

# sequanamedical annual report 2018

# sequanamedical annual report 2018

# **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.

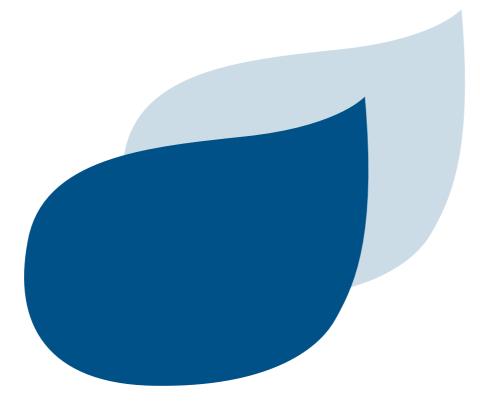
# **Regulatory disclaimers**

Any statement in this 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 is still in development and it should be noted that any statements regarding safety and efficacy arise from ongoing pre-clinical and clinical investigations which have yet to be completed.

 $There is no link between DSR the rapy and ongoing investigations with the {\it alfapump system in Europe}, the {\it U.S.} and {\it Canada}.$ 

# GONTENT



Sequana Medical at a glance	
Message from the Chairman	
and the CEO	8
Our Business	12
Corporate governance	48
Financial report	94

We are a commercial stage medical device company focused on the development of innovative treatment solutions for the management of liver disease, heart failure, malignant ascites and other fluid imbalance disorders.

Our focus markets of liver disease and heart failure are large and growing due to unhealthy lifestyles and ageing populations.

Our technology is based on the alfapump®, a proven step change for automatic and continuous removal of fluid build-up in the abdomen which is applicable across multiple life-threatening disorders. The alfapump is a fully-implanted, programmable, wirelessly charged, CE-marked system that automatically pumps fluid from the abdomen into the bladder, where the body eliminates the fluid naturally through urination.

The alfapump is being commercialised in Europe 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 700 systems have been implanted. Since April 2018, the alfapump has been included in the EASL (European Association for the Study of the Liver) clinical practice guidelines for the management of patients with decompensated cirrhosis, which we believe is a key step in the widespread commercial acceptance of the alfapump.

We intend to expand our commercial footprint into the North American market, where we expect to start a pivotal clinical study with the alfapump for the treatment of recurrent or refractory liver ascites in the second half of 2019. In January 2019, the U.S. Food and Drug Administration (FDA) granted the alfapump Breakthrough Device Designation for the treatment of recurrent or refractory liver ascites.

In addition, we have built on the proven alfapump platform to deliver alfapump DSR (Direct Sodium Removal), a novel and proprietary approach to the treatment of volume overload in heart failure. Animal studies have demonstrated that DSR therapy is safe and effective and a first-in-human study is currently ongoing at Yale University, U.S.

We are headquartered in Ghent, Belgium and raised €27.5 million in a successful IPO on Euronext Brussels in February 2019, supported by renowned life science investors. 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).

## alfapump is endorsed by key authorities in U.S. and Europe

Included in EASL clinical practice guidelines for decompensated cirrhosis

Recommended by UK NICE for treatment of refractory ascites caused by cirrhosis under special arrangements

Granted US FDA Breakthrough Device Designation for treatment of recurrent or refractory liver ascites



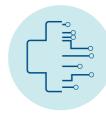
Founded in 2006



Headquarters in Ghent, Belgium



Manufacturing in Zurich, Switzerland



Groundbreaking, proprietary technology platform based on the alfapump addressing high unmet needs in large, growing patient populations



Over 700 **alfa**pumps implanted to date



34 Employees



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



Raised approximately €117 million, including €27.5 million in a successful IPO on Euronext Brussels



Supported by renowned specialist life science investors

# MESSAGE FROM THE CHAIRMAN AND THE CEO

Dear Shareholders, Colleagues and Business Partners,

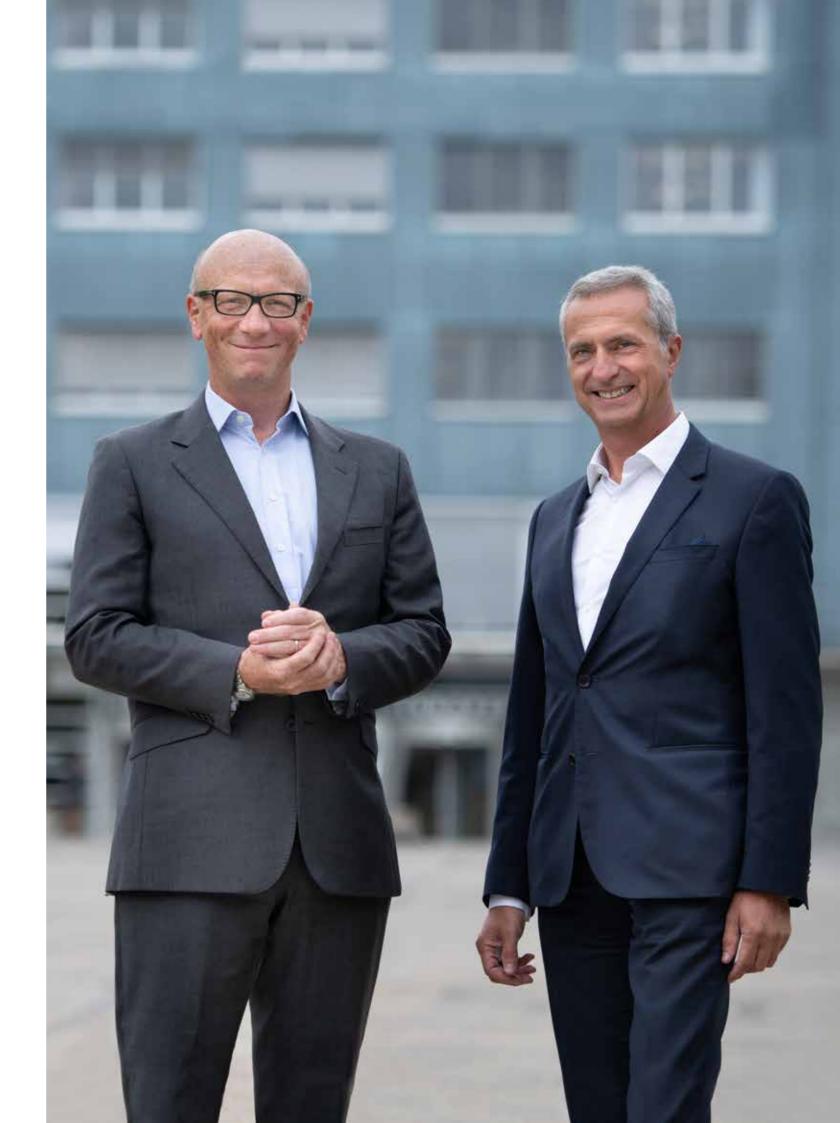
It is a pleasure to welcome you to Sequana Medical. We recently completed our first months as a publicly traded company and are pleased to report on our progress over the past year and what we expect in the year ahead.

2018 was a busy and productive year for Sequana Medical. In October, we successfully established our new corporate headquarters in Ghent, Belgium. This has enabled us to benefit from Belgium's attractive healthcare ecosystem and support for life sciences companies, culminating in our successful IPO on Euronext Brussels in February 2019 which raised €27.5 million. We further strengthened our leadership team with the appointment of Kirsten Van Bockstaele as Chief Financial Officer and more recently expanded the Board of Directors with the appointments of Wim Ottevaere as an independent Non-Executive Director and Pierre Chauvineau as independent We are focused on developing innovative treatment solutions for the management of liver disease, heart failure, malignant ascites and other fluid imbalance disorders. With our alfapump® platform, we have the potential to tap into multiple markets where fluid accumulation in the body can be debilitating for patients unless effectively treated. Liver disease and heart failure are our two focus areas, both of which are large and growing markets due to the rise in unhealthy lifestyles and ageing populations. Current available therapies often only provide short-term symptomatic relief, require numerous hospital visits and place a significant burden both on the patient's quality of life and the healthcare system.

We have worked hard in recent years to demonstrate the benefits of the alfapump to patients, clinicians and healthcare systems. We do this through close collaboration with our clinical partners as well as continued investment into clinical studies. As a result of this ongoing investment, an increasing number of influential organisations in the U.S. and

Europe are recognising the benefits of the alfapump. In April 2018, the alfapump was included in the European Association for the Study of the Liver (EASL) clinical practice guidelines for the management of patients with decompensated cirrhosis. Then in November, the U.K. National Institute for Health and Care Excellence (NICE) recommended the use of the alfapump for the treatment of refractory ascites caused by cirrhosis under special arrangements. Finally, in January 2019, the U.S. Food and Drug Administration (FDA) granted the alfapump Breakthrough Device Designation for the treatment of recurrent or refractory liver ascites, which is a further recognition of the potential of the alfapump.

We have continued to raise awareness of the alfapump across the medical community throughout 2018. Two studies were published in peer-reviewed journals on the use of the alfapump in patients with refractory liver ascites: the first highlighted the improvement in quality of life (QoL) compared to standard of care in the European



Message from the Chairman and the CEO sequana medical

Randomised Controlled Trial and the second, the improvement in clinical outcomes in routine clinical use from use of our new peritoneal catheter. Professor Wong of University of Toronto presented the results from the North American MOSAIC alfapump feasibility study at the American Association for the Study of Liver Disease meeting in November 2018. These demonstrated a significant reduction in large volume paracentesis (LVP) as well as improved nutritional status and OoL during at least one year follow-up. Finally, Professor Dr. Fotopoulou of Imperial College, London presented the results of the retrospective Malignant Ascites Study at two international conferences, demonstrating that the alfapump was effective in treating palliative patients with malignant ascites and improving their QoL.

"We are delighted with the progress we have made in 2018, and believe we are closer to fulfilling our commitment to improving patient lives."

Demonstrating performance in routine clinical use is a key step in growing the adoption of the alfapump amongst patients, clinicians and payers. To do this, we need to collect high quality and accurate information from our patients in the form of an outcomes registry. We successfully enrolled the first patient in our TOPMOST European registry study in cirrhosis patients implanted with the alfapump for the management of refractory liver ascites. The data we will collect from our patients over the coming years will form the basis of important future publications.

As we look to expand reimbursement for the alfapump in Europe beyond Switzerland and Germany, economic studies are often required to demonstrate the cost-effectiveness of the alfapump compared to the current standard of care. To support reimbursement in France, the ARIA pump study was initiated in 2018 and is being run by key French clinicians and funded by the French government.

Beyond Europe, North America remains a very important target market for us, mainly due to the relatively high incidence of Non-Alcoholic Steatohepatitis (NASH)-related ascites. Following the successful completion of MOSAIC, we expect to start POSEIDON, our North American pivotal clinical study, in the second half of 2019 to support approval and reimbursement in the U.S. and Canada. We have already had several meetings with the FDA and anticipate

filing the clinical trial application with the FDA and Health Canada later this quarter. Having received Breakthrough Device Status for the alfapump from the FDA earlier this year, we are benefiting from frequent interactions with the FDA's experts and will also be eligible for prioritized review of the submission package in order to support regulatory approval in the U.S.

Our heart failure programme made important progress in 2018. Fluid overload is a key clinical problem in heart failure, a condition that results in \$13 billion of U.S. hospital admission costs annually. We are building on our extensive alfapump clinical and technical experience as we are developing the alfapump DSR (Direct Sodium Removal), a novel and breakthrough approach to treat the problem of fluid overload in diuretic-resistant heart failure patients. In 2018, we achieved pre-clinical proof-of-concept for our DSR therapy and a first-in-human single dose DSR study has started at Yale University in the U.S.

Overall, we are delighted with the progress we have made in 2018, and believe we are closer to fulfilling our commitment to improving patient lives with our alfapump platform and bringing innovative treatment solutions to those who need them most.

Looking ahead, we are excited to further build on the achievements of 2018 and expect to report important progress throughout the year. This includes data from the firstin-human DSR heart failure study as well as the launch of a prospective clinical study in patients with malignant ascites and POSEIDON, the North American pivotal study in recurrent or refractory liver ascites.

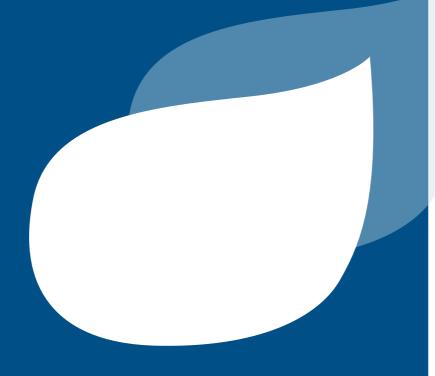
We are fortunate to be reminded repeatedly of how the alfapump can transform patients' lives through the feedback we receive from clinicians, patients and the patients' families. These messages motivate us all to strive for the broadest alfapump availability and the opportunity to change many more lives. Please take a moment to view the alfapump patient stories on our website. These stories give a very personal view of what it means to patients of having an alfapump implanted.

We want to thank all of our employees for their hard work and commitment to Sequana Medical.

Our thanks also go to our scientific and clinical partners and advisors for their continued support, and to all our shareholders for their confidence in Sequana Medical's ambition.

> Pierre Chauvineau, Chairman Ian Crosbie, CEO





# **OUR BUSINESS**

1.	Achievements in 2018	16
2.	Achievements in 2019 - year-to-date	17
3.	Outlook for the remainder of 2019	17
4.	alfapump - proven step change in the management of ascites in liver disease and cancer	19
5.	alfapump DSR - potential breakthrough treatment of volume overload in heart failure	39

Recommendation by the U.K.
National Institute for Health and
Care Excellence (NICE) for use
of the alfapump for treatment
of refractory ascites caused
by cirrhosis under special
arrangements.

Inclusion of the alfapump in the European Association for the Study of the Liver (EASL) clinical practice guidelines for decompensated cirrhosis.

Two peer-reviewed **alfa**pump publications highlighting the improvement in patient quality of life (QoL) compared to standard of care in the European Randomised Controlled Trial (RCT) and the improvement in clinical outcomes in routine clinical practice from the use of the new peritoneal catheter.

Presentation of the North American MOSAIC **alfa**pump feasibility study demonstrating a significant reduction in large volume paracentesis (LVP) as well as improved nutritional status and QoL of the patient during at least one year follow-up.

Enrolled first patient in TOPMOST European registry study in cirrhosis patients implanted with the alfapump for the management of refractory liver ascites. Presentation of the retrospective Malignant Ascites study demonstrating that the **alfa**pump was effective in treating palliative patients and improving their QoL.

Maintained clear improvement in clinical outcomes with average duration of alfapump therapy exceeding 450 days.

Presentation of the pre-clinical proof-of-concept data for Direct Sodium Removal (DSR) therapy in the management of volume overload due to heart failure demonstrating the removal of clinically relevant amounts of sodium and

First-in-human single dose DSR study commenced at Yale University, U.S.

Established new corporate headquarters in Ghent, Belgium.

Raised €8.5 million in private financing rounds from leading Belgian investors including Newton Biocapital, PMV and SFPI-FPIM, as well as existing shareholders.

Appointed Kirsten Van Bockstaele as Chief Financial Officer and Lies Vanneste as Director. Investor Relations.

# ACHIEVEMENTS IN 2019 YEAR-TO-DATE



# OUTLOOK FOR THE REMAINDER OF 2019

The North American POSEIDON pivotal study in recurrent or refractory liver ascites to support approval of the **alfa**pump in the U.S. and Canada is planned to begin in the second half of 2019. Filing of the clinical trial application with the FDA and Health Canada is planned for later this month.

We expect to start two prospective **alfa**pump clinical studies in the second quarter of 2019, i) a study in malignant ascites patients and ii) a study in refractory liver ascites patients to evaluate the impact of albumin replacement therapy. Furthermore, in the second half of 2019, we expect to receive reimbursement of the **alfa**pump in the Netherlands.

Interim results from the single dose first-in-human DSR therapy study are expected to be reported during the second quarter of 2019. The outcome of this study is an important milestone in the heart failure program and will provide data on safety and tolerability of DSR therapy in human subjects, as well as efficient sodium removal and inter-patient variability. Final results from this study are expected in the second half of 2019. The repeated dose first-in-human study of alfapump DSR in patients with volume overload due to heart failure is planned to begin in the second half of this year, with initial results expected by the year-end.

We expect the results of our investments in the European commercial team to result in growth of revenues versus 2018.



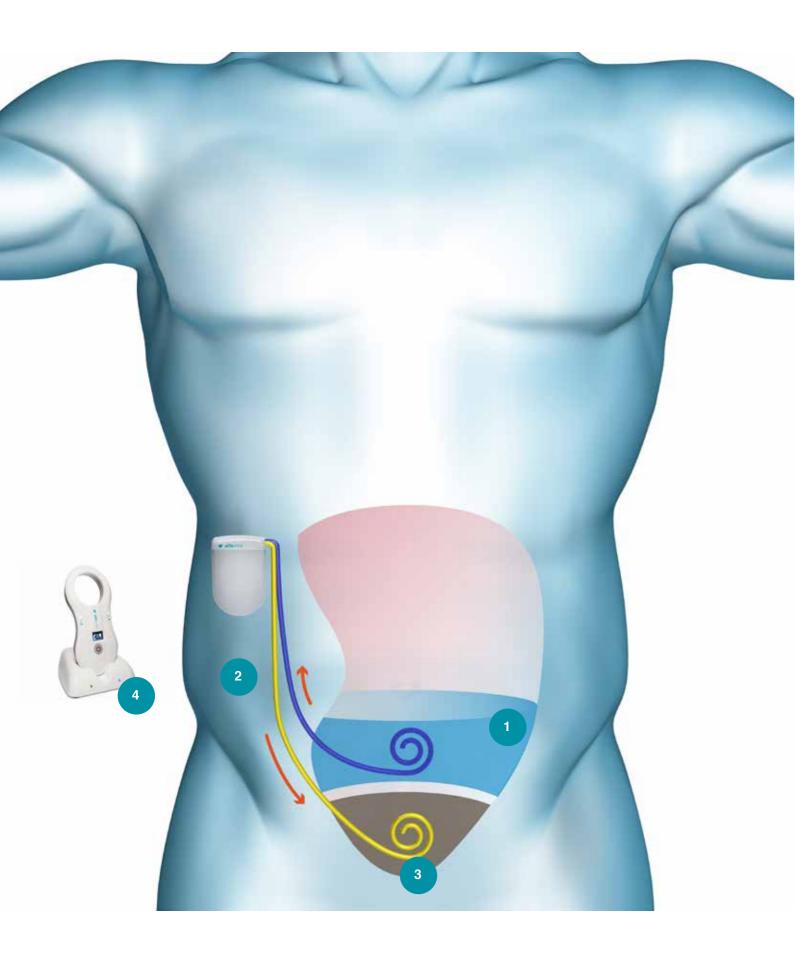
Proven step change in the management of ascites in liver disease and cancer

The alfapump provides an innovative treatment solution for the long-term management of refractory liver ascites and malignant ascites with proven safety, efficacy and quality of life benefits demonstrated in multiple clinical studies. The alfapump is currently being commercialised in Europe where it received a CE-Mark for the treatment of refractory liver ascites, and for the treatment of malignant ascites. Since April 2018, the alfapump has been included in the EASL clinical practice guidelines for the management of patients with decompensated cirrhosis. In November 2018, the UK National Institute for Health and Care Excellence (NICE) recommended use of the alfapump for the treatment of refractory ascites caused by liver cirrhosis under special arrangements. These achievements are key to obtaining widespread commercial acceptance of the alfapump. To date, over 700 alfapump systems have been implanted.

In January 2019, the U.S. Food and Drug Administration (FDA) granted the alfapump Breakthrough Device Designation for the treatment of recurrent or refractory liver ascites. A North American pivotal study (POSEIDON) is planned to start in the second half of 2019 to support approval and reimbursement in the U.S. and Canada for the treatment of recurrent or refractory liver ascites.



**sequana**medical



# THE ALFAPUMP **SYSTEM**

The alfapump system was developed to provide an automated system for the removal of ascites without the need for repeated invasive procedures. Put simply, no needles, no external tubes, no repeated needle punctures.

The alfapump is a subcutaneously implanted battery-powered pump that ensures the controlled and continuous removal of ascites from the abdominal cavity into the bladder.

The alfapump prevents fluid build-up and its possible complications, thereby improving a patient's quality of life and nutrition, and reducing the number of hospital visits and potentially lower healthcare costs.

# **Fully implantable** pump system

The alfapump is implanted under the patient's skin using minimally invasive surgery. This simple procedure usually takes between 45 and 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.

