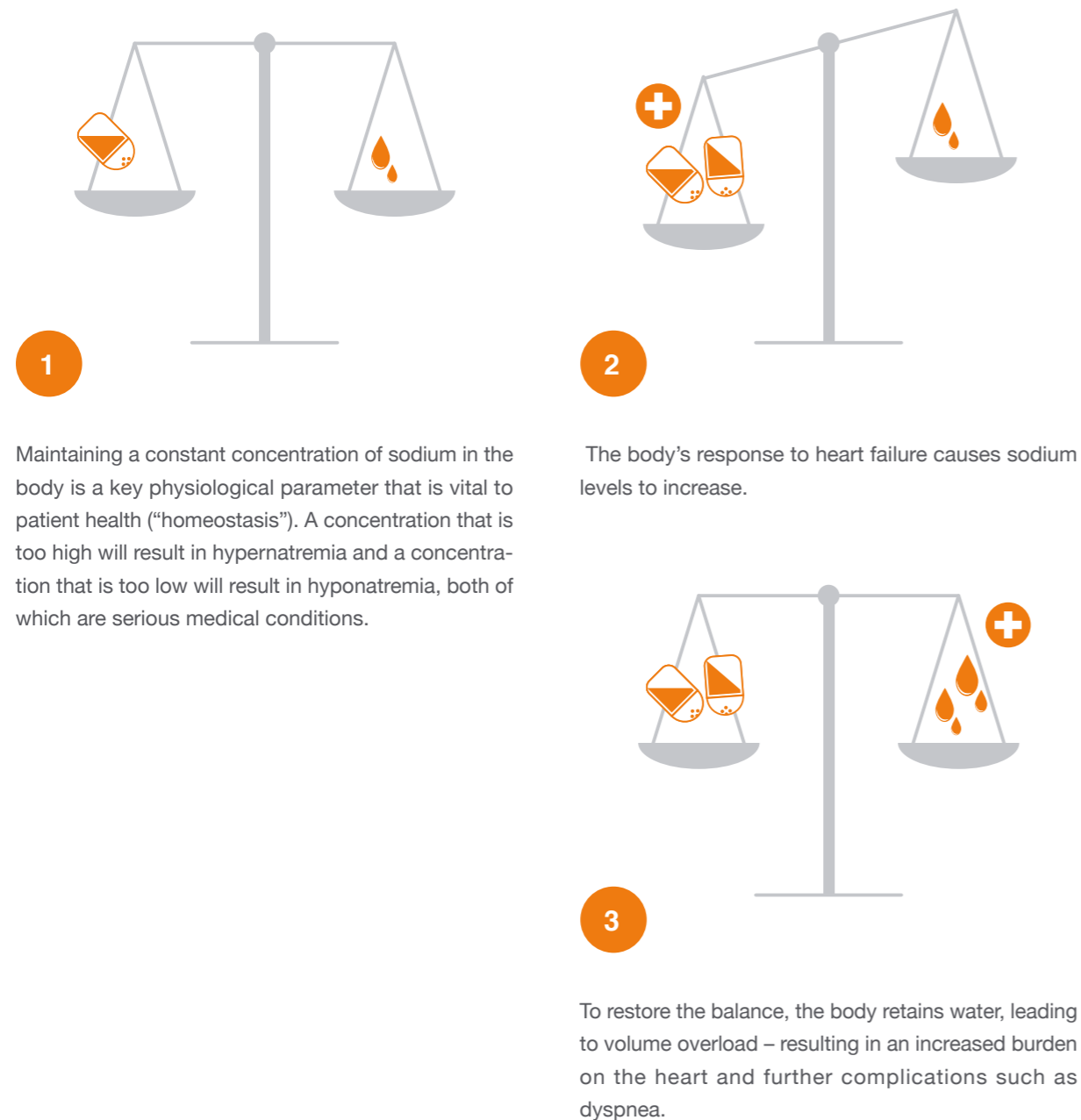
We are privileged to work with Dr. Javed Butler, Dr. Maria Rosa Costanzo, Dr. Wilson Tang and Dr. Jeffrey Testani, pre-eminent figures in the heart failure clinical community who have been appointed as our Heart Failure Scientific Advisors for the development of **alfapump** DSR.



## Direct Sodium Removal

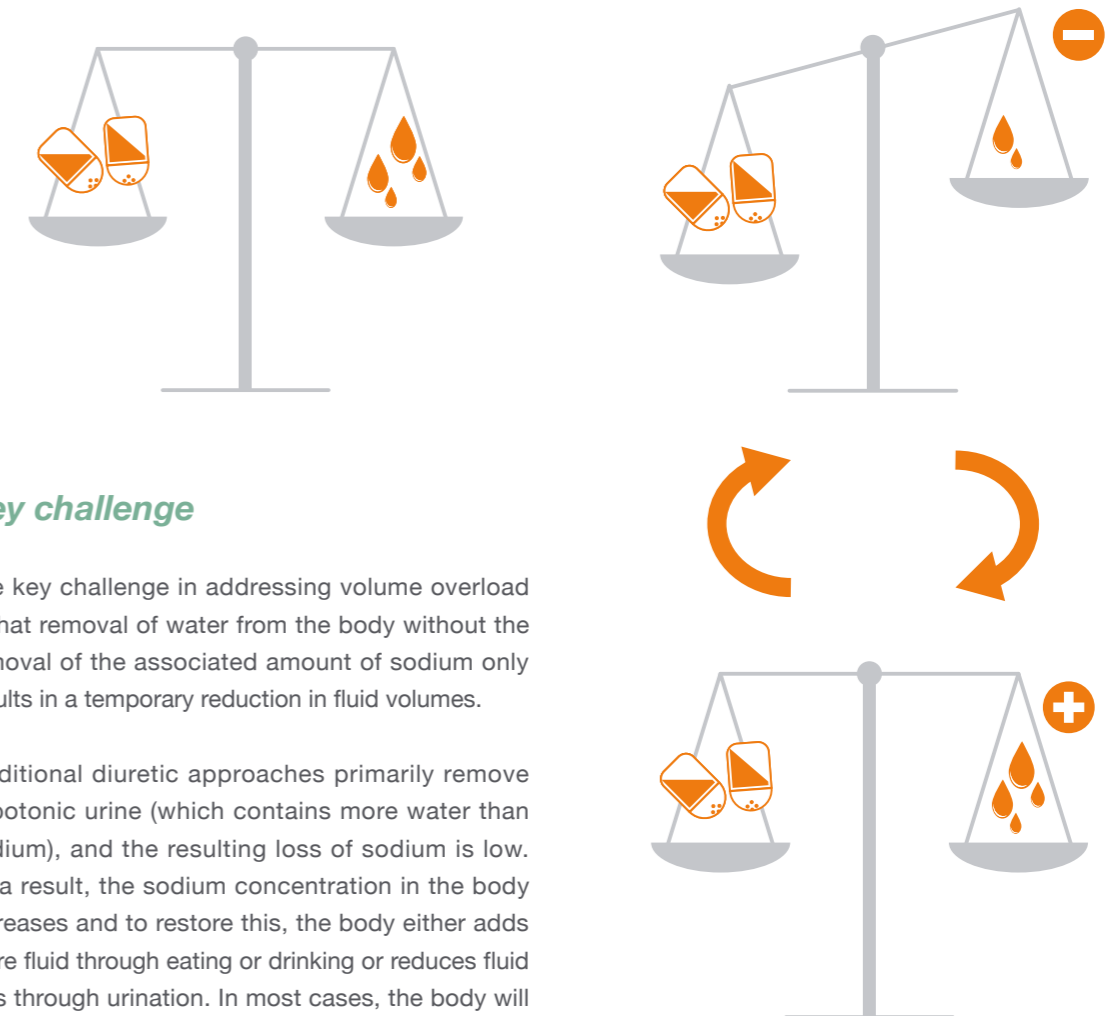
Direct Sodium Removal (DSR) is our proprietary therapy for the management of volume overload in heart failure.

### Key principle



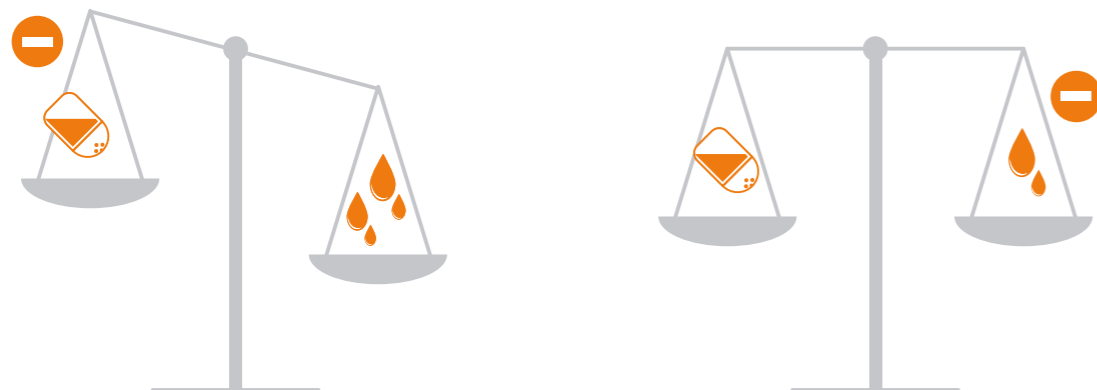
## Volume overload in heart failure

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



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.<sup>23</sup>



*DSR approach*

The DSR approach is to remove excess sodium in patients with residual renal function.

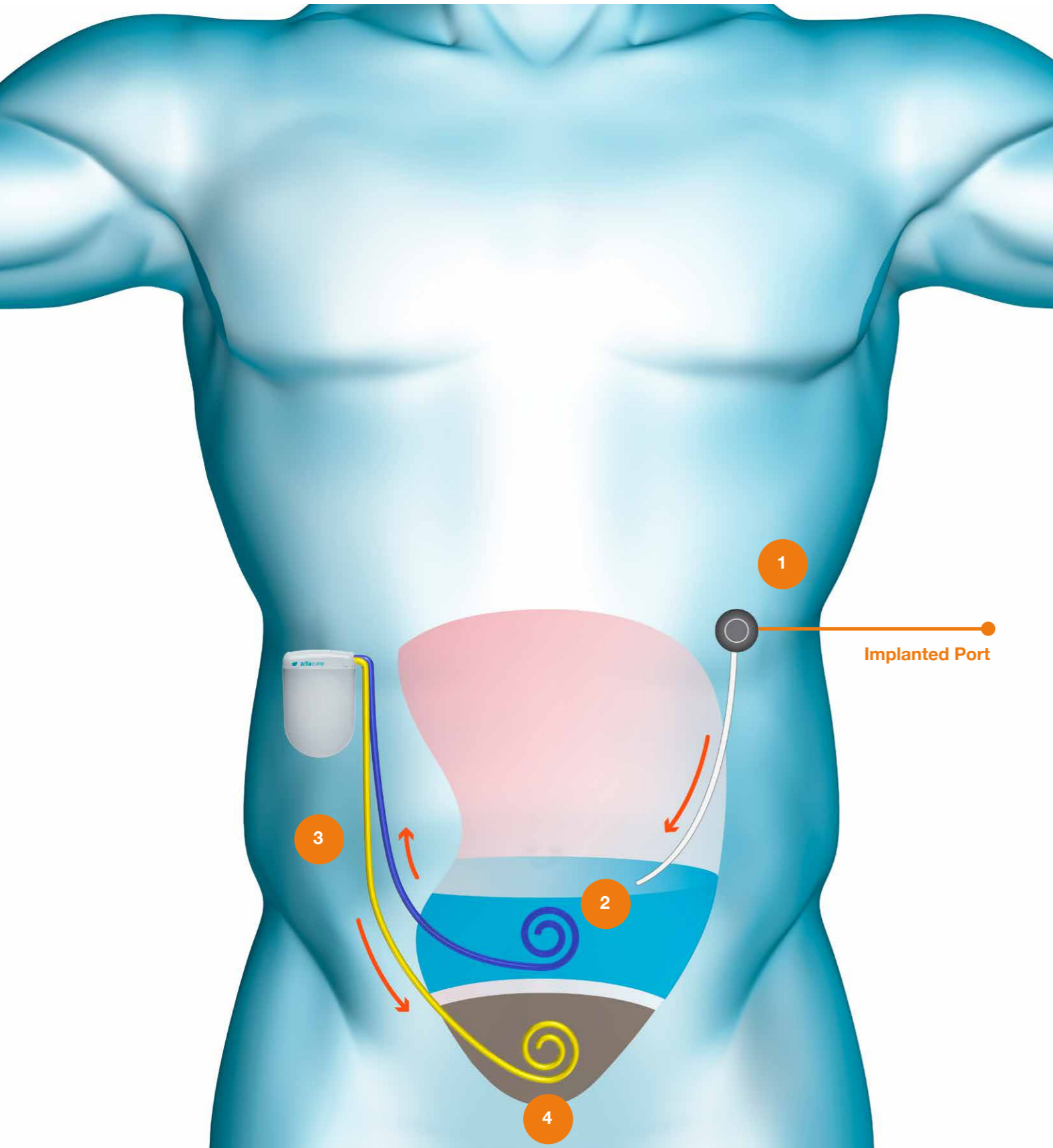
As a result, the body acts to restore the sodium concentration in the body by eliminating fluid through urination and osmotic ultrafiltration, resulting in a sustained level of fluid loss.

DSR therapy involves the use of the peritoneal cavity for the removal of sodium via diffusion. The peritoneal cavity 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 abdomen 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. Circulation keeps the effective blood sodium concentration high. 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 **alfapump** DSR combines three proven elements, (i) DSR, (ii) the **alfapump** system, and (iii) 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 **alfapump** where it is eliminated via urination.

We believe that our accumulated experience of over 750 implanted **alfapump** systems and the clinical proof-of-concept of DSR potentially de-risks the technical and clinical development of **alfapump** DSR.

In addition to the direct removal of the sodium and associated elimination of fluid, we believe that the ability of **alfapump** DSR to remove any spontaneous accumulation of fluid (which is likely to be isotonic to the body) in the abdomen will further enhance the efficacy of **alfapump** DSR therapy. Furthermore, the ability of the **alfapump** DSR to monitor changes in the rate of spontaneous accumulation of fluid in the abdomen and changes in intra-abdominal pressure is believed to deliver significant diagnostic information to clinicians, potentially providing advance warning of decompensation. We believe this data monitoring 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 alfapump 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 volume overload
- leverages natural processes for fluid removal
- leverages proven elements: DSR, **alfapump**, surgically implanted port
- allows flexible dosing of DSR infusate

## Market opportunity and limitations of current therapies

Heart failure is a progressive disease that results in the heart being unable to pump enough blood and thereby supply oxygen to support other organs in the body. 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.<sup>20</sup> It is estimated that at least 26 million people are living with heart failure worldwide<sup>21</sup>. Total direct medical costs for the U.S. heart failure market are projected to reach \$53 billion in 2030<sup>22</sup>.

Heart failure can disturb the normal functioning of the kidney, diminishing its ability to excrete sodium from the body and triggering compensatory mechanisms that cause water retention resulting in volume overload. Patients with heart failure commonly experience shortness of breath, fatigue, difficulty exercising and swelling of the legs. The increase in fluid volume increases the burden on the weakened heart, further exacerbating the problem clinically.

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

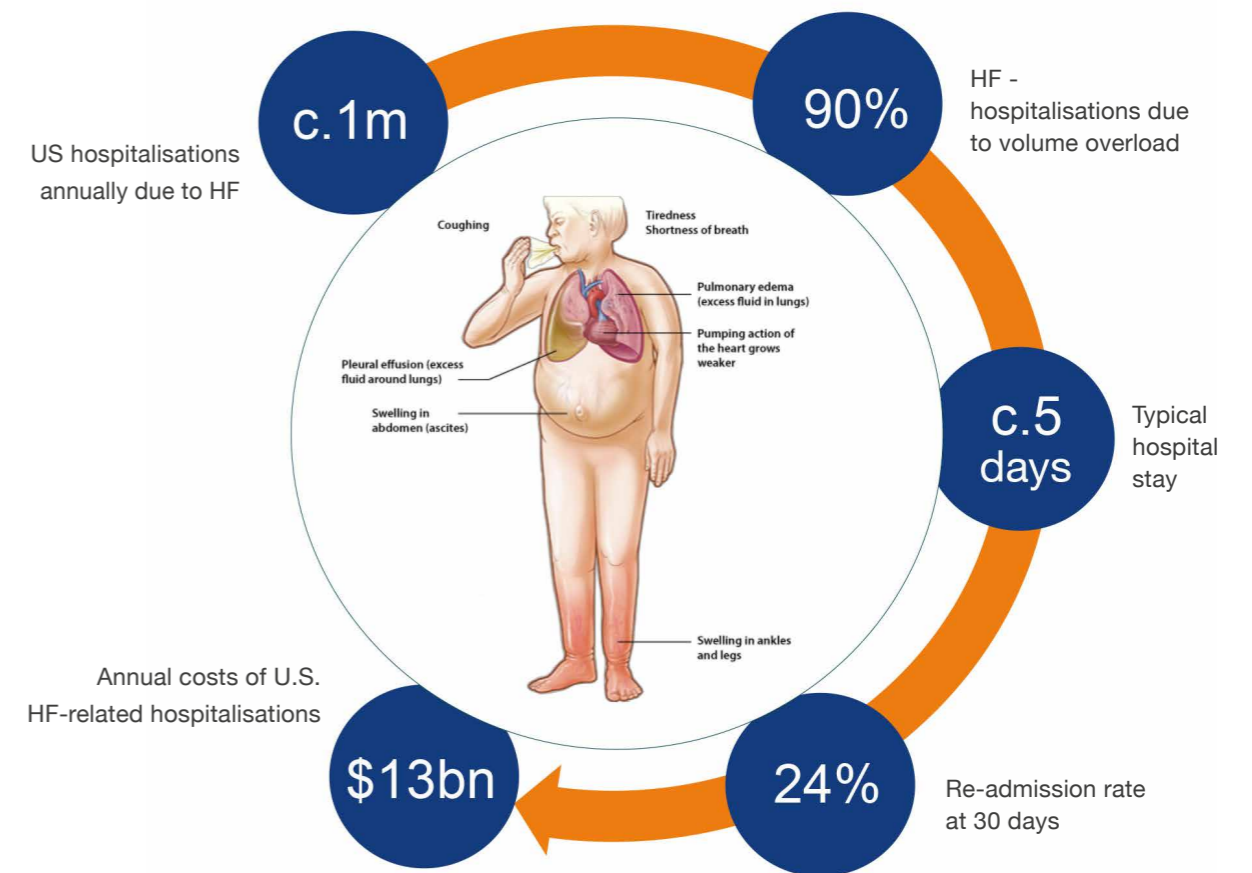
24% hospital re-admission within 30 days

Volume overload, which presents in Class III and IV patients under the NYHAFC (New York Heart Association Functional Classification), is currently treated with diuretics, which is 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<sup>23</sup>. The clinical hallmarks of diuretic agent resistance are insufficient symptom relief, higher risk of in-hospital worsening of heart failure, increased mortality after discharge, and a 3-fold increase in re-hospitalization rates<sup>24</sup>. Once patients no longer respond to or cannot handle the side-effects of diuretics, clinical alternatives are limited and have significant limitations. The course of their disease typically accelerates dramatically due to the strain that the excess fluid places on their heart. 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 semi-permeable 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<sup>24</sup>.

Volume overload in the body is a major clinical problem and the leading cause of hospitalisations for patients suffering from heart failure<sup>25</sup>. There are approximately one million hospitalisations for heart failure annually in the U.S., costing approximately \$13 billion each year<sup>26</sup>. Of these admissions, 90% are due to symptoms of volume overload,<sup>25</sup> with an average length of stay of 5 days<sup>27</sup>.

It is estimated that nearly 50% of hospitalised patients with heart failure are discharged with residual fluid excess.<sup>25</sup> By not truly addressing the volume overload problem, patients are being readmitted to hospital too frequently, with 30-day readmission rate of 24%<sup>28</sup>.

There is a significant unmet medical need for a safe and effective, long-term treatment for volume overload caused by heart failure in diuretic resistant patients that is cost-effective, reducing the number of hospitalisations and improving patient quality of life.





## Clinical development

### Completed studies

#### PRE-CLINICAL STUDIES

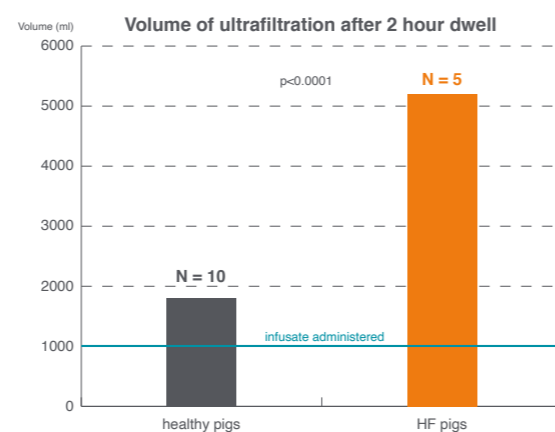
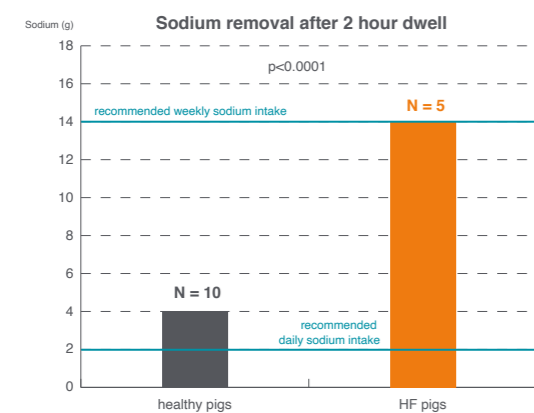
The impact of administering a single dose DSR infusate to the peritoneal cavity, and the resulting sodium and fluid removal, was evaluated in 20 pigs, of which five had experimentally-induced heart failure.

Name of Study	Description	Number of Animals
<b>Healthy pig DSR proof-of-concept study</b>	Single dose, single arm proof of concept study to assess impact of direct sodium removal therapy in healthy pigs.	15
<b>Heart failure pig DSR proof-of-concept study</b>	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

The study demonstrated that DSR therapy was capable of removing large quantities of fluid and sodium whilst having a negligible impact on the sodium concentration in the bloodstream.

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.<sup>29</sup> 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.<sup>26</sup> and approximately 5 litres of fluid from the peritoneal cavity (i.e., a net of 4 litres was removed).



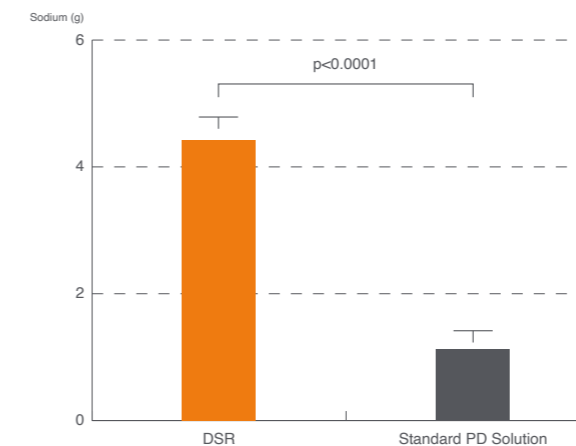
The serum sodium levels were analysed regularly during the 2-hour dwell period and there was a negligible impact on the concentration of sodium in the bloodstream of the pigs. The findings of these studies were presented at EuroPCR 2018 and HFSA 2018.

#### FIRST-IN-HUMAN STUDY

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.

Name of Study	Description <sup>(6)</sup>	Number of subjects
<b>Single Dose DSR Proof of Concept study</b>	First-in-human clinical study to demonstrate the safety, tolerability and dynamics of a single dose DSR therapy (without alfapump).	10

The study demonstrated that DSR therapy was safe and well-tolerated during a single dose administration and met its primary endpoint of non-discontinuation of the protocol due to discomfort or adverse events, with similar tolerability to standard PD solution.



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).

The results were presented at key medical conferences, including Heart Failure 2019, HFSA Annual Scientific Meeting and TCT 2019, and published in the high impact cardiovascular journal, *Circulation*.

### Ongoing / planned clinical studies

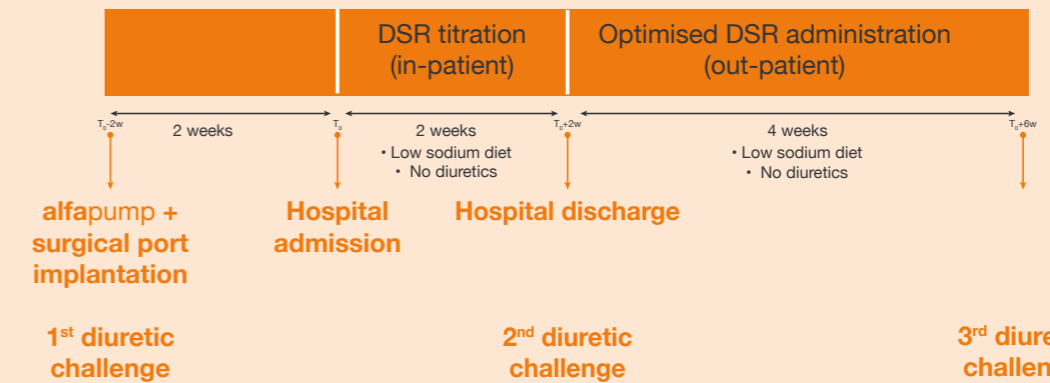
Following pre-clinical and clinical proof-of-concept of DSR therapy, we have started the first-in-human study of **alfapump** DSR (RED DESERT), combining DSR therapy with our proven **alfapump** platform. Following RED DESERT, we plan to initiate a feasibility study. The results of this feasibility study will be used to find a strategic partner for the further clinical development of the **alfapump** DSR.

The timings presented in the table below reflect pre-COVID-19 expectations and are likely to be delayed given the current global health situation.

Name of Study	Description <sup>(1)</sup>	Ongoing			
		2019	2020	2021	2022
<b>Repeated Dose alfapump DSR study (RED DESERT)</b>	Study in up to 10 diuretic-resistant heart failure patients to demonstrate the safety, tolerability and efficacy of the <b>alfapump</b> DSR using repeated dose DSR therapy over a 6-week period.		➔		
<b>Feasibility study of alfapump DSR</b>	Feasibility study to assess safety and efficacy of <b>alfapump</b> DSR in patients with heart failure induced volume overload.			➔	

(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



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

Following **alfapump** DSR system implantation, patients will undergo a diuretic challenge with timed biospecimen collection. On day 14 post-implant (day 0), the patient will be admitted for a 14-day in-patient period in which diuretics will be withheld and patients will be put on a strict low-sodium diet. During the first seven days (day 0 to day 6), patients will be treated with DSR infusate on Monday, Wednesday and Friday, administered through the implanted surgical port into the peritoneal cavity. The DSR infusate will remain in the peritoneal cavity for a two-hour dwell time, after which fluid will be eliminated from the peritoneal cavity through the bladder using the **alfapump** system. During the following seven days (day 7 to day 13), the optimal DSR therapy (frequency of administration and volume of DSR infusate) will be evaluated

for each patient. Following the 14-day in-patient period, patients will undergo a second diuretic challenge. Thereafter, diuretics will continue to be withheld and patients will come into clinic for their DSR infusate administration over the subsequent four weeks. After completion of the study period, patients will 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 the **alfapump** 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 will evaluate the potential impact of DSR to restore response to diuretics following DSR therapy.

Initial results were expected to be reported in Q2 2020 and full results planned for Q3 2020 but are likely to be delayed due to the COVID-19 pandemic.



# Other potential applications

Through the development and optimisation of the **alfapump** for liver ascites and malignant ascites, we have developed a system with a range of important capabilities that is clinically proven in the real world setting as well as in multiple clinical studies. These include a fully implanted pump capable of pumping up to 4 litres of biological matter per day and being charged wirelessly. The system does not cause significant heating of the body and the system can be controlled wirelessly.

The **alfapump** already enables the monitoring of key performance parameters through our proprietary DirectLink system. We intend to build upon the existing monitoring capabilities to integrate additional parameters (e.g., temperature, blood pressure, weight) so that clinicians can more closely monitor their patients, optimise care, and potentially identify adverse events earlier. We believe this will deliver improved clinical outcomes and lower care costs for high acuity patient groups.

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 **alfapump** technology 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 **alfapump** 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 **alfapump** DSR therapy may be able to reverse such resistance leading to increased treatment options. This may lead to use of **alfapump** therapy in conditions such as renal failure.



# Investor relations

## The shares in 2019

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 2019, the share capital of the Company amounted to €1,306,939.52 represented by 12,611,900 shares.

In addition to the outstanding shares, the total number of outstanding subscription rights on 31 December 2019 amounted to 1,356,278, entitling their holders (if exercised) to subscribe to 1,855,825 new shares with voting rights in total.

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

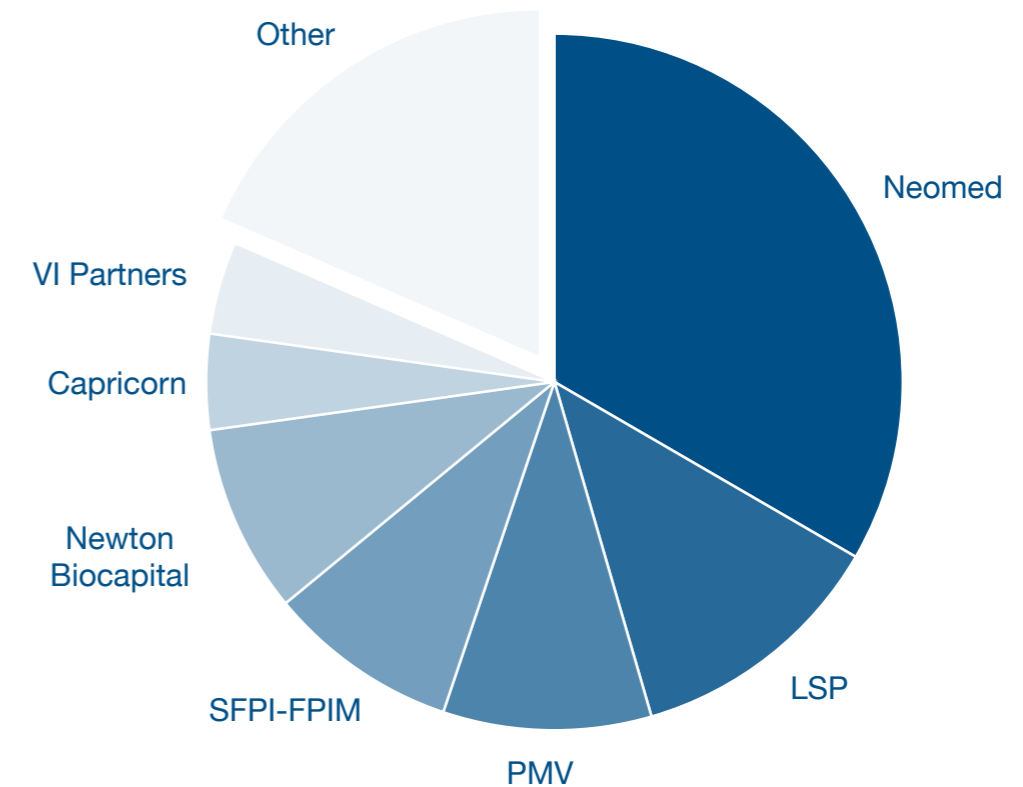


### Trading volume in 2019

Average daily volume	4,058
Average value	€26,922
Total traded volume	888,794
Total traded volume	€5,895,847

## 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 2019 and the transparency notifications received until that date, the shareholder structure of the Company as per 31 December 2019 was as follows:



Neomed	Norway	33.3%
LSP	the Netherlands	12.2%
PMV	Belgium	9.7%
SFPI-FPIM	Belgium	8.8%
Newton Biocapital	Belgium	8.7%
Capricorn	Belgium	4.7%
VI Partners	Switzerland	4.2%

## Analyst coverage

Sequana Medical was covered by four brokers at the end of 2019

Broker	Analyst
KBC Securities	Sandra Cauwenberghs & Lenny Van Steenhuyse
Kempen	Ingrid Gafanhão
Kepler Cheuvreux	Matthias Maenhaut & Kris Kippers
Mirabaud	Daniel Jelovcan

## Financial calendar

28 May 2020	Annual General Meeting 2020
3 September 2020	Half year results 2020

## Investor relations contact

For all your investor relations questions, please contact us at [IR@sequanamedical.com](mailto:IR@sequanamedical.com) or via:

Lies Vanneste, Director IR  
 Sequana Medical NV  
 Technologiepark 122  
 9052 Zwijnaarde, Belgium  
 T: +32 498 053579

# Operational and other information

## Investments

Sequana Medical invests substantial amounts in the development of the **alfapump** and more specifically in clinical studies to demonstrate the safety and efficacy of the **alfapump** and the **alfapump** DSR.

The amounts spent during the past three years are as follows (in million euro):

	2019	2018	2017
<b>Clinical studies</b>	3.92	1.67	1.75

In the last two years, Sequana Medical invested significantly in the expansion of their commercial teams in Europe. The evolution of the sales & marketing expenses is presented in the table below:

	2019	2018	2017
<b>Sales &amp; Marketing</b>	2.84	2.44	1.51

The costs of obtaining and maintaining regulatory approval for the **alfapump** (and potentially in the future the **alfapump** DSR) as well as for the preparations for the new Medical Devices Regulation (Regulation 2017/745), are included within quality and regulatory expenses. The Company invests substantial amounts in the quality and regulatory processes. The evolution of the quality and regulatory expenses is presented in the table below:

	2019	2018	2017
<b>Quality &amp; Regulatory</b>	1.82	1.37	1.23

Sequana Medical strengthened their financing structure through the IPO in 2019 and invested in new corporate headquarters through the relocation from Switzerland to Belgium. As a public company, continuing investments in the structure are required. These costs are reported in the General & Administrative category and the evolution of these General & Administrative expenses is presented in the table below:

	2019	2018	2017
<b>General &amp; Administrative</b>	4.26	5.76	1.99

The investments in tangible fixed assets (capex) are not considered to be material. There were no investments in financial assets, except for some cash guarantees which are not considered to be material, during the past three years.

Sequana Medical continues to invest substantially and more specifically, in the area of the clinical studies with the focus on the **alfapump** POSEIDON pivotal study in recurrent and refractory ascites due to liver cirrhosis and the **alfapump** DSR RED DESERT study in patients with diuretic-resistant heart failure.

The investments in these strategic, important clinical studies are determined and monitored at the level of the corporate headquarters in Belgium. The clinical studies are primarily carried out in the US, Canada and Europe.



These investments, which are crucial for the further development of the Company, will be funded through existing resources and new funds raised from existing investors and new experienced life science investors and industry experts.

Sequana Medical has no material contracted expenditures for the acquisition of property, plant and equipment. There are no material capital commitments resulting from operating lease contracts.

## Joint ventures

There are no joint ventures and undertakings, in which the Company holds a proportion of the capital likely to have a significant effect on the assessment of its own assets and liabilities, financial position or profits and losses.

## Environmental issues

There are no environmental issues, which may affect the Company's utilisation of the tangible fixed assets.

## Cash flows

The Company successfully raised EUR 19 million in January 2020 by means of a private equity placement via an accelerated bookbuild offering. The net proceeds from the private placement are expected to extend the current cash runway of the Company from Q2 2020 into H1 2021.

Net cash outflow from operating activities was €18.48 million in 2019 compared to a net cash outflow of €9.88 million in 2018. The difference mainly relates to the increase in operating loss and the increase in working capital.

Cash flow from investing activities resulted in a net outflow of €0.34 million in 2019 compared to a net outflow of €0.05 million in 2018. The net cash outflow mainly relates to the investment in leasing of cars and buildings (IFRS 16 applied).

Cash flow from financing activities resulted in a net inflow of €23.22 million in 2019, mainly as a result of the IPO proceeds, compared to a net inflow of €9.47 million in 2018, as a result of the proceeds of several convertible loans.

The Company ended 2019 with a total liquidity position of €5.59 million (2018: €1.32 million).

## Restrictions on the use of capital resources

As a security for the fulfilment of the financial obligation, the Company has pledged Intellectual Property as well as the related assets to the venture debt provider Bootstrap Europe S.C.Sp. Total outstanding debt due to Bootstrap amounts to €2,720,401 as per 31 December 2019.

## Trend information

**Trends in sales:** Following the focus on its core commercial markets and the growing evidence of the benefits of the **alfapump** in patients with refractory liver ascites, Sequana Medical observed steady growth in sales from Germany in 2019 offset by a decline in non-core markets. We had originally expected this growth in core markets to continue in 2020, leading sales to increase from the 2019 level. However, the impact of the global health situation caused by the spread of the COVID-19 coronavirus and its impact on global health systems, specifically current restrictions on non-essential medical procedures and hospital visits, will impact sales in 2020.

**Trends in inventory:** At the date of this report, inventory levels are more or less in line with the levels at 31 December 2019.

**Trends in costs and selling prices:** At the date of this report, costs and selling prices did not change since the end of the reporting period.

**Trends in production and engineering:** Sequana Medical continues to use its experience in developing the **alfapump** to: (i) improve **alfapump** performance (e.g. extend **alfapump** life through improving the production process and minor design modifications), (ii) deliver enhanced DirectLink capabilities, enabling a broader range of parameter monitoring including sensors inside and outside of the body to deliver a disease management platform, and (iii) reduce production cost through optimised design and purchasing efficiencies.

## Employees

The number of temporary employees is considered to be not material, nor does Sequana Medical employ a significant number of temporary contractors or consultants.



2

Corporate  
Governance





## Corporate Governance

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# 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 2019.

### 1.1. Developments, results, risks and uncertainties

(Article 3:32, 1° BCAC)

#### 1.1.1. Operational review

**alfapump North America – clear progress in pursuing approval in the U.S. and Canada, large market opportunities driven by NASH-related cirrhosis**

- In January 2019, Breakthrough Device Designation received from the U.S. FDA for the **alfapump** for the treatment of recurrent and refractory liver ascites. This allows for more frequent interactions with FDA experts and makes the **alfapump** eligible for prioritized review of the submission package to obtain regulatory approval in the U.S.

- In June 2019, unconditional IDE<sup>(i)</sup> approval received from the U.S. FDA to start the POSEIDON pivotal study to support the North American approval of the **alfapump**, using an optimised clinical trial design. Up to 50 patients with recurrent or refractory ascites due to liver cirrhosis across up to 20 centres will be implanted with the **alfapump** for primary endpoint analysis at nine months after enrolment. Up to a further 30 patients will be enrolled in a roll-in cohort, to ensure centres are experienced with the **alfapump** prior to implantation in the pivotal study cohort.
- In September 2019, first patient enrolled in the pivotal POSEIDON study.
- As a result of the optimised POSEIDON trial design and Breakthrough Device Designation, the planned U.S. launch of the **alfapump** has been brought forward to H1 2022. This timing is likely to be delayed given the current global health crisis.
- The final ruling from CMS<sup>(ii)</sup> in August 2019 regarding the new technology add-on payment (NTAP) pathway for breakthrough devices is expected to further support reimbursement and accelerate market adoption of the **alfapump** in the U.S.
- In January 2020, the results of the North American feasibility study (MOSAIC) of the **alfapump** in recurrent and refractory liver ascites were published in *Liver Transplantation*, concluding that implantation of the **alfapump** may be a definitive treatment for refractory ascites in cirrhosis, especially in patients who are not TIPS<sup>(iii)</sup> candidates.