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

# Unique capabilities to manage ascites

- Fully implantable
- · Easy, long-term implantation & catheter patency
- Automatic operation, removing up to 4 litres of fluid per day
- · Pump volume easily adjusted
- · Monitors bladder and peritoneal pressure via pressure sensors
- · Battery charged through the
- No significant heating during charging and operation
- Virtually non-clogging
- · Remote data monitoring
- · Strong IP barriers through extensive patent portfolio & know-how

- **Automatic and continuous** removal of ascites from the abdomen
- **Ascites leaves the body** through normal urination
- Ascites is pumped into bladder
- Wireless charging and communication for monitoring

# Wirelessly charged through the skin

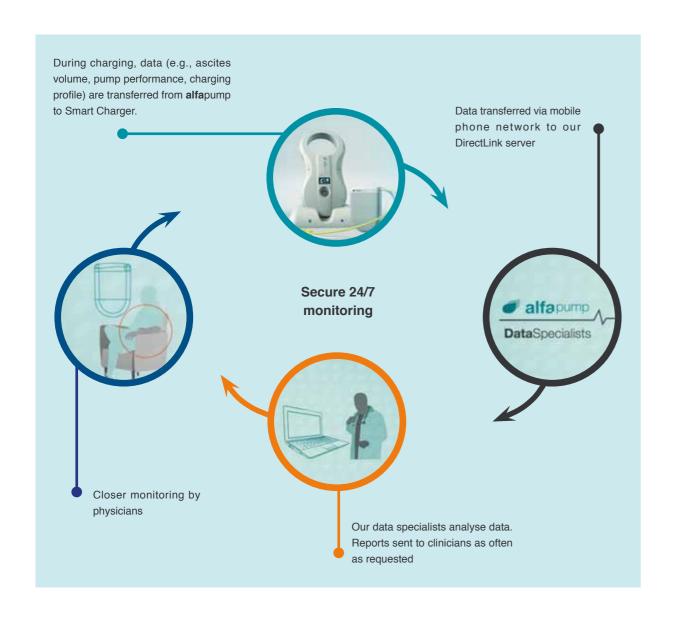
The only patient interaction is the need to recharge the battery each day with a wireless charger (the Smart Charger) through the skin for approximately 20 minutes (depending on the amount of fluid pumped each day).

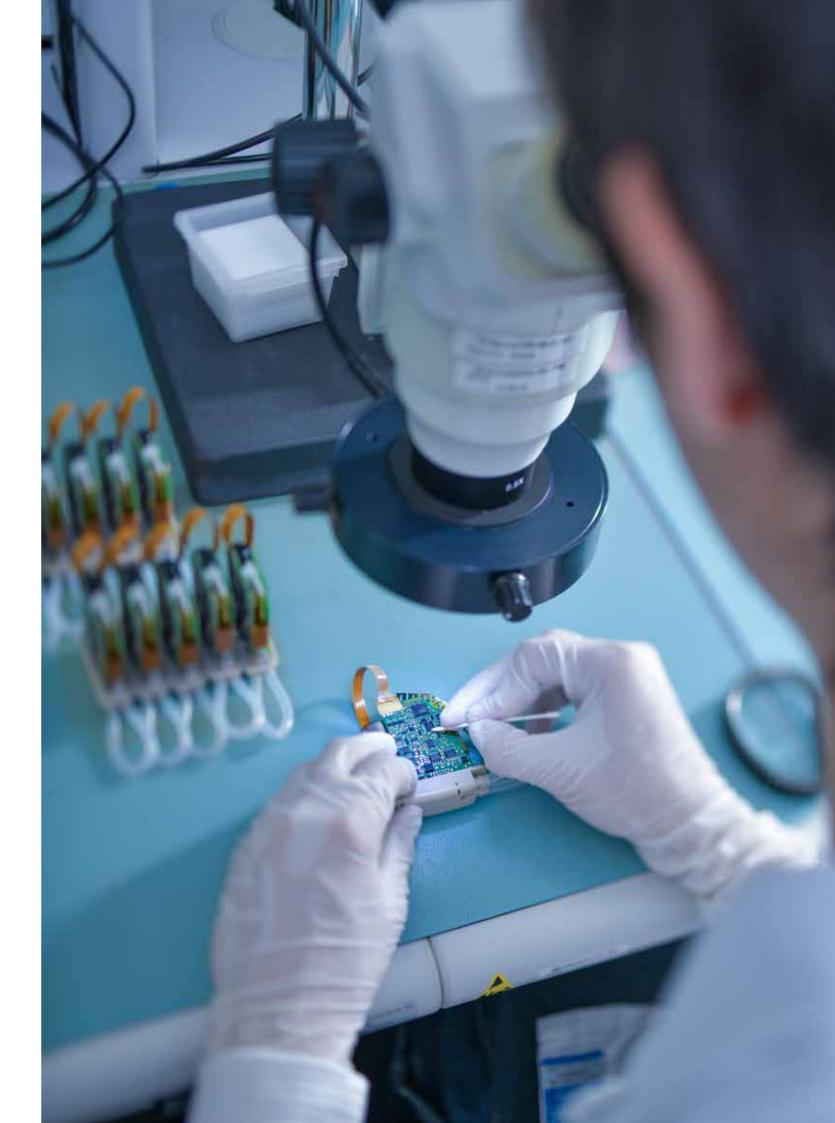
While charging, data from the alfapump are transferred to this charger, which are downloaded and evaluated by the physician.

# DirectLink Technology

With the DirectLink Technology built into the alfapump system, patients and physicians are offered an unprecedented level of comfort and convenience.

Via this DirectLink Technology, the alfapump performance data are continuously collected via the mobile phone network and transferred to secure servers for analysis – coverage that is 24 hours a day, 7 days a week.





# **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.

## **alfa**pump

The **alfa**pump is a high performance, automatic and programmable pump implanted under the skin that can pump up to 4 litres of ascites per full battery charge. The **alfa**pump monitors pressure in the bladder and abdominal cavity via pressure sensors to ensure optimal fluid management and contains anti-clogging control algorithms to prevent 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 ascites from the abdominal cavity and deliver it to the bladder. These catheters are implanted inside the body and are not visible from the outside. (1)

(I) The catheter presented in the image is the one used in



# **Smart Charger**

The Smart Charger is a hand-held charging device that charges the **alfa**pump 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.



# MARKET OPPORTUNITY

# in liver disease and cancer

# Liver disease (cirrhotic 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>1</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>2</sup> and approximately a quarter to one-third of NAFLD cases are classified as NASH3. NASH is a silent disease due to the difficulty in diagnosing it, making early stage intervention clinically challenging. It is estimated that about 10% of the NASH population will progress to liver cirrhosis in the near-to medium-term4.

A key complication of liver cirrhosis is ascites. Around 50% of cirrhotic patients develop ascites within 10 years of the diagnosis of cirrhosis<sup>5</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 ascites6, which is ascites that is unresponsive to a sodium-restricted diet and high-dose diuretic treatment or which recurs rapidly after drainage.

It is estimated that there are approximately 18,000 patients with refractory liver ascites in the U.S. and 17,000 in EU5 (across the U.K., France, Germany, Italy and Spain)7. By 2030, this number is expected to grow to approximately 151,000 in the

restriction are no longer effective, the common treatment of ascites is drainage ("paracentesis").



Paracentesis is a bedside or clinic procedure

U.S. and 89,000 in EU58.

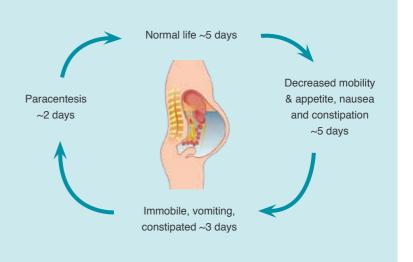
When drug therapy and dietary



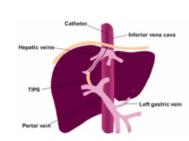
peritoneal cavity to remove the ascitic fluid.

# **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.



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 30% to 50% of patients)9, 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  $^{\mbox{\tiny 10}}$  , and many patients with ascites due to NASH are forecast to exceed this age bracket.

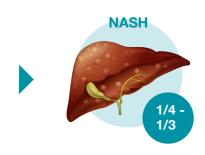
# **Ascites**

Ascites is the accumulation of fluid within the abdomen.

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.

# **HEALTHY LIVER**









# **REFRACTORY ASCITES**



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.

The only curative treatment for liver disease is a 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.

# Cancer (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".

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>12</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>12,13</sup>.

As with ascites due to liver disease, 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 their quality of life.

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

A further
benefit of the alfapump
in malignant ascites is that
the physician is able to conduct
regular liquid biopsies through
the analysis of urine samples.
These will contain significant
material direct from the peritoneal
cavity, including cancer cells.

# Living with refractory ascites, before and after 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 constant worrying when not around.

Patients with refractory liver ascites who had been implanted with the **alfa**pump 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 **alfa**pump, 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.



"My life style has changed 100%. We are participating in things like darts, carts and dancing, enjoying life again."

70-yr old patient from Toronto



"I've got my freedom back. We are now with friends entertaining again. It's amazing, he's actually dancing with me again."

Wife of patient from Toronto

**sequana**medical

Our business

# **COMPLETED CLINICAL STUDIES**

## Liver disease

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.

The key findings from these studies with the alfapump for the management of liver disease 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

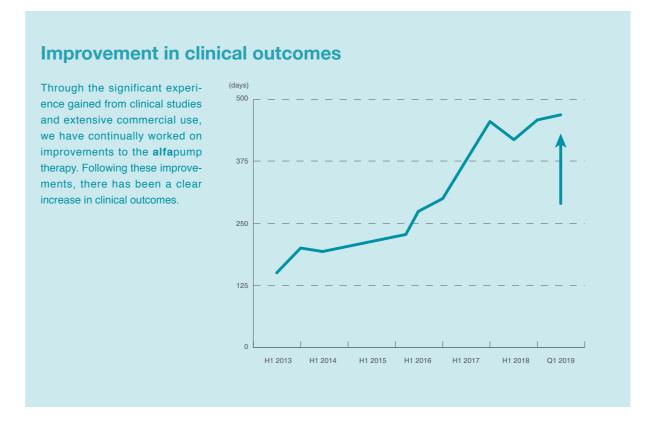


refractory liver ascites patients treated with the alfapump demonstrated a clear nutritional benefit versus patients treated with LVP standard of care over 30-day and 90-day periods.

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

(1) Data on initial 56 patients has been published. Data on all 100 patients is intended to be submitted for publication in the second quarter of 2019.

By the end of 2018, seven publications on clinical study results had been issued in peer-reviewed journals, which we believe are essential to support the acceptance of the alfapump.



# **Malignant ascites**

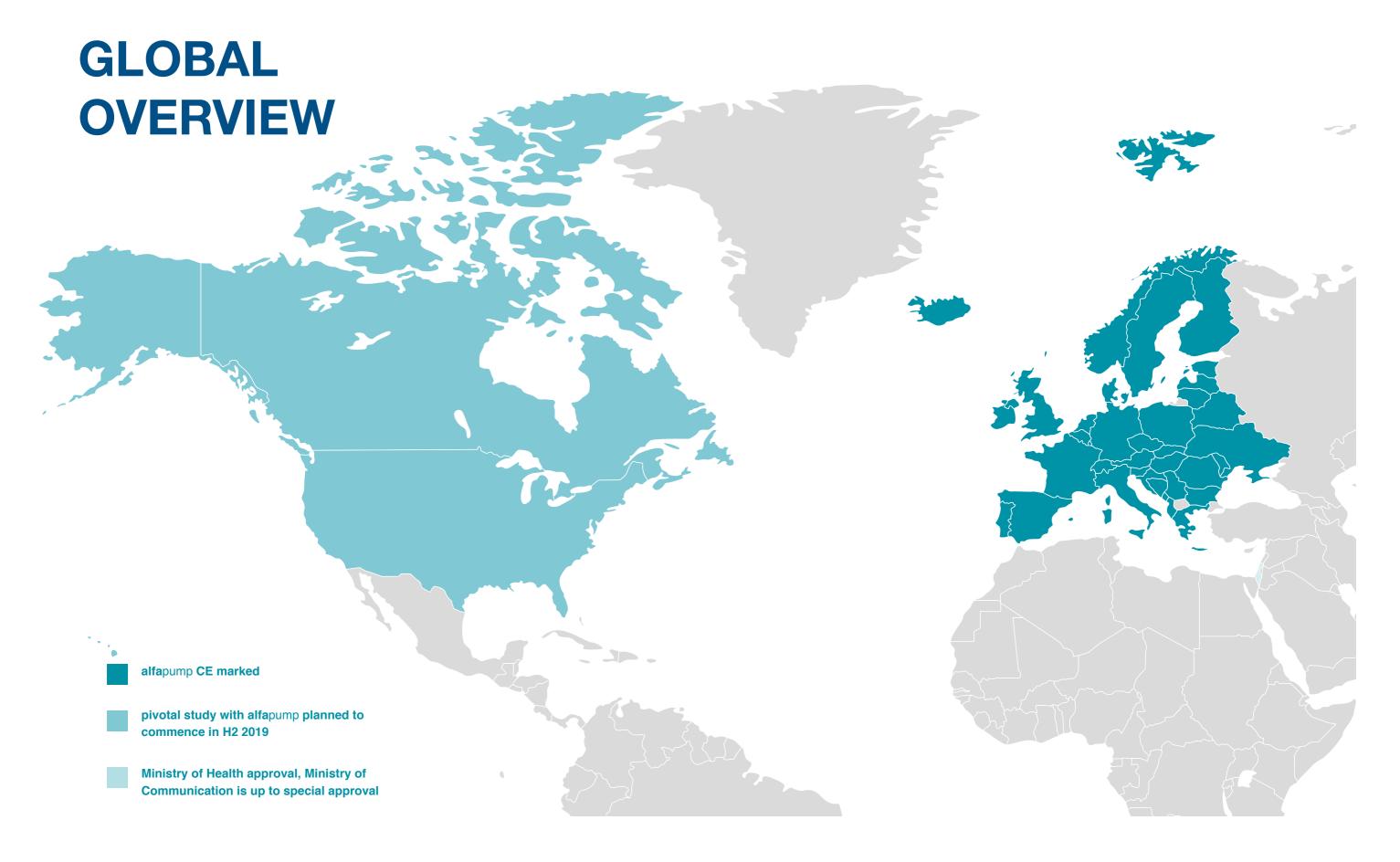
In addition to the clinical studies in patients with liver disease, we have also completed a clinical study in patients with malignant ascites. This retrospective study demonstrated that the alfapump was effective in palliative patients with malignant ascites and has the potential to improve quality of life and clinical outcomes for late-stage cancer patients.

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



"The alfapump is an exciting new technique. Patients don't have to go to the hospital so often. It allows for the patient to be free, mobile and self-caring."

Prof. Rajiv Jalan, Royal Free Hospital, London



# ONGOING/PLANNED CLINICAL STUDIES

# **Liver disease**

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

Name of Study	Description <sup>(1)</sup>				
Ongoing		2018	2019	2020	2021
ARIA Pump Study	Randomised, open-label health economic study in France in 90 patients with refractory liver ascites to evaluate the cost utility of the alfapump vs. standard of care (60 patients not waiting for liver transplant and 30 patients as bridge to transplant) over 12 months to support French reimbursement. <sup>(2)</sup>			<b>→</b>	
TOPMOST <sup>(3)</sup>	European registry study in cirrhosis patients that have been implanted with the alfapump.				
Planned					
POSEIDON (North American pivotal) Study	North American pivotal study in up to 100 patients with refractory and recurrent liver ascites to demonstrate the efficacy and cost-effectiveness of the <b>alfa</b> pump. <sup>(4)</sup>		•		<b>-</b>
Step Counter Study	Quality of life study in 20 patients to measure the impact of the <b>alfa</b> pump vs. standard of care on patient activity.			<b>→</b>	
Albumin Replacement Study	European study on the impact of albumin replacement therapy on clinical outcomes in 10-15 patients implanted with the alfapump.				<b>→</b>

# **Malignant ascites**

Following positive results in the Retrospective Malignant Study, we expect to begin a prospective, controlled study in selected European countries in the first half of 2019 to confirm the efficacy and clinical impact of the alfapump in patients with malignant ascites in a controlled manner. Based on discussions with potential investigators, the study is expected to enrol up to 40 patients with gynaecologic malignancies (ovarian, breast).

Name of Study	Description <sup>(5)</sup>	Description <sup>(5)</sup>				
Planned		2018	2019	2020	2021	
Malignant Ascites Controlled Trial	Controlled study in Europe to evaluate the efficacy and clinical impact of the alfapump vs. standard of care in up to 40 malignant ascites patients.		_		<b>-</b>	

<sup>(</sup>I) The descriptions and timing of these studies presented in this table reflect our current expectations. These expectations 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.

<sup>(2)</sup> Funded by the French government and conducted by leading French clinicians.

<sup>(3)</sup> The dashed shading of the arrow indicates that the study is expected to extend beyond 2021.

<sup>(4)</sup> Subject to feedback from FDA and Health Canada.

<sup>(5)</sup> The descriptions and timing of this study presented in this table reflects our current expectations. These expectations 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.

36 Our business

sequanamedical 37

# **COMMERCIAL OPERATIONS**

# Approval and reimbursement

The alfapump has a CE-Mark for the removal of refractory ascites in patients with liver cirrhosis or malignant ascites.

The alfapump 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) providing reimbursement of €27,000, covering both the pump and the implantation procedure.

In France, the ARIA pump study, which is funded by the French government, is ongoing to support French reimbursement, potentially in 2022.

To date, over 700 alfapump systems have been implanted, of which 80% were commercial implants and 20% were implants as part of a clinical 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. We expect to receive reimbursement in the Netherlands in the second half of 2019 and in Belgium in the first half of 2020, in partnership with Fresenius, our distributor in those markets.

Reimbursement in Italy and Spain is determined at a regional and local (i.e. hospital) level, and we are currently conducting a market research study in both countries to further understand the key hospitals, key decision makers, current standard of care and existing pricing environment.

## **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 to support the market development and adoption of the alfapump.

# Sales and marketing

We have a commercial team of 12 people focussing on our key markets, including Germany, Switzerland, the U.K. and France. Outside of those markets, we have entered into exclusive distribution agreements with Fresenius Medical Care Deutschland GmbH in Belgium and the Netherlands, Vingmed Holding in Denmark and Gamida Ltd. in Israel.

Upon approval of the alfapump in the U.S. and Canada, we intend to establish direct commercial activities in these markets. We continuously evaluate the opportunity to enter into other markets based on the commercial potential and the likelihood to get reimbursement. In those



"We had followed up patients for more than one year. The experience with these patients is particular positive because their quality of life is definitely improved."

Prof. Andrea De Gottardi, Inselspital, Bern

markets, we will either establish a direct commercial presence or work with distributors.

To raise awareness of the alfapump therapy amongst clinicians, patients and their relatives, we actively 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. We have two websites (www.sequanamedical.com and www.alfapump.com), which provide information to patients, their families and clinicians on the alfapump. Our YouTube videos on the alfapump have received more than 300,000 views.





Annual Report 2018

# alfapump DSR

Potential breakthrough treatment of volume overload in heart failure

> proven alfapump platform, to deliver a convenient and fully implanted system for Direct Sodium Removal (DSR) therapy for the management of volume overload in heart failure. Data from animal studies showed that DSR therapy was safe and effective. A first-inhuman study for DSR therapy is currently ongoing at Yale University,

# 41

# DIRECT SODIUM REMOVAL (DSR)

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

# **Key principle**



Maintaining a constant concentration of sodium in the body is a key physiological parameter that is vital to patient health. A concentration that is too high or too low will result in serious medical conditions.



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



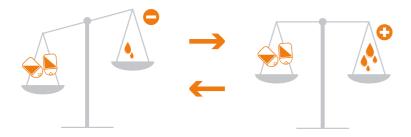
To restore the balance, the body retains water, leading to volume overload and an increased burden on the heart.

# **Key challenge**

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

Traditional diuretic approaches primarily remove hypotonic urine (which contains more water than sodium), and the resulting loss of sodium is low. As a result, the sodium concentration in the body increases and to restore this, the

body either adds more fluid through eating or drinking or reduces fluid loss through urination. In most cases, the body will retain its sodium reserves, as sodium is regarded by the body as a scarce resource.





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

# **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**

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, a sodium-free infusate is administered to the abdomen and allowed to dwell for a pre-defined period. During this time, sodium diffuses from the body down a steep diffusion gradient into the infusate. Circulation keeps the effective blood sodium concentration high. The 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.

We have leveraged our alfapump experience to develop alfapump DSR. The alfapump DSR combines three proven elements, (i) the alfapump system, (ii) a surgically implanted port and (iii) DSR infusates (a sodium-free infusate).

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

We consider that our accumulated experience of over 700 implanted alfapump systems de-risks the technical and clinical development of alfapump DSR.

before the DSR infusate and the extracted sodium is pumped to the bladder.