**alfapump DSR – clinical proof-of-concept of DSR, potential breakthrough therapy for treatment of heart failure patients with volume overload**

- In May 2019, Dr. Testani of Yale University reported clinical proof-of-concept of DSR therapy. Primary and secondary endpoints in the first-in-human single dose DSR study were met, demonstrating that single dose DSR therapy was safe and well-tolerated and resulted in a clinically relevant removal of sodium with consistent results across treated patients.
- Dr. Testani presented positive pre-clinical and clinical proof-of-concept data of DSR therapy at Heart Failure 2019, HFSA Annual Scientific Meeting and TCT 2019.
- In September 2019, Dr. Javed Butler, Dr. Maria Rosa Costanzo, Dr. Wilson Tang and Dr. Jeffrey Testani, pre-eminent figures in the heart failure clinical community, were appointed as the Company’s Heart Failure Scientific Advisors.
- In December 2019, first patient enrolled in RED DESERT, the first-in-human repeated dose **alfapump** DSR study, with Dr. Bartunek, Associate Director at Cardiovascular Center Aalst (Belgium) as the principal investigator.
- In January 2020, positive pre-clinical and clinical proof-of-concept data of DSR therapy were published in *Circulation*, a top tier peer-reviewed cardiovascular journal.
- Preparations are underway for a meeting with the FDA to discuss the start of clinical studies to support the regulatory pathway of the **alfapump** DSR in the U.S.

**alfapump Europe – expanding clinical and commercial experience in key European territories; growth in Germany**

- In May 2019, the **alfapump** was included in the DGVS (“German Society of Gastroenterology Digestive and Metabolic Diseases”) guidelines

for complications of liver cirrhosis, positioning the **alfapump** as a good and safe alternative to repeated LVP and stating that the **alfapump** may also be considered in patients contraindicated for a TIPS.

- In December 2019, results from the retrospective Malignant Ascites study were published in *BMC Palliative Care* highlighting that the **alfapump** was effective in treating palliative patients and improving their quality of life.
- In February 2020, the surgical technique for the implantation of the **alfapump** was published in *Langenbeck’s Archives of Surgery* summarising the experience of leading European **alfapump** implanters.
- Preparations are ongoing for initiation of the ProMAS study, in which up to 40 patients with various malignancies will be recruited across clinical sites in Belgium, the U.K. and Switzerland. This single arm, post-marketing study will evaluate the efficacy of the **alfapump** and its impact on quality of life in patients with malignant ascites. Furthermore, the ProMAS study will evaluate the ability to obtain viable liquid biopsies in a non-interventional manner after implantation of the **alfapump**. This study may be delayed due to the current global health crisis.
- Preparations are ongoing for the Step Counter study to measure the impact of the **alfapump** on patient activity, stress and sleep quality in patients with refractory ascites due to liver cirrhosis, using fitness loggers. This study may be delayed due to the current global health crisis.
- Enrolment continued in the French ARIA pump study to support reimbursement of the **alfapump** for treatment of refractory liver ascites in France. The study, conducted and sponsored by French clinicians and funded by the French government, is expected to be completed by end 2022<sup>(iv)</sup>, subject to potential delays from the current global health crisis.

(i) Investigational Device Exemption

(ii) Centers for Medicare and Medicaid Services

(iii) Transjugular Intrahepatic Portosystemic Shunt

(iv) Clintrials.gov NCT03506893.



- Annual renewal of German NUB received. The Company will focus on annual renewal of the NUB<sup>(v)</sup> until a German DRG<sup>(vi)</sup> hospital reimbursement code has been obtained, which requires a high number of implants in select hospitals.
- Following increased investment in the Company's core markets and the strengthening of the commercial team, year over year sales increased in 2019 in Germany by 30%. This growth was offset by lower sales in non-core / distributor markets.

## 1.1.2. Commentary on the consolidated annual accounts

### 1.1.2.1. CONSOLIDATED STATEMENTS OF PROFIT AND LOSS

#### Revenue

Revenue (€0.97 million) remained relatively at a similar level compared to the same period last year (€1.03 million).

#### Cost of goods sold

Cost of goods sold (€0.20 million) remained relatively at a similar level compared to last year (€0.16 million).

#### Operating expenses

Despite a significant increase in Clinical expenses related to the progress in the development of **alfapump** and **alfapump** DSR, total operating expenses increased by only 6% to €14.74 million compared to 2018 (€13.95 million).

*Sales and marketing* expenses increased +16% from €2.44 million to €2.84 million primarily as a result of the expansion of the commercial team in Europe.

*Clinical* expenses more than doubled from €1.67 million to €3.92 million mainly as a result of costs related to the North American pivotal study (POSEIDON), the DSR proof-of-concept studies and the Prospective Malignant Ascites Study (ProMAS).

*Quality and regulatory* expenses increased from €1.37 million to €1.82 million, mainly driven by costs linked to external advice for the POSEIDON study and the preparations for the new Medical Devices Regulation (Regulation 2017/745).

*Supply chain* expenses remained stable at €0.93 million (FY 2018: €0.96million).

*Engineering* expenses decreased from €1.81 million to €0.98 million largely as a result of the completion of the **alfapump** development project.

*General and administration* expenses decreased from €5.76 million to €4.26 million mainly as a result of the costs related to the preparation of the Initial Public Offering (IPO) and relocation to Belgium in 2018.

#### EBIT

As a result of the above, earnings before interest and taxes (EBIT) increased from a loss of €13.08 million in 2018 to a loss of €13.96 million in 2019 largely due to increased clinical activities, partially offset by lower expenses in engineering and G&A.

#### Total net finance expenses

Net finance cost (€0.88 million) remained at the same level as 2018 (€0.88 million) and consists mainly of interest expenses related to the Bootstrap loan.

#### Income tax expense

Income tax expense increased from €0.02 million in 2018 to €0.14 million in 2019. These expenses largely reflect taxes payable in Switzerland.

#### Net loss for the period

As a result of the above, the net loss increased from €13.98 million in 2018 to €14.98 million in 2019.

#### Basic losses per share (LPS)

Basic losses per share for 2019 amounted to €1.22, compared to €1.40 in 2018.

### 1.1.2.2. CONSOLIDATED BALANCE SHEET

#### Net debt

Net debt<sup>(vii)</sup> at 31 December 2019 decreased by €15.70 million, resulting in a positive net cash position of €2.36 million compared to a net debt of €13.34 million at 31 December 2018, mainly as a result of the proceeds from the IPO in February 2019.

#### Working Capital

Working capital<sup>(viii)</sup> from 2018 to 2019 increased by €3.15 million, mainly as a result of a decrease in both trade payables and accrued liabilities for IPO expenses.

#### Consolidated statements of cash flows

Net cash outflow from operating activities was €18.48 million compared to a net cash outflow of €9.88 million in 2018. The difference mainly relates to the increase in operating loss and the increase in working capital.

Cash flow from investing activities resulted in a net outflow of €0.34 million compared to a net outflow of €0.05 million in 2018. The net cash outflow mainly relates to the investment in leasing of cars and buildings (IFRS 16 applied).

Cash flow from financing activities resulted in a net inflow of €23.22 million in 2019, mainly as a result of the IPO proceeds, compared to a net inflow of €9.47 million in 2018, as a result of the proceeds of several convertible loans.

The Company ended 2019 with a total liquidity position of €5.59 million (2018: €1.32 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 novel coronavirus (COVID-19) or any other infectious disease outbreak or other serious public health concern could result in delays to Sequana Medical's sales and 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 **alfapump**<sup>®</sup> and/or the **alfapump**<sup>®</sup> 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.

(vii) Net debt is calculated by adding short-term, long-term financial and lease debt and deducting cash and cash equivalents.

(viii) 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.

(v) Neue Untersuchungs- und Behandlungsmethoden or New Diagnostic and Therapeutic Methods.

(vi) Diagnosis Related Group.

- Sequana Medical will likely require additional funds in the future in order to meet its capital and expenditure needs and further financing may not be available when required or could significantly limit Sequana Medical's access to additional capital.

#### **Risks relating to clinical development**

- Sequana Medical is required to conduct clinical studies for regulatory approvals and other purposes. Clinical studies require approvals, carry substantial risks and may be costly and time consuming, with uncertain results.
- If Sequana Medical experiences delays or difficulties in the recruitment of Investigators, obtaining necessary approvals from study sites or the enrolment of subjects in clinical studies, its receipt of necessary regulatory approvals could be delayed or prevented.

#### **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's manufacturing facilities 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.

#### **Risks relating to the 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 **alfapump®** and **alfapump®** 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 **alfapump®** and **alfapump®** 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.

#### **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. Healthcare policy changes, including legislation to reform the U.S. healthcare system, could have a material adverse effect on Sequana Medical. Sequana Medical could fail to achieve or maintain reimbursement levels sufficient to support a commercial infrastructure or realise an appropriate return on its investment in product development, which could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

#### **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.

#### **Risks relating to the stock market**

- 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.

- 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.

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

*(Article 3:32, 2° BCAC)*

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

### **1.3. Information on the circumstances that could significantly influence the development of the Sequana Medical Group**

*(Article 3:32, 3° BCAC)*

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

### **1.4. Research and development**

*(Article 3:32, 4° BCAC)*

The following R&D programs have been undertaken in the course of 2019 with the objective to further develop the **alfapump**:

- First patient enrolled in the **alfapump** POSEIDON pivotal study which is planned to support approval and reimbursement in the U.S. and Canada for the treatment of recurrent and refractory liver ascites.
- Positive Direct Sodium Removal (DSR) clinical proof-of-concept data from the first-in-human single dose study, presented at world-leading conferences in the field including Heart Failure 2019, HFSA Annual Scientific Meeting and TCT 2019, demonstrated that single dose DSR therapy was safe and well-tolerated and resulted in a clinically relevant removal of sodium with consistent results across all treated patients.
- First patient enrolled in the **alfapump** DSR RED DESERT study. The RED DESERT study is a repeated dose proof-of-concept study with **alfapump** DSR in diuretic-resistant heart failure patients.

### **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 2.4 in the corporate governance section.

### **1.7. Internal control and risk management**

*(Article 3:32, 7° BCAC)*

We refer to 2.12 in the corporate governance section.



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

(Article 3:32, 8° BCAC)

We refer to 2.15 in the corporate governance section.

## 1.9. Branch offices

(Article 3:6,5° BCAC)

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

## 1.10. Justification of valuation rules

(Article 3:6,6° BCAC)

The Company is still in its start-up 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.

The impact of COVID-19 on the Company's ability to secure additional financing rounds or undertake capital market transactions is 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 balance sheet as at 31 December 2019 shows a positive equity in the amount of EUR 0.93 million. The Company will continue to require additional financing in the near future and in that

respect already successfully raised EUR 19 million in January 2020 in a private equity placement via an accelerated book building offering.

Together with existing cash resources, the net proceeds from this private placement are expected to extend the current cash runway of the Company from Q2 2020 into H1 2021. The Company continues to evaluate equity and non-dilutive financing options, including discussions with existing and/or new investors including the refinancing of the Bootstrap loan (of which an amount in principal of EUR 3.17 million is outstanding).

As a result the board of directors remains confident that the liquidity requirements for the next twelve months can be secured. Based on the above, the executive management and the board of directors remain confident about the strategic plan, which comprises additional financing measures including equity and/or non-dilutive financing sources, and therefore consider the preparation of the present financial statements on a going concern basis as appropriate.

## 1.11. Conflicts of interests procedure

(Article 7:96, §1 BCAC)

On 28 January 2019, the board of directors of the Company decided to approve (in principle) the launch of the Company's initial public offering with admission to trading of the Company's shares on the regulated market of Euronext Brussels ("IPO") and related aspects.

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 (former Article 523 of the Belgian Companies Code of 7 May 1999) 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 28 January 2019

#### "PRIOR DECLARATIONS BY INDIVIDUAL DIRECTORS

*Prior to the deliberation and resolutions by the board of directors, Rudy Dekeyser, Erik Amble and Diego Braguglia, each director of the Company, made the following declarations as far as needed and applicable in accordance with Article 523 of the Belgian Companies Code:*

*The meeting of the board of directors will deliberate and resolve in relation to the contemplated IPO Capital Increase by the Company with the issuance of new shares of the Company, with a view to an IPO with admission of the Company's shares to listing and trading on the regulated market of Euronext Brussels. The resolution to increase the Company's share capital and a number of additional resolutions in connection therewith were approved by the EGM of the Company held on 18 January 2019, prior to the meeting of the board of directors.*

*The meeting of the board of directors will also deliberate and resolve in relation to the ratification, as far as needed, of a number of Amended and Restated Pre-IPO Investment Commitment Agreements. Notably, in the context of the IPO a number of existing shareholders of the Company and other investors (the "Participating Investors") have entered into a commitment pursuant to the respective Amended and Restated Pre-IPO Investment Commitment Agreements to, among others, (a) contribute their Payables under the outstanding Convertible Loan Agreements to the share capital of the Company in the context of the Loan Conversion Capital Increase, (b) subscribe for new shares of the Company for an aggregate amount (including issue premium) of EUR 20,507,236.43 (which amount can be reduced by the amount of the outstanding principal amounts due by the Company pursuant to the respective Convertible Bridge Loans provided by several of such Participating Investors), and (c) contribute the payables due by the Company to the Participating Investors pursuant to the Convertible Bridge Loans in kind in the context of the IPO Capital Increase.*

#### Declaration by Rudy Dekeyser

- Rudy Dekeyser informed the board of directors that LSP Health Economics Fund Management BV ("LSP"), in its capacity as managing partner of LSP HEF Holding CV, is a Participating Investor. Rudy Dekeyser has (indirectly) an important interest in LSP HEF Holding CV, which company has nominated him (via LSP) as a director of the Company. This Participating Investor has on the basis of the Amended and Restated Shareholders PIICA, which was entered into by LSP (among others) with the Company, committed to, on the occasion of the IPO, (x) contribute the outstanding Payable of EUR 298,008.60 that LSP has pursuant to the 2018 Convertible Loan Agreement entered into with the Company to the share capital of the Company, (y) subscribe for new shares of the Company within the framework of the IPO for an amount of EUR 1,132,432.67, and (z) contribute the outstanding Bridge Loan Payable (as defined in the EGM Resolutions) of EUR 59,601.72 that*

LSP has pursuant to the Convertible Bridge Loan entered into with the Company. LSP has also committed not to transfer its shares in the Company during a certain period after the IPO. The same commitment has also been entered into by other shareholders of the Company.

- Rudy Dekeyser also informed the board of directors that LSP will commit to lend certain of its shares in the Company to KBC Securities NV/SA within the framework of the IPO in order to allow over-allotments of shares in the IPO and this in accordance with the provisions of the Stock Lending Agreement.
- As a result, Rudy Dekeyser may have a financial interest that is in conflict with the resolutions that will be passed by the board of directors. Rudy Dekeyser is, however, of the opinion that the contemplated resolutions in connection with the IPO and the Amended and Restated Shareholders PIICA are in the interest of the Company, as the resolutions will allow the Company to (i) further enlarge its shareholder base, which is in the interest of the further stability of the Company and its shareholder structure; (ii) to attract additional institutional financial and strategic investors, which could possibly contribute to the further development and growth of the Company's business; (iii) to attract additional international investors, which could improve the international profile of the Company, which could possibly contribute to the further development and growth of the Company's business; and (iv) allow the Company to increase the chances of success of the IPO taking into account the subscription commitment provided for in the Amended and Restated Shareholders PIICA. Rudy Dekeyser also notes that by providing for a mechanism pursuant to which LSP can contribute its Payable and Bridge Loan Payable as provided in the Amended and Restated Shareholders PIICA and the EGM Resolutions, the Company will be able to satisfy its obligation to settle these payables without having to use existing funds or new funds, which is in the interest of the Company. For more information on the justification of the contemplated

transactions in relation to the IPO, reference is made to the report of the board of directors of 21 December 2018 in accordance with articles 596, 598 and 602 of the Belgian Companies Code which was submitted to the EGM.

#### Declaration by Erik Amble

- Erik Amble informed the board of directors that NeoMed IV Extension L.P. ("Neomed IV X") and NeoMed Innovation V L.P. ("Neomed V"), two companies in which Erik Amble has an important interest and which have nominated him as a director of the Company, are Participating Investors. These Participating Investors have on the basis of the Amended and Restated Shareholders PIICA, which was entered into by Neomed IV X and Neomed V (among others) with the Company, committed to, on the occasion of the IPO, (x) contribute the outstanding Payables of respectively EUR 593,052.02 and EUR 266,871.66 that Neomed IV X and Neomed V have pursuant to the 2018 Convertible Loan Agreement entered into with the Company to the share capital of the Company, (y) subscribe for new shares of the Company within the framework of the IPO for an amount of respectively EUR 2,372,208.09 and EUR 1,067,486.62, and (z) contribute the outstanding Bridge Loan Payables of respectively EUR 118,610.40 and EUR 53,374.33 that Neomed IV X and Neomed V have pursuant to the Convertible Bridge Loan entered into with the Company. Neomed IV X and Neomed V have also committed not to transfer their shares in the Company during a certain period after the IPO. The same commitment has also been entered into by other shareholders of the Company.
- Erik Amble also informed the board of directors that Neomed IV X will commit to lend certain of its shares in the Company to KBC Securities NV/SA within the framework of the IPO in order to allow over-allotments of shares in the IPO and this in accordance with the provisions of the Stock Lending Agreement.

- As a result, Erik Amble may have a financial interest that is in conflict with the resolutions that will be passed by the board of directors. Erik Amble is, however, of the opinion that the contemplated resolutions in connection with the IPO and the Amended and Restated Shareholders PIICA are in the interest of the Company, as the resolutions will allow the Company to (i) further enlarge its shareholder base, which is in the interest of the further stability of the Company and its shareholder structure; (ii) to attract additional institutional financial and strategic investors, which could possibly contribute to the further development and growth of the Company's business; (iii) to attract additional international investors, which could improve the international profile of the Company, which could possibly contribute to the further development and growth of the Company's business; and (iv) allow the Company to increase the chances of success of the IPO taking into account the subscription commitment provided for in the Amended and Restated Shareholders PIICA. Erik Amble also notes that by providing for a mechanism pursuant to which Neomed IV X and Neomed V can contribute their Payables and Bridge Loan Payables as provided in the Amended and Restated Shareholders PIICA and the EGM Resolutions, the Company will be able to satisfy their obligation to settle these payables without having to use existing funds or new funds, which is in the interest of the Company. For more information on the justification of the contemplated transactions in relation to the IPO, reference is made to the report of the board of directors of 21 December 2018 in accordance with articles 596, 598 and 602 of the Belgian Companies Code which was submitted to the EGM.

#### Declaration by Diego Braguglia

- Diego Braguglia informed the board of directors that Venture Incubator AG ("VI AG") and VI Partners ("VI Partners"), two companies in which Diego Braguglia has an important interest and which have nominated him as a director of the

Company, are Participating Investors. These Participating Investors have on the basis of the Amended and Restated Shareholders PIICA, which was entered into by VI AG and VI Partners (among others) with the Company, committed to, on the occasion of the IPO, (x) contribute the outstanding Payables of respectively EUR 218,231.42 and EUR 5,021.49 which VI AG and VI Partners have pursuant to the 2018 Convertible Loan Agreement entered into with the Company to the share capital of the Company, (y) subscribe for new shares of the Company within the framework of the IPO for an amount of respectively EUR 828,414.60 and EUR 18,897.82, and (z) contribute the outstanding Bridge Loan Payables of respectively EUR 43,600.77 and EUR 994.62 that VI AG and VI Partners have pursuant to the Convertible Bridge Loan entered into with the Company. VI AG and VI Partners have also committed not to transfer their shares in the Company during a certain period after the IPO. The same commitment has also been entered into by other shareholders of the Company.

- As a result, Diego Braguglia may have a financial interest that is in conflict with the resolutions that will be passed by the board of directors. Diego Braguglia is, however, of the opinion that the contemplated resolutions in connection with the IPO and the Amended and Restated Shareholders PIICA are in the interest of the Company, as the resolutions will allow the Company to (i) further enlarge its shareholder base, which is in the interest of the further stability of the Company and its shareholder structure; (ii) to attract additional institutional financial and strategic investors, which could possibly contribute to the further development and growth of the Company's business; (iii) to attract additional international investors, which could improve the international profile of the Company, which could possibly contribute to the further development and growth of the Company's business; and (iv) allow the Company to increase the chances of success of the IPO taking into account the subscription commitment provided for in the Amended and



Restated Shareholders PIICA. Diego Braguglia also notes that by providing for a mechanism pursuant to which VI AG can contribute its Payables and Bridge Loan Payables as provided in the Amended and Restated Shareholders PIICA and the EGM Resolutions, the Company will be able to satisfy its obligation to settle these payables without having to use existing funds or new funds, which is in the interest of the Company. For more information on the justification of the contemplated transactions in relation to the IPO, reference is made to the report of the board of directors of 2 November 2018 in accordance with articles 596, 598 and 602 of the Belgian Companies Code which was submitted to the EGM.

#### General

- The aforementioned directors will each inform the statutory auditor of the Company of the foregoing as far as needed and applicable in accordance with the provisions of Article 523 of the Belgian Companies Code.
- The aforementioned declarations of Rudy Dekeyser, Erik Amble and Diego Braguglia will be included in the annual report of the Company, as far as needed and applicable, in accordance with the provisions of Article 95 and Article 523 of the Belgian Companies Code.”

### 1.11.2. 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.”

### 1.11.3. 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.”

### 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 2019.

### 1.13. Transactions under the authorised capital

(Article 7:203 BCAC)

In 2019, the board of directors of the Company did not issue any shares, convertible bonds or subscription rights in the context 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 in accordance 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.

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 2019 (dated 27 January 2020) in accordance with Article 3:6, §2 of 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 new 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 of 23 March 2019 (as amended) (the "**Belgian Companies and Associations Code**"). The 2020 Belgian Corporate Governance Code applies compulsorily to reporting years beginning on or after 1 January 2020 (compulsory application). However, companies may already choose to apply the 2020 Belgian Corporate Governance Code for reporting years beginning on or after 1 January 2019 (optional application).

The Company has decided not to apply the 2020 Belgian Corporate Governance Code prior to 1 January 2020 and therefore still applied during the financial year ended on 31 December 2019 the Belgian Code on Corporate Governance of 12 March 2009 (the "**2009 Belgian Code on Corporate Governance**").

During the financial year ended on 31 December 2019, the Company applied and complied with the nine corporate governance principles contained in the 2009 Belgian Code on Corporate Governance, except in relation to the matters set out below in section 2.2.

On the date of this statement, the Company complies with the provisions set forth in the 2020 Belgian Corporate Governance Code. On 23 April 2020, the board of directors will approve an amended and restated version of the Company's corporate governance charter to align it with the provisions of the 2020 Belgian Code on Corporate Governance and the Belgian Companies and Associations Code.

The 2020 Belgian Corporate Governance Code and the 2009 Belgian Corporate Governance Code can be accessed on the following website: [www.corporate-governancecommittee.be/](http://www.corporate-governancecommittee.be/).

### 2.2. Corporate Governance Charter

As from 12 February 2019, being the date of the completion of the Company's initial public offering with admission to trading of the Company's shares on the regulated market of Euronext Brussels (the "**IPO**") and during the remainder of 2019, the Company applied a corporate governance charter that was in line with the 2009 Belgian Code on Corporate Governance. The Company's board of directors approved the charter on 28 January 2019 subject to and with effect as of the closing of the IPO. 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 2019, the Company applied the nine corporate governance principles contained in the 2009 Belgian Code on Corporate Governance and complied with

the corporate governance provisions set forth in the 2009 Belgian Code on Corporate Governance, except in relation to the following:

- Before the entry into force of the Belgian Companies and Associations Code, share options have been granted to non-executive directors (including to independent directors). The aforementioned was contrary to provision 7.7 of the 2009 Belgian Code on Corporate Governance, and is contrary to provision 7.5 of the 2020 Belgian Code on Corporate Governance, that provided that non-executive directors should not be entitled to performance-related remuneration such as, amongst others, share-related long-term incentive schemes. The Company believed that these provisions of the 2009 Belgian Code on Corporate Governance were 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 with share options allowed 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-executive directors the opportunity to be remunerated in part in share-based incentives rather than all in cash enables the non-executive directors to link their effective remuneration to the performance of the Company and to strengthen the alignment of their interests with the interests of the Company's shareholders. This is in the interest of the Company and its stakeholders. Furthermore, this is customary for directors active in companies in the life sciences industry.
- Pursuant to Article 7:91 of the Belgian Companies and Associations Code (former Article 520ter of the Belgian Companies Code of 7 May 1999), the guideline to provision 7.13 of the 2009 Belgian Code on Corporate Governance, and provision 7.11 of the 2020 Belgian Code on Corporate Governance, shares should not vest and share options should not be exercisable within three

years as of their granting. The Company's board of directors has been explicitly authorised in the Company's articles of association to deviate from this rule (by reference to the former Article 520ter of the Belgian Companies Code of 7 May 1999) (in connection with stock based incentive plans, compensations, awards and issuances to employees, directors and service providers of the Company and/or its subsidiaries (from time to time)). At the occasion of the annual general meeting of shareholders of 28 May 2020, an amended and restated version of articles of association will be submitted to the shareholders in which the board of directors will be explicitly authorised to deviate from the rule of Article 7:91 of the Belgian Companies and Associations Code. 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.

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. As set out above, the board of directors will approve an amended and restated version of the Company's corporate governance charter on 23 April 2020 to align it with the provisions of the 2020 Belgian Code on Corporate Governance and the Belgian Companies and Associations Code.

The articles of association and the corporate governance charter are available on the Company's website ([www.sequanamedical.com](http://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
<b>Mr Pierre Chauvineau</b>	56	Chair, Independent Non-Executive Director	2019	2022
<b>Mr Ian Crosbie</b>	52	CEO, Executive Director	2019	2022
<b>Mr Rudy Dekeyser</b>	58	Non-Executive Director	2019	2022
<b>Mr Erik Amble</b>	68	Non-Executive Director	2019	2022
<b>Mr Wim Ottevaere<sup>(ix)</sup></b>	63	Independent Non-Executive Director	2019	2022
<b>Mr Jason Hannon</b>	48	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

(ix) Acting as permanent representative of WIOT BV.

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 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 €280 million fund investing in medical device, diagnostic and digital health compa-

nies 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. 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 commercialization 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.

(x) 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
<b>Mr Ian Crosbie</b>	52	Chief Executive Officer
<b>Mrs Kirsten Van Bockstaele<sup>(x)</sup></b>	45	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 health-care industry. Mrs Van

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

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

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

Name	Age	Position
<b>Dr Gijs Klarenbeek</b>	43	Chief Medical Officer
<b>Mr Martijn Blom</b>	46	Chief Commercial Officer
<b>Mr Timur Resch</b>	38	Global Vice President Quality Management and Regulatory Affairs
<b>Mr Dirk Fengels<sup>(xi)</sup></b>	48	Global Vice President Engineering and Manufacturing



**Dr Gijs Klarenbeek** is the chief medical officer 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 Martijn Blom** is the chief commercial officer of the Company. Mr Blom has over 15 years' experience in the life sciences industry. Most recently he was the Director of International Marketing at Myriad

Genetics, responsible for the marketing development of genetic testing in the international markets. Previous to Myriad, he worked as Director of Marketing and Market Development at PulmonX, a start up from Redwood City focusing on developing and marketing minimally-invasive medical devices and technologies to expand and improve treatment options for emphysema patients. Prior to this he was Director International Marketing at Alere where he spent more than 7 years leading the marketing, training and marketing communications teams, for all of their business units: Cardiology, Women's Health, Oncology, Infectious Diseases, Blood Borne Pathogens, Toxicology and Health Management. Mr Blom studied economics at the MEAO in Breda and specialised at de Rooi Pannen in Marketing and Sales management.



**Mr Timur Resch** is the global Vice President Quality Management and Regulatory Affairs of Sequana Medical. Mr Resch has 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.



**Mr Dirk Fengels** is the global Vice President Engineering and Manufacturing of the Company. He has over 15 years experience in research and development and spent the majority of his career in a multidisciplinary high-tech

environment. Mr Fengels has extensive expertise in developing innovative solutions for the medical device industry. Prior to joining the Company, he led the Sensors & Systems group at the Swiss Center for Electronics and Microtechnology (CSEM) for 10 years, where his team specialised in developing innovative sensors, mechatronic systems and automated fluid handling solutions to create unique selling

propositions on behalf of various industry partners. In his role, Mr Fengels was also responsible for aligning the research strategy in the automation field with industry needs and he mentored research and industry projects. Prior to CSEM, he was responsible for the development of next generation products in two medical start-up companies, one in Switzerland and one in Silicon Valley. Mr Fengels holds a Master's degree in Electrical Engineering from the Swiss Federal Institute of Technology, Zürich (ETH).

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.

(xi) Mr Dirk Fengels' function will shift from a full time position (100%) to a part-time position (40%) as of 30 April 2020.



### 2.3.3. Other mandates by Directors and Executive Managers

In the five years preceding the date of this report, the directors and members of the executive management have held the following directorships (apart from their functions within the Company) and memberships of administrative, management or supervisory bodies and/or partnerships:

Name	Current	Past
<b>Rudy Dekeyser</b>	Celyad SA	Ablynx NV
	Remynd NV	CropDesign NV
	Curetis NV	Actogenix NV
	Emblem GmbH	Pronota NV
	Life Sciences Partners	Multiplicom NV
	Lumeon Inc	
	R.A.D. Life Sciences BVBA	
<b>Erik Amble</b>	SystemUnoDue GCV	
	NeoMed Management Ltd	Sonendo Inc.
	JenaValve Technology GmbH	Index Pharmaceuticals AB
	CorFlow Therapeutics AG	Vessix Vascular Inc.
	Axonics Modulation Technologies Inc.	
<b>Wim Ottevaere (WIOT BV)</b>	Serca Pharmaceuticals AS	
	Woconsult BV	Ablynx NV <sup>(xii)</sup>
<b>Pierre Chauvineau</b>	Vlaams Instituut voor Biotechnologie	
	Creavo Medical Technologies Ltd	Boston Scientific Inc.
	Rhythm AI in London NED	
<b>Jason Hannon</b>	Pathena	
	Mainstay Medical BV	Nemaris, Inc.
	Mainstay Medical Limited	MIS Spine Comercial
	Mainstay Medical (Australia) PTY Limited	Cervitech, Inc.
	Mainstay Medical Distribution Limited	NeuroMed, Inc.
	Mainstay Medical GmbH	NuVasive and subsidiaries
<b>Ian Crosbie</b>	Kuros Inc	
	N/A	GC Aesthetics Ltd
<b>Kirsten Van Bockstaele<sup>(xiii)</sup></b>	Fin-2K BV	Fagron Inc

(xii) Acting through Woconsult BV.

(xiii) Acting through Fin-2K BV.

### 2.3.4. Confirmations by Directors and Executive Managers

Each of the directors and each of the members of executive management, confirmed to the Company that neither he or she nor the company through which he or she acts (as the case may be) was subject to (i) any convictions in relation to fraudulent offenses during the past five years or (ii) any official public incrimination and/or sanctions of such members by statutory or regulatory authorities (including designated professional bodies), or disqualification by a court from acting as a member of the administrative, management or supervisory bodies of an issuer or from acting in the management or conduct of the affairs of any issuer during the past five years. In addition, each of them has confirmed to the Company that neither he or she nor the company through which he or she acts (as the case may be) is subject to any bankruptcies, receiverships, liquidations or administration of any entities in which he, she or it held any office, directorships, or partner or senior management positions during the past five years.

## 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 current version of the corporate governance charter, as well as the revised version of the corporate governance charter (to be 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 current version of the Company’s articles of association, the board of directors must consist of at least three directors. The Company’s current version of the corporate governance charter, as well as the revised version of the corporate governance charter (to be 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 2009 Belgian Code on Corporate Governance and 2020 Belgian Code on Corporate Governance, 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 2009 Belgian Code on Corporate Governance, respectively the 2020 Belgian Code on Corporate Governance. By 1 January 2024, at least one third of the members of the board of directors must be of the opposite gender.

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

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

The board of directors elects a chair from among its non-executive members on the basis of his knowledge, skills, experience and mediation strength. The chair should be a person trusted for his or her professionalism, independence of mind, coaching capabilities, ability to build consensus, and communication and meeting management skills. The chair is responsible for the leadership and the proper and efficient functioning of the board of directors. He or she leads the meetings of the board of directors and ensures that there is sufficient time for consideration and discussion before decision-making. On the date of this report, Dr Pierre Chauvineau is chair of the board of directors and Mr Ian Crosbie is the chief executive officer. If the board of directors envisages appointing a former chief executive officer as chair, it should carefully consider the

positive and negative implications of such a decision and disclose why such appointment will not hamper the required autonomy of the chief executive officer.

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

During 2019, 14 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 with effect as of the closing of the IPO in 2019, 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, provision 5.2 of the 2009 Belgian Code on Corporate Governance and provision 4.10 of the 2020 Belgian Code on Corporate Governance) and the remuneration and nomination committee (in accordance with Article 7:100 of the Belgian Companies and Associations Code, provision 5.3 and 5.4 of the 2009 Belgian Code on Corporate Governance and provision 4.17 and 4.19 of the 2020 Belgian Code on Corporate Governance). The terms of reference of these board committees are primarily set out in the current version of the corporate governance charter, as well as the revised version of the corporate governance charter (to be 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 2009 Belgian Code on Corporate Governance and the 2020 Belgian Code on Corporate Governance, 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 2019, 5 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 2009 Belgian Code on Corporate Governance and the 2020 Belgian Code on Corporate Governance (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 2019, 2 meetings of the remuneration and nomination committee were held.

## 2.6. Activity Report and Attendance at Board and Committee Meetings during 2019

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 <sup>(xiv)</sup>	12 out of 14 meetings	5 out of 5 meetings	1 out of 2 meetings
Mr Ian Crosbie <sup>(xiv)</sup>	12 out of 14 meetings	5 out of 5 meetings	2 out of 2 meetings
Mr Rudy Dekeyser	14 out of 14 meetings	N/A <sup>(xv)</sup>	2 out of 2 meetings
Mr Erik Amble	14 out of 14 meetings	5 out of 5 meetings	N/A <sup>(xv)</sup>
Mr Wim Ottevaere <sup>(xiv)(xvi)</sup>	11 out of 14 meetings	4 out of 5 meetings	2 out of 2 meetings
Mr Jason Hannon <sup>(xvii)</sup>	7 out of 14 meetings	N/A <sup>(xv)</sup>	1 out of 2 meetings
Mr Diego Braguglia <sup>(xviii)</sup>	2 out of 14 meetings	N/A <sup>(xv)</sup>	N/A <sup>(xv)</sup>

## 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

(xiv) Only in function as director of the Company since 12 February 2019.

(xv) Acting as permanent representative of WIOT BV.

(xvi) Resigned as director of the Company on 12 February 2019.

(xvii) Only in function as director of the Company since 23 May 2019.

(xviii) The board member is not a member of the specific committee.

- 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 Code on Corporate Governance. The aforementioned directors also complied with the criteria for being an independent director in 2019 pursuant to the former Belgian Companies Code of 7 May 1999 and the 2009 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 current version of the corporate governance charter, as well as the revised version of the corporate governance charter (to be 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 current version of the corporate governance charter, as well as the revised version of the corporate governance charter (to be 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. 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 be evaluated as part of the annual management review.
- **External Audit:** In Sequana Medical's review of the annual accounts, the statutory auditor focuses on the design and effectiveness of internal controls and systems relevant for the preparation of the financial statements. The outcome of the audits, including work on internal controls, is reported to management and the audit committee.
- **Audit Committee:** The board of directors and the audit committee have the ultimate responsibility with respect to internal control and risk management. For more detailed information on the composition and functioning of the audit committee, see section 2.4.1. of this Corporate Governance Statement.

### 2.12.7. 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 the date of this report. 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.



	Date of Notification	Number of Shares	% of the voting rights attached to Shares <sup>(xix)</sup>
<b>Société Fédérale de Participations et d'Investissement SA – Federale Participatie- en Investeringsmaatschappij NV / Belfius Insurance SA<sup>(xx)</sup></b>	18 February 2020	2,004,358	12.70%
<b>Capricorn Partners NV<sup>(xxi)</sup></b>	14 February 2020	N/A <sup>(xxii)</sup>	N/A <sup>(xxi)</sup>
<b>GRAC Société Simple<sup>(xxiii)</sup></b>	30 January 2020	833,333	5.28%
<b>NeoMed IV Extension L.P. / NeoMed Innovation V L.P.<sup>(xxiv)</sup></b>	30 January 2020	4,270,807	27.07%

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

(xx) 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.

(xxi) 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.

(xxii) 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%.

(xxiii) 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.

(xxiv) 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 <sup>(xix)</sup>
<b>Newton Biocapital I Pricav Privée SA<sup>(xxv)</sup></b>	21 February 2019	1,102,529	6.99%
<b>Venture Incubator AG / VI Partners AG<sup>(xxvi)</sup></b>	21 February 2019	525,501	3.33%
<b>LSP Health Economics Fund Management B.V.<sup>(xxvii)</sup></b>	19 February 2019	1,539,407	9.76%
<b>Participatiemaatschappij Vlaanderen NV<sup>(xxviii)</sup></b>	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](http://www.sequanamedical.com)).

(xxv) 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.

(xxvi) 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.

(xxvii) 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.

(xxviii) 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 the date of this report, 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 Company has a number of outstanding options that are exercisable into ordinary shares, consisting of:

- one subscription right that was granted in 2016 to 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**"). Bootstrap will be entitled to subscribe to 302,804 ordinary shares when exercising its Bootstrap Subscription Right.
- 104,378 share options out of the maximum available 111,177 share options, that were granted in 2018 to members of the staff, as well as consultants of the Company, subject to the terms and conditions that are determined by the board of directors (the "**Executive Share Options**"). 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 options.
- 278,745 share options out of the maximum available 1,263,755 share options, that were granted in 2019 to members of the staff, as well as consultants of the Company, subject to the terms and conditions that are determined by the board of directors (the "**2018 Share Options**"). Each holder of an 2018 Share Option will be entitled to subscribe to one (1) ordinary share when exercising one of his or her share options.

### 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 disapplication 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. The Company is currently preparing a listing prospectus to have the 644,287 unlisted shares admitted to trading on the regulated market of

Euronext Brussels. All of the other 12,611,900 existing 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) on, except in the event a single representative is appointed for the exercise of the voting right;
- 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.

### 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 2019 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, on the date of this report, the Bootstrap Loan (as defined below) includes covenants which may limit the Company's ability (or require Bootstrap's prior consent) to make distributions by way of dividends or otherwise.

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 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.

- (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 3.7. 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 current versions of 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 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:

- a loan agreement entered into between the Company and Bootstrap Europe S.C.Sp. ("Bootstrap") (the "Bootstrap Loan") provides that Bootstrap may cancel any undrawn part of the facility and declare all outstanding amounts under the Bootstrap Loan immediately due and payable if a change of control occurs, whereby "change of control" is to be understood as the key shareholders collectively ceasing to directly hold or have the power to cast, or control the cast of, at least 50.1% of (i) the issued share capital or (ii) the voting rights relating to the issued share capital, or any sale of (a) any or all assets related to the Company's liver or heart business with a minimum net value of at least CHF 10 million or (b) all or substantially all of the assets or business of the Company;
- 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 a year, 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 report

### 3.1. Introduction

The Company has prepared this remuneration report relating to the remuneration of directors and the executive management of the Company. This remuneration report is part of the Corporate Governance Statement, which is part of the Company's annual report of the board of directors on the statutory accounts for the financial year ended on 31 December 2019 (dated 27 January 2020) 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 28 May 2020 for approval.