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 the alfapump DSR. Furthermore, we can develop the alfapump DSR system with the ability to monitor changes in the rate of spontaneous accumulation of fluid in the abdomen and changes in intra-abdominal pressure that would deliver significant diagnostic information to clinicians, potentially providing

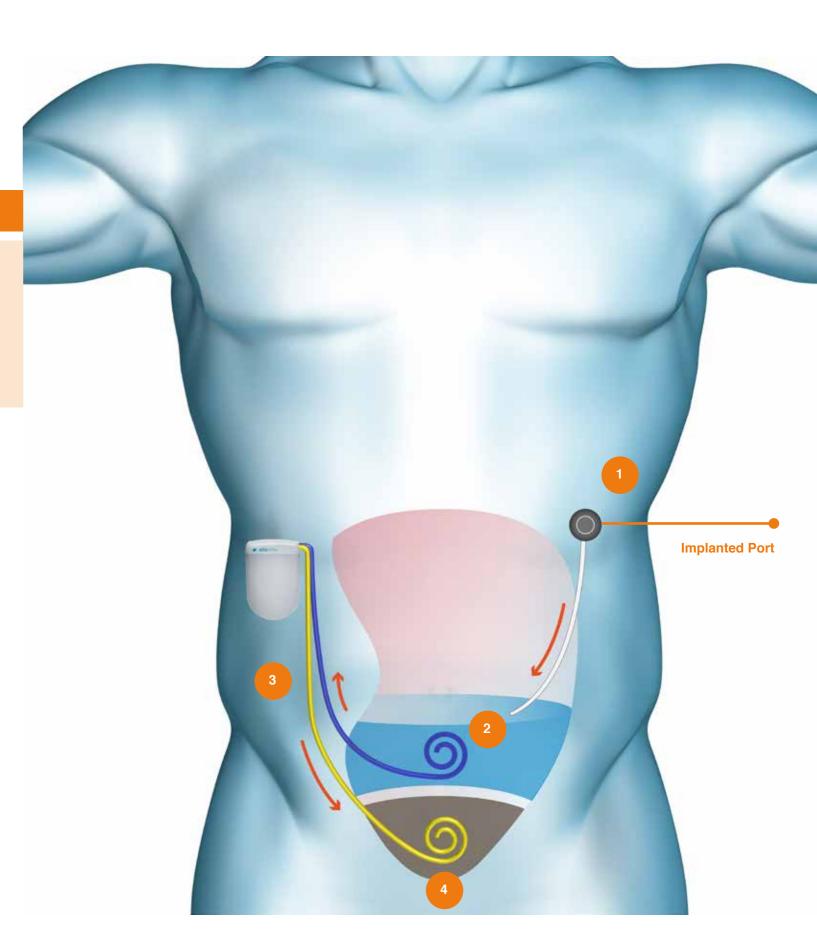
## alfapump DSR:

- directly tackles fundamental problem of volume overload
- leverages natural processes for fluid removal
- leverages proven elements: alfapump, implantable port, sodium-free infusate
- allows flexible dosing of DSR infusate

advance warning of decompensation. It has been demonstrated that integrated monitoring systems have the potential to extend and improve patients' lives while decreasing the burden of care and reducing costs.

**Administration of DSR infusate** 

- to abdomen via Implanted Port
- Sodium from systemic circulation diffuses into DSR infusate
- alfapump pumps sodium-rich fluid into the bladder
- Body eliminates excess fluid through osmotic ultrafiltration & urination



sequanamedical

# **MARKET OPPORTUNITY**

# in heart failure

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

Physicians usually classify heart failure according to the severity of their symptoms. The New York **Heart Association Functional** Classification (the "NYHAFC") is one of the most commonly used classifications. Class III heart failure under the NYHAFC is categorised as a marked limitation of physical activity (comfortable at rest) where less than ordinary activity causes fatigue, palpitation or dyspnea. Class IV heart failure under the NYHAFC is categorised as being unable to carry on any physical activity without discomfort (symptoms of heart failure at rest), and if any physical activity is undertaken, discomfort increases. It is estimated that there are 1.7 million Class III and Class IV heart failure patients in the U.S. (based on the NYHAFC)17.

by 2030<sup>14</sup>. It is estimated that at least 26 million people are living with heart failure worldwide<sup>15</sup>. Total direct medical costs for the U.S. heart failure market are projected to reach \$53 billion in 203016.

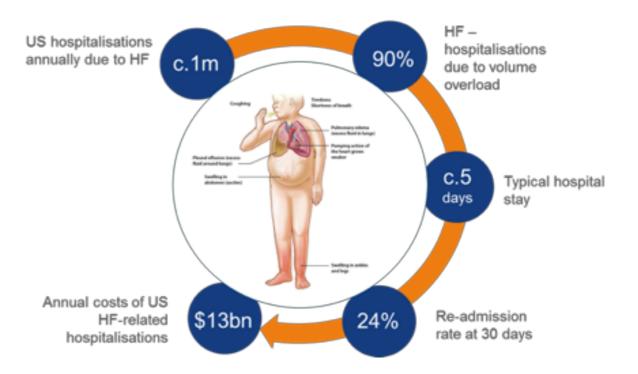
Heart failure can disturb the normal functioning of the kidney, diminishing its ability to excrete sodium from the body and triggering compensatory mechanisms that cause water retention resulting in volume overload. Patients with heart failure commonly experience shortness of breath, fatigue, difficulty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

Volume overload, which presents in Class III and IV patients under the NYHAFC, is currently treated through the administration of diuretics, which frequently cause patients to develop kidney failure and an estimated 40% of heart failure patients experience diuretic resistance or intolerance<sup>18</sup>. Once patients become resistant or intolerant to diuretics or begin to experience kidney failure, clinical alternatives are limited (eg. ultrafiltration) and have significant limitations.

Volume overload in the body is a major clinical problem and the leading cause of hospitalisations for patients suffering from heart failure19. There are approximately I million hospitalisations for heart failure annually in the U.S., costing the U.S. approximately \$13 billion each year<sup>20</sup>. Of these admissions, 90% are due to symptoms of volume overload19, with an average length of stay of 5 days21.

It is estimated that nearly 50% of hospitalised patients with heart failure are discharged with residual fluid excess<sup>19</sup>. By not truly addressing the volume overload problem, patients are being readmitted to hospital too frequently, with 30-day readmissions of 24%22.

There is a significant unmet medical need for a safe and effective, longterm 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.



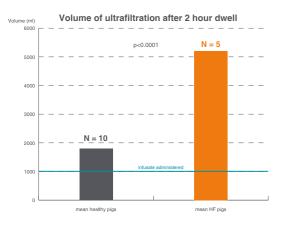
46

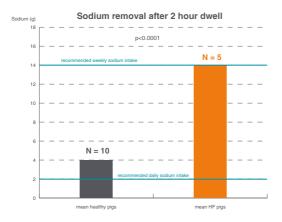
# **COMPLETED STUDIES**

The impact of administering a sodium-free infusate to the peritoneal cavity, and the resulting sodium and fluid removal, was evaluated in a preclinical study with 15 pigs, of which five had experimentally induced heart failure.

Name of Study	Description	Animals
Healthy pig DSR proof of concept study	Single dose, single arm proof of concept study to assess impact of direct sodium removal therapy in healthy pigs.	10
Heart failure pig DSR proof of concept study	Single dose, single arm proof of concept study to assess impact of direct sodium removal therapy in pigs with experimentally induced heart failure via tamponade.	5

In the healthy pigs, administration of I litre of the sodium-free infusate and a 2-hour dwell period, resulted in removal of approximately 2 litres of fluid from the peritoneal cavity (i.e., a net of I litre was removed) and 4 grams of sodium which represents two times the recommended daily sodium intake for adults in the U.S<sup>23</sup>.





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 the study were presented at EuroPCR 2018 and HFSA 2018.

In the pigs with experimentally induced heart failure, administration of I litre of the sodium-free infusate and a 2-hour dwell period, resulted in removal of approximately 5 litres of fluid from the peritoneal cavity (i.e., a net of 4 litres was removed) and I4 grams of sodium, which represents the recommended weekly intake of sodium for adults in the U.S<sup>33</sup>.

The study demonstrated that DSR therapy is capable of removing large quantities of fluid and sodium whilst having a negligible impact on the sodium concentration in the bloodstream, indicating the potential of this therapeutic approach.

# ONGOING / PLANNED CLINICAL STUDIES

Following the proof-of-concept studies in pigs, first-in-human clinical studies for the management of volume overload in heart failure have begun.

Name of Study Description <sup>(5)</sup>				
Ongoing / Planned		2018	2019	2020
Single Dose DSR Proof of Concept	First-in-human clinical study in up to 20 patients to demonstrate the safety, tolerability and dynamics of a single dose of DSR therapy (no alfapump).	-	<b>&gt;</b>	
Repeated Dose DSR Proof of Concept	Study in approximately 5-10 patients with volume overload in heart failure to demonstrate the safety, tolerability and efficacy (sodium and fluid removal) of the alfapump DSR in connection with multiple dose DSR therapy over a 90-day period.			<b>&gt;</b>

The single dose DSR proof-of-concept study is being conducted by Dr. Testani in the U.S. at Yale University. Presentation of initial results are anticipated in the first half of 2019. The repeated dose DSR proof-of-concept study is expected to be conducted at clinical centres in Europe. Presentation of initial results are anticipated in the second half of 2019, with presentation of full results anticipated in the first half of 2020.

<sup>(5)</sup> The descriptions and timing of these studies reflect our current expectations. These expectations 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.





# **CORPORATE GOVERNANCE**

1.	Report of the board of directors	52
2.	Corporate Governance Statement	64
3.	Remuneration report	86

# REPORT OF THE BOARD OF DIRECTORS

This report of the board of directors has been prepared in accordance with the Articles 95, 96, §1 and 119, §1 of the Belgian Companies Code and relates to the position 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"), and the Company's annual accounts for the financial year ended on 31 December 2018.

On 27 February 2019, the new Belgian Code on Companies and Associations was approved by the Belgian Chamber of Representatives. These new rules were published in the Belgian Official Gazette on 4 April 2019 and will in principle become applicable to the Company on 1 January 2020. The contents of this report has been prepared in accordance with the Belgian Companies Code of 7 May 1999 (as amended), which is still in force on the date of this report, and references herein to the Belgian Companies Code of 7 May 1999 (as amended) ("BCC"), unless indicated otherwise herein.

# 1.1. Developments, results, risks and uncertainties

(Article 119, 1° BCC)

## 1.1.1. Operational review

ALFAPUMP – PROVEN STEP CHANGE IN THE MANAGEMENT OF ASCITES IN LIVER DISEASE AND CANCER

Since April 2018, the alfapump has been included in the EASL clinical practice guidelines for the management of patients with decompensated cirrhosis. The Company considers this a key step in the potential widespread commercial acceptance of the alfapump.

To support French reimbursement of the alfapump, a study in patients with refractory liver ascites (the ARIA pump study) was initiated in 2018. This study is funded by the French government and is being conducted and sponsored by leading clinicians in France.

In June 2018, results from the multicentre RCT of the alfapump in 58 patients with refractory liver ascites were published in Quality of Life Research, demonstrating an improved patient QoL in the alfapump group compared to the standard of care group.

In September 2018, results from the retrospective study of the alfapump in 21 patients with refractory liver ascites in a real-world setting at Hannover Medical School were published in the European Journal of Gastroenterology & Hepatology.

Also in September 2018, results from the retrospective Malignant Ascites study of the alfapump in 17 patients with malignant ascites were presented at the International Gynaecologic Cancer Society congress in Kyoto and the Pelvic Surgeons Annual Meeting in Romania, by Principal Investigator Prof. Dr. Fotopoulou from Imperial College in London. The study demonstrated that the alfapump was effective in treating palliative patients with malignant ascites and improving their QoL.

In November 2018, results from the North American MOSAIC study, an IDE (Investigational Device Exemption) feasibility study, of the alfapump in 30 patients with recurrent or refractory liver ascites were presented at the American Association for the Study of Liver Disease (AASLD) by Principal Investigator Prof. Wong from the University of Toronto. Results demonstrated a significant reduction in LVP, the current standard of care, as well as improved nutritional status and patient QoL during at least one year follow-up.

Furthermore, in November 2018, the U.K. NICE recommended use of the alfapump for the treatment of refractory ascites caused by liver cirrhosis under special arrangements. This improved guidance is important to support market adoption of the alfapump in the U.K.

In December 2018, the first patient was enrolled in the TOPMOST registry, a European registry to collect data from prospectively enrolled alfapump patients with refractory liver ascites. These realworld data will be important for healthcare providers and payers, and to increase awareness of the alfapump.

By the end of 2018, the average duration of alfapump therapy exceeded 450 days. This is the result of continuous work to further improve the design and use of the alfapump including pre- and post- implant care based on feedback from Key Opinion Leaders (KOLs) and clinical experience.

# ALFAPUMP DSR – POTENTIAL BREAKTHROUGH TREATMENT OF VOLUME OVERLOAD IN PATIENTS WITH HEART FAILURE

Direct Sodium Removal (DSR) is Sequana Medical's proprietary therapy for the management of volume overload in heart failure patients. The Company has leveraged its alfapump experience and is developing alfapump DSR, a fully implanted system to deliver a commercially attractive approach to implement DSR therapy.

In September 2018, results from the DSR pre-clinical proof-of-concept study in 15 healthy and 5 experimentally induced heart failure pigs were presented at the Annual Scientific Meeting of the Heart Failure Society of America (HFSA) by Principal Investigator Dr. Testani from Yale University. These data demonstrated that DSR therapy resulted in the removal of clinically relevant amounts of sodium and fluid in the studied pigs. The stable serum sodium concentration is an encouraging signal for the safety of DSR therapy.

By the end of 2018, the first patient was enrolled in the first-in-human Single Dose DSR study to demonstrate the safety, tolerability and efficacy of a single dose of DSR therapy in approximately 20 human subjects. Interim results are expected to be reported in the second quarter of 2019 and full results in the second half of 2019.

**sequana**medical

# 1.1.2. Commentary on the consolidated annual accounts

### CONSOLIDATED STATEMENTS OF PROFIT AND LOSS

### REVENUE

Total revenues decreased by 21% to €1.03 million (2017: €1.30 million), mainly as a result of a strategic decision to focus principally on Sequana Medical's focus markets in Europe (Switzerland, Germany, France and the U.K.).

### COST OF GOODS SOLD

Cost of goods sold decreased from €0.21 million to €0.16 million in line with the decrease in revenue.

## **OPERATING EXPENSES**

Total operating expenses increased to €13.95 million (2017: €8.51 million).

Sales and marketing expenses increased from €1.51 million to €2.45 million mainly as a result of the expansion of the commercial team and increased marketing activities.

Clinical expenses decreased from €1.75 million to €1.67 million principally as a result of lower expenses for the MOSAIC (North American IDE feasibility) study in 2018 versus 2017, due to completion of the study, partly offset by higher expenses for the DSR proof-of-concept animal studies.

Quality and regulatory expenses increased from €1.23 million to €1.37 million, principally as a result of external advice regarding the POSEIDON (North

54

sequana medical

American pivotal) study and the preparation for the new Medical Devices Regulation (Regulation 2017/745).

Supply chain expenses decreased from €1.04 million to €0.96 million, mainly as a result of the decrease in revenue.

Engineering expenses increased from €I.00 million to €I.8I million largely as a result of the costs related to the further development of the alfapump and costs related to the preparation for the new Medical Device Regulation.

General and administration expenses increased from €1.99 million to €5.76 million mainly as a result of the costs related to the preparation of the Initial Public Offering (IPO) and relocation to Belgium.

### **EBIT**

As a result of the above, earnings before interest and taxes (EBIT) increased from a loss of €7.42 million in 2017 to a loss of €13.08 million in 2018 largely due to costs related to the preparation of the IPO and relocation to Belgium, increased marketing activities and a lower gross profit due to a decrease in sales (partially offset by lower expenses in clinical affairs).

### TOTAL NET FINANCE EXPENSES

Net finance cost increased from €0.79 million to €0.88 million mainly as a result of the interest expense related to the convertible loans received in 2018. The remainder of the costs relate to the Bootstrap loan.

### **INCOME TAX EXPENSE**

Income tax expense was €0.02 million for 2018 and was broadly flat compared to 2017. These expenses largely reflect taxes payable in Germany.

### NET LOSS FOR THE PERIOD

As a result of the above, the net loss increased from €8.23 million in 2017 to €13.98 million in 2018.

### BASIC LOSSES PER SHARE (LPS)

Basic losses per share for 2018 amounted to €1.40, compared to €0.88 in 2017.

### CONSOLIDATED BALANCE SHEET

### NET DEBT

Net debt<sup>(1)</sup> at December 31, 2018 amounted to €13.34 million, compared to €2.89 million in 2017, as a result of several new convertible loan agreements<sup>(2)</sup> entered into in 2018.

### WORKING CAPITAL

Working capital<sup>(3)</sup> from 2017 to 2018 decreased with €3.73 million, which was a result of an increase in trade payables and accrued liabilities.

### CONSOLIDATED STATEMENTS OF CASH FLOWS

Net cash outflow from operating activities was €9.88 million compared to a net outflow of €8.38 million in 2017. The difference mainly relates to a general increase in the net loss partly offset by the decrease in working capital.

Cash flow from investing activities resulted in a net outflow of €0.05 million compared to a net outflow of €0.01 million in 2017. The net cash outflow mainly relates to the down payment for the new office lease in Ghent, Belgium.

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

Cash flow from financing activities remained broadly flat. In 2018, cash inflow amounted to €9.47 million, as a result of the proceeds of several convertible loans, compared to a net inflow of €9.50 million in 2017, resulting from the issuance of shares in 2017.

The Company ended the period with a total liquidity position of €I.32 million (2017: €I.68 million) which consists fully of highly liquid cash and cash equivalents.

# 1.1.3. Information regarding major risks and uncertainties

We refer to the risk factors described in the Prospectus dated 30 January 2019 related to Sequana Medical's Initial Public Offering and to note 3 under the 'Notes to the consolidated financial statements' in the financial report section of this Annual Report.

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

(Article 119, 2° BCC)

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 Group

(Article 119, 3° BCC)

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

# 1.4. Research and development

(Article 119, 4° BCC)

The following R&D programs have been undertaken in the course of 2018 with the objective to further develop the alfapump:

- Presentation of the North American MOSAIC alfapump feasibility study demonstrating a significant reduction in large volume paracentesis (LVP) as well as improved nutritional status and QoL of the patient during at least one year follow-up.
- Presentation of the retrospective Malignant Ascites study demonstrating that the **alfapump** was effective in treating palliative patients and improving their QoL.
- Enrolled first patient in TOPMOST
  European registry study in cirrhosis
  patients implanted with the alfapump for
  the management of refractory liver ascites.
- Presentation of the pre-clinical proof-ofconcept data for Direct Sodium Removal (DSR) therapy in the management of volume overload due to heart failure demonstrating the removal of clinically relevant amounts of sodium and fluid.
- First-in-human single dose DSR study commenced at Yale University, U.S.

# 1.5. Use of financial instruments

(Article 119, 5° BCC)

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 119, 6° BCC)

We refer to 1.4 in the corporate governance section.

<sup>(2)</sup> The following conversion option was foreseen in the convertible loan agreements, in the event of an IPO: There will be a mandatory conversion where 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.

<sup>(3)</sup> 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.

**sequana**medical

# 1.7. Internal control and risk management

(Article 119, 7° BCC)

We refer to 2.12 in the corporate governance section.

## 1.8. Branch offices

(Article 96,5° BCC)

The company has a branch in Switzerland, Technoparkstrasse I, 8005 Zurich.

# 1.9. Justification of valuation rules

(Article 96,6° BCC)

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 in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows. 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 2018 shows a negative equity in the amount of EUR 18.8 million. The Company signed a Convertible Loan Agreement with existing Shareholders in February 2018, which guarantees liquid funds of EUR 1.7 million (CHF 2 million) in total. Three additional convertible loan agreements have been signed in June 2018 (EUR 1.7 million), July 2018 (EUR 2 million) and August 2018 (EUR 0.5 million) with new investors. In October and December, additional funds amounting to EUR 2.6 million and EUR 1.0 million have been raised.

In the meantime, the Company successfully launched its Initial Public Offering (IPO) and as a result of that, the board of directors remains

confident that the liquidity requirements for 2019, estimated to be EUR 14.8 million (CHF 17.1 million) can be secured. The Company continues to evaluate equity financing options, including discussions with existing and/or new investors. Based on the above, the executive management and the board of directors remain confident about the strategic direction, comprising financing measures such as additional financing rounds or capital market transactions, and therefore consider the preparation of the present financial statements on a going concern basis as appropriate.

# 1.10. Conflicts of interests procedure

(Article 523, §1 BCC)

In relation to the Company's initial public offering with admission to trading of the Company's shares on the regulated market of Euronext Brussels ("IPO"), a meeting of the board of directors was held on 20 November 2019 in which it approved the launch of the IPO and related aspects. Due to an administrative delay in completing the move of the Company's business from Switzerland to Belgium, the timelines for launching the IPO were moved to January 2019.