### 3.2. Remuneration policy

Sequana Medical's remuneration policy is designed to:

- enable the Company to attract and retain talented employees,
- promote continuous improvement in the business, and
- reward performance in order to motivate employees to deliver increased shareholder value through superior business results.

The Company obtains independent advice from external professionals to ensure the remuneration structure represents industry best practice, and achieves the twin goals of (i) retaining talented employees, and (ii) meeting shareholder expectations.

While there are no plans to amend the remuneration policy and remuneration over the next two years, the remuneration policy and remuneration is reviewed from time to time and monitored to be in line with market practice.

The remuneration policy that has been determined in relation to the directors and the executive management is further described below. This remuneration policy applied as from the Company's initial public offering with admission to trading of the Company's shares on the regulated market of Euronext Brussels, which was completed on 12 February 2019 (the "IPO").

### 3.3. Directors

#### 3.3.1. General

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

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

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



- been determined in advance and that can be measured objectively over a period of at least three years; and
- (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).
  - (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 3.6. 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 current version of the articles of association, the board of directors is explicitly authorised to deviate from the provisions of the former Article 520ter of the Belgian Companies Code of 7 May 1999 in connection with share-based incentive plans, compensation, awards or issues to employees, directors and service providers of the Company and/or its subsidiaries. At the occasion of the annual general meeting of shareholders of 28 May 2020, an amended and restated version of articles of association will be submitted to the shareholders in which the board of directors will be explicitly authorised to deviate from the rule of Article 7:91 of the Belgian Companies and Associations Code. 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.
- In 2019, share options have been granted to non-executive directors (including to independent directors), based on a resolution approved by the general shareholders' meeting. The aforementioned was contrary to provision 7.7 of the 2009 Belgian Code on Corporate Governance, and is contrary to provision 7.5 of the 2020 Belgian Code on Corporate Governance, that provided that non-executive directors should not be entitled to performance-related remuneration such as, amongst others, share-related long-term incentive schemes. The Company believed that these provisions of the 2009 Belgian Code on Corporate Governance were 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 with share options allowed 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-executive directors the opportunity to be remunerated in part in share-based incentives rather than all in cash enables the non-executive directors to link their effective remuneration to the performance of the Company and to strengthen the alignment of their interests with the interests of the Company's shareholders. This is in the

interest of the Company and its stakeholders.

Furthermore, this is customary for directors active in companies in the life sciences industry.

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

- Annual fixed fees:
  - The chair of the board of directors receives an annual fixed fee of €60,000.
  - The chair of the audit committee receives an annual fixed fee of €15,000.
  - The chair of the remuneration and nomination committee receives an annual fixed fee of €15,000.
  - The other independent non-executive directors receive an annual fixed fee of €25,000.
  - The members of the audit committee and the remuneration and nomination committee (other than the chair of such committees) receive an annual fixed fee of €10,000.
- Share based awards: Each non-executive director is in principle entitled to receive share options or subscription rights. Part of the 2018 Share Options can be used for this purpose.

There are currently no plans to change the remuneration policy or remuneration of non-executive directors. However, the Company will continuously review the remuneration of non-executive directors against market practice, and the new 2020 Belgian Corporate Governance Code and Belgian Companies and Associations Code, which entered into force since 1 January 2020.

The Company also reimburses reasonable out of pocket expenses of directors (including travel 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.

### 3.3.2. Remuneration and compensation in 2019

During 2019, the non-executive directors received the following compensation, based on the approved fees in 3.3.1.

Name	Amount (in €)
Pierre Chauvineau	70,000.00
Wim Ottevaere (WIOT BV)	50,000.00
Jason Hannon <sup>(xxix)</sup>	24,219.18

No remuneration, compensation or other benefits were paid to the other directors of the Company, 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.

## 3.4. Executive Management

### 3.4.1. General

The remuneration of the chief executive officer and the other member of the executive management is based on recommendations made by the remuneration and nomination committee. The chief executive officer participates in the meetings of the remuneration and nomination committee in an advisory capacity each time the remuneration of another member of the executive management is being discussed.

(xxix) the amounts are pro rate the term that the director is appointed.

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 the former Article 520ter of the Belgian Companies Code of 7 May 1999 in connection with share-based incentive plans, compensations, awards and issuances to employees, directors and service providers of the Company and/or its subsidiaries. At the occasion of the annual meeting of shareholders of 28 May 2020, an amended and restated version

of articles of association will be submitted to the shareholders in which the board of directors will be explicitly authorised to deviate from the rule of Article 7:91 of the Belgian Companies and Associations Code. The Company believes that this allows for more flexibility when structuring share-based awards.

In relation to point (ii) above, before the entry into force of the Belgian Companies and Associations Code, 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; and
- a performance bonus.

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.

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.

There are currently no plans to change the remuneration policy or remuneration of members of the executive management. However, the Company will continuously review the remuneration of members of the executive management against market practice. In addition, the board of directors will further review the changes that shall be required in view of the 2020 Belgian Corporate Governance Code, which (amongst other things) requires that (i) the board of directors sets a minimum threshold of shares to be held by the executives, (ii) the board of directors approves the main terms and conditions of the contracts of the chief executive officer and the other executives (further to the advice of the remuneration and nomination committee), and (iii) the board of directors includes provisions that would enable the Company to recover variable remuneration paid, or withhold the payment of variable remuneration, and specifies the circumstances in which it would be appropriate to do so, insofar as enforceable by law.

### 3.4.2. Remuneration and compensation in 2019

In 2019, the following remuneration, compensation and other benefits were paid to the two members of the executive management:

	Chief executive officer (€)		Other member of the executive management (€)	
	Amount	%	Amount	%
Annual base salary	284,835.37	62.46	193,200.00	88.60
Pension plan <sup>(xxx)</sup>	14,241.77	3.12	N/A	N/A
Insurance plan <sup>(xxxii)</sup>	1,145.86	0.25	N/A	N/A
Car lease/transport allowance	11,605.22	2.54	N/A	N/A
Medical plan	6,693.54	1.47	N/A	N/A
Bonus plan <sup>(xxxii)</sup>	137,513.75	30.15	24,854.79	11.40
<b>Total</b>	<b>456,035.50</b>	<b>100.00</b>	<b>218,054.79</b>	<b>100.00</b>

(xxx) 5% of the annual base salary.

(xxxii) The Company pays a life insurance plan for the CEO.

(xxxii) Bonus has been paid in cash.



In 2019, 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 168,193 EUR.

### 3.4.3. Claw-back right relating to variable remuneration

There are no contractual provisions in place between the Company and the CEO 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. However, this will be further reviewed against the requirements of provision 7.12 of the 2020 Belgian Corporate Governance Code.

### 3.4.4. 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 executive 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 executive officer subject to a notice period of three months. The agreement may be terminated by either the Company or the chief executive officer with immediate effect and without notice period (or, in case of termination by the Company, without notice period or indemnity) in case of wilful or serious breach or violation by a party of any of its covenants, obligations or duties under the agreement, or any wilful or serious neglect of or refusal to perform any of such covenants, obligations or duties.

### 3.5. Indemnification and Insurance of Directors and Executive Management

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

### 3.6. Description of share option plans

The Company has a number of outstanding options that are exercisable into ordinary shares, consisting of:

- 104,378 share options out of the maximum available 111.177 share options, that were granted in 2018 to members of the staff, as well as consultants of the Company, subject to the terms

and conditions that are determined by the board of directors (the "Executive Share Options"). 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 options.

- 278,745 share options out of the maximum available 1,263,755 share options that were granted in 2019 to members of the staff and directors, as well as consultants of the Company, subject to the terms and conditions that are determined by the board of directors (the "2018 Share Options"). Each holder of an 2018 Share Option will be entitled to subscribe to one (1) ordinary share when exercising one of his or her share options.

The table below provides an overview of the number of shares which each member of the executive management is entitled to acquire upon exercise of the outstanding and granted Executive Share Options and 2018 Share Options that are held by him or her on the date of this report.

Name	Number of Shares issuable	
	Executive Share Options	2018 Share Options
Ian Crosbie	216,442	40,766
Kirsten Van Bockstaele <sup>(xxxiii)</sup>	6,226	20,383

(xxxiii) Acting through Fin-2K BV.

### 3.7. Terms and conditions of the share option plans

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

- The Executive Share Options could be granted to the employees, consultants and directors of the Company or its subsidiaries.
- The Executive Share Options are in registered form.
- The Executive Share Options are in principle non-transferable, and the holders of the Executive Share Options are not permitted to transfer the Executive Share Options nor the underlying Shares issuable upon exercise of the Executive Share Options for a period of two years as from the initial public offering of the Company's shares, except as provided otherwise in the grant agreement or by the board of directors, and except in case of death of the beneficiary and in the context of inheritance planning by the beneficiary. In case of death, only Executive Share Options that have vested prior to the time of death can be transferred.
- Each holder of an Executive Share Option will be entitled to subscribe to ca. 2.88 ordinary shares when exercising one of his or her share option. The exercise price of the Executive Share Options shall be determined by the board of directors of the Company, taking into account applicable laws.
- If an Executive Share Option which is not exercisable or which cannot be exercised pursuant to the issuance conditions (as determined in the Executive Share Option Plan or in the relevant Sub-Plan and/or Share Option Agreement) becomes prematurely exercisable on the basis of the provisions of Article 7:71 of the Belgian Companies and Associations Code (or any other provision having the same purport) and is also exercised pursuant to said provision, the shares obtained by exercising the Executive Share Options shall not be transferable, unless explicitly agreed upon by the board of directors of the

Company, until the time the underlying Executive Share Options would have become exercisable in accordance with the Executive Share Option Plan and the relevant sub-plan or share option agreement.

- Pursuant to Belgian company law, the Executive Share Options have a maximum term of 10 years as of their issuance.
- 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 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.



### **3.8. Shareholding and Share Options**

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).

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, 2019 and 2018

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# 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.

Ian Crosbie,  
CEO and Director

Pierre Chauvineau,  
Chairman

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 2019

April 23, 2020

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 2 consecutive years.

### 2.1. Report on the consolidated accounts

#### 2.1.1. Unqualified opinion

We have performed the statutory audit of the Group's consolidated accounts, which comprise the consolidated statement of financial position as at 31 December 2019, 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 9.350.142 and a loss for the year of EUR 14.977.445.

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 2019, 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 start-up 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. The impact of COVID-19 on the Company's ability to secure additional financing rounds or undertake capital market transactions is 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 balance sheet as at 31 December 2019 shows a positive equity in the amount of EUR 8,4 million. The Company will continue to require additional financing in the near future and in that respect already successfully raised EUR 19 million in January 2020 in a private equity placement via an accelerated book building offering. Together with existing cash resources, the net proceeds from this private placement are expected to extend the current cash runway of the Company from Q2 2020 into H1 2021. The Company continues to evaluate equity and non-dilutive financing options, including discussions

with existing and/or new investors including the refinancing of Bootstrap (of which an amount in principal of EUR 3.17 million is still outstanding).

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

### 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 annual accounts of the current period. These matters were addressed in the context of our audit of the annual 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 the financial-reporting framework 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.

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 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 director's report 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 mandate 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, April 23, 2020

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

Roel Boons  
Réviseur d'Entreprises / Bedrijfsrevisor

## 3. Consolidated income statement for the years ended December 31

In EUR	Notes	2019	2018
<b>Revenue</b>	5	<b>970,636</b>	<b>1,029,171</b>
Costs of goods sold		(197,756)	(158,056)
<b>Gross Margin</b>		<b>772,880</b>	<b>871,115</b>
Sales & Marketing		(2,838,080)	(2,444,945)
Clinical		(3,921,531)	(1,670,798)
Quality & Regulatory		(1,817,236)	(1,372,260)
Supply Chain		(930,654)	(964,182)
Engineering		(982,515)	(1,808,386)
General & administration	7.2	(4,264,188)	(5,760,912)
Other income		17,713	73,726
<b>Total Operating Expenses</b>		<b>(14,736,490)</b>	<b>(13,947,757)</b>
<b>Earnings before interests and taxes (EBIT)</b>		<b>(13,963,610)</b>	<b>(13,076,642)</b>
Finance income	7.4	52,755	309,200
Finance cost	7.4	(930,592)	(1,192,231)
Net Finance Cost		<b>(877,837)</b>	<b>(883,031)</b>
Income Tax Expense	7.5	(135,998)	(23,551)
<b>Net loss for the period</b>		<b>(14,977,445)</b>	<b>(13,983,224)</b>
Attributable to Sequana shareholders		(14,977,445)	(13,983,224)
Basic Loss per share	7.6	(1.22)	(1.40)

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	2019	2018
<b>Net loss for the period</b>		<b>(14,977,445)</b>	<b>(13,983,224)</b>
Components of other comprehensive income (OCI) items that will not be reclassified to profit or loss:			
Remeasurements of defined benefit plans	8.7	209,155	102,253
Items that may be reclassified subsequently to profit or loss:			
Currency translation adjustments		75,465	(76,480)
<b>Total other comprehensive income/(loss)-net of tax</b>		<b>284,620</b>	<b>25,773</b>
<b>Total comprehensive income</b>		<b>(14,692,825)</b>	<b>(13,957,451)</b>
Attributable to Sequana shareholders		(14,692,825)	(13,957,451)

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



# 5.

## Consolidated statement of financial position

In EUR	Notes	Total December 31, 2019	Total December 31, 2018
<b>Property, Plant and Equipment</b>		<b>765,396</b>	<b>183,696</b>
Laboratory	8.4	70,684	5,768
Information Technology (IT)	8.4	158,694	138,234
RD Tools	8.4	4,129	7,421
Right-of-use assets	8.4	510,453	-
Other tangible Fixed Assets	8.4	21,436	-
Assets under construction	8.4	-	32,274
<b>Financial assets</b>		<b>63,149</b>	<b>58,008</b>
Financial assets - Rental deposit		63,149	58,008
<b>Total non-current assets</b>		<b>828,545</b>	<b>241,705</b>
<b>Trade Receivables</b>		<b>117,520</b>	<b>96,608</b>
Trade Receivables - Third Parties	8.2	117,520	96,608
<b>Other Receivables</b>		<b>1,219,983</b>	<b>449,720</b>
Other Receivables - Third parties	8.2	507,130	333,347
Other Receivables - prepaid expenses	8.2	712,853	116,372
<b>Inventory</b>		<b>1,597,623</b>	<b>1,235,426</b>
Inventory	8.3	1,597,623	1,235,426
<b>Cash and cash equivalents</b>		<b>5,586,470</b>	<b>1,317,697</b>
Cash and cash equivalents	8.1	5,586,470	1,317,697
<b>Total current assets</b>		<b>8,521,597</b>	<b>3,099,450</b>
<b>TOTAL ASSETS</b>		<b>9,350,142</b>	<b>3,341,155</b>

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

In EUR	Notes	Total December 31, 2019	Total December 31, 2018
<b>Total Equity</b>		<b>925,932</b>	<b>(18,759,746)</b>
Share Capital	8.5	1,306,940	887,977
Other equity		-	184,478
Share premium	8.5	100,660,934	64,963,284
Reserves		(1,651,931)	(451,652)
Loss brought forward		(99,974,015)	(85,003,302)
Cumulative Translation Adjustment		584,005	659,469
<b>Long term financial debts</b>		<b>2,260,905</b>	<b>2,582,087</b>
Long term financial debts	8.6	2,260,905	2,582,087
<b>Long term lease debts</b>		<b>305,046</b>	<b>-</b>
Long term lease debts	8.6	305,046	-
<b>Retirement benefit obligation</b>		<b>543,601</b>	<b>792,225</b>
Retirement benefit obligation	8.7	543,601	792,225
<b>Total non-current liabilities</b>		<b>3,109,553</b>	<b>3,374,312</b>
<b>Short term financial debts</b>		<b>459,495</b>	<b>12,072,571</b>
Short term financial debts	8.6	459,495	12,072,571
<b>Short term lease debts</b>		<b>199,158</b>	<b>-</b>
Short term lease debts	8.6	199,158	-
<b>Trade Payables</b>		<b>2,476,373</b>	<b>2,753,182</b>
Trade Payables - Third parties	8.8	1,687,460	1,907,992
Contract liabilities	5	788,913	845,189
<b>Other payables</b>		<b>1,269,415</b>	<b>1,095,136</b>
Other payables - Third parties		1,269,415	1,095,136
<b>Accrued liabilities</b>		<b>910,216</b>	<b>2,805,700</b>
Accrued liabilities - Provision warranty	8.8	70,268	67,090
Accrued liabilities - Third parties	8.8	839,947	2,738,610
<b>Total current liabilities</b>		<b>5,314,657</b>	<b>18,726,588</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>9,350,142</b>	<b>3,341,155</b>

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	Own shares	Share premium	Reserves	Loss brought forward	Currency translation differences	Total shareholder equity
<b>Balance at 1 January 2018</b>		954,577	-	(193,275)	65,156,559	(182,510)	(71,081,972)	735,948	(4,610,672)
Net loss for the period							(13,983,224)		(13,983,224)
Other comprehensive income	8.7				102,253			(76,480)	25,773
Capital increase (net of costs)		1,591							1,591
Liquidation own shares				193,275	(193,275)				-
Conversion share capital into EUR		(68,191)							(68,191)
Transaction costs for equity instruments	7.2					(611,951)			(611,951)
Conversion rights on convertible loans	8.6		184,478						184,478
Share-based compensation	9				240,555		61,894		302,449
<b>December 31, 2018</b>		<b>887,977</b>	<b>184,478</b>	<b>-</b>	<b>64,963,284</b>	<b>(451,653)</b>	<b>(85,003,302)</b>	<b>659,468</b>	<b>(18,759,747)</b>
<b>Balance at 1 January 2019</b>		<b>887,977</b>	<b>184,478</b>	<b>-</b>	<b>64,963,284</b>	<b>(451,652)</b>	<b>(85,003,302)</b>	<b>659,469</b>	<b>(18,759,746)</b>
Change in accounting policy	2.3.4						6,732		6,732
<b>Restated total equity at 1 January 2019</b>		<b>887,977</b>	<b>184,478</b>	<b>-</b>	<b>64,963,284</b>	<b>(451,652)</b>	<b>(84,996,571)</b>	<b>659,469</b>	<b>(18,753,014)</b>
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
<b>December 31, 2019</b>		<b>1,306,940</b>	<b>-</b>	<b>-</b>	<b>100,660,934</b>	<b>(1,651,931)</b>	<b>(99,974,015)</b>	<b>584,005</b>	<b>925,932</b>

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

## 7. Consolidated statement of cash flows

In EUR	Notes	2019	2018
<b>Net loss for the period</b>		<b>(14,977,445)</b>	<b>(13,983,224)</b>
Income tax expense	7.5	135,998	23,551
Financial result	7.4	877,837	883,031
Depreciation		244,088	80,769
Change in defined benefit plan	8.7	(68,061)	43,388
Share-based compensation	9	389,156	240,555
Changes in trade and other receivables	8.2	(791,176)	(77,090)
Changes in inventories	8.3	(362,197)	79,999
Changes in trade and other payables / accrued liabilities	8.8	(3,921,680)	2,838,674
Taxes paid		(8,872)	(4,999)
<b>Cash flow from operating activities</b>		<b>(18,482,352)</b>	<b>(9,875,346)</b>
Investments in tangible fixed assets	8.4	(333,024)	(38,622)
Investments in financial assets		(4,000)	(16,263)
<b>Cash flow used for investing activities</b>		<b>(337,024)</b>	<b>(54,885)</b>
Proceeds from capital increase	8.5	26,164,837	1,591
(Repayments)/Proceeds from financial debts	8.6	(1,667,495)	9,583,315
Interest paid	8.6	(1,279,416)	(115,440)
<b>Cash flow from financing activities</b>		<b>23,217,926</b>	<b>9,469,466</b>
<b>Net change in cash and cash equivalents</b>		<b>4,398,550</b>	<b>(460,765)</b>
<b>Cash and cash equivalents at the beginning of the period</b>		<b>1,317,697</b>	<b>1,683,828</b>
Net effect of currency translation on cash and cash equivalents		(129,776)	94,633
<b>Cash and cash equivalents at the end of the period</b>		<b>5,586,470</b>	<b>1,317,697</b>

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.

#### 1.1. Group information

##### 1.1.1. Information about the subsidiaries

The consolidated financial statements of Sequana Group include:

Company	Purpose	Share capital	Investment 2019	Investment 2018
Sequana Medical NV	Holding/Sales	EUR 1,306,940	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%

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

Sequana is a commercial stage medical device company and an innovator in the management of fluid overload. The first and up to date only product, **alfapump**, is a fully implantable, programmable, transcutaneous-charged, battery-powered pump for the management of refractory ascites (chronic fluid build-up in the abdomen). Through the experience from the design, development, manufacture and commercialization of the **alfapump**, together with the extensive intellectual property portfolio, Sequana is developing an enabling platform for the management of heart failure and other fluid-imbalance disorders.

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, 2019, is as follows:

Shareholder	Shares	%
Neomed	4,196,641	33.3%
LSP	1,539,411	12.2%
PMV	1,223,906	9.7%
SFPI-FPIM	1,105,246	8.8%
Newton Biocapital	1,102,529	8.7%
Capricorn	598,978	4.7%
VI	525,501	4.2%
<b>Total threshold</b>	<b>10,292,212</b>	<b>81.61%</b>
Other	2,319,688	18.39%



## 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&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 **alfapump**.

The costs of obtaining and maintaining regulatory approval for the **alfapump** (and potentially in the future the **alfapump** 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 23 April 2020.

### 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 2019 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 recognized in other comprehensive income.

On consolidation, exchange differences arising from the translation of any net investment in foreign entities are recognized 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 2019 and the comparative periods to translate the following currencies into EUR, are as follows:

Currency	December 31, 2019		December 31, 2018	
	Year-end	Average Rate	Year-end	Average Rate
Swiss Franc (CHF)	1.0854	1.1124	1.1269	1.1550
US Dollar (USD)	1.1234	1.1195	1.1450	1.1810

### 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 recognized is derecognized 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 derecognized.

### 2.3.1.7. TRADE RECEIVABLES

In accordance with IFRS 9, trade receivables are classified and measured at amortized 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.

### 2.3.1.8. 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.

### 2.3.1.9. 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.

### 2.3.1.10. 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.

### 2.3.1.11. 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

### 2.3.1.12. 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.

### 2.3.1.13. 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 CHF 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 amortized 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.

There are two methods with respect to the accounting treatment for a liability with an embedded derivative (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 amortized 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.

#### 2.3.1.14. TRADE PAYABLES

Payables after and within one year are measured at amortized cost, i.e. at the net present value of the payable amount. Unless the impact of discounting is material, the nominal value is taken.

#### 2.3.1.15. 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 recognized 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.

#### 2.3.1.16. LEASES

##### Accounting policy until 1 January 2019

Until the end of 2018, leases of property, plant and equipment were classified as either finance or operating leases.

##### Finance leases

Leases of property, plant and equipment for which the Group has substantially all the risks and rewards of ownership are classified as finance leases. Finance leases are capitalized at the lease's commencement at the lower of the fair value of the leased property and the present value of the minimum lease payments. Each lease payment is allocated between the liability and finance charges so as to achieve a constant rate on the remaining balance of the liability. Finance expenses are recognized immediately in profit or loss, unless they are directly attributable to qualifying assets in which they are capitalized. Contingent rentals are recognized as expenses in the periods in which they are incurred.

If there is reasonable certainty that the Group will obtain ownership by the end of the lease term, the asset shall be depreciated over the useful life. In all other circumstances the asset is depreciated over the shorter of the useful life of the assets or the lease term.

##### Operating leases

A lease agreement is classified as an operating lease if all of the risks and rewards of ownership have not been transferred to the lessee. Payments under operating leases (net of any incentives received from the lessor) are charged to the income statement on a straight-line basis over the period of the lease.

### Accounting policy as from 1 January 2019

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.

### 2.3.1.17. 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 2019 and 2018 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
- **Fair value of financial instruments (convertible loans)**
- **Share-based compensation**

#### 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 non-related parties.

The following table presents the group's financial liabilities measured and recognized at fair value at 31 December 2019 and 31 December 2018:

Description	Note	Level	At 31 december 2019 in EUR	At 31 december 2018 in EUR
<b>EUR denominated convertible loans at fair value through PL</b>	8.6	3	0	7,882,397

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 12% in the most recent loan with non-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

Since there are no convertible loans as per 31 December 2019, the following table is only applicable for the comparable figures as per 31 December 2018 and summarizes the quantitative information about the significant unobservable inputs used in level 3 fair value measurements.

Description/Financial statement	Liability component of convertible bond denominated in EUR including the conversion option
<b>Class of subsequent measurement</b>	Fair value through profit or loss
<b>Fair value at 31 Dec. 2018</b>	7,882,397
<b>Unobservable inputs</b>	Discount rate / market rate
<b>Input range (probability-weighted average)</b>	10%-14% (12%)
<b>Relationship of unobservable inputs to fair value</b>	An increase/decrease of the market interest rate of +2%/-2% would change the fair value of the liability by EUR – 67,018/+ 67,018

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.

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 extraordinary 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 share price considered is EUR 6.47 and is calculated as the average of the historical actual share prices for the period March till June 2019.

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

#### 2.3.3.1. IFRS ACCOUNTING STANDARDS TO BE ADOPTED AS FROM 2019 ONWARDS

The following new standard is mandatory for the first time for the financial year beginning 1 January 2019 and has been endorsed by the European Union and has a material impact on the Sequana Group consolidated financial statements:

**IFRS 16, 'Leases'** (effective 1 January 2019). This standard replaces the current guidance in IAS 17 and is a far reaching change in accounting by lessees in particular. Under IAS 17, lessees were required to make a distinction between a finance lease (on balance sheet) and an operating lease (off balance sheet). IFRS 16 requires lessees to recognize a lease liability reflecting future lease payments and a 'right-of-use asset' for virtually all lease contracts. For lessors, the accounting stays almost the same. However, as the IASB has updated the guidance on the definition of a lease (as well as the guidance on the combination and separation of contracts), lessors will also be affected by the new standard. Under IFRS 16, a contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

We refer to section 2.3.4 for more details about the impact of adoption of IFRS 16 by the Group.

The following amendments and annual improvements to standards are mandatory for the first time for the financial year beginning 1 January 2019 and have no material impact on the Sequana Group consolidated financial statements:

**Amendments to IFRS 9, 'Prepayment features with negative compensation'** (effective 1 January 2019 with the EU). An amendments to allow companies to measure particular prepayable financial assets with so-called negative compensation at amortized cost or at fair value through other comprehensive income if a specified condition is met—instead of at fair value through profit or loss, because they would otherwise fail the SPPI-test. In addition, this amendment clarifies an aspect of the accounting for financial liabilities following a modification.

**IFRIC 23, 'Uncertainty over income tax treatments'** (effective 1 January 2019). This interpretation clarifies the accounting for uncertainties in income taxes. The interpretation is to be applied to the determination of taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates, when there is uncertainty over income tax treatments under IAS 12.

**Amendments to IAS 28, 'Long term interests in associates and joint ventures'** (effective 1 January 2019). Clarification regarding the accounting for long-term interests in an associate or joint venture, to which the equity method is not applied, under IFRS 9. Specifically, whether the measurement and impairment of such interests should be done using IFRS 9, IAS 28 or a combination of both.

**Amendments to IAS 19, 'Plan Amendment, Curtailment or Settlement'** (effective 1 January 2019). The amendments require an entity to use updated assumptions to determine current service cost and net interest for the remainder of the period after a plan amendment, curtailment or settlement. In addition, an entity will have to recognize in profit or loss as part of past service cost, or a gain or loss on settlement, any reduction in a surplus, even if that surplus was not previously recognized because of the impact of the asset ceiling. The amendments will affect any entity that changes the terms or the membership of a defined benefit plan such that there is past service cost or a gain or loss on settlement.

**Annual improvements to IFRS Standards 2015-2017 cycle**, applicable as of 1 January 2019 and containing the following amendments to IFRSs:

- **IFRS 3 Business combination, paragraph 42A:** The amendments clarify that, when an entity obtains control of a business that is a joint operation (as defined in IFRS 11), it applies the requirements for a business combination achieved in stages, including re-measuring previously held interests in the assets and liabilities of the joint operation at fair value. In doing so, the acquirer re-measures its entire previously held interest in the joint operation.
- **IFRS 11 Joint Arrangements, paragraph B33CA:** A party that participates in, but does not have joint control of, a joint operation might obtain joint control of the joint operation in which the activity of the joint operation constitutes a business as defined in IFRS 3. In such cases, previously held interests in the joint operation are not re-measured.
- **IAS 12 Income Taxes, paragraph 57A:** The amendments clarify that the income tax consequences of dividends are linked more directly to past transactions or events that generated distributable profits than to distributions to owners. Therefore, an entity recognizes the income tax consequences of dividends in profit or loss, other comprehensive income or equity according to where the entity originally recognized those past transactions or events.
- **IAS 23 Borrowing Costs, paragraph 14:** The amendments clarify that an entity treats as part of general borrowings any borrowing originally made to develop a qualifying asset when substantially all of the activities necessary to prepare that asset for its intended use or sale are complete. An entity applies those amendments to borrowing costs incurred on or after the beginning of the annual reporting period in which the entity first applies those amendments.

### 2.3.3.2. IFRS ACCOUNTING STANDARDS TO BE ADOPTED AS FROM 2020 ONWARDS

A number of new standards, amendments to existing standards and annual improvement cycles have been published and are mandatory for the first time for the financial year beginning on or after January 1, 2020, or later periods, and have not been early adopted. Those which may be the most relevant to the Sequana Group financial statements are set out below:

**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 Group is currently assessing the impact of the new standards. The Group expects 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

This note explains the impact of the adoption of IFRS 16 Leases on the Group’s financial statements and discloses the new accounting policies that have been applied from 1 January 2019.

The Group has adopted IFRS 16 as from 1 January 2019, but has not restated comparatives for the 2018 reporting period, as permitted under the specific transitional provisions in the standard. The reclassifications and adjustments arising from the new leasing rules are therefore recognized in the opening balance sheet on 1 January 2019.

The selected transition method is the simplified transition approach.

#### 2.3.4.1. ADJUSTMENTS RECOGNIZED ON ADOPTION OF IFRS 16

On adoption of IFRS 16, the Group recognized lease liabilities in relation to leases which had previously been classified as ‘operating leases’ under the principles of IAS 17 Leases. These liabilities were measured at the present value of the remaining lease payments, discounted using the lessee’s incremental borrowing

rate as of 1 January 2019. The interest rate implicit in the lease is not readily determinable. The lessee’s annual incremental borrowing rate applied to the lease liabilities on 1 January 2019 was 12%.

The associated right-of-use assets for property leases were measured on a retrospective basis as if the new rules had always been applied. Other right-of-use assets were measured at the amount equal to the lease liability, adjusted by the amount of any prepaid or accrued lease payments relating to that lease recognized in the balance sheet as at 31 December 2018. There were no onerous lease contracts that would have required an adjustment to the right-of-use at the date of initial application.

The recognized right-of-use assets (net amounts) relate to the following types of assets:

	31 December 2019	1 January 2019
<b>Buildings</b>	317,469	253,157
<b>Vehicles</b>	192,984	53,239
<b>Total right-of-use assets</b>	510,453	306,395

The change in accounting policy affected the following items in the balance sheet on 1 January 2019:

- Right-of-use assets – increase by EUR 306,395
- Lease liabilities – increase by EUR 299,664

The effect of the change in accounting policy in EBITDA is immaterial.

In applying IFRS 16 for the first time, the Group has used the following practical expedients permitted by the standard:

- The accounting for operating leases with a remaining lease term of less than 12 months as at 1 January 2019 as short-term leases;
- The exclusion of initial direct costs for the measurement of the right-of-use asset at the date of initial application;

- The use of hindsight in determining the lease term where the contract contains options to extend or terminate the lease, if applicable.

The amount of the non-lease components is not explicitly determined in the contracts of the buildings. In view of materiality (minimum amounts overall), Sequana decided not to separate the lease and non-lease components.

The Group has also elected not to reassess whether a contract is, or contains a lease at the date of initial application. Instead, for contracts entered into before the transition date the Group relied on its assessment made applying IAS 17 and IFRIC 4 *Determining whether an Arrangement contains a Lease*.

#### 2.3.4.2. THE ACCOUNTING TREATMENT OF THE GROUP’S LEASING ACTIVITIES

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 recognized 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 recognized 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.

### 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) in relation to procurement and financing.

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:

	31.12.2019 CHF
<b>Assets</b>	
Inventory	1,801,841
Cash and cash equivalents	663,204
<b>Liabilities</b>	
Long term debt	2,453,987
Short term debt	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:



(EUR)	Impact on income statement and equity	
	As at 31 December 2019	As at 31 December 2018
5% decrease of average foreign exchange rate	-321,532	-302,431
5% increase of average foreign exchange rate	+322,082	+302,424

As of 31 December 2019, 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 321,532 EUR higher (2018: 302,431 EUR). 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 322,082 EUR lower (2018: 302,424 EUR).

### 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.

(EUR)	CARRYING AMOUNT 31.12.2019	Cash outflows		
		Total	Up to 1 year	1 to 3 years
Trade payable	2,476,373	2,476,373	2,476,373	
Other payables	1,773,619	1,773,619	1,468,573	305,046
Financial debt at amortized costs	3,168,636	3,168,636	780,375	2,388,261
<b>Total</b>	<b>7,418,628</b>	<b>7,418,628</b>	<b>4,725,321</b>	<b>2,693,307</b>

(EUR)	CARRYING AMOUNT 31.12.2018	Cash outflows			
		Total	Up to 1 year	1 to 3 years	More than 3 years
Trade payable	2,753,183	2,753,183	2,752,061	1,122	
Other payables	1,095,136	1,095,136	1,095,136		
Financial debt at amortized costs	13,835,837	13,835,837	11,253,750	2,582,087	
Interest payment on financial debt	818,821	818,821	818,821		
<b>Total</b>	<b>18,502,977</b>	<b>18,502,977</b>	<b>15,919,768</b>	<b>2,583,209</b>	<b>-</b>

### 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:

(EUR)	Impact on income statement and equity	
	As at 31 December 2019	As at 31 December 2018
50 basis points increase/decrease	-/+ 53,309	-/+ 33,866

### 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 6 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 2019 and 2018.

## 4. Going concern

The Company is still in its start-up 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.

The impact of COVID-19 on the Company's ability to secure additional financing rounds or undertake capital market transactions is 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 balance sheet as at 31 December 2019 shows a positive equity in the amount of EUR 0.93 million. The Company will continue to require additional financing in the near future and in that respect already successfully raised EUR 19 million in January 2020 in a private equity placement via an accelerated book building offering. Together with existing cash resources, the net proceeds from this private placement are expected to extend the current cash runway of the Company from Q2 2020 into H1 2021. The Company continues to evaluate equity and non-dilutive financing options, including discussions with existing and/or new investors including the refinancing of Bootstrap (of which an amount in principal of EUR 3.17 million is still outstanding).

As a result, the board of directors remains confident that the liquidity requirements for the next twelve months can be secured. Based on the above, the executive management and the board of directors remain confident about the strategic plan, which comprises additional financing measures including equity and/or non-dilutive financing sources, and therefore consider the preparation of the present financial statements on a going concern basis as appropriate.

We refer for more details about the private placement to note 15 Events after the reporting period.

## 5. Revenues from customers

The Group generates sales solely from the sale of **alfapump**, 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	2019	2018
<b>Trade receivables</b>	117,520	96,608
<b>Contract liabilities (relating to customers' advance payments)</b>	788,913	845,189

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	2019	2018
<b>Revenue recognized in the period (included in contract liability at the beginning of the period)</b>	(57,357)	(272,511)
<b>Increases due to cash received as advance payment</b>	-	-
<b>Effect of currency translation</b>	1,081	14,482

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, **alfapump** 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	2019	2018
Switzerland	107,659	54,734
Germany	761,875	584,175
UK		67,966
Rest of the world	101,103	322,296
<b>Total revenue</b>	<b>970,636</b>	<b>1,029,171</b>

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, 46% of the assets are located in Switzerland compared to 94% last year, due to the registration of Sequana Medical NV in Belgium on October 1<sup>st</sup>, 2018. 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	2019	2018
Personnel costs	6,098,516	5,383,862
Clinical Studies	2,520,685	934,798
External consultancy	1,266,069	2,263,723
External accounting & legal services	494,412	2,478,239
Travel & Lodging	869,096	577,537
Rent & infrastructure expenses	204,698	407,572
Intellectual Property	210,366	188,996
Insurance & IT	625,714	219,669
Marketing	263,653	347,678
Depreciation and amortization <sup>(1) (2)</sup>	244,088	81,812
Quality Audits / Regulatory Fees	785,768	161,383
Other	1,153,424	902,487
<b>Total operating expenses</b>	<b>14,736,490</b>	<b>13,947,757</b>

### 7.2. Operating Expenses – General and Administration

Expenses in EUR	2019	2018
IPO related expenses	548,824	2,445,467

The total amount of known and accrued IPO related expenses for 2019 is 2,347,414, of which 548,824 EUR has been recognized in the Profit and Loss statement as G&A expenses and 1,798,590 EUR has been reported under equity. The IPO expenses accounted

for in equity relate to the issuance of equity instruments and represent the incremental costs attributed to new shares.

In 2018, the total amount of known and accrued IPO related expenses was 3,057,418 EUR, of which 2,445,467 EUR has been recognized in the Profit and Loss statement as G&A expenses and 611,951 EUR 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	148,149
Cars	28,385
<b>Total</b>	<b>176,534</b>

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.

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

(2) Following the implementation of IFRS 16, the depreciation on the on-balance leasings is included in the 2019 figure. We refer for more details to section 2.3.4 Change in accounting policy.



## 7.4. Financial result

The financial result is split into the following categories:

In EUR	2019	2018
<b>Finance income</b>	<b>52,755</b>	<b>309,200</b>
Interest income	190	10
Foreign exchange gains	52,565	309,190
<b>Finance cost</b>	<b>(930,592)</b>	<b>(1,192,230)</b>
Interest costs	(724,964)	(921,956)
Interest costs IFRS 16	(45,623)	-
Foreign exchange losses	(160,005)	(270,274)
<b>Net financial result</b>	<b>(877,837)</b>	<b>(883,030)</b>

## 7.5. Income taxes

### 7.5.1. Income tax expense

(EUR)	2019	2018
<b>Current income taxes</b>	<b>(135,998)</b>	<b>(23,551)</b>
<b>Total income tax expense</b>	<b>(135,998)</b>	<b>(23,551)</b>

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

(EUR)	2019	2018
<b>Loss before tax</b>	<b>(14,841,447)</b>	<b>(13,586,785)</b>
Current income taxes	29,58%	20,00%
<b>Income tax income at the applicable tax rate</b>	<b>(4,390,100)</b>	<b>(2,717,357)</b>
Effect of non-recognition of tax losses in current year	(4,254,102)	(2,693,806)
<b>Effective income tax expense</b>	<b>(135,998)</b>	<b>(23,551)</b>

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 2019 and 2018, 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, 2019	December 31, 2018
<b>Deferred tax assets not recognized on deductible temporary differences</b>	-	(259,579)
<b>Deductible temporary differences for which no deferred tax asset has been recognized</b>	-	1,297,896
<b>Belgium</b>	<b>13,054,511</b>	<b>693,417</b>
<b>Switzerland</b>	-	70,203,667
<b>USA</b>	<b>718,960</b>	<b>617,785</b>
<b>Total unused tax losses</b>	<b>13,773,471</b>	<b>71,514,869</b>

The unused tax losses were mainly incurred by the former Swiss holding 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. Additionally, a large portion of the tax losses carried forward has been used in the context of the tax exit fee (see below).