On 28 January 2019, a new meeting of the Company's board of directors was held in which it finally approved the launch of the IPO and related aspects.

The conflicts of interests procedure of Article 523 of the Belgian Companies Code was applied during both of the aforementioned board meetings. Please find below, in accordance with the Articles 523 and 95 of the Belgian Companies Code, relevant extracts of the aforementioned board meetings.

# 1.10.1. Extract of the Minutes of the Meeting of the Board of **Directors of 20 November 2018**

### 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 20 November 2018, 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 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 Pre-IPO Investment Commitment Agreements to (a) contribute their Payables under the outstanding Convertible Loan Agreements to the share capital of the Company and (b) subscribe for new shares of the Company for an aggregate amount (including issue premium) of EUR 20,507,236.43.

## 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 shall on the basis of the Shareholders PIICA, which was entered into by LSP (among others) with the Company, commit 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, and (y) subscribe for new shares of the Company within the framework of the IPO for an amount of EUR 1,192,034.39. LSP will also commit not to transfer its shares in the Company during a certain period after the IPO. The same commitment will also be 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 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) as the subscription commitment provided for in the Shareholders PIICA may allow the Company to increase the chances of success of the IPO. Rudy Dekeyser also notes that

by providing for a mechanism pursuant to which LSP can contribute its Payable as provided in the Shareholders PIICA and the EGM Resolutions, the Company will be able to satisfy its obligation to settle this Payable 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.

### 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 shall on the basis of the Shareholders PIICA, which was entered into by Neomed IV X and Neomed V (among others) with the Company, commit 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, and (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. Neomed IV X and Neomed V will also commit not to transfer their shares in the Company during a certain period after the IPO. The same commitment will also be 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 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) as the subscription commitment provided for in the Shareholders PIICA may allow the Company to increase the chances of success of the IPO. Erik Amble also notes that by providing for a mechanism pursuant to which Neomed IV X and Neomed V can contribute their Payables as provided in the 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 2 November 2018 in accordance with articles 596, 598 and 602 of the Belgian Companies Code.

### 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 shall on the basis of the Shareholders PIICA, which was entered into by VI AG and VI Partners (among others) with the Company, commit

- to, on the occasion of the IPO, (x) contribute the outstanding Payables of respectively EUR 217,641.87 and EUR 5,007.93 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, and (y) subscribe for new shares of the Company within the framework of the IPO for an amount of respectively EUR 872,925.70 and EUR 20,085.97. VI AG and VI Partners will also commit not to transfer their shares in the Company during a certain period after the IPO. The same commitment will also be 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 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) as the subscription commitment provided for in the Shareholders PIICA may allow the Company to increase the chances of success of the IPO. Diego Braguglia also notes that by providing for a mechanism pursuant to which VI AG can contribute its Payable as provided in the Shareholders PIICA and the EGM Resolutions, the Company will be able to satisfy its obligation to settle this Payable 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.

# 1.10.2. Extract of the Minutes of the 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

60

Corporate Governance sequanamedical

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 Pavables 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.

**sequana**medical

62

· 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."

# 1.11. Acquisition of own shares

(Article 624 BCC)

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 2018. As of 31 December 2018, the Group does not hold any treasury Shares. Prior to the Belgian

Seat Transfer, the Group held II7,569 of its own Shares as treasury stock. These shares were acquired in 2017 from the estate of the former chief executive officer. All of the treasury shares were cancelled on I October 2018, immediately following the Belgian Seat Transfer, in order to simplify the Group's capital structure with no impact on the share capital amount.

# 1.12. Article 633 and 634 of the Belgian Companies Code

In accordance with article 633 of the Belgian Companies Code, a general shareholders' meeting of the Company must be convened if as a result of incurred losses the net equity of the Company has fallen below 50% of the share capital of the Company in order to deliberate and resolve upon the dissolution of the Company or any other measures announced in the agenda of such general shareholders' meeting. The same requirement applies when the net equity has fallen below an amount equal to 25% of the share capital of the Company. Article 634 of the Belgian Companies Code provides that when the equity has fallen below the amount of EUR 61,500, each interested party or the Belgian public prosecutor's office (openbaar ministerie) may request the dissolution of the Company before a court of law. Where appropriate, the court of law can grant the Company a binding period in which it has to regularise its situation.

At the occasion of the preparation of the statutory (non-consolidated) financial statements of the Company for the financial year ended 31 December 2018, the board of directors of the Company has determined that, based on these statutory (non-consolidated) financial statements, the Company's (non-consolidated) accounting net equity as at 31 December 2018 was negative, being -EUR 18,588,252. This was due to losses incurred by the Company. The amount of the share capital on 31 December 2018 amounted to EUR 887,977. Consequently, based on the aforementioned statutory financial statements, it appears that on 31 December 2018 the Company's (non-consolidated) accounting net equity had fallen below the thresholds of the articles 633 and 634 of the Belgian Companies Code.

The aforementioned statutory (non-consolidated) financial statements for the financial year ended 31 December 2018 have been prepared in accordance with generally accepted accounting principles in Belgium and will be submitted to the annual general meeting of shareholders of the Company to be held on 23 May 2019 (the "AGM"). For more information on this financial statement, reference is made to the documentation submitted to the AGM.

Since 31 December 2018, the Company has incurred further losses. These and the aforementioned past losses are the result of the costs related to the development and commercialisation of the alfapump® technology, as well as general and administrative costs related to the Company's operations and the increase in production scale, as well as the costs related to the launch of the initial public offering of the Company's shares listed on the regulated market of Euronext Brussels (the "initial public offering" or "IPO").

Notwithstanding the aforementioned losses, the net equity of the Company has substantially increased on 12 February 2019, and this as a result of the following capital increases:

- capital increase at the occasion of the conversion of a number of convertible loans entered into in 2018, as a result of which the Company's net equity was increased by an amount of EUR 8,616,522.87, whereby an amount of EUR 83,785.59 was booked as share capital and an amount of EUR 8,532,737.28 was booked as share premium, and
- a capital increase at the occasion of the completion by the Company of the IPO, as a result of which the Company's net equity was increased by an amount of EUR 27,499,999.00, whereby an amount of EUR 335,176.46 was booked as share capital and an amount of EUR 27,164,822.54 was booked as share premium.

The aforementioned capital increases have been approved by the general meetings of shareholders held on 20 November 2018 and 18 January 2019.

As a reminder, in November 2018 it was also already established that the Company's accounting net equity had fallen below the thresholds of articles 633 and 634 of the Belgian Company Code. The general meeting held on 20 November 2018 nevertheless decided not to dissolve the Company, but to continue the activities of the Company, taking into account the aforementioned transactions.

The capital increases of 12 February 2019 resulted in an increase of the (non-consolidated) accounting net equity of the Company after 31 December 2018 with a total amount of EUR 36,116,521.87, and had as consequence that the share capital currently amounts to EUR 1,306,939.52.

The amount of EUR 36,II6,521.87 which has strengthened the Company's (non-consolidated) accounting net equity after 31 December 2018 is substantially higher than the amount of additional losses incurred after 31 December 2018 and the negative amount of net equity at 31 December 2018. Consequently, the Company's (non-consolidated) accounting net equity is currently again well above the thresholds provided for in Articles 633 and 634 of the Belgian Company Code.

sequanamedical

# 2 CORPORATE GOVERNANCE STATEMENT

Sequana Medical NV (the "Company" or "Sequana Medical") has prepared this Corporate Governance Statement in accordance with the Belgian Code on Corporate Governance of 12 March 2009. This Corporate Governance Statement is included in the Company's report of board of directors on the statutory accounts for the financial year ended on 31 December 2018 (dated 17 April 2019) in accordance with article 96 of the Belgian Companies Code.

On 27 February 2019, the new Belgian Code on Companies and Associations was approved by the Belgian Chamber of Representatives. These new rules were published in the Belgian Official Gazette on 4 April 2019 and will in principle become applicable to the Company on 1 January 2020. The contents of this Corporate Governance Statement and this report have been prepared in accordance with the Belgian Companies Code of 7 May 1999 (as amended), which is still in force on the date of this report, and references herein to the Belgian Companies Code of 7 May 1999 (as amended), unless indicated otherwise herein.

The Company applies the nine corporate governance principles contained in the Belgian Code on Corporate Governance, except in relation to the situations set out below. The Company complies with the provisions set forth in the Belgian Code on Corporate Governance.

# 2.1. Corporate Governance Charter

The Company has adopted a corporate governance charter that is in line with the Belgian Code on Corporate Governance of 12 March 2009 and that entered into force on 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"). 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 describes 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 must be read together with the Company's articles of association.

The Company applies the nine corporate governance principles contained in the Belgian Code on Corporate Governance and complies with the corporate governance provisions set forth in the Belgian Code on Corporate Governance, except in relation to the following:

- At the date of this report, share options have been granted to non-executive directors.
- The Company intends to continue to award share-based incentives to the non-executive directors, upon advice of the remuneration and nomination committee. This is contrary to provision 7.7 of the Belgian Code on Corporate Governance that provides that non-executive directors should not be entitled to performance-related remuneration such as, amongst others, share-related long-term incentive schemes. The Company believes that this provision of the Belgian Code on Corporate Governance is not appropriate and adapted to take into account the realities of companies in the life sciences industry that are still in a development phase. Notably, the ability to remunerate non-executive directors with share options allows Sequana Medical 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 Sequana Medical 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. In any event, the Company intends that the portion of the remuneration payable in share options will be limited.

- Pursuant to article 520ter of the Belgian Companies Code and the guideline to provision 7.13 of the 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 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). 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.
- At the date of this report, there are only two independent directors on the Company's board of directors. This is contrary to provision 2.3 of the Belgian Code on Corporate Governance which provides that at least one half of the board should comprise non-executive directors and at least three of the non-executive directors should be independent directors. The board of directors proposed to appoint a third independent director, namely Jason Hannon. Please see his biography under the section "Board of Directors" below. The proposed appointment of Mr Hannon will be submitted to the annual general shareholders' meeting of the Company to be held on 23 May 2019.

What constitutes good corporate governance will evolve with the changing circumstances of a company and with the standards of corporate governance globally, and must be tailored to meet those changing circumstances. The board of directors intends to update the corporate governance charter as often as required to reflect changes to the Company's corporate governance.

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

# 2.2. Board of Directors, Executive Management and Senior Management

### **Board of Directors**

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

Name	Age	Position	Start of Current Term	End of Current Term
Mr Pierre Chauvineau	55	Chair, Independent Non-Executive Director	2019	2022
Mr Ian Crosbie	51	CEO, Executive Director	2019	2022
Mr Rudy Dekeyser	57	Non-Executive Director	2019	2022
Mr Erik Amble	67	Non-Executive Director	2019	2022
Mr Wim Ottevaere(1)	62	Independent Non-Executive Director	2019	2022
Mr Jason Hannon <sup>(2)</sup>	47	Independent Non-Executive Director	2019	2022



Mr Pierre Chauvineau is an independent non-executive director and the chairperson of the Company's board of directors. Mr Chauvineau has over 26 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 work for Boston Scientific as an executive advisor on a part-time basis. He is also an executive board member with U.K. based Creavo Medical Technologies. Pierre Chauvineau holds an MBA degree in International

Management from the Monterey Institute of International Studies (Monterey, California, U.S.A.) and a BA degree from IPAG (Paris, France).



Mr Ian Crosbie is an executive director of the Company and the Company's chief executive officer. Mr Crosbie has over 25 years of experience in the healthcare sector, both in-house at medical device and pharma-

ceutical 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 latestage 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 II, a €280 million fund investing in medical device, diagnostic

and digital health companies in Europe and the US. Besides serving on the Company's board of directors, Dr Dekeyser currently also serves on the board of directors of 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 co-founders of VIB and co-managing director of this leading life sciences research institute for 17 years, during which he was also responsible for the 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 holds a Ph.D in molecular biology from the University of Ghent where he was also professor innovation management until 2012.



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 is an independent non-executive director of the Company. Mr Ottevaere was the chief financial officer of Ablynx until September 2018, a Belgian biopharmaceutical company

**sequana**medical

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.



Subject to approval of his appointment by the Company's annual general meeting of shareholders to be held on Thursday 23 May 2019, Mr Jason Hannon will be an independent non-exec-

utive director of the Company. Mr. Hannon has extensive experience in the medical devices industry and is currently also Chief Executive Officer at Mainstay Medical International plc, a global medical device company focused on the development and commercialisation of an innovative implantable neurostimulation system designed to treat chronic low back pain. Mr. Hannon previously served as President and Chief Operating Officer of NuVasive (NASDAQ:NUVA), a leading medical device company focused on transforming spine surgery with minimally disruptive, procedurally-integrated solutions. He helped grow NuVasive

Annual Report 2018

<sup>(</sup>I) Acting as permanent representative of WIOT BVBA.

 $<sup>(2) \ \</sup> Subject to approval of Mr \ Hannon's appointment by the Company's annual general meeting of shareholders to be held on Thursday 23 May 2019.$ 

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, Mr. Hannon led the international business, was responsible for business development and strategy, and also served as general counsel. During his tenure, the NuVasive's commercial presence was expanded globally to more than 40 countries, revenue grew from \$61 million to almost \$1 billion, and the product portfolio expanded to over 100 products. Mr. Hannon 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.

# **Executive Management and Senior Management**

The executive management of the Company consists of the following members:

Name	Age	Position
Mr Ian Crosbie	51	Chief Executive Officer
Mrs Kirsten Van Bockstaele <sup>(1)</sup>	44	Chief Financial Officer



Mr Ian Crosbie is the chief executive officer and a director of the Company. Please see his biography under the section "Board of Directors" above.



Mrs Kirsten Van Bockstaele is the chief financial officer of Sequana Medical. She is a seasoned finance executive with extensive international experience in the healthcare

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

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

Name	Age	Position
Dr Gijs Klarenbeek	42	Chief Medical Officer
Mr Martijn Blom	45	Chief Commercial Officer
Mr Timur Resch <sup>(2)</sup>	37	Global Vice President Quality Management and Regulatory Affairs
Mr Dirk Fengels	47	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 as from 1 May 2019. 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 IIII 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

<sup>(</sup>I) Acting as permanent representative of Fin-2K BVBA.

<sup>(2)</sup> Mr Timur Resch will be Global Vice President Quality Management and Regulatory Affairs with effect as of 1 May 2019. On the date of this report, this position is held by Mr Orlando Antunes.

Corporate Governance sequanamedical

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.

### 2.3. Board of Directors' role

The Company has 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 purpose. The board of directors has all powers except for those reserved to the general shareholders' meeting by law or the Company's articles of association. The board of directors acts as a collegiate body.

Pursuant to the Company's corporate governance charter, the role of the board of directors is to pursue the long term success of the Company by providing entrepreneurial leadership and enabling risks to be assessed and managed. 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 a number of committees in relation to specific matters. The committees advise the board of directors on these matters, but the decision making remains with the board of directors as a whole.

The board of directors has the power to appoint and remove the chief executive officer. The role of the chief executive officer is to implement the mission, strategy and targets set by the board of directors and to assume responsibility for the day-to-day management of the Company. The chief executive officer reports directly to the board of directors.

Pursuant to the Belgian Companies Code and the Company's articles of association, the board of directors must consist of at least three directors. The Company's corporate governance charter provides that the composition of the board of directors should ensure that decisions are made in the corporate interest. It should be determined on the basis of diversity, as well as complementary skills, experience and knowledge. Pursuant to the 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 Code and in the Belgian Code on Corporate Governance. As stated in "Corporate Governance Charter", there will only be two independent directors on the Company's board of directors. By I 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 remuneration and nomination committee. 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 board of directors elects a chairperson from among its non-executive members on the basis of his knowledge, skills, experience and mediation strength. The chairperson is responsible for the leadership and the proper and efficient functioning of the board of directors. On the date of this report, Dr Pierre Chauvineau is chairperson 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 chairperson, it should carefully consider the positive and negative aspects of such a decision and disclose why such appointment is in the best interest of the Company.

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 chairperson of the board of directors will have a casting vote.

During 2018, 12 meetings of the board of directors were held.

### 2.4. 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 526bis of the Belgian Companies Code and provision 5.2 of the Belgian Code on Corporate Governance) and the remuneration and nomination committee (in accordance with article 526quater of the Belgian Companies Code and provision 5.3 and 5.4 of the Belgian Code on Corporate Governance). The terms of reference of these board committees are primarily set out in the corporate governance charter.

#### **Audit Committee**

The audit committee of the Company consists of three directors. According to the Belgian Companies 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 526ter of the Belgian Companies Code. The chairperson of the audit

committee is to be appointed by the members of the audit committee. The following directors are the members of the audit committee: Mr Wim Ottevaere, Mr Pierre Chauvineau and Dr Erik Amble. The composition of the audit committee complies with the Belgian Code on Corporate Governance, which requires 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

 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.

In 2018, the audit committee was not yet established.

### Remuneration and Nomination Committee

The remuneration and nomination committee consists of at least three directors. In line with the Belgian Companies Code and the 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 chairperson of the board of directors or another non-executive director appointed by the committee. On the date of this report, the following directors are the members of the remuneration and nomination committee: Dr Rudy Dekeyser, Mr Wim Ottevaere and Mr Pierre Chauvineau. Subject to the appointment of Mr Hannon as Director by the Company's annual general shareholders' meeting to be held on Thursday 23 May 2019, Mr Jason Hannon will replace Mr Pierre Chauvineau as member of the remuneration and nomination committee.

Pursuant to the Belgian Companies 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.

Pursuant to the Belgian Code on Corporate Governance, 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 2018, the remuneration and nomination committee was not yet established.

### 2.5. Activity Report and Attendance at Board and Committee Meetings during 2018

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>(1)</sup>	N/A	N/A <sup>(2)</sup>	N/A <sup>(2)</sup>
Mr Ian Crosbie <sup>(1)</sup>	N/A	N/A <sup>(2)</sup>	N/A <sup>(2)</sup>
Mr Rudy Dekeyser	12 out of 12 meetings	N/A <sup>(2)</sup>	N/A <sup>(2)</sup>
Mr Erik Amble	12 out of 12 meetings	N/A <sup>(2)</sup>	N/A <sup>(2)</sup>
Mr Wim Ottevaere (1)(3)	N/A	N/A <sup>(2)</sup>	N/A <sup>(2)</sup>
Mr Diego Braguglia <sup>(4)</sup>	12 out of 12 meetings	N/A <sup>(2)</sup>	N/A <sup>(2)</sup>

<sup>(</sup>I) Only in function as director of the Company since 12 February 2019.

 $<sup>(2) \ \</sup> The \ committees \ of \ the \ board \ of \ directors \ of \ the \ Company \ were \ not \ yet \ established \ in \ 2018.$ 

<sup>(3)</sup> Acting as permanent representative of WIOT BVBA.

<sup>(4)</sup> Resigned as director of the Company on 12 February 2019

**Corporate Governance** 

### 2.6. Independent Directors

A director will only qualify as an independent director if he or she meets at least the criteria set out in article 526ter of the Belgian Companies Code, which can be summarised as follows:

- Not being an executive member of the board of directors, exercising a function as a member of the executive management or as a person entrusted with the daily management of the Company or a company or person affiliated with the Company, and not having been in such a position during the previous five years before his or her nomination.
- Not having served for more than three terms as a non-executive director of the board of directors, without exceeding a total term of more than twelve years.
- Not being an employee of the senior management (as defined in article 19, 2° of the Belgian Act of 20 September 1948 regarding the organisation of the business industry) of the Company or a company or person affiliated with the Company and not having been in such a position for the previous three years before his or her nomination.
- Not receiving, or having received, any significant remuneration or other significant advantage of a financial nature from the Company or a company or person affiliated with the Company, other than any bonus or fee (tantièmes) he or she receives or has received as a non-executive member of the board of directors.
- Not holding (directly or via one or more companies under his or her control) any shareholder rights representing 10% or more of the shares or of a class of the shares (as the case may be), and not representing a shareholder meeting this condition.
- If the shareholder rights held by the director (directly or via one or more companies under his or her control) represent less than 10%, the disposal of such shares or the exercise of the rights attached thereto may not be subject to contracts or unilateral undertakings entered

- into by the director. The director may also not represent a shareholder meeting this condition.
- Not having, or having had within the previous financial year, a significant business relationship with the Company or a company or person affiliated with the Company, either directly or as partner, shareholder, member of the board of directors, member of the senior management (as defined in article 19, 2° of the aforementioned Belgian Act of 20 September 1948) of a company or person who maintains such a relationship.
- Not being or having been within the last three years, a partner or employee of the current or former statutory auditor of the Company or a company or person affiliated with the current or former statutory auditor of the Company.
- Not being an executive director of another company in which an executive director of the Company is a non-executive member of the board, and not having other significant links with executive directors of the Company through involvement in other companies or bodies.
- Not being a spouse, legal partner or close family member (by marriage or birth) to the second degree of a member of the board of directors, a member of the executive management, a person charged with the daily management, or a member of the senior management (as defined in article 19, 2° of the aforementioned Belgian Act of 20 September 1948) of the Company or a company or person affiliated with the Company, or of a person who finds him or herself in one or more of the circumstances described in the previous bullets.

The resolution appointing the director must mention the reasons on the basis of which the capacity of independent director is granted. Mr Pierre Chauvineau and Mr Wim Ottevaere are the Company's current independent directors. Subject to Mr Hannon's appointment by the Company's annual general shareholders' meeting, Mr Hannon will be the third independent director.

In the absence of guidance in the law or case law, the board of directors has not further quantified or specified the aforementioned criteria set out in article 526ter of the Belgian Companies Code. The Company is of the view that the independent directors comply with each of the criteria of the Belgian Companies Code and Belgian Code on Corporate Governance. An independent director who ceases to satisfy the requirements of independence must immediately inform the board of directors thereof.

### 2.7. Performance Review of the Board of Directors

The board of directors evaluates its own size, composition, performance and interaction with executive management and that of its committees on a continuous basis.

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 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 chairperson or member of a committee of the board of directors, as well as their relevant responsibilities and time commitment.

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

### 2.8. 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 Company's executive management does not constitute a directiecomité/comité de direction within the meaning of article 524bis of the Belgian Companies Code. The executive management is responsible and accountable to the board of directors for the discharge of its responsibilities.

The executive management is responsible for:

- operating the Company;
- implementing the policy and plans of the Company as defined by the board of directors and in accordance with its instructions;
- executing the decisions made by the board of directors;
- assessing the achievement of the targets for the business of the Company and its subsidiary;
- preparing corporate policies, strategies and strategic plans for the attention of and approval by the board of directors or its committees;
- promoting an active internal and external communications policy;
- ensuring that management capacity, financial and other resources are provided and used efficiently;
- submitting to the board of directors or to one of its committees for approval or advice in accordance with such regulations and standards as are promulgated by the board of directors from time to time: (a) capital investment, financial measures and acquisition or divesture of companies, participations and businesses of material significance, and (b) material agreements with third parties and engagement in new business activities;
- preparing the Company's yearly business plan and yearly budget to be submitted to the board of directors;
- establishing an independent internal audit function with resources and skills adapted to the company's nature, size and complexity. If the Company does not have an internal audit function, the need for one shall be reviewed at least annually by the audit committee;
- setting up the Company's internal control and risk management systems and submit them for approval to the board of directors;

Corporate Governance

- promulgating guidelines, including guidelines for planning, controlling, reporting, finance, personnel, information and other technologies; and
- dealing with such other matters as are delegated by the board of directors from time to time.

### **Chief Executive Officer**

The chief executive officer is responsible for the day-to-day management of the Company. He may be granted additional well-defined powers by the board of directors. He 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 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.

### 2.9. Scientific Advisory Board

In connection with a convertible loan entered into between the Company and Newton Biocapital I Pricav Privée SA ("NBC"), the Company agreed to establish a scientific advisory board that will advise the Company within the framework of its DSR program. The scientific advisory board will be composed of at least three members who will be selected on the basis of their international proven track record in the field. As long as the payment under this convertible loan is due, or NBC is a shareholder of the Company, NBC will have the right to appoint one of its representatives as a member of the scientific advisory board. The Company agreed that, upon establishment of the scientific advisory board, Guy Heynen, senior clinical and regulatory partner at NBC shall be a member of the scientific advisory board. The

scientific advisory board will convene at least two times per year to discuss amongst others the clinical and regulatory progress and plans of the DSR program. It is the Company's current intention that the members of the scientific advisory board and the terms of reference of the scientific advisory board will be determined in the second half of 2019. The scientific advisory board will be an informal body that will provide advice to the Company. It will not be a part of the board of directors.

### 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 523 of the Belgian Companies Code) on any matter before the board of directors must bring it to the attention of both the statutory auditor and fellow directors, and take no part in any deliberation or voting related thereto. The corporate governance charter contains the procedure for transactions between the Company and the directors which are not covered by the legal provisions on conflicts of interest. The corporate governance charter 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. The dealing code is attached to the Company's corporate governance charter.

### 2.12. Internal Control and Risk Management

### Introduction

The Company and its subsidiaries (the "Sequana Medical Group" or the "Group") operate a risk management and control framework in accordance with the Belgian Companies Code and the 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 senior management 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 objectives;

**sequana**medical

- · achieving operational excellence;
- ensuring correct and timely financial reporting; and
- compliance with all applicable laws and regulations.

### **Control Environment**

### THREE LINES OF DEFENCE

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

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

### **POLICIES, PROCEDURES AND PROCESSES**

Sequana Medical 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 Companywide policies, procedures and processes such as the Quality Management System and the Delegation of Authorities rule set. The executive and senior management fully endorses these initiatives.

Corporate Governance sequana medical

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 organisation.

### **GROUP-WIDE FINANCIAL SYSTEM**

The Sequana Medical 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 standardised and key controls are enforced. The systems also allow detailed monitoring of activities and direct access to data.

### Risk management

Sound risk management starts with identifying and assessing the risks associated with the Company's business and external factors. Once the relevant risks are identified, the Company strives to prudently manage and minimise 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. The employees of the Sequana Medical Group are accountable for the timely identification and qualitative assessment of the risks within their area of responsibility.

### **Control activities**

Control measures are in place to minimise the effect of risk 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 organisation, 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 being implemented for selected risk categories that cannot be absorbed without material effect on the Company's balance sheet.

### Information and communication

The Sequana Medical Group recognises 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.

### 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 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
- 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 is reported to executive 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 above in this Corporate Governance Statement.

# 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 of directors 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 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, the United States, 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 the voting rights attached to shares before dilution <sup>(1)</sup>	% of the voting rights attached to shares on a fully diluted basis <sup>(2)</sup>
NeoMed IV Extension L.P. / NeoMed Innovation V L.P <sup>(3)</sup> .	20 February 2019	4,196,641	33.28	28.94
LSP Health Economics Fund Management B.V <sup>(4)</sup> .	19 February 2019	1,539,407	12.21	10.62

- (I) The percentage of voting rights is calculated on the basis of the 12,611,900 outstanding shares, each share giving right to one vote (being 12,611,900 voting rights in total). The trading of the Company's shares on the regulated market of Euronext Brussels started on an "if-and-when-issued-and/or-delivered" basis on II February 2019. The calculation does not take into account the number of shares issuable upon exercise of the 2011 Share Options, the Bootstrap Warrant, the Executive Share Options and the 2018 Share Options. For further information on the number of shares issuable upon exercise of the 2011 Share Options, the Bootstrap Warrant, the Executive Share Options and the 2018 Share Options, see "Share Capital and Shares" below.
- (2) The percentage of voting rights is calculated on the basis of 12,611,900 outstanding shares, assuming that all 2011 Share Options, the Bootstrap Warrant, the Executive Share Options and the 2018 Share Options have been exercised into 1,887,312 new shares. For further information on the number of shares issuable upon exercise of the 2011 Share Options, the Bootstrap Warrant, the Executive Share Options and the 2018 Share Options, see "Share Capital and Shares" below.
- (3) 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 20 February 2019, that, as a result of the completion of the Offering, on II February 2019, their joint shareholding crossed the threshold of 30% of the outstanding voting rights of the Company. The joint notification specifies furthermore that both NeoMed IV and NeoMed V are a private limited company incorporated in Jersey and are controlled by their investment manager NeoMed Management (Jersey) Limited (a private limited company incorporated in Jersey). NeoMed Management (Jersey) Limited is controlled by Erik Amble, Claudio Nessi, Dina Chaya and Pâl Jensen within the meaning of the articles 5 and 7 of the Belgian Companies Code. The notification also states that (a) NeoMed IV and NeoMed V do not own the securities of the Company but manage the funds that own the voting rights attached to the securities of the Company, and (b) as management companies, NeoMed IV and NeoMed V exercise the voting rights attached to the securities of the Company at their discretion in the absence of specific instructions.
- (4) 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 Offering, on II 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 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.

	Date of Notification	Number	% of the voting rights attached to shares before dilution <sup>(1)</sup>	% of the voting rights attached to shares on a fully diluted basis <sup>(2)</sup>
Participatiemaatschappij Vlaanderen				
NV <sup>(3)</sup>	18 February 2019	1,223,906	9.70	8.44
Federale Participatie- en				
Investeringsmaatschappij NV <sup>(4)</sup>	18 February 2019	1,105,246	8.76	7.62
Newton Biocapital I Pricav Privée SA(7)(5)	21 February 2019	1,102,529	8.74	7.60
Venture Incubator AG / VI Partners AG(6)	21 February 2019	525,501	4.17	3.62
Capricorn Health-tech Fund NV / Quest				
for Growth NV <sup>(7)</sup>	18 February 2019	598,978	4.75	4.13

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.

- (i) The percentage of voting rights is calculated on the basis of the 12,611,900 outstanding shares, each share giving right to one vote (being 12,611,900 voting rights in total). The trading of the Company's shares on the regulated market of Euronext Brussels started on an "if-and-when-issued-and/or-delivered" basis on II February 2019. The calculation does not take into account the number of shares issuable upon exercise of the 2011 Share Options, the Bootstrap Warrant, the Executive Share Options and the 2018 Share Options. For further information on the number of shares issuable upon exercise of the 2011 Share Options, the Bootstrap Warrant, the Executive Share Options and the 2018 Share Options, see "Share Capital and Shares" below.
- (2) The percentage of voting rights is calculated on the basis of 12,611,900 outstanding shares, assuming that all 2011 Share Options, the Bootstrap Warrant, the Executive Share Options and the 2018 Share Options have been exercised into 1,887,312 new shares. For further information on the number of shares issuable upon exercise of the 2011 Share Options, the Bootstrap Warrant, the Executive Share Options and the 2018 Share Options, see "Share Capital and Shares" below.
- (3) 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 Offering, 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 and that Het Vlaams Gewest is not controlled.
- (4) A parent undertaking or a controlling person of Federale Participatie- en Investeringsmaatschappij N.V. ("SFPI-FPIM"), informed the Company, by means of a notification dated 18 February 2019 that, as a result of the completion of the Offering, on 11 February 2019, SFPI-FPIM's shareholding crossed the threshold of 5% of the outstanding voting rights of the Company. The notification specifies furthermore that SFPI-FPIM is controlled by the Belgian State within the meaning of the articles 5 and 7 of the Belgian Companies Code and that SFPI-FPIM acts in its own name, but on behalf of the Belgian State.
- (5) 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 Offering, on II 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.

  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.
- (6) 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 Offering, on II 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. 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.
- (7) Capricorn Venture Partners ("CVP"), a person that notifies alone, informed the Company, by means of a notification dated 18 February 2019 that, as a result of the completion of the Offering, on II February 2019, the joint shareholding of its funds Capricorn Health-tech Fund NV and Quest for Growth NV crossed the threshold of 3% of the outstanding voting rights of the Company. The joint notification specifies furthermore that (a) CVP 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) CVP exercises the voting rights of both funds as management company, and (c) CVP is not controlled within the meaning of the articles 5 and 7 of the Belgian Companies Code. The notification also states that (a) the securities giving voting rights are owned by two funds managed by CVP, and (b) CVP can exercise the voting rights of the funds at its own discretion at the general meeting of shareholders of the Company.

82 Corporate Governance

**sequana**medical

### 2.14. Share Capital and Shares

On the date of this report, the share capital of the Company amounts to EUR 1,306,939.52 and is fully paid-up. It is represented by 12,611,900 ordinary shares, each representing a fractional value of (rounded) EUR 0.1036 and representing one 12,611,900th 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:

- 752,500 share options that were granted to employees and consultants of the Company, subject to the terms and conditions that are set out in the Stock Option Plan Regulation 2011, dated I September 2011 (the "2011 Share Options"). Each holder of 2011 share Options will only be entitled to subscribe for one (I) ordinary share when exercising all of his or her share options.
- one warrant 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,
  I October 2018, and 20 December 2018 (the
  "Bootstrap Warrant"). Bootstrap will be
  entitled to subscribe to 320,740 ordinary shares
  when exercising its Bootstrap Warrant.
- III,I77 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.
- I,26I,190 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 Executive Share Option will

be entitled to subscribe to one (I) ordinary share when exercising one of his or her share options.

### 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, subject to any transactional restrictions in connection with the IPO of the Company.

### 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 auro

### **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, 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 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 Code, the voting rights attached to shares owned by the Company, as the case may be, are suspended.

### **Dividends and Dividend Policy**

All of the shares of the Company entitle the holder thereof to an equal right to participate in dividends declared after the 12 February 2019, in respect of the financial year ending 31 December 2018 and future years. All of the shares participate equally in the Company's profits (if any). Pursuant to the Belgian Companies 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 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 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.

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 Royal Decree dated 14 November 2007:

- (i) The share capital of the Company amounts to EUR 1,306,939.52 and is fully paid-up. It is represented by 12,611,900 ordinary shares, each representing a fractional value of (rounded) EUR 0.1036 and representing one 12,611,900th 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, the Company's articles of association, and any transactional restrictions in connection with the IPO of the Company, there are no restrictions on the transfer of shares.

**Corporate Governance** 

- (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, other than any transactional restrictions in connection with the IPO of the Company
- (vii) The rules governing appointment and replacement of board members and amendment to articles of association are set out in the Company's articles of association and the Company's Corporate Governance Charter.
- (viii) The powers of the board of directors, more specifically with regard to the power to issue or redeem shares are set out in the Company's articles of association. The board of directors was not granted the authorization to purchase its own shares "to avoid imminent and serious danger to the Company" (i.e., to defend against public takeover bids). The Company's articles of association of association do not provide for any other specific protective mechanisms against public takeover bids.
- (ix) At the date of this report, the Company is a party to the following significant agreements which, upon a change of control of the Company or following a takeover bid can enter into force or, subject to certain conditions, as the case may be, can be amended, be terminated by the other parties thereto or give the other parties thereto (or beneficial holders with respect to

- bonds) a right to an accelerated repayment of outstanding debt obligations of the Company under such agreements:
- 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 ore 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.

Finally, the warrant agreement entered into between the Company and Bootstrap also contains take-over protection provisions. No takeover bid has been instigated by third parties in respect of the Company's equity during the current financial year.

### 2.16. Diversity & Inclusiveness

Due to the fact that the Company has only been listed for two months, 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, at least for the timeline set by provision 518bis of the Belgian Companies Code.

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

**Corporate Governance** 

**sequana**medical

# REMUNERATION REPORT

### 3.1. Introduction

Sequana Medical NV (the "Company" or "Sequana Medical") 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 a part of the annual report of the Company. The remuneration report will be submitted to the annual general shareholders' meeting on 23 May 2019 for approval.

### 3.2. Remuneration policy

Sequana Medical's remuneration policy is designed

- 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 applies 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

#### 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 Belgian law, the general shareholders' meeting approves the remuneration of the directors, including inter alia, each time as relevant:

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

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

Notwithstanding point (i) above, pursuant to the Company's articles of association, the board of directors is explicitly authorised to deviate from the provisions of article 520ter of the Belgian Companies Code in connection with share-based incentive plans, compensation, awards or issues to employees, directors and service providers of the Company and/or its subsidiaries. The Company believes 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 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 share option plans can, under certain conditions, vest earlier than three years as of their grant, as referred to in paragraph (i) above.
- The general shareholders' meeting approved that the share options under the respective 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.
- With respect to the matter in paragraph (iii) above, at the date of this report, share options have been granted to the following non-executive directors.

The Company intends to continue to award stockbased incentives to the non-executive directors, upon advice of the remuneration and nomination committee.

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 chairperson of the board of directors receives an annual fixed fee of €40,000.
  - The chairperson of the audit committee receives an annual fixed fee of €15,000.
  - The chairperson of the remuneration and nomination committee receives an annual fixed fee of €15,000.
  - The other independent non-executive directors receives an annual fixed fee of €25,000.
  - The members of the audit committee and the remuneration and nomination committee (other than the chairpersons of such committees) receive an annual fixed fee of €10,000.
- Share based awards: Each independent director will be entitled to receive share options or warrants. Part of the 2018 Share Options will 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.

The Company has awarded and intends to continue to award share-based incentives to the non-executive directors, upon advice of the remuneration and nomination committee. This is contrary to provision 7.7 of the Belgian Code on Corporate Governance that provides that non-executive directors should not be entitled to performance-related remuneration such as, amongst others, stock-related long-term incentive schemes. The Company believes that this provision of the Belgian Code on Corporate Governance is

not appropriate and adapted to take into account the realities of companies in the biotech and life sciences industry that are still in a development phase.

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.

### Remuneration and compensation in 2018

During 2018, which is prior to the completion of the IPO, no remuneration, compensation or other benefits were paid to the 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

### General

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

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

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

- (ii) in relation to the remuneration of members of the executive management and other executives, an exemption from the rule that (unless the variable remuneration is less than a quarter of the annual remuneration) at least one quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least two years and that at least another quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least three years, and
- (iii) any service agreements to be entered into with members of the executive management and other executives (as the case may be) providing for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration and nomination committee, eighteen months' remuneration).

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

In relation to point (ii) above, the Company takes 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 can 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.

### **Remuneration and Compensation in 2018**

In 2018, which is prior to the completion of the IPO, the following remuneration, compensation and other benefits were paid to the two members of the executive management:

	Chief executive office	er (€)	Other member of the executive	management (€)
	Amount	%	Amount	%
Annual base salary	284,619.63	69.20	87,750.00	100
Pension plan <sup>(1)</sup>	14,230.36	3.46	N/A	N/A
Insurance plan <sup>(2)</sup>	1,144.99	0.28	N/A	N/A
Car lease/transport allowance	10,929.36	2.66	N/A	N/A
Medical plan	9,291.73	2.26		
Bonus plan <sup>(3)</sup>	91,077.98	22.14	N/A	N/A
Total	411,294.05	100.00	87,750.00	100.00

In 2018, 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 92,145 EUR.

<sup>(</sup>i) 5% of the annual base salary.

<sup>(2)</sup> The Company pays a life insurance plan for the CEO.

<sup>(3)</sup> Bonus has been paid in cash.

Corporate Governance

### Claw-back right relating to variable remuneration

There are no contractual provisions in place between the Company and the chief executive officer or the other member of the executive management that give the Company a contractual right to reclaim from said executives the variable remuneration that would be awarded based on erroneous financial information.

### Payments upon termination

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

entitled. The employment agreement also provides for a number of instances in which the agreement can be immediately terminated by the Company, including for cause.

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

# 3.5. Indemnification and Insurance of Directors and Executive Management

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

### 3.6. Description of share option plans

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

- 752,500 share options that were granted to employees and consultants of the Company, subject to the terms and conditions that are set out in the Stock Option Plan Regulation 2011, dated I September 2011 (the "2011 Share Options"). Each holder of 2011 share Options will only be entitled to subscribe for one (I) ordinary share when exercising all of his or her share options.
- III,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.

**sequana**medical

• I,26I,190 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 Executive Share Option will be entitled to subscribe to one (I) ordinary share when exercising one of his or her share options.

The table below provide 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 2011 Share Options, the Executive Share Options and 2018 Share Options that are held by him or her on the date of this report.

#### **Number of Shares**

Name	2011 Share Options	<b>Executive Share Options</b>	2018 Share Options
Ian Crosbie	1	216,442	40,766
Kirsten Van Bockstaele <sup>(1)</sup>	0	6,226	20,383

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

The key features of the 2011 Share Options can be summarised as follows:

- The 2011 Share Options could be granted to the employees, consultants and directors of the Company or its subsidiaries.
- The share options are in registered form.
- Exercisable share options are freely transferable.
   Share options granted to members of the board of directors, whether or not exercisable, can only be transferred after approval by the plan administrator.
- Each holder of 2011 share Options will only be entitled to subscribe for one (I) ordinary share when exercising all of his or her share options.
- The share options are granted for free, i.e. no consideration is due upon the grant of the share options.

- Unless determined otherwise by the plan administrator, the share options expire 10 years after the date of grant.
- Unless determined otherwise by the plan administrator, 25% of the share options granted vest 12 months from the date of grant, after which the balance of share options will vest in equal parts on the first calendar date of each quarter over the subsequent three years, such that 100% of the share options are vested on the fourth anniversary of the date of grant. However, there is an accelerated vesting of the share options in the event of (i) a transfer of securities possessing more than 50% of the total combined voting power of the Company's outstanding securities to a person or persons (other than purely financial investors) that are different from the persons holding those securities immediately prior to such transfer without such person(s) having at least 50% of the total combined voting power prior to such transaction; and (ii) the sale, transfer or

<sup>(</sup>I) Acting through Fin-2K BVBA.