The Group obtained a tax ruling with the Swiss tax authorities. In case of an IPO event within 6 months after the transfer of seat to Belgium, a tax exit fee to move out of Switzerland was due. The tax exit fee was calculated taking into account a value upon exit representing 75% of the IPO value, corrected with certain elements. The final assessment over 2018 has been received in 2019 and neither direct taxes nor withholding taxes were due. As a result, the remainder of the Swiss tax losses are entirely forfeited.

In the tax ruling, it also has been agreed that the Swiss branch will be taxable on a cost-plus basis. The cost-plus percentage is 10%. The 2019 estimated tax amount, amounting to 159,039 CHF or 146,526 EUR 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 9.6), which may have a dilutive effect on the basic earning per share.

For the purpose of calculating diluted earning per share, the number of ordinary shares shall be the weighted average number of ordinary shares plus the weighted average number of ordinary shares that would be issued in case of conversion into ordinary shares of all instruments that can be converted into ordinary shares.

Due to the losses incurred by the Group, these instruments had an anti-dilutive effect on the loss per share. Instruments that can be converted into ordinary shares shall only be treated as when their conversion into ordinary shares would decrease earnings per share or increase loss per share from continuing operations.

(EUR, except number of shares)	2019	2018
<b>Net loss attributable to shareholders</b>	<b>(14,977,445)</b>	<b>(13,983,224)</b>
<b>Weighted average number of shares – basic</b>	<b>12,296,042</b>	<b>9,999,366</b>
<b>Basic loss per share</b>	<b>(1.22)</b>	<b>(1.40)</b>

## 8. Detailed information on balance sheet items

### 8.1. Cash and cash equivalents

The Group held cash and cash equivalents of 5,586,470 EUR at 31 December 2019 (2018: EUR 1,317,697).

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

(EUR)	December 31, 2019	December 31, 2018
Trade receivables	117,520	96,608
Other receivables - Third parties	507,130	333,347
Other receivables - prepaid expenses	712,853	116,372

Other receivables – Third parties mainly consist of VAT.

The total amount of Other receivables – prepaid expenses in the Balance Sheet amounts to 712,853 EUR (in 2018: 116,372 EUR). For 2019 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 the UK. 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 2019 and 2018 past due, but not impaired, are as follows:

2019 (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 is a provision for bad debt, amounting to EUR 24,075.

2018 (EUR)	Not past due	Total past due	0-90 days	180 days	180-360 days	More than 360 days
Trade receivables	24,538	72,070	72,070			
Weighted average loss rate	0%					

### 8.3. Inventories

Inventories are categorized as follows:

(EUR)	December 31, 2019	December 31, 2018
Finished goods	362,498	296,166
Subassembly	158,629	63,076
Components	1,076,496	876,184
<b>Total</b>	<b>1,597,623</b>	<b>1,235,426</b>

No inventory write-down has been recorded.

### 8.4. Property, plant and equipment

Reconciliation of beginning and ending balance by classes of assets:

Cost (in EUR)	Leased Fixed Assets						Other tangible fixed assets	Assets under construction	Total
	Laboratory	IT	RD Tools	Buildings	Cars				
<b>December 31, 2017</b>	<b>23,399</b>	<b>356,819</b>	<b>17,437</b>	-	-	-	-	<b>397,656</b>	
Additions	3,283	(46,016)	4,110				32,274	(6,349)	
Currency translation effects	979	12,547	772					14,299	
<b>December 31, 2018</b>	<b>27,662</b>	<b>323,351</b>	<b>22,320</b>	-	-	-	<b>32,274</b>	<b>405,607</b>	
Additions	74,084	74,459	-	465,619	221,369	23,151	(32,404)	826,277	
Currency translation effects	(1,480)	(4,347)	(341)	-	-	-	130	(6,038)	
<b>December 31, 2019</b>	<b>100,267</b>	<b>393,462</b>	<b>21,979</b>	<b>465,619</b>	<b>221,369</b>	<b>23,151</b>	-	<b>1,225,846</b>	

Accumulated depreciation (in EUR)	Leased Fixed Assets						Other tangible fixed assets	Assets under construction	Total
	Laboratory	IT	RD Tools	Buildings	Cars				
<b>December 31, 2017</b>	<b>13,604</b>	<b>170,989</b>	<b>7,108</b>	-	-	-	-	<b>191,701</b>	
Additions	7,721	6,956	7,290					21,967	
Currency translation effects	570	7,172	501					8,243	
<b>December 31, 2018</b>	<b>21,895</b>	<b>185,117</b>	<b>14,899</b>	-	-	-	-	<b>221,910</b>	
Additions	8,098	54,446	3,301	148,149	28,385	1,715	-	244,094	
Currency translation effects	(410)	(4,795)	(350)					(5,554)	
<b>December 31, 2019</b>	<b>29,583</b>	<b>234,768</b>	<b>17,850</b>	<b>148,149</b>	<b>28,385</b>	<b>1,715</b>	-	<b>460,450</b>	

<b>Net book value</b>								
<b>December 31, 2018</b>	<b>5,768</b>	<b>138,234</b>	<b>7,421</b>	-	-	-	<b>32,274</b>	<b>183,696</b>
<b>December 31, 2019</b>	<b>70,684</b>	<b>158,694</b>	<b>4,129</b>	<b>317,469</b>	<b>192,984</b>	<b>21,436</b>	-	<b>765,396</b>

## 8.5. Share capital and Share Premium

The share capital of the Company is EUR 1,306,940 and is represented by 12,611,900 common shares. The share capital is fully paid-in. During 2019, a number of capital increases and a share consolidation took place.

EUR Except number of shares	Shares	Share capital	Share premium	Total
<b>31 December 2018</b>	<b>9,930,784</b>	<b>887,977</b>	<b>64,963,284</b>	<b>65,851,261</b>
Capital increase IPO (convertible loans)	937,199	83,786	8,532,737	8,616,523
IPO share consolidation	(1,491,377)	-	-	-
<b>Subtotal</b>	<b>9,376,606</b>			
Capital increase IPO (contribution in cash)	3,078,205	318,902	25,845,840	26,164,743
Capital increase IPO (contribution in kind)	157,089	16,274	1,319,073	1,335,347
<b>Subtotal</b>	<b>3,235,294</b>			
<b>December 31, 2019</b>	<b>12,611,900</b>	<b>1,306,940</b>	<b>100,660,934</b>	<b>101,967,874</b>

At 31 December 2018, the share capital of the Company was EUR 887,977. It was divided into 543,682 registered preferred A-shares, 2,167,115 registered preferred B-shares, 1,724,337 registered preferred C-shares, 205,501 registered preferred D-shares, 2,099,236 registered preferred E-shares and 3,194,913 registered common shares of EUR 0.096 nominal value each.

At 12 February 2019 - closing of the offering (IPO) - the outstanding Convertible Loans were converted into series E preferred Shares. The preference triggered upon the closing of the Offering (IPO) and resulted in a conversion and consolidation of the outstanding Shares into a new number of outstanding Shares reflecting the priority among the current shareholders of the Company as a result of the Offering (IPO) (not including the Offered Shares blank to be issued upon the closing of the Offering (including pursuant to the conversion of the Bridge Loans) and the exercise of the Over-allotment Option).

Upon closing of the Offering and after conversion of the convertible loans, a share consolidation was accomplished. A consolidation ratio was applied so that the existing shares after the IPO share consolidation was equal to the IPO price that was determined in the context of the IPO capital increase. The IPO share consolidation was realized with regard to all

outstanding shares and warrants of the Company. The share capital of the Company, after IPO share consolidation, was represented by 9,376,606 (common) shares that each represent an equal part of the share capital.

The capital increase through contribution in cash and in kind resulted in 3,235,294 new common shares at the IPO price of EUR 8.50 per new share. The IPO price of the new shares was allocated to the share capital of the Company in such a way that per share issued a part of the IPO price equal to the fractional value of the existing shares of the Company immediately prior to the IPO capital increase (taking into account the IPO share consolidation) was booked as share capital (being EUR 0.1036 rounded per new share), and the balance of the IPO price was booked as share premium.

The new shares issued within the framework of the IPO 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 (taking into account the IPO share consolidation).

As of 31 December 2019, 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.

With the exception of the event described above, no repayments of the principal amount are due until 31 December 2020. After that period, the entire outstanding principal amount shall be due in four substantially equal consecutive instalments on each of 31 December 2020, 31 January 2021, 28 February 2021 and 31 March 2021. As a result of this modification, the first instalment due on 31 December 2020 has been classified as current debt. The remaining three instalments have been classified as non-current debt.

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.

### 8.6.2. Convertible loans denominated in CHF

At 12 February 2019 - closing of the offering (IPO) -, all outstanding Convertible Loans were converted into series E preferred Shares.

The effect of the conversion options in 2019 was immaterial.

For comparison reasons, we indicate below the 2018 information as reported in the annual report 2018.



The Company signed a Convertible Loan Agreement with existing Shareholders in February 2018, which guaranteed liquid funds of EUR 1.7 million (CHF 2 million) in total.

The following conversion options were foreseen in the Agreement:

- In the event of an IPO, Mandatory conversion: the entire outstanding Convertible Loan Amounts shall automatically be converted into shares of the Company in the event of, and simultaneously with the initial closing of, the next increase of the Company's share capital ("next financing round"). The number of shares to be issued upon such conversion shall be equal to the entire outstanding Convertible Loan Amounts divided by the price per share paid by the investor/s at the occasion of such Next Financing Round. Otherwise, the issuance of the shares shall be upon the terms and subject to the conditions applicable to such Next Financing Round. The "fixed-for-fixed" criteria fails for this option, and thus this component of the instrument together with the loan itself represents a liability.
- Voluntary conversion: The lenders' majority may at any time prior the maturity date (including without limitation, prior to an IPO, Liquidity Event or a Next Financing Round) decide to convert the entire outstanding Convertible Loan Amounts into the most senior class of preferred shares at CHF 10.48 per share. This conversion option qualifies as "fixed-for-fixed", and thus represents an equity component.

The convertible loans denominated in CHF are initially recognized at fair value. The impact resulting from the fair value measurement is a decrease of the face value of the convertible loans with EUR 184,478. The liability is subsequently recognized on an amortized cost basis until extinguished on conversion or maturity of the bonds. The remainder of the proceeds is allocated to the conversion option, recognized in shareholders'

equity, and not subsequently re-measured. The mandatory conversion option is not material and therefore has not been accounted for separately.

The initial assessment was made as per 30 September 2018 and the loans are not subsequently re-measured.

The loans were initially granted until 31 December 2018, and on 20 December 2018, as part of the amended and restated Pre-IPO Investment Commitment Agreement of 2 November 2018, they were extended until 15 February 2019. The exchange rate of conversion is fixed to 1.1399 CHF for 1 EUR. These modifications to the initial loan agreements are not considered as significant. Hence, no subsequent re-measurement has been done.

- The Group entered into three additional convertible loan agreements, dated 25 October 2018, 30 October 2018 and 2 November 2018, respectively, with two individuals and BioMedInvest II LP pursuant to which BioMedInvest II LP granted a loan to the Group in a principal amount of CHF 198,000 and the two individuals granted a loan to the Group in a principal amount of respectively CHF 100,000 and CHF 52,400. The loans were initially granted until 31 December 2018. The loans do not bear an interest. The loans can be converted at any time prior to the maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share. In the event of a capital increase, such as the Offering, the loans are also subject to a mandatory conversion into share capital of the Issuer. The number of shares to be issued upon such conversion shall be equal to the entire outstanding Convertible Loan Amounts divided by the price per share paid by the investor/s at the occasion of such Next Financing Round. Otherwise, the issuance of the shares shall be upon the terms and subject to the conditions applicable to such Next Financing Round. The "fixed-for-fixed" criteria fails for this option, and thus this component of the instrument together with the loan itself represents a liability.

On 20 December 2018, as part of the amended and restated Pre-IPO Investment Commitment Agreement of 2 November 2018, they were extended until 15 February 2019.

These three new convertible loans are in the aggregate considered as not significant and therefore, no additional assessment has been done. They are initially recognized at fair value through P&L (FVTPL), in the same manner as the other convertible loans denominated in CHF.

Transaction costs incurred are not material and thus expensed as incurred.

### 8.6.3. Convertible loans denominated in EUR

At 12 February 2019 - closing of the offering (IPO) -, all outstanding Convertible Loans were converted into series E preferred Shares.

For comparison reasons, we indicate below the 2018 information as reported in the annual report 2018.

An additional Convertible Loan Agreement with funds of EUR 1.7 million was signed in June 2018 with a new investor, Participatiemaatschappij Vlaanderen NV ("PMV").

The following conversion options were foreseen in the PMV Agreement:

PMV is entitled to convert the loan and the accrued interest at any time prior to the maturity on a voluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per Share.

In August and September 2018, two additional Convertible Loan Agreements with funds of EUR 2.5 million have been signed with two new investors, Federale Participatie- en Investeringsmaatschappij NV ("FPIM") and Cofipalux Invest SA ("Vlerick").

The following conversion options were foreseen in both the FPIM and Vlerick Agreements:

- In the event of an IPO, Mandatory conversion: the entire outstanding Convertible Loan Amounts shall automatically be converted into shares of the Company in the event of, and simultaneously with the initial closing of, the next increase of the Company's share capital ("next financing round"). The number of shares to be issued upon such conversion shall be equal to the entire outstanding Convertible Loan Amounts divided by CHF 10.48 per share.
- Voluntary conversion: The lenders' majority may at any time prior the maturity date (including without limitation, prior to an IPO, Liquidity Event or a Next Financing Round) decide to convert the entire outstanding Convertible Loan Amounts into the most senior class of preferred shares at CHF 10.48 per share.

The **PMV, FPIM and Vlerick** convertible debentures denominated in EUR, are classified entirely as liabilities as they were issued in a currency other than the functional currency of the company. As the instrument contains an embedded derivative, 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 Company and **Newton** Biocapital I Pricav Privée SA ("Newton") have entered into a convertible loan agreement, dated 11 October 2018, pursuant to which Newton granted a loan to the Issuer in a principal amount of EUR 2,000,000. The loan was granted until 31 December 2018. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment.

The Newton Convertible Loan furthermore contains a negative pledge on the Issuer and its subsidiaries.

In addition, **PMV** agreed on 23 October 2018 via an **addendum** to the original contract signed on 6 June 2018, to increase their maximum amount from EUR 1,7 million to EUR 2 Million, with no further changes to the initial conditions.

The following conversion options were foreseen in both the “Newton” and “PMV Addendum” Agreements:

- In the event of an IPO, Mandatory conversion: the entire outstanding Convertible Loan Amounts shall automatically be converted into shares of the Company in the event of, and simultaneously with the initial closing of, the next increase of the Company’s share capital (“next financing round”). The number of shares to be issued upon such conversion shall be equal to the entire outstanding Convertible Loan Amounts divided by CHF 10.48 per share.
- Voluntary conversion: The lenders’ majority may at any time prior the maturity date (including without limitation, prior to an IPO, Liquidity Event or a Next Financing Round) decide to convert the entire outstanding Convertible Loan Amounts into the most senior class of preferred shares at CHF 10.48 per share.

The **Newton** and **PMV addendum** convertible debentures denominated in EUR and issued in the currency equal to the functional currency of the company, are classified entirely as liabilities. As the instrument contains an embedded derivative, 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.

On November 2, 2018, all investing parties entered into a **Pre-IPO Investment Commitment** agreement where all parties committed to invest EUR 20,500,000 upon launch of the Offering.

On 20 December 2018, an amended and restated pre-IPO investment commitment agreement has been signed where the current convertible loans have been extended till February 15, 2019.

In addition, a new set of new **convertible bridge loans** amounting to 1.024.238 EUR representing 5% from the Pre-IPO Investment Commitment amount, has been agreed with most of the existing investors at a yearly interest rate of 8%. The new convertible bridge loans are to be deducted from the total Pre-IPO Investment Commitment as agreed on 2 November, 2018 in the Pre-IPO Investment Commitment agreement. Pursuant to the Pre-IPO Investment Commitment Agreements, the relevant Participating Investors agreed to convert the principal amount and accrued interest of the Bridge Loans into New Shares at the Offer Price upon the closing of the Offering. The conversion will be implemented by means of a contribution in kind of the outstanding payable amounts under the Bridge Loans. The remaining portion of the Subscription Commitments (not including the amounts due pursuant to the Bridge Loans Loan for an aggregate principal amount of EUR 6,340.91) will be subscribed for in cash upon the closing of the Offering.

These modifications of the terms of the contract have not been substantial, and as such have not resulted in the extinguishment of the financial liability. The above described modifications to the PMV, FPIM and Vlerick contracts, as well as those to the Newton and PMV addendum, have fixed the exchange rate used to convert the options, as a result of which the embedded conversion option is to be considered as an equity component. As the fair value of this conversion option was considered not to be significant, this was not adjusted.

The **convertible bridge loans** denominated in EUR and issued in the currency equal to the functional currency of the company, are classified entirely as liabilities. As the instrument contains an embedded derivative, 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.

Transaction costs incurred are not material and thus expensed as incurred.

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	2019	2018
<b>Cash and cash equivalents</b>	5,586,470	1,317,697
<b>Borrowings - repayable within one year</b>	(459,495)	(12,072,571)
<b>Borrowings - repayable after one year</b>	(2,260,905)	(2,582,087)
<b>Net financial debt</b>	<b>2,866,070</b>	<b>(13,336,961)</b>

in EUR	Cash and cash equivalents	Borrowings due within 1 year	Borrowings due after 1 year	Total
<b>Net financial debt as per 31 December 2018</b>	1,317,697	(12,072,571)	(2,582,087)	(13,336,961)
Cash flows	4,398,550	1,667,495		6,066,045
Accrued interest (non-cash)		313,096		313,096
Transfer (non-cash)		(409,686)	409,686	-
Converted to equity (non-cash)		9,851,810	-	9,851,810
Foreign exchange impact (non-cash)	(129,776)	190,360	(88,504)	(27,920)
<b>Net financial debt as per 31 December 2019</b>	5,586,470	(459,495)	(2,260,905)	2,866,069

The loans are presented in the balance sheet as follows:

in EUR	December 31, 2019	December 31, 2018
Face value of convertible loans issued in CHF <sup>(2)</sup>	-	1,751,681
Interest expenses accrued on convertible loans in CHF <sup>(1)</sup>	-	(184,478)
Face value of convertible loans issued in EUR	-	7,882,397
Other loans	2,720,401	5,205,058
<b>Total short term and long term debt</b>	<b>2,720,401</b>	<b>14,654,658</b>

### 8.6.4. Lease debts

On adoption of IFRS 16, the Group recognized 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, 2019	December 31, 2018
Long term lease debts	305,046	-
Short term lease debts	199,158	-
<b>Total</b>	<b>504,204</b>	<b>-</b>

## 8.7. Post-employment benefits

The Group operates different employee benefit plans. For Switzerland, the defined benefit plan has switched from AXA to PKG resulting in a plan amendment as of the 1<sup>st</sup> of January 2019. For Germany, the defined contribution plan remained unchanged. In Belgium, a new defined contribution plan which in fact is a

defined benefit plan due to the legally minimum guaranteed benefits, has been implemented in the second half of the year 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 recognized in the statement of financial position at the end of period

	2019	2018
Defined benefit obligation	2,013,959	2,478,405
Fair value of plan assets	1,476,753	1,686,189
Deficit	537,205	792,217
<b>Net defined benefit liability</b>	<b>537,205</b>	<b>792,217</b>

The decrease in net defined benefit liability is partially related to the plan amendment/ past service cost of EUR 114,149, which is recognized in P&L.