Corporate Governance

other disposition of all or substantially all of the Company's assets (together with (i), and for the purposes of this paragraph, a "Change of Control Transaction"). Notwithstanding the above, there is no accelerated vesting if (i) the share options, in connection with the Change of Control Transaction, are either to be assumed by the successor corporation or parent thereof, or to be replaced with a similar option to purchase equity of the successor corporation or parent thereof, (ii) the share options as to be replaced with a cash incentive program of the successor corporation which preserves the economic value applicable to the share options under the 2011 SOP, or (iii) the share options are repurchased by the Company or a third party designated by the Company for a cash consideration equivalent to the economic value applicable to the share options under the 2011 SOP. Furthermore, the board of directors may decide upon an acceleration of the vesting in the event of an initial public offering of the Company, or in the event of any transaction that would result in a Change of Control Transaction. On the date of this report, the board of directors of the Company did not yet resolve upon an acceleration of the vesting of the 2011 Share Options.

- The share options of beneficiaries that are no longer employed by or in function with the Company can lapse.
- The terms of the share options are governed by the laws of Switzerland.

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 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 options. The exercise price of the Executive Share Options shall be determined by the board of directors of the Company, taking into account applicable laws.
- 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 IPO, 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 IPO 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 warrants 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 share.
- The exercise price of the 2018 Share Options shall be determined by the board of directors of the Company, taking into account applicable laws.
- The 2018 Share Options are granted for free, i.e. no consideration is due upon the grant of the 2018 Share Options, unless the grant agreement provides otherwise.
- Pursuant to Belgian company law, the 2018 Share Options have a maximum term of 10 years as of their issuance.
- Unless stipulated otherwise in the grant agreement, one third of the 2018 Share Options granted to a beneficiary shall vest one year after the date of grant, the remaining two thirds will vest in in 8 equal instalments, whereby on each first calendar day of the 8 quarters following first anniversary of the date of grant falls, I/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.

**sequana**medical

- 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 7,000 shares of the Company, none of the directors of the Company hold shares. However, 2018 Share Options have been granted to non-executive directors Mr Wim Ottevaere (10,192) and Mr Pierre Chauvineau (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 the executive management. Please see above in the section "Description of share option plans".





### **FINANCIAL REPORT**

# FOR THE FINANCIAL YEARS ENDED DECEMBER 31, 2018 AND 2017

1.	Statement of the Board of Directors	98
2.	Statutory auditor's report	99
3.	Consolidated income statement for the years ended December 31	104
4.	Consolidated statement of comprehensive income for the years ended	105
5.	Consolidated statement of financial position	106
6.	Consolidated statement of changes in equity	108
7.	Consolidated statement of cash flows	109
8.	Notes to the consolidated financial statements	110
9	Condensed statutory financial statements	159

Financial Report

**sequana**medical

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

Ian Crosbie CEO and Director

Pierre Chauvineau Chairman

Kirsten Van Bockstaele CFO entities included in the consolidation, as well as a description of the principal risks and uncertainties facing them in accordance with Article 12  $\S$  2  $3^\circ$ , 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.

# 2 STATUTORY AUDITOR'S REPORT

STATUTORY AUDITOR'S REPORT TO THE GENERAL SHAREHOLDERS' MEETING OF THE COMPANY SEQUANA MEDICAL NV ON THE CONSOLIDATED ACCOUNTS FOR THE YEAR ENDED DECEMBER 31, 2018

April 18, 2019

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. October 1, 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 December 31, 2020. We have performed the statutory audit of the consolidated accounts of Sequana Medical NV for the first year.

### 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 December 31, 2018, 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 3.341.155 and a loss for the year of EUR 13.983.224.

In our opinion, the consolidated accounts give a true and fair view of the Group's net equity and consolidated financial position as at December 31, 2018, 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 (ISAs) as approved by the IAASB for the years ending as from December 31, 2018, 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.

Financial Report sequana medical

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 in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows. The consolidated balance sheet as at 31 December 2018 shows a negative equity in the amount of EUR 18.8 million. These events or conditions as set forth in Note 4 indicate that a material uncertainty exists that may cast significant doubt on the Group's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

### 2.1.4. Key audit matters

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

### 2.1.4.1. PRESENTATION AND VALUATION OF SHARE-BASED PAYMENTS: NOTES 2.3.1.15, 2.3.2.3 AND 9

### Description of the Key Audit Matter

The Group has offered share-based compensation plans to its employees, executive management and consultants.

We consider this matter to be a key audit matter because of the significance of the expense, the fact that accounting for share-based compensation is a technically complex matter, and in view of the judgements and assumptions associated with calculating the fair value at grant date, in particular share price volatility and share price at the time of grant.

### How our Audit addressed the Key Audit Matter

We have read the board minutes, as well as the grant agreements, and assessed whether all applicable grants were disclosed and accounted for.

We have asked management to substantiate its key assumptions, including share price volatility and share price (i.e. fair value) at the time of grant.

We have validated the integrity of supporting calculations and, where applicable, corroborated information with third party sources, including share price volatility and share price at the time of grant.

We have obtained and evaluated management's sensitivity analyses to ascertain the impact of reasonably possible changes. In addition, we have performed our own independent sensitivity calculations to quantify the effect of changes to management's models.

We have found the related disclosures in the consolidated financial statements to be sufficient and appropriate.

## 2.1.4.2. RESPONSIBILITIES OF THE BOARD OF DIRECTORS FOR THE PREPARATION OF THE CONSOLIDATED ACCOUNTS

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

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

## 2.1.4.3. 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.

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

- Identify and assess the risks of material misstatement of the consolidated accounts, whether
  due to fraud or error, design and perform audit
  procedures responsive to those risks, and obtain
  audit evidence that is sufficient and appropriate
  to provide a basis for our opinion. The risk of
  not detecting a material misstatement resulting
  from fraud is higher than for one resulting from
  error, as fraud may involve collusion, forgery,
  intentional omissions, misrepresentations, or the
  override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the board of directors.
- Conclude on the appropriateness of the board of directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our statutory auditor's report to the related disclosures in the consolidated accounts or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our statutory auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the consolidated accounts, including the disclosures, and whether the consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.

**Financial Report** 

**sequana**medical

 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.

### 2.1.5. Other legal and regulatory requirements

### 2.1.5.1. RESPONSIBILITIES OF THE BOARD OF DIRECTORS

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

#### 2.1.5.2. STATUTORY AUDITOR'S RESPONSIBILITIES

In the context of our mandate and in accordance with the Belgian standard (Revised in 2018) 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 and to report on these matters.

# 2.1.5.3. ASPECTS RELATED TO THE DIRECTORS' REPORT ON THE CONSOLIDATED ACCOUNTS AND TO THE OTHER INFORMATION INCLUDED IN THE ANNUAL REPORT

In our opinion, after having performed specific procedures in relation to the directors' report on the consolidated accounts, this report is consistent with the consolidated accounts for the year under audit, and it is prepared in accordance with article 119 of the Companies' 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 and to the other information included in the annual report materially misstated or contain 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.

### 2.1.5.4. 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 134 of the Companies' Code are correctly disclosed and itemized in the notes to the consolidated accounts.

#### 2.1.5.5. OTHER STATEMENTS

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

Antwerp, April 18, 2019

The statutory auditor PwC Bedrijfsrevisoren CVBA Represented by

Peter D'hondt Réviseur d'Entreprises / Bedrijfsrevisor

### **CONSOLIDATED INCOME STATEMENT FOR THE YEARS ENDED DECEMBER 31**

In EUR	Notes	2018	2017
Revenues	5	1,029,171	1,303,975
Costs of goods sold		(158,056)	(212,427)
Gross Margin		871,115	1,091,548
Sales & Marketing		(2,444,945)	(1,506,396)
Clinical Affairs		(1,670,798)	(1,749,035)
Quality & Regulatory		(1,372,260)	(1,225,319)
Supply Chain		(964,182)	(1,040,672)
Engineering		(1,808,386)	(1,004,312)
General & administration	7.2	(5,760,912)	(1,987,813)
Other income		73,726	3,563
Total Operating Expenses		(13,947,757)	(8,509,982)
Earnings before interests and taxes (EBIT)		(13,076,642)	(7,418,434)
Finance income	7.4	309,200	107,053
Finance cost	7.4	(1,192,231)	(895,458)
Net Finance Cost		(883,031)	(788,405)
Income Tax Expense	7.5	(23,551)	(18,350)
Net loss for the period		(13,983,224)	(8,225,189)
Attributable to Sequana shareholders		(13,983,224)	(8,225,189)
Basic Loss per share	7.6	(1.40)	(0.88)

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

### **CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME FOR THE YEARS ENDED**

In EUR	Notes	2018	2017
Net loss for the period		(13,983,224)	(8,225,189)
Components of other comprehensive income (OCI) items that will not be reclassified to profit or loss:			
Remeasurements of defined benefit plans	8.7	102,253	129,225
		102,253	129,225
Items that may be reclassified subsequently to profit or loss:			
Currency translation adjustments		(76,480)	509,804
		(76,480)	509,804
Total other comprehensive income/(loss)-net of tax		25,773	639,029
Total comprehensive income		(13,957,451)	(7,586,160)
Attributable to Sequana shareholders		(13,957,451)	(7,586,160)

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

# **CONSOLIDATED STATEMENT OF FINANCIAL POSITION**

In EUR	Notes	Dece	Total mber 31, 2018	Dece	Total mber 31, 2017
Property, Plant and Equipment			183,697		205,955
Laboratory	8.4	5,768		9,795	
Information Technology (IT)	8.4	138,234		185,830	
RD Tools	8.4	7,421		10,330	
Assets under construction	8.4	32,274			
Financial assets			58,008		41,745
Financial assets - Rental deposit		58,008		41,745	
Loans to related parties		-		-	
Total non-current assets			241,705		247,699
Trade Receivables			96,608		164,622
Trade Receivables - Third Parties		96,608		164,622	
Other Receivables			449,719		152,256
Other Receivables - Third parties		333,347		129,751	
Other Receivables - Related Parties		-		9,147	
Other Receivables - prepaid expenses		116,372		13,358	
Inventory			1,235,426		1,270,803
Inventory	8.3	1,235,426		1,270,803	
Cash and cash equivalents			1,317,697		1,683,828
Cash and cash equivalents	8.1	1,317,697		1,683,828	
Total current assets			3,099,450		3,271,509
TOTAL ASSETS			3,341,155		3,519,208

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

In EUR			Total ember 31, 2018	Dece	Total ember 31, 2017	
Total Equity			(18,759,747)		(4,610,672)	
Share Capital	8.5	887,977		954,577		
Other equity	8.6	184,478				
Own shares		_		(193,275)		
Share premium		64,963,284		65,156,559		
Reserves		(451,653)		(182,510)		
Loss brought forward		(85,003,302)		(71,081,972)		
Cumulative Translation Adjustment		659,469		735,948		
Long term financial debts			2,582,087		1,757,267	
Long term financial debts	8.6	2,582,087		1,757,267		
Retirement benefit obligation			792,225		818,583	
Retirement benefit obligation	8.7	792,225		818,583		
Total non-current liabilities			3,374,312		2,575,850	
Short term financial debts			12,072,571		2,820,494	
Short term financial debts	8.6	12,072,571		2,820,494		
Trade Payables			2,753,183		2,012,131	
Trade Payables - Third parties	8.8	1,907,992		908,911		
Contract liabilities	5	845,191		1,103,220		
Other payables			1,095,136		270,487	
Other payables - Third parties		1,095,136		270,487		
Accrued liabilities			2,805,700		450,919	
Accrued liabilities - Provision warranty	8.8	67,090		29,227		
Accrued liabilities - Third Parties	8.8	2,738,610		421,692		
Total current liabilities			18,726,590		5,554,031	
TOTAL EQUITY AND LIABILITIES			3,341,155		3,519,208	

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

# 6 CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

							Loss	Currency trans- lation	Total
In EUR	Notes	Share capital	Other Equity	Own shares	Share premium	Reserves	brought forward	differ- ences	shareholder equity
December 31, 2016		859,985	-	-	55,437,784	(334,683)	(62,856,783)	226,144	(6,667,553)
Net loss							(8,225,189)		(8,225,189)
Other compre- hensive income	8.7					129,225		509,804	639,029
Capital increase (net of costs)	8.5	94,592			9,718,775	-			9,813,367
Acquisition of own shares (non-cash trans-	0.5			(100.075)					(100.075)
action)	8.5			(193,275)					(193,275)
Share-based compensation	9					22,948			22,948
December 31, 2017		954,577	-	(193,275)	65,156,559	(182,510)	(71,081,972)	735,948	(4,610,672)
Net loss							(13,983,224)		(13,983,224)
Other compre- hensive income	8.7					102,253		(76,480)	25,773
Capital increase (net of costs)	8.5	1,591							1,591
Liquidation own shares	8.5			193,275	(193,275)				-
Conversion share capital into EUR	8.5	(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
December 31, 2018		887,977	184,478	0	64,963,284	(451,653)	(85,003,302)	659,468	(18,759,747)

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

# CONSOLIDATED STATEMENT OF CASH FLOWS

In EUR	Notes	2018	2017
Net loss for the period		(13,983,224)	(8,225,189)
Income tax expense	7.5	23,551	18,350
Financial result	7.4	883,031	788,405
Depreciation		80,768.6	77,911
Change in defined benefit plan	8.7	43,388	63,950
Share-based compensation	9	240,555.0	22,948
Changes in trade and other receivables		(77,090)	145,576
Changes in inventories	8.3	79,999.5	555,963
Changes in trade and other payables /provisions	8.8	2,838,674	(1,807,495)
Taxes paid		(4,999)	(18,350)
Cash flow from operating activities		(9,875,346)	(8,377,931)
Investments in tangible fixed assets	8.4	(38,622)	(6,516)
Investments in financial assets		(16,263)	(3,788)
Cash flow used for investing activities		(54,885)	(10,304)
Proceeds from capital increase	8.5	1,591	9,814,516
Proceeds from financial debts	8.6	9,583,315	-
Interest paid	8.6	(115,440)	(314,329)
Cash flow from financing activities		9,469,466	9,500,187
Net change in cash and cash equivalents		(460,765)	1,111,952
Cash and cash equivalents at the beginning of the year (1 January)		1,683,828	797,457
Net effect of currency translation on cash and cash equivalents		94,634	(225,581)
Cash and cash equivalents at the end of the year (31 December)		1,317,697	1,683,828

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

# 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/sociéte 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 I, 2018). As a result, the Sequana Medical NV became a limited liability company organised under the laws of Belgium.

As from October I, the registered office's address is Technologiepark I22, AA Tower, 9052 Ghent, Belgium. Sequana is a commercial stage medical device company and an innovator in the management of liver disease. 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 commercialisation 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.

### Group information

#### Information about the subsidiaries

The consolidated financial statements of Sequana Group include:

Company	Purpose	Share capital	Investment 2018	Investment 2017
Sequana Medical NV	Holding/Sales	EUR 887,977	n/a	n/a
Sequana Medical branch (Switzerland)	Production and research	n/a	n/a	n/a
Sequana Medical GmbH (Germany)	Distribution	EUR 29,450	100%	100%
Sequana Medical Inc. (USA)	Administration	USD 0	100%	100%

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

### The holding company

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

### Shareholders with influence over the Group:

Shareholders' interest (%)	As of December 31 2018
NeoMed IV Extension / Innovation V	35.93%
LSP Health Economics Fund Management	10.85%
Venture Incubator	10.01%
Entrepreneurs Fund	8.75%
BioMedInvest	8.22%
Capricorn Health-tech Fund	8.09%
Others (each below 3%)	18.16%
Total	100 00%

# 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 17 April 2019.

### 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 rick

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 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

Financial Report

necessarily correspond to the functional currency of the parent. The functional currencies as per 31.12.2018 are as follows:

• Sequana Medical NV : EUR

Sequana Medical branch: CHFSequana Medical Gmbh: EUR

• Sequana Medical Inc : USD

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

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

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

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

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

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

sold, the associated exchange differences are reclassified to profit or loss, as part of the gain or loss on sale.

The following foreign exchange rates, which were applied for the consolidated financial statements at 31 December 2018 and the comparative periods to translate the following currencies into EUR, are as follows:

Currency	December 31, 2018		Decem	nber 31, 2017
		Aver-		Aver-
	Year-	age	Year-	age
	end	Rate	end	Rate
Swiss Franc (CHF)	1.1269	1.1550	1.1702	1.1116
US Dollar (USD)	1.1450	1.1810	1.2008	1.1289

### 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. Cost 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.

**sequana**medical

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

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

#### 2.3.1.7. TRADE RECEIVABLES

In accordance with IFRS 9, trade receivables are classified and measured at amortised cost. The measurement bases are contractual terms, payment history and other sales evidence. Adjustments for doubtful receivables are only allowed to the extent losses are expected in the future or individually determinable. Any losses caused by amortization of receivables are booked in income statements. The Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables. To measure the expected credit losses, trade receivables have been grouped based on shared credit risk characteristics and the days past due. The historical loss rates are adjusted to

**Financial Report** 

**sequana**medical

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 are rated AA.

#### **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:

- the Group has a present legal or constructive obligation as a result of past events;
- it is probable that an outflow of resources will be required to settle the obligation; and
- 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 detailed formal plan identifying the main features of the restructuring; and
- 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

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 Group has no further payment obligations once the contributions have been paid. 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 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 amortised cost, using the effective interest method. Non-equity derivatives (if any) that are not closely related to the host debt contract are accounted for separately and subsequently measured at fair value. Equity components are not remeasured subsequently.

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:

 both the liability (host contract) and embedded derivative are classified at FVTPL (fair value through Profit and Loss)

or

2) the derivative is split and shown separately and accounted for at FVTPL (fair value through Profit and Loss) while the liability part (host contract) is valued at amortised cost.

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

The Group has elected to apply the method I):

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 remeasurement 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 amortised cost, i.e. at the net present value of the payable amount. Unless the impact of discounting is material, the nominal value is taken.

### 2.3.1.15. 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 recognised in the income statement over the remaining vesting period with a corresponding adjustment to equity.

When the options are exercised, the proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium.

The social security contributions payable in connection with the grant of the options are considered as a part of the grant itself.

#### 2.3.1.16. 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.

#### 2.3.1.17. EARNINGS 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 2018 and 2017 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 Report

financial years, are also described in the individual notes of the related financial statement line items in section 6.

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 tax, pension liabilities or provisions 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 I: 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 the 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 2018 and 31 December 2017:

Description	EUR denominated convertible loans at fair value through PL
Note	8.6
Level	3
At 31 December 2018 in EUR	7,882,397
At 31 December 2017 in EUR	0

The carrying amounts of other financial instruments that are not measured subsequently at fair value are not materially different from their fair values due to their nature.

#### Valuation techniques used to determine fair values

The fair value of the company's convertible loans is determined using discounted cash flow analysis, based on interest rate of 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.

**sequana**medical

Financial Report

#### Valuation inputs and relationships to fair value

The following table 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
Class of subsequent measurement	Fair value through profit or loss
Fair value at 31 Dec. 2018	7,882,397
Unobservable inputs	Discount rate / market rate
Input range (probability-weighted average)	10%-14% (12%)
Relationship of unobservable inputs to fair value	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. 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.

# 2.3.3. Issued standards, amendments or interpretations adopted and not yet adopted

### IFRS accounting standards to be adopted as from 2018 onwards

The following amendments and annual improvements to standards are mandatory for the first time for the financial year beginning I January 2018 and have no material impact on Sequana Group financial statements:

IFRS 9, 'Financial instruments' (effective I January 2018). This standard, which covers financial instruments on both the asset as well as the liability side, describes the criteria for recognition, classification and derecognition of such instruments, in addition to the allowed measurement methods. The Group has adopted IFRS 9 Financial instruments as from I January 2018. IFRS 9 replaces the provisions of IAS 39 that relate to the recognition, classification and measurement of financial assets and financial liabilities, derecognition of financial instruments, impairment of financial assets and hedge accounting. The adoption of IFRS 9 did not result in any in changes in terms of measurement of financial assets and financial liabilities but impacted accounting policies regarding the methodology used for impairment of financial assets whereby the Group has adopted the new expected credit loss model. However, such change of methodology did not lead to any adjustments to the amounts recognised in the financial statements as per 31 December 2017. The new accounting policies regarding the impairment

of financial assets are set out in note 2.3.1.7. As there was no impact on the amounts recognised in the financial statements as per 31 December 2017, the opening equity as per 1 January 2018 was not impacted by the adoption of IFRS 9.

IFRS 15, 'Revenue from contracts with customers' (effective I January 2018). The IASB and FASB have jointly published a standard regarding revenue from contracts with customers. The standard will result in better financial reporting and will improve the comparability of the top line in financial statements globally. Companies using IFRS are be required to apply the revenue standard for annual periods beginning on or after I January 2018.

IFRIC 22,' Foreign currency transactions and advance consideration (effective I January 2018): 'This IFRIC addresses foreign currency transactions or parts of transactions where there is an advance consideration that is denominated or priced in a foreign currency. The interpretation provides guidance for when a single payment/receipt is made as well as for situations where multiple payments/receipts are made. The guidance aims to reduce diversity in practice.