### Components of defined benefit cost in profit or loss

	2019	2018
Current service cost (employer)	140,831	154,776
Plan amendment / Past Service Cost	(114,149)	-
Interest expense on defined benefit obligation	22,207	16,201
Interest income on plan assets	(16,011)	(11,114)
Administration cost excl. cost for managing plan assets	5,915	1,435
<b>Defined benefit cost recognized in profit or loss</b>	<b>38,794</b>	<b>161,298</b>
thereof service cost and administration cost	32,598	156,211
thereof net interest on the net defined benefit liability (asset)	6,196	5,087

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

### Defined benefit obligation (DBO)<sup>(1)</sup>

For each leaver, the savings capital was transferred to their new pension fund. This led to an actuarial gain of EUR 199,457 resulting from the experience adjustments because the transferred savings capital was lower than the DBO considered. This is partially offset by the change in financial assumptions (decrease in discount rate), which led to an actuarial loss of EUR 164,185. These two components led to a total actuarial gain of EUR 35,272.

The plan assets are carried forward until 31 December 2019 taking into consideration employee's 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 2019 corresponds to an actuarial gain of EUR 180,279.

The total actuarial gains of EUR 215,551 (gains on defined benefit obligations of 35,272 EUR and gains on plan assets of EUR 180,279) have been recognized in OCI.

(1) Interest expense calculation based on the effective interest rate of 12.0% to the liability component

(2) The loans denominated in CHF have been converted at the exchange rate of 1.1399 as per agreement

(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	2019	2018
Actuarial (gain) / loss on defined benefit obligation	(35,272)	(131,998)
Return on plan assets excl. interest income	(180,279)	29,745
<b>Defined benefit cost recognized in OCI</b>	<b>(215,551)</b>	<b>(102,253)</b>

Components of actuarial gain/losses on obligations	2019	2018
Actuarial (gain) / loss arising from changes in financial assumptions	164,185	(61,499)
Actuarial (gain) / loss arising from changes in demogr. assumptions	-	(45,953)
Actuarial (gain) / loss arising from experience adjustments	(199,457)	(24,547)
<b>Actuarial (gain) / loss on defined benefit obligation</b>	<b>(35,272)</b>	<b>(131,998)</b>

Reconciliation in net defined benefit liability	2019	2018
Net defined benefit liability at 1.1.	792,217	818,583
Defined benefit cost recognized in profit or loss	38,794	161,298
Defined benefit gain recognized in OCI	(215,551)	(102,253)
Contributions by the employer	(106,855)	(117,910)
Currency translation adjustments	28,601	32,499
<b>Net defined benefit liability at 31.12.</b>	<b>537,205</b>	<b>792,217</b>

Reconciliation of defined benefit obligation	2019	2018
Defined benefit obligation at 1.1.	2,478,405	2,833,898
Interest expense on defined benefit obligation	22,207	16,201
Current service cost (employer)	140,831	154,776
Contributions by plan participants	106,855	117,910
Plan amendment / Past Service Cost	(114,149)	-
Benefits (paid) / deposited	(672,905)	(614,497)
Administration cost (excl. cost for managing plan assets)	5,915	1,435
Actuarial (gain) / loss on defined benefit obligation	(35,272)	(131,998)
Currency translation adjustments	82,070	100,680
<b>Defined benefit obligation at 31.12.</b>	<b>2,013,959</b>	<b>2,478,405</b>

Reconciliation of fair value of plan assets	2019	2018
Fair value of plan assets at 1.1.	1,686,189	2,015,315
Interest income on plan assets	16,011	11,114
Contributions by the employer	106,855	117,910
Contributions by plan participants	106,855	117,910
Benefits (paid) / deposited	(672,905)	(614,497)
Return on plan assets excl. interest income	180,279	(29,745)
Currency translation adjustments	53,469	68,182
<b>Fair value of plan assets at 31.12.</b>	<b>1,476,753</b>	<b>1,686,189</b>

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	2019	2018
Weighted average duration of DBO in years	22.8	20.4

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

For the reporting year 2020, employer contributions of EUR 106,256 are expected.

#### Significant actuarial assumptions:

Actuarial assumptions	2019	2018
Discount rate (DR) at 1.1.	0.90%	0.60%
Discount rate (DR) at 31.12.	0.30%	0.90%
Interest rate on retirement savings capital (IR) at 31.12.	0.30%	0.90%
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.	1.00%	0.00%
Mortality tables	BVG 2015 GT	BVG2015 GT
Date of last actuarial valuation	31/12/2019	31/12/2018

#### Sensitivities of significant actuarial assumptions

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

Sensitivity	2019	2018
DBO = Defined benefit obligation, SC = Service cost (employer)		
DBO at 31.12. with DR -0.25%	2,136,846	2,609,466
DBO at 31.12. with DR +0.25%	1,901,334	2,359,113
DBO at 31.12. with IR -0.25%	1,981,771	2,422,511
DBO at 31.12. with IR +0.25%	2,055,472	2,536,255
DBO at 31.12. with SI -0.25%	1,983,761	2,448,305
DBO at 31.12. with SI +0.25%	2,045,170	2,508,334
DBO at 31.12. with life expectancy +1 year	2,055,825	2,509,261
DBO at 31.12. with life expectancy -1 year	2,059,674	2,447,379
SC of next year with DR +0.25%	138,796	125,668
SC of next year with IR +0.25%	158,249	143,285

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:

$$\text{Net DBL} = - (\text{DBO} - \text{Assets})$$

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 2019, the Net Defined Benefit Liability equals to 6,396 Euro.

As per 31 December 2019, there are 8 employees in the plan.

<b>Funded status and recognized/unrecognized amounts</b>	<b>2019</b>
Defined benefit obligation at 31.12.	59,947
Fair value assets at 31.12.	53,551
Funded status: plan assets above/(below) DBO	(6,396)
Unrecognized net (gain)loss	
Unrecognized past service costs	
Unrecognized net transition obligation/(asset)	
Unrecognized balance sheet asset (because of limit)	
<b>Net benefit Liability at 31.12.</b>	<b>6,396</b>

The contributions recognized in 2019 for the new defined contribution plan in Belgium amounted to EUR 54.800.

For the reporting year 2020, employer contributions of EUR 43,168 are expected.

In view of materiality, Sequana 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 6,903 (2018: EUR 7,652).

### 8.8. Trade payables, other payables and accrued liabilities

<b>(EUR)</b>	<b>December 31, 2019</b>	<b>December 31, 2018</b>
Trade payables	2,476,373	2,753,182
Other payables	1,269,415	1,095,136
Accrued liabilities:	910,216	2,805,700
<b>Provision warranty</b>	<b>70,268</b>	<b>67,090</b>
<b>Third Parties</b>	<b>839,947</b>	<b>2,738,610</b>

Other payables mainly consist of salary related provisions, VAT, Social Security and Employee Insurances like e.g. Health and Pension plan.

The total amount of Accrued Liabilities-Third parties in the Balance Sheet amounts to 839,947 EUR (in 2018: 2,738,610 of which 2,243,951 EUR for the IPO related expenses). For 2019 this is related to normal course of business.

## 9. Share-based compensation

### 9.1. 2011 Share Options

The Company has introduced a stock option plan in 2011 to promote the interests of the Company by providing eligible persons with the opportunity to acquire a share of the Company as an incentive to remain in the service of the Company.

Due to the share consolidation exercise in October 2018 in preparation of the IPO, the number of 2011 share options has not been changed but the number of shares that can be granted at the moment of exercising all 2011 share options has been changed. As a result, the 2011 share options are in that way diluted so that each holder of 2011 share options is only entitled to subscribe one common share when he/she all of his/her 2011 share options exercises. Since the 2011 share options' exercise price has not been changed as a consequence of the share consolidation, this means that each holder of 2011 share options will need to pay a substantial high amount for the creation of one common share. Therefore, the 2011 share options have no longer economical value and they should no longer be exercised.

As per 31 December 2019, the 2011 share options are all forfeited.

### 9.2. Executive Share Options

Early October, 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	2019
Number of warrants granted	111,177
Number of warrants forfeited	(6,799)
Number of warrants not vested at 31 dec 2019	36,748
Exercise price (in Euro) <sup>(1)</sup>	
CEO <sup>(1a)</sup>	0.92
Other	9.19
Expected dividend yield	0%
Expected stock price volatility <sup>(2)</sup>	49%
Risk-free interest rate <sup>(3)</sup>	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.

(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

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 2019 profit & loss of the Group is an expense of 281,153 EUR. The same amount goes through reserves in equity so that the net effect on the Group's equity is zero.

### 9.3. 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	2019
Number of warrants granted	290,601
Number of warrants forfeited	(11,856)
Number of warrants not vested at 31 Dec 2019	278,745
Exercise price (in Euro) <sup>(1)</sup>	
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 <sup>(2)</sup>	49%
Risk-free interest rate <sup>(3)</sup>	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

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 effect of the share-based payment transactions on the 2019 profit & loss of the Group is an expense of 108,003 EUR. 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

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

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



## 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 2019.

### 11.2. Capital commitments resulting from operating lease contracts

There are no material capital commitments resulting from operating lease contracts.

### 11.3. Asset pledges

As a security for the fulfilment of the financial obligation, the Company has pledged Intellectual Property as well as the related assets to the venture debt provider Bootstrap Europe S.C.Sp. Total outstanding debt due to Bootstrap amounts to 2,720,401 EUR as per 31.12.2019.

## 12. Transactions with related parties

As part of our business, Sequana Medical has entered into several transactions with related parties. Related parties primarily comprise members of Executive Management, members of the Board of Directors and significant shareholders.

### 12.1. Consolidated companies

We refer to note 1 for the list of subsidiaries.

### 12.2. Relations with the shareholders

We refer to sections 8.7 Share Capital and 8.8 Financial Debt for the changes in the relations with the shareholders.

As a consequence of the changes in 2019, there exist currently no longer relations with the shareholders.

### 12.3. Relations with non-executive members of the Board of Directors

During 2019, the non-executive directors received the following compensation, based on the approved fees:

	Amount EUR
Pierre Chauvineau	70,000,00
Wim Ottevaere	50,000,00
Jason Hannon <sup>(1)</sup>	24,219,18

During 2018, 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:

EUR, except number of share options	Short-term Employee benefits	Post-employment benefits	Number of share options
Ian Crosbie	441,794	14,242	257,208
Kirsten Van Bockstaele	218,055	-	26,609
<b>Total</b>	<b>659,849</b>	<b>14,242</b>	<b>283,817</b>

## 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 2019	Investment 2018
Sequana Medical NV	Holding/Sales	EUR 1,306,940	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

	2019	2018
Average number of employees	33.8	23.4

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

EUR	2019	2018
Short term employee benefits	441,794	397,064
Post-employment benefits	14,422	14,231
Number of share options	40,766	216,442

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

## 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. will negotiate the terms of their future relationship. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the U.K. and the E.U. and, in particular, any arrangements for the U.K. to retain access to E.U. markets either during a transitional period or more permanently. Brexit has created additional uncertainties that may ultimately result in new regulatory costs and challenges for medical device companies. The U.K. will be one of Sequana Medical’s focus markets, and the additional uncertainties arising from Brexit could adversely affect the ability of Sequana Medical to conduct and expand its operations in the U.K.

## 15. Events after the reporting period

### 15.1. Private placement

The Company announced on 22 January 2020 that it 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 Company currently envisages using the net proceeds to continue to advance its North American pivotal study (POSEIDON) of the **alfapump** for the treatment of recurrent and refractory ascites due to liver cirrhosis (interim results are expected in H2 2020, and the primary endpoint results are expected in mid-2021<sup>(1)</sup>) and its first-in-human repeated dose study of **alfapump** DSR (Direct Sodium Removal) for the treatment of diuretic-resistant heart failure patients (RED DESERT) (results are expected in Q2 and Q3 2020<sup>(1)</sup>), as well as for working capital and other general corporate purposes. The net proceeds from the Offering are expected to extend the current cash runway of the Company from Q2 2020 into H1 2021.

In relation to the number of new shares that is greater than 20% of the currently outstanding shares of the Company already admitted to trading on Euronext Brussels, the Company and Underwriters will have the ability to allocate to certain investors new shares that shall not be immediately admitted to listing upon their issuance. The Company will use reasonable best efforts to obtain the listing of those unlisted new shares within ninety (90) days following their issuance.

The new shares to be issued will have the same rights and benefits as, and rank *pari passu* in all respects with, the existing and outstanding shares of Sequana Medical at the moment of their issuance and will be

entitled to distributions in respect of which the relevant record date or due date falls on or after the date of issue of the new shares.

As a result of the issuance of new shares, the Company’s share capital will increase from EUR 1,306,939.52 to EUR 1,635,006.12 and its issued and outstanding shares will increase from 12,611,900 to 15,778,566 shares, representing an increase of the share capital and number of shares of 25.11%.

### 15.2. COVID-19

Sequana Medical is closely following the evolution of the COVID-19 global health crisis and is in constant dialogue with its partners to assess the impact and adapt its operations as necessary. Although it is difficult to draw conclusions at this point on the systemic risk this disease could pose, the Company has put in place mitigation plans to minimise delays. Nevertheless, the impact of increased demands on the healthcare systems, restrictions on non-essential hospital visits and procedures, social-distancing and travel restrictions are expected to result in delays to execution of clinical studies and impact sales. Sequana Medical will update its guidance on the expected impact and any material change in the Company’s operations and outlook when the situation is clarified.

(1) This timing is likely to be delayed given the current global health crisis, caused by COVID-19.



## 16. Audit fees

In EUR	2019
Fees of the independent auditor with the respect to the statutory audit mandate for the Company and the group (Belgium)	62,500
Additional Services rendered by the auditor's mandate:	
Audit related fees	
Tax advisory & compliance services	
Due diligence fees	
Other Services	8,500
<b>Subtotal</b>	<b>71,000</b>
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	
<b>Subtotal</b>	<b>-</b>
<b>Total</b>	<b>71,000</b>

# 9.

## Condensed statutory financial statements of Sequana Medical NV

### 1. Statutory Income Statement

(In EUR)	2019	2018
Operating income	970,636	1,029,171
Operating charges	(16,669,331)	(14,487,939)
<b>Operating loss</b>	<b>(15,698,694)</b>	<b>(13,458,768)</b>
Financial result	(830,958)	(881,366)
<b>Loss for the period before taxes</b>	<b>(16,529,652)</b>	<b>(14,340,134)</b>
Income taxes	(131,848)	(3,315)
<b>Loss for the period</b>	<b>(16,661,500)</b>	<b>(14,343,450)</b>

### 2. Statutory Balance Sheet

(In EUR)	2019	2018
<b>Assets</b>	<b>8,955,576</b>	<b>3,544,378</b>
<b>Fixed assets</b>	<b>342,842</b>	<b>270,905</b>
Tangible assets	254,943	183,696
Financial fixed assets	62,899	57,758
Participating interests	25,000	29,450
<b>Current assets</b>	<b>8,612,734</b>	<b>3,273,473</b>
Inventory	1,597,623	1,235,426
Amounts receivable within one year	2,818,900	697,136
Deferred charges and accrued income	712,853	116,372
Cash and cash equivalents	3,483,358	1,224,539
<b>Equity and liabilities</b>	<b>8,955,576</b>	<b>3,544,378</b>
Capital	1,306,940	887,977
Share premium	100,660,934	64,963,284
Reserves	817,559	449,182
Accumulated losses	(101,550,195)	(84,888,695)
<b>Provisions</b>	<b>543,601</b>	<b>792,225</b>
Amounts payable after more than one year	2,260,905	2,582,087
Financial debt	2,260,905	2,582,087
Financial debt	459,495	12,257,049
Trade debts	2,442,175	2,726,702
Taxes, remuneration and social security	1,157,852	989,716
Other amounts payable	-	-
Accruals and deferred income	856,310	2,784,850

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.

# 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)
- 5 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.
- 6 Management estimate using historical liver cirrhosis mortality rates based on Mokdad AA, Lopez AD, Shahrzaz 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.
- 7 U.S. Centers for Disease Control and Prevention (<https://www.cdc.gov/nchs/fastats/liver-disease.htm>).
- 8 Estes C, Razavi H, Loomba R, Younossi Z, Sanyal AJ. Modeling the epidemic of nonalcoholic fatty liver disease demonstrates an exponential increase in burden of disease. *Hepatology* (Baltimore, Md). 2018;67(1):123-133. doi:10.1002/hep.29466.; Chalasani N, Younossi Z, Lavine JE, Diehl AM, Brunt EM, Cusi K, et al.; American Gastroenterological Association; American Association for the Study of Liver Diseases; American College of Gastroenterology. The diagnosis and management of non-alcoholic fatty liver disease: practice guideline by the American Gastroenterological Association, American Association for the Study of Liver Diseases, and American College of Gastroenterology. *Gastroenterology* 2012;142:1592-1609; Rinella ME. Nonalcoholic fatty liver disease: a systematic review. *JAMA* 2015;313:2263-2273.; Angulo P. Nonalcoholic fatty liver disease. *N Engl J Med* 2002;346:1221-1231.; Kim YS, Jung ES, Hur W, Bae SH, Choi JY, Song MJ, et al. Noninvasive predictors of nonalcoholic steatohepatitis in Korean patients with histologically proven nonalcoholic fatty liver disease. *Clin Mol Hepatol* 2013;19:120-130.
- 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, Shahrzaz 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)
- 15 European Association for the Study of the Liver. EASL clinical practice guidelines on the management of ascites, spontaneous bacterial peritonitis, and hepatorenal syndrome in cirrhosis. *Journal of Hepatology*. 2010 vol. 53. 397-417. p. 402.
- 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.
- 20 Benjamin et al. (2013).
- 21 Savarese et al. (2017).
- 22 Ziaieian B, Fonarow GC. *Nat Rev Cardiol*. 2016 Jun;13(6):368-78. doi: 10.1038/nrcardio.2016.25.
- 23 Testani JM, Hanberg JS, Cheng S, et al. Rapid and Highly Accurate Prediction of Poor Loop Diuretic Natriuretic Response in Patients With Heart Failure. *Circulation Heart failure*. 2016;9(1):e002370. doi:10.1161/CIRCHEARTFAILURE.115.002370.
- 24 Costanzo et al., *J Am Cardiol*, 2017
- 25 Costanzo et al. (2007).
- 26 Kilgore et al. (2017); Ambrosy et al. (2014).
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- 28 Ross et al. (2010).
- 29 U.S. Centers for Disease Control and Prevention ([www.cdc.gov](http://www.cdc.gov))

## 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 **alfapump** has not yet received regulatory approval in the U.S. and Canada. Any statement in this annual report about safety and efficacy of the **alfapump** does not apply to the U.S. and Canada because the device is currently undergoing clinical investigation in these territories.

DSR therapy and **alfapump** DSR are still in development and it should be noted that any statements in this annual report regarding safety and efficacy arise from pre-clinical studies and ongoing clinical investigations which have yet to be completed. There is no link between DSR therapy, **alfapump** DSR and ongoing investigations with the **alfapump** system in Europe, the U.S. and Canada.

# Glossary

Abbreviation	Significance
CE	Conformité Européenne
CMS	Centers for Medicare and Medicaid Services
DGVS	German Society of Gastroenterology Digestive and Metabolic Diseases
DRG	Diagnosis-related group
DSR	Direct Sodium Removal
EASL	European Association for the Study of the Liver
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
KOL's	Key Opinion Leaders
LVP	Large Volume Paracentesis
NAFLD	Non-Alcoholic Fatty Liver Disease
NASH	Non-Alcoholic SteatoHepatitis
NICE	National Institute for Health and Care Excellence
NTAP	New Technology Add-on Payment (add-on payment in US reimbursement system for new treatment methods)
NUB	Neue Untersuchungs- und Behandlungsmethode (add-on payment in German reimbursement system for new treatment methods)
NYHAFC	New York Heart Association Functional Classification
PD	Peritoneal dialysis
PMSR	Post Marketing Surveillance Registry
RCT	Randomised Controlled Trial
SF 36	Short Form 36
TCT	Transcatheter Cardiovascular Therapeutics
TIPS	Transjugular Intrahepatic Portosystemic Shunt



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