Amendments to IFRS 2, Share-based payments (effective I January 2018): The amendment clarifies the measurement basis for cash-settled payments and the accounting for modifications that change an award from cash settled to equity settled. It also introduces an exception to the principles in IFRS 2 that will require an award to be treated as if it was wholly equity-settled, where an employer is obliged to withhold an amount for the employee's tax obligation associated with a share-based payment and pay the amount to the tax authorities.

### IFRS accounting standards to be adopted as from 2019 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 I, 2019, 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:

IFRS 16, 'Leases' (effective I 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 recognise 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.

The Group is currently assessing the impact of the new standard. As at December 31, 2018, the Group had non-cancellable (undiscounted) operating lease commitments of 426,268 EUR.

The Group will opt for the modified retrospective transition method where no re-assessment will be done for lease contracts entered into before January 1st, 2019. The Group has elected to apply the following practical expedients: the standard will not be applied on short term and low value leases < 5,000 EUR.

If the standard would have been adopted before January 1st, 2019, the impact on balance sheet and PL would have been an increase of the financial liabilities with EUR 207,257, an increase in the net tangible assets amounting to EUR 239,007 and an increase in the retained earnings amounting to EUR 31,750.

Amendments to IFRS 9, 'Prepayment features with negative compensation' (effective I January 2019 with the EU). An amendment to allow companies to measure particular prepayable financial assets with so-called negative compensation at amortised 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

Financial Report

**sequana**medical

would otherwise fail the SPPI-test. In addition, this amendment clarifies an aspect of the accounting for financial liabilities following a modification.

The Group is currently assessing the impact of the new standard. The Group expects no material impact on the Sequana Group financial statements.

IFRIC 23, 'Uncertainty over income tax treatments' (effective I 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.

The Group is currently assessing the impact of the new standard. The Group expects no material impact on the Sequana Group 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.

# 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 monetary assets and monetary liabilities in CHF at the end of the reporting period are as follows:

	31.12.2018 CHF
Assets	
Inventory	1,394,631
Cash and cash equivalents	48,203
Liabilities	
Long term debt	2,757,788
Short term debt	3,103,879

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:

**Financial Report** 

### Impact on income statement and equity

(EUR)	As at 31 December 2018	As at 31 December 2017
5% decrease of average foreign exchange rate	-302,431	-395,000
5% increase of average foreign exchange rate	+302,424	380,000

As of 31 December 2018, 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 302,431 EUR higher (2017: 395,000 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 302,424 EUR lower (2017: 380,000 EUR).

### 3.1.2. Interest rate risks

Interest rate risks arise from changes in interest rates, which have negative repercussions on the Group's asset and earnings situation. Interest rate fluctuations lead to changes in interest income and interest expense on interest-bearing assets and liabilities.

The following table shows the sensitivity to interest rate changes, with all other variables held constant, of the Group's income statement and equity:

### Impact on income statement and equity

(EUR)	As at 31 December 2018	As at 31 December 2017
50 basis points increase/		
decrease	+/-33,866	+/-21,500

### 3.2. Liquidity risk

The Group's objective is to maintain sufficient cash and the availability of funding through an adequate amount of committed credit facilities to meet obligations when due. Sequana defines Liquidity risk, a risk of being unable to raise funds to meet payment obligations when they fall due.

### Cash outflows

(EUR)	CARRYING AMOUNT 31.12.2018	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		
Total	18,502,977	18,502,977	15,919,768	2,583,209	

#### Cash outflows

(EUR)	CARRYING AMOUNT 31.12.2017	Total	Up to 1 year	1 to 3 years	More than 3 years
Trade payable	2,012,131	2,012,131	2,012,131		
Other payables	270,487	270,487	270,487		
Financial debt at amortized costs	4,577,161	4,577,161	2,820,494	1,757,267	
Interest payment on financial debt	0	605,000	500,000	105,000	
Total	6,859,778	7,464,778	5,603,111	1,862,267	-

### 3.3. Capital Management

Management presently monitors its capital structure based on its legal, statutory requirements for standalone 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 2018 and 2017.

### 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 in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows. 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 2018 shows a negative equity in the amount of EUR 18.8 million. The Company signed a Convertible Loan Agreement with existing Shareholders in February 2018, which guarantees liquid funds of EUR 1.7 million (CHF 2 million) in total. Three additional convertible loan agreements have been signed in June 2018 (EUR 1.7 million), July 2018 (EUR 2 million) and August 2018 (EUR 0.5 million)

with new investors. In October and December, additional funds amounting to EUR 2.6 million and EUR 1.0 million have been raised.

In the meantime, the Company successfully launched its Initial Public Offering (IPO) and as a result of that, the board of directors remains confident that the liquidity requirements for 2019, estimated to be EUR 14.8 million (CHF 17.1 million) can be secured. The Company continues to evaluate equity financing options, including discussions with existing and/or new investors. Based on the above, the executive management and the board of directors remain confident about the strategic direction, comprising financing measures such as additional financing rounds or capital market transactions, and therefore consider the preparation of the present financial statements on a going concern basis as appropriate.

We refer for more details about the IPO 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	2018	2017
Trade receivables	96,608	164,622
Contract liabilities (relating to customers' advance		
payments)	845,191	1,103,220

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	2018	2017
Revenue recognized in the period (included in contract liability at the beginning of the period)	(272,511)	(394,947)
Increases due to cash received as advance payment	-	117,865
Effect of currency translation	14,482	(40,401)

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.

**Financial Report** 

### 6. Segment information

Operating segments requiring 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	2018	2017
Switzerland	54,734	125,228
Germany	584,175	764,175
UK	67,966	68,448
Rest of the world	322,296	346,124
Total revenue	1,029,171	1,303,975

All revenue is recognized at a point in time, being when the device has been implanted into the patient.

As the Swiss branch is the sole operating entity within the Group, the majority of the assets (94%) are located in Switzerland. 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         2018         2017           Personnel costs         5,383,863         4,156,440           Clinical Studies         934,798         1,173,775           External         2018         1,173,775           External         2,275,799         548,468           External accounting         4,156,440           External accounting         2,275,799         548,468           External accounting         2,532,090         522,740           Travel & Lodging         577,537         478,825           Rent & infrastructure         407,572         377,787           Intellectual Property         188,996         177,039           Insurance & IT         219,669         132,212           Marketing         347,927         99,538           Depreciation and amortization(1)         21,967         77,911           Quality Audits / Regulatory Fees         161,383         77,642           Other         931,181         687,604           Total operating expenses         13,982,782         8,509,982			
Clinical Studies 934,798 1,173,775  External consultancy 2,275,799 548,468  External accounting & legal services 2,532,090 522,740  Travel & Lodging 577,537 478,825  Rent & infrastructure expenses 407,572 377,787  Intellectual Property 188,996 177,039  Insurance & IT 219,669 132,212  Marketing 347,927 99,538  Depreciation and amortization(1) 21,967 77,911  Quality Audits / Regulatory Fees 161,383 77,642  Other 931,181 687,604  Total operating 13,982,782 8,509,982	In EUR	2018	2017
External consultancy 2,275,799 548,468  External accounting & legal services 2,532,090 522,740  Travel & Lodging 577,537 478,825  Rent & infrastructure expenses 407,572 377,787  Intellectual Property 188,996 177,039  Insurance & IT 219,669 132,212  Marketing 347,927 99,538  Depreciation and amortization(1) 21,967 77,911  Quality Audits / Regulatory Fees 161,383 77,642  Other 931,181 687,604  Total operating 13,982,782 8,509,982	Personnel costs	5,383,863	4,156,440
consultancy         2,275,799         548,468           External accounting & legal services         2,532,090         522,740           Travel & Lodging         577,537         478,825           Rent & infrastructure expenses         407,572         377,787           Intellectual Property         188,996         177,039           Insurance & IT         219,669         132,212           Marketing         347,927         99,538           Depreciation and amortization(1)         21,967         77,911           Quality Audits / Regulatory Fees         161,383         77,642           Other         931,181         687,604           Total operating         13,982,782         8,509,982	Clinical Studies	934,798	1,173,775
& legal services       2,532,090       522,740         Travel & Lodging       577,537       478,825         Rent & infrastructure expenses       407,572       377,787         Intellectual Property       188,996       177,039         Insurance & IT       219,669       132,212         Marketing       347,927       99,538         Depreciation and amortization(1)       21,967       77,911         Quality Audits /       Regulatory Fees       161,383       77,642         Other       931,181       687,604         Total operating       13,982,782       8,509,982	=/11011101	2,275,799	548,468
Rent & infrastructure expenses       407,572       377,787         Intellectual Property       188,996       177,039         Insurance & IT       219,669       132,212         Marketing       347,927       99,538         Depreciation and amortization <sup>(1)</sup> 21,967       77,911         Quality Audits / Regulatory Fees       161,383       77,642         Other       931,181       687,604         Total operating       13,982,782       8,509,982	•	2,532,090	522,740
expenses         407,572         377,787           Intellectual Property         188,996         177,039           Insurance & IT         219,669         132,212           Marketing         347,927         99,538           Depreciation and amortization <sup>(1)</sup> 21,967         77,911           Quality Audits / Regulatory Fees         161,383         77,642           Other         931,181         687,604           Total operating         13,982,782         8,509,982	Travel & Lodging	577,537	478,825
Insurance & IT 219,669 132,212  Marketing 347,927 99,538  Depreciation and amortization <sup>(1)</sup> 21,967 77,911  Quality Audits /  Regulatory Fees 161,383 77,642  Other 931,181 687,604  Total operating 13,982,782 8,509,982		407,572	377,787
Marketing 347,927 99,538  Depreciation and amortization <sup>(1)</sup> 21,967 77,911  Quality Audits /  Regulatory Fees 161,383 77,642  Other 931,181 687,604  Total operating 13,982,782 8,509,982	Intellectual Property	188,996	177,039
Depreciation and amortization <sup>(1)</sup> 21,967 77,911  Quality Audits /  Regulatory Fees 161,383 77,642  Other 931,181 687,604  Total operating 13,982,782 8,509,982	Insurance & IT	219,669	132,212
amortization <sup>(1)</sup> 21,967 77,911  Quality Audits /  Regulatory Fees 161,383 77,642  Other 931,181 687,604  Total operating 13,982,782 8,509,982	Marketing	347,927	99,538
Regulatory Fees     161,383     77,642       Other     931,181     687,604       Total operating     13.982,782     8.509,982	•	21,967	77,911
Total operating 13.982.782 8.509.982		161,383	77,642
10.902.702 0.009.902	Other	931,181	687,604
		13,982,782	8,509,982

### 7.2. Operating Expenses – General and Administration

Expenses in EUR	2018	2017
IPO related expenses	2,445,467	-

The total amount of known and accrued IPO related expenses is 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. Operating leases

The German subsidiary and Sequana Medical NV have entered into various lease contracts to lease cars for its employees which are classified as operating leases. Sequana Medical NV has operating building leases as well.

The lease commitment as per December 31, 2018 amounts to EUR 426,268 (2017: EUR 361,549) and the operating lease charge in 2018 amounts to EUR 197,678 (2017: EUR 20,109).

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

### 7.4. Financial result

The financial result is split into the following categories:

In EUR	2018	2017
Finance income	309,200	107,053
Interest income	10	11
Foreign exchange gains	309,190	107,042
Finance cost	(1,192,231)	(895,458)
Interest costs	(921,956)	(635,512)
Foreign exchange losses	(270,274)	(259,946)
Net financial result	(883,031)	(788,405)

### 7.5. Income taxes

#### Income tax expense

(EUR)	2018	2017
Current income taxes	(23,551)	(18,350)
Total income tax expense	(23,551)	(18,350)

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

(EUR)	2018	2017
Loss before tax	(13,586,785)	(8,206,838)
Applicable tax rate	20.0%	20.0%
Income tax income at the applicable tax rate	2,717,357	1,641,368
Effect of non-recognition of tax losses in current		
year	(2,693,806)	(1,659,718)
Effective income tax expense	(23,551)	(18,350)

The applicable tax rate is the domestic rate of tax in Switzerland. No income tax was applicable for any items recorded directly in equity or OCI.

As from the transfer of seat (October 1st, 2018), the applicable tax rate will be the Belgian tax rate with the Swiss tax rate still applicable to the Swiss branch.

#### Taxes on unremitted earnings

At 31 December 2018 and 2017, there was no recognized deferred tax liability for taxes that would be payable on the unremitted earnings of certain of the Group's subsidiaries. The Group does not expect any distribution of retained earnings to the parent company within the next twelve months.

### Deductible temporary differences and available tax loss carry – forwards

Deductible temporary differences and unused tax losses for which no deferred tax asset has been recognized:

In EUR	December 31, 2018	December 31, 2017
Deferred tax assets not recognised on deductible temporary differences	(259,579)	(349,108)
Deductible temporary differences for which no deferred tax asset has been recognised	1,297,896	1,745,543
Belgium	693,417	-
Switzerland	70,203,667	61,374,975
USA	617,785	617,785
Total unused tax losses	71,514,869	61,992,760

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).

On December 14, 2018, 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 is due. The tax exit fee is calculated taking into account a value upon exit representing 75% of the IPO value, corrected with certain elements. Subject to further verification and the approval of the tax authorities, it is expected that

neither direct taxes or withholding taxes will be due. There is also agreed that a tax rate of 10% will be applicable as from 2019 on the expenses registered in the Swiss branch.

### 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) and has certain convertible loans (see note 8.6), 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)	2018	2017
Net loss attributable to shareholders	(13,983,224)	(8,225,189)
Weighted average number of shares – basic	9,999,366	9,327,947
Basic earnings per share	(1.40)	(0.88)

Financial Report

### lical 135

## 8. Detailed information on balance sheet items

### 8.1. Cash and cash equivalents

The Group held cash and cash equivalents of EUR 1,317,697 at 31 December 2018 (2017: EUR 1,683,823). The cash is held with bank and financial institutions which are rated AA. All investments are highly liquid.

### 8.2. Trade receivables

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 2018 and 2017 past due, but not impaired, are as follows:

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

2017 (EUR)	Trade receivables	Weighted average loss rate
Not past due	78,941	0%
Total past due	85,681	
0-90 days	24,075	
90-180 days	26,606	
180-360 days	15,000	
More than 360 days	0	

### 8.3. Inventories

Inventories are categorized as follows:

In EUR	December 31, 2018	December 31, 2017
Finished goods	296,166	224,751
Subassembly	63,076	696,487
Components	876,184	349,565
Total	1,235,426	1,270,803

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)	Laboratory	IT	RD Tools	Assets under construction	Total
At December 31, 2016	25,541	382,732	19,033	-	427,307
Additions	-	6,516	-		6,516
Currency translation effects	(2,142)	(32,429)	(1,596)		(36,167)
At December 31, 2017	23,399	356,819	17,437	-	397,656
Additions	3,283	(46,016)	4,110	32,274	(38,622)
Currency translation effects	979	12,547	772		14,299
At December 31, 2018	27,662	323,351	22,320	32,274	405,607

Accumulated depreciation (in EUR)	Laboratory	IT	RD Tools	Assets under construction	Total	
At December 31, 2016	9,376	114,813	4,333	-	128,522	
Additions	5,398	69,210	3,304		77,911	
Currency translation effects	(1,170)	(13,034)	(529)		(14,732)	
At December 31, 2017	13,604	170,989	7,108	-	191,701	
Additions	7,721	6,956	7,290		21,967	
Currency translation effects	570	7,172	501		8,242	
At December 31, 2018	21,895	185,117	14,899	-	221,910	
Net book value December 31, 2017	9,795	185,830	10,330	_	205,955	
Net book value December 31, 2018	5,768	138,234	7,421	32,274	183,697	

Financial Report sequana medical

### 8.5. Share capital

The share capital per 31 December 2017 is represented by 6,746,244 preferred shares of nominal CHF 0.10 per share and 3,283,641 common shares of nominal CHF 0.10 per share, all fully paid-in.

	Shares	Nominal value in CHF	Share capital in CHF	Share capital in EUR
31 December 2016	8,980,267	0.10	898,027	859,985
Capital increase of preference shares	1,049,618	0.10	104,962	94,592
31 December 2017	10,029,885	0.10	1,002,989	954,577
Capital increase through the exercise of options	18,468	0.10	1,847	1,591
Liquidation own shares	(117,569)	-	0	-
Conversion share capital in EUR	0	-	0	(68,191)
31 December 2018	9,930,784		1,004,835	887,977

In 2017, due to the passing of the former CEO, the Company signed a settlement agreement with the wife of the former CEO, in relation to among others the outstanding payment of wages, severance and bonuses for a total amount of USD 308,446. In addition, the Company signed a stock option and share purchase agreement with the wife of the former CEO to acquire his 117,569 common Shares and 90,845 Share options by offsetting outstanding payables by the Group in the amount of CHF 226,161.

As of 31 December 2018, the Group does not hold any treasury Shares. Prior to the Belgian Seat Transfer, the Group held 117,569 of its own Shares as treasury stock, consisting of 107,196 common

Shares, 4,773 series B preferred Shares, 1,600 series C preferred Shares and 4,000 series D Preferred Shares.

These Shares were acquired in 2017 from the estate of the former chief executive officer, as indicated above. All of the treasury shares were cancelled on I October 2018, immediately following the Belgian Seat Transfer, in order to simplify the Group's capital structure with no impact on the share capital amount.

On I October 2018, the shareholders' meeting decided to convert the share capital from CHF I,004,835.30 into EUR 887,977.47. This conversion resulted in a loss amounting to EUR 68,191 due to the applied foreign currency rate at that moment.

	Common shares	Preference A shares	Preference B shares	Preference C shares	Preference D shares	Preference E shares	Total
31 December 2016	3,283,641	543,682	2,176,662	2,195,850	780,432	-	8,980,267
Capital increase of preference shares			(4,774)	(469,913)	(574,931)	2,099,236	1,049,618
31 December 2017	3,283,641	543,682	2,171,888	1,725,937	205,501	2,099,236	10,029,885
Capital increase through the exercise of options	18,468						18,468
Liquidation treasury shares	(107,196)		(4,773)	(1,600)	(4,000)	-	(117,569)
31 December 2018	3,194,913	543,682	2,167,115	1,724,337	201,501	2,099,236	9,930,784

The share capital of the Company is EUR 887,977.

It is 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. The share capital is fully paid-in.

In addition, there are a number of outstanding Convertible Loans that are convertible into series E preferred Shares, a number of Bridge Loans that will be converted into New Shares upon the closing of the Initial Public Offering (IPO), and a number of outstanding Share options that are exercisable for common Shares and series E preferred Shares

The preferred shares are not redeemable and there is no mandatory dividend attached to the preferred shares. Each common and preferred share shall entitle one vote.

Certain of the currently outstanding preferred Shares benefit from special governance rights (such as in relation to the appointment of candidate directors and special majorities for decisions by the board of directors and the general shareholders' meeting). In addition, all of the preferred Shares benefit from a specific priority in case of Share transfers and in case of certain liquidity events such as a bankruptcy, liquidation or winding-up of the Company, a sale of the Group, a sale or divestment of all or substantially all of the assets of the Company, or a merger or consolidation of the Company. The preference will also be triggered upon closing of the Offering (IPO) and will result 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 Overallotment Option).

In the event of (each a "Liquidity Event")

- a) voluntary or involuntary liquidation, dissolution, winding up or bankruptcy of the Company;
- b) any sale, lease, transfer license or other disposition of all or substantially all of the Company's assets;
- c) any transformation of the Company, including separation and merger of the Company, except when the shareholders will hold more than 50% of the surviving/acquiring company and their rights provided for hereunder are maintained;
- d) a subscription of shares in the frame-work of an initial public offering;

The liquidation, sale and transformation proceeds shall be distributed as follows:

- a) firstly, the series E preferred Shares will have a priority for a value of up to three times CHF 10.48 per series E preferred Share, then:
- b) secondly, the series D preferred Shares will have a priority for a value of up to the aggregate subscription price paid for the series D preferred Shares; then
- c) thirdly, the series C preferred Shares will have a priority for a value of up to the aggregate subscription
- d) price paid for the series C preferred Shares; then
- e) fourthly, the series B preferred Shares will have a priority for a value of up to half of the aggregate subscription price paid for the series B preferred Shares; then
- f) fifthly, the series A preferred Shares will have a priority for a value of up to half of the aggregate subscription price paid for the series A preferred Shares; and
- g) finally, any remaining value would accrue to the common Shares and preferred Shares on a pro rata basis.

Dividends, if any, shall be distributed in accordance with the distribution water-fall set out above until the aggregate distributions to holders of a class of shares is equal to the amount they would receive in case of a Liquidity Event. Distributions to the next junior ranking class of shares shall be made only thereafter.

38 Financial Report

**sequana**medical

In case of an initial public offering in the sense of a "Liquidity Event" as described above, the liquidation preferences will be achieved through a transfer of shares between the existing shareholders considering the dilution principle as described before and upon an IPO each preference share would be converted into one common share.

The right of the Board of Directors to increase the share capital has expired by 24 April 2018.

#### Conditional capital as per December 31, 2018:

Conditional capital available for the exercise of options granted to employees and members of the Board of Directors: EUR 42.721 (485.464 common shares at nominal value of CHF 0.10/EUR 0.088 per share).

Conditional capital available for the exercise of option rights that are granted to lenders of Venture Debt Financing: EUR 12,496 (142,000 preference E shares at nominal value of CHF 0.10/EUR 0.088 per share).

Conditional capital available for the exercise of options granted to investors of strategic importance: CHF 8,317.30 (83,173 preference E shares at nominal value of CHF 0.10 per share).

In 2018 and 2017, Sequana did not pay any dividends to shareholders.

### 8.6. Financial debts / Net debt

### 8.6.1. Loan agreement with Bootstrap

In 2016, the Group has entered into a loan agreement with Bootstrap Europe S.C.Sp to grant a loan facility of max. CHF 10 million. A first drawdown of CHF 5 million (EUR 4.7 million) was made in 2016. The loan has to be fully repaid within 36 months from the drawdown date, i.e. is due in 2019. However, the Company may repay on any repayment date any outstanding advance. The interest is 12% per annum and is payable over the period as agreed between both parties.

In 2017, the loan agreement was amended and both parties agreed that the second advance of CHF 5 million would be cancelled.

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. The Intellectual Property has not been capitalized.

On October 1, 2018, the agreement for the Bootstrap Loan was further 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. As disclosed in the subsequent event note 15, the final amount repaid based on the gross proceeds of EUR 27,500,089 was EUR 1,375,004 (CHF 1,560,768). As a result, this amount has been presented in the 2018 consolidated financial statements as short-term debt.

In addition, Sequana Medical granted Bootstrap additional rights to subscribe to new shares in the Company. The New Shares in the Offering can 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. As provided for by the Bootstrap Loan, the Exit Fee Amount shall not exceed a maximum of CHF 750,000. The exit fee mentioned above shall be settled by issuance of

common shares of Sequana Medical at the time of the Offering and does not result in an increase of the contractually agreed cash flows.

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, these amounts 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 I January 2018 through 31 October 2018 amounting to EUR 0.41 million will be due at the time of the Offering, including the balance of unpaid interest from I May 2017 to 31 December 2017 in the amount of EUR 0.44 million to be 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

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 are 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.

Financial Report sequenamedical

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

### 8.6.3. Convertible loans denominated in EUR

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

The following conversion options are 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 are 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 II 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 are 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 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 November 2,2018 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

143

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	2018	2017
Cash and cash equivalents	1,317,697	1,683,828
Borrowings - repayable within one year	(12,072,571)	(2,820,494)
Borrowings - repayable after one year	(2,582,087)	(1,757,267)
Net financial debt	(13,336,961)	(2,893,933)

in EUR	Cash and cash equivalents	Borrowings due within 1 year	Borrowings due after 1 year	Total
Net financial debt as per 31 December 2017	1,683,828	(2,820,494)	(1,757,267)	(2,893,933)
Cash flows	(460,765)	(9,583,315)		(10,044,080)
Accrued interest (non-cash)		(334,598)		(334,598)
Transfer (non-cash)		738,847	(738,847)	0
Foreign exchange impact (non-cash)	94,634	(73,011)	(85,973)	(64,350)
Net financial debt as per 31 December 2018	1,317,697	(12,072,571)	(2,582,087)	(13,336,961)

The convertible loans are presented in the balance sheet as follows:

In EUR	31 December 18	31 December 17
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	5,205,058	4,577,761
Total short term and long term debt	14,654,658	4,577,761

 $<sup>\</sup>hbox{(I)} \quad \text{Interest expense calculation based on the effective interest rate of 12.0\% to the liability component } \\$ 

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

#### 8.7. Post-employment benefits

The Group operates different employee benefit plans: Whilst the pension plans in Germany is a defined contribution plan, Sequana operates a defined benefit plan in Switzerland. The defined benefit obligation is determined applying the projected unit credit method. Related plan assets are measured at fair value.

Reconciliation of the amounts recognised in the

Datatice Stieet	December 31, 2016	December 31, 2017
Defined benefit obligation	2,478,405	2,833,898
Fair value of plan assets	1,686,189	2,015,315
Deficit	792,217	818,583
Net defined benefit liability	792,217	818,583

December 21 2019

In Belgium, the defined contribution plan was not yet finalized as per 31.12.2018.

#### 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 in benefits by altering the conversion rates or increasing current contributions. Under the BVG employer has to fund at least 50% of the potential restructuring.

The Sequana Pension Fund has entered into an agreement with AXA Foundation (AXA). AXA 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. AXA has set up investment guidelines, defining in particular the strategic allocation with margins. AXA has reinsured its actuarial risks consisting of demographic risks (primarily life expectancy) and the financial

risk (primarily the discount rate, future increases in salaries/wages, and the return on plan assets). In addition, an actuarial report is drawn up annually in accordance with BVG requirements.

Components of defined benefit cost in profit or loss	2018	2017
Current service cost (employer)	154,776	177,801
Interest expense on defined benefit obligation	16,201	19,194
Interest income on plan assets	(11,114)	(13,422)
Administration cost excl. cost for managing plan assets	1,435	1,615
Defined benefit cost recognized in profit or loss	161,298	185,189
thereof service cost and administration cost	156,211	179,416
thereof net interest on the net defined benefit liability (asset)	5,087	5,773

There were no plan amendments nor settlements in the years 2018 and 2017.

Components of defined benefit cost in OCI	2018	2017
Actuarial (gain) / loss on defined benefit obligation	(131,998)	(195,728)
Return on plan assets excl. interest income	29,745	66,503
Defined benefit cost recognised in OCI	(102,253)	(129,225)

Components of actuarial gain/losses on obligations	2018	2017
Actuarial (gain) / loss arising from changes in financial assumptions	(61,499)	0
Actuarial (gain) / loss arising from changes in demogr. assumptions	(45,953)	0
Actuarial (gain) / loss arising from experience adjustments	(24,547)	(195,728)
Actuarial (gain) / loss on defined benefit obligation	(131,998)	(195,728)

Reconciliation in net defined benefit liability	2018	2017
Net defined benefit liability at 1.1.	818,583	968,277
Defined benefit cost recognised in profit or loss	161,298	185,189
Defined benefit gain recognised in OCI	(102,253)	(129,225)
Contributions by the employer	(117,910)	(121,238)
Currency translation adjustments	32,499	(84,419)
Net defined benefit liability at 31.12.	792,217	818,583

Reconciliation of defined benefit obligation	2018	2017
Defined benefit obligation at 1.1.	2,833,898	3,348,779
Interest expense on defined benefit obligation	16,201	19,194
Current service cost (employer)	154,776	177,801
Contributions by plan participants	117,910	121,238
Benefits (paid) / deposited	(614,497)	(360,129)
Administration cost (excl. cost for managing plan assets)	1,435	1,615
Actuarial (gain) / loss on defined benefit obligation	(131,998)	(195,728)
Currency translation adjustments	100,680	(278,873)
Defined benefit obligation at 31.12	2,478,405	2,833,898

<b>equana</b> medical	1

Reconciliation of fair value of plan assets	2018	2017
Fair value of plan assets at 1.1.	2,015,315	2,380,502
Interest income on plan assets	11,114	13,422
Contributions by the employer	117,910	121,238
Contributions by plan participants	117,910	121,238
Benefits (paid) / deposited	(614,497)	(360,129)
Return on plan assets excl. interest income	(29,745)	(66,503)
Currency translation adjustments	68,182	(194,454)
Fair value of plan assets at 31.12	1,686,189	2,015,315

Asset allocation: 100% of the plan assets are held via the insurance contract with AXA.

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	2018	2017
Weighted average duration of DBO in years	20.4	17.6

There are no retired plan participants for the years 2018 and 2017.

For the reporting year 2019 employer contributions of EUR 128,984 are expected.

The contributions paid to the defined contribution plan in Germany amounted to EUR 7,652 (2017: EUR 5,098).

The contributions paid to the defined contribution plan in Belgium amounted to EUR o in 2018, as the plan is not yet finalised.

#### Significant actuarial assumptions:

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

Actuarial assumptions	2018	2017
Discount rate (DR) at 1.1.	0.60%	0.60%
Discount rate (DR) at 31.12.	0.90%	0.60%
Interest rate on retirement savings capital (IR) at 31.12.	0.90%	0.60%
Future salary increases (SI) at 31.12.	1.00%	1.00%
Future pension increases (PI) at 31.12.	0.00%	0.00%
Future inflation at 31.12.	0.00%	1.00%
Mortality tables	BVG2015 GT	BVG2015 GT
Date of last actuarial valuation	31-12-2018	31-12-2017

#### Sensitivities of significant actuarial assumptions

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

Sensitivity	2018	2017
DBO = Defined benefit obligation, SC = Service cost (employer)		
DBO at 31.12. with DR -0.25%	2,609,466	2,939,660
DBO at 31.12. with DR +0.25%	2,359,113	2,712,668
DBO at 31.12. with IR -0.25%	2,422,511	2,789,709
DBO at 31.12. with IR +0.25%	2,536,255	2,890,923
DBO at 31.12. with SI -0.25%	2,448,305	2,803,869
DBO at 31.12. with SI +0.25%	2,508,334	2,863,752
DBO at 31.12. with life expectancy +1 year	2,509,261	2,866,938
DBO at 31.12. with life expectancy -1 year	2,447,379	2,800,672
SC of next year with DR +0.25%	125,668	146,389
SC of next year with IR +0.25%	143,285	166,613

The sensitivity analysis is based on reasonable possible changes as at the end of the reporting year. Each change in a significant actuarial assumption was analysed separately as part of the test. Interdependencies were not taken into account.

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

In EUR	December 31, 2018	December 31, 2017
Trade Payables	2,753,183	2,012,131
Other Payables	1,087,858	270,487
Accrued liabilities:	2,805,700	450,919
Provision Warranty	67,090	29,227
Third Parties	2,738,610	421,692

Other payables relate mainly to 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 2,738,610 EUR of which 2,243,951 EUR for the IPO related expenses. Other accruals included are salary- and liability related.

### 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.

Options granted under this plan enables the employees (and in rare circumstances members of the board of directors) to acquire a pre-defined number of shares as listed in the respective grant notice. The Company's board of directors determines the maximum number of shares. A plan administrator is a person designated by the Company's board of director and is acting within the guidelines of the stock option plan and who administers the plan.

The options are granted free of charge and the exercise price is fixed by the plan administrator. The exercise price for all options granted has been aligned with the nominal value of the underlying share. The plan is defined as equity settled plan and therefore the fair value is determined at grant date and will not be re-assessed in subsequent periods. For the expense recognised for this plan refer to the statement of changes in equity.

#### Number of options granted:

	Options
31 December 2016	346,364
Granted	556,000
Forfeited	(90,845)
Exercised	-
31 December 2017	811,519
Granted	
Forfeited	(40,551)
Exercised	(18,468)
31 December 2018	752,500

The options expire after 10 years from its grant date, i.e. the options that were granted in 2011 will expire in 2021. 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.

Therefore, the cumulated impact of previous years and current year of this plan on the Group's financial statements has been reversed as per 31.12.2018. The net impact of this reversal on equity amounts to 17,895 EUR. We refer to note 15.2 Events after the reporting period since a new plan has been implemented.

#### 9.2. Executive Share Options

Early October, Sequana Medical implemented a new option plan for a certain group of employees and granted III,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	2018
Number of warrants granted	111,177
Number of warrants not vested at 31 dec 2018	-
Exercise price (in Euro) <sup>(1)</sup> :	
CEO <sup>(2)</sup>	0.92
Other	9.19
Expected dividend yield	0%
Expected stock price volatility <sup>(3)</sup>	49%
Risk-free interest rate <sup>(4)</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.

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

The effect of the share-based payment transactions on the profit & loss of the Group is an expense of 284,554 EUR. The same amount goes through Other Comprehensive income (OCI) so that the net effect on the Group's equity is zero.

<sup>(</sup>I) Equals the market value of the underlying shares on the grant date

<sup>(2)</sup> 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

<sup>(3)</sup> Based on peer companies listed on the STOXX Medtech stock exchange

<sup>(4)</sup> 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 2018.

### 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 5,201,643 EUR as per 31.12.2018.

**sequana**medical

### **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 I for the list of subsidiaries.

### 12.2. Relations with the shareholders

Currently, most of the existing shareholders have entered into the Shareholders' Agreement, containing, amongst others, terms regarding the Issuer's business and governance, as well as pre-emptive rights and transfer restrictions regarding the Shares. The Shareholders' Agreement was entered into on 1 October 2018, and is an amendment and restatement of a previous shareholders' agreement that had been entered into prior to the Belgian Seat Transfer. The Shareholders' Agreement will be terminated effective as of the closing of the Offering.

The Company and certain of its shareholders have entered into a convertible loan agreement, dated 16 February 2018, pursuant to which these shareholders granted a non-interest-bearing loan to the Issuer in a principal amount of CHF 2 million (the "February 2018 Convertible Loan"). The loan was granted until 31 December 2018, but can be extended if lenders representing more than 50% of the principal amount of the loan agree with the extension. The loan must be converted in a number of circumstances, including at the time of an initial public offering. The loan can be converted at any time prior to maturity on avoluntary basis, including prior to the Offering, in consideration of new series E preferred Shares at CHF 10.48 per

Share if lenders representing more than 50% of the principal amount of the loan agree with the conversion.

The Company and Participatiemaatschappij Vlaanderen NV ("PMV"), Federale Participatie- en Investeringsmaatschappij NV ("FPIM"), Cofipalux Invest SA ("Vlerick"), Newton Biocapital I Pricav Privée SA ("Newton") have entered into a convertible loan agreement, dated 6 June 2018, dated 27 July 2018, dated 30 August 2018, dated 11 October 2018 respectively, pursuant to which PMV, FPIM, Vlerick and Newton granted a loan to the Group in a principal amount of EUR 1,680,000 (the "PMV Convertible Loan"), EUR 2,000,000 (the "FPIM Convertible Loan") and EUR 500,000 (the "Vlerick Convertible Loan"), and EUR 2,000,000 (the "Newton Convertible Loan") respectively. The loan was granted until 31 December 2018. The loan bears an interest of 2% per annum, payable at maturity or upon early repayment, PMV, FPIM, Vlerick and Newton are 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. The PMV, FPIM, Vlerick and Newton Convertible Loans furthermore contain a negative pledge on the Company and its subsidiaries.

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 Company 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 (respectively, the "BioMed Convertible Loan" and the "Individual Convertible Loans", and together with the February 2018 Convertible Loan, the PMV Convertible Loan, the FPIM Convertible Loan, and the Cofipalux Convertible Loan and the Newton

Convertible Loan, the "Convertible Loans"). The loans were 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 Company.

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 and the payables under the February 2018 Convertible Loan for an aggregate principal amount of EUR 6,340.91) will be subscribed for in cash upon the closing of the Offering. We refer to note 8.6 for the accounting treatment related to these financial instruments.

#### 12.3. Relations with nonexecutive members of the Board of Directors

During 2018 and 2017, no remuneration or compensation was paid to the non-executive directors, other than (i) EUR 70,883 paid in 2017 to Rolf Classon, and (ii) 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	2018 (2 members)	2017 (1 member)
Short-term Employee benefits	484,813	337,420
Post-employment benefits	14,231	14,166
Share-based compensation	88,855	69,023
Total compensation	587,899	420,609

There were no other members of the executive management other than the chief executive officer in 2017.

### 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 2018	Investment 2017
Sequana Medical NV	Holding/Sales	EUR 877,977		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

	2018	2017
Average number of employees	23.4	25.7

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

EUR	2018	2017
Short-term employee benefits	484,813	337,420
Post-employment benefits	14,231	14,166
Share-based compensation	88,855	69,023
Total compensation	587,899	420,609

### **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." As a result of the referendum, the British government is negotiating the terms of the U.K.'s future relationship with the E.U. 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 in the U.K., which will be one of Sequana Medical's focus markets.

156

**Financial Report** 

### 15. Events after the reporting period

#### 15.1. IPO

On January 31, 2019, the Group launched its Initial Public Offering (IPO) on Euronext Brussels.

The Offering is an offering of up to 3,235,294 new shares of the Company (the "New Shares", and each existing share or New Share representing the Company's share capital a "Share").

On February 8, 2019, the Group announced the results of its initial public offering of new shares, with the admission of all of its shares to trading on the regulated market of Euronext Brussels under the symbol "SEQUA", launched on 31 January 2019 (the "Offering"). The final offer price for the Offering has been set at EUR 8.50, giving the Company an initial market capitalisation of EUR 107.2 million. Gross proceeds for the Company from the Offering amounted to EUR 27.5 million.

An over-allotment option to subscribe for 25,577 additional new Shares at the Offer Price, has been granted to KBC Securities NV/SA, as stabilisation manager (the "Stabilisation Manager"), acting on behalf of KBC Securities NV/SA, Kempen & Co N.V. and Mirabaud Securities Limited, to cover over-allotments or short positions, if any, in connection with the Offering (the "Over-allotment Option", and (i) the New Shares, and (ii) the additional new Shares issued pursuant to the Over-allotment Option collectively being referred to as the "Offered Shares"). The Over-allotment Option will be exercisable for a period of 30 calendar days following the Listing Date (as defined below). The Company will announce if and when the Over-allotment Option is exercised.

327,092 Shares, representing approximately 10% of the Offered Shares in the Offering, have been placed with retail investors in Belgium. To retail investors, 100% of the shares for which they have subscribed will be allocated.

The existing investors that committed to subscribe for an aggregate amount of €20.5 million in the Offering at the Offer Price, subject to the closing of the Offering (the "Subscription Commitments") were allocated an aggregate of 2,413,909 New Shares in the Offering on the basis of their Subscription Commitments.

The Group announced on March 18, 2019 the end of the stabilisation period in the framework of the initial public offering of new shares of the Company with the admission of all of its shares to trading on the regulated market of Euronext Brussels under the symbol "SEQUA" (the "Offering"). Within the framework of the Offering, KBC Securities NV/SA ("KBC Securities") was appointed by the Company as stabilisation manager (the "Stabilisation Manager").

An over-allotment warrant to subscribe for 25,656 additional new shares at the final offering price of EUR 8.50 per share was granted to the Stabilisation Manager, acting on behalf of the Underwriters (as defined below), to cover any over-allotments or short positions in relation to the Offering (the "Over-allotment Warrant"). The Over-allotment Warrant was not exercised and the 25,656 shares that were borrowed by NeoMed IV Extension L.P. ("NeoMed") and LSP Health Economics Fund Management B.V. ("LSP") to KBC Securities as Stabilisation Manager for the duration of the stabilisation period will be returned to NeoMed and LSP at the latest on 19 March 2019.

As a result, the total number of new shares that was issued by the Company in the Offering amounts to 3,235,294 shares. Furthermore, the maximum number of share options, named the "2018 Share Options", that were created by the Company for directors, employees and other staff members of the Company, is finally set at 1,261,190, being 10% of the number of outstanding shares after the completion of the Offering.

#### Bootstrap agreement

On October 1, 2018, the agreement for the Bootstrap Loan 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).

34,409 New Shares in the Offering have been subscribed for through a contribution in kind by Bootstrap of 50% of the payable due by the Issuer upon the closing of the Offering as an "Exit Fee" pursuant to the Bootstrap Loan. The remaining portion of the Exit Fee shall be repaid in cash by the Issuer following the closing of the Offering. As provided for by the Bootstrap Loan, the Exit Fee shall not exceed a maximum of CHF 750,000. The final exit fee amounts to CHF 663.997 which is not higher than the agreed maximum of CHF 750.000.

50% equals to CHF 331.998 which has been converted into EUR 292,483. The portion of the Exit Fee payable that shall be so contributed, but that cannot be used for the subscription for a whole number of New Shares at the Offer Price shall not be contributed in kind, but remains payable in cash (subject to the terms of the Bootstrap Loan).

### 15.2. New Share Option plan implemented in February 2019

As a result of the closing of the Offering, the Company has created 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 will be 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.

### **16.** Audit fees

In EUR	2018
Fees of the independent auditor with respect to the statutory audit mandate for the Company and the Group (Belgium)	50,000
Additional Services rendered by the auditor's mandate:	
Audit related fees	65,600
Tax advisory & compliance services	0
Due diligence fees	0
Other Services	0
Subtotal	115,600
Fees of independent auditor's network with respect to a statutory audit mandate at the level of the Group (foreign operations)	136,450
Additional Services rendered by the auditor's mandate:	
Audit related fees	493,262
Tax advisory & compliance services	0
Due diligence fees	0
Other Services	0
Subtotal	629,712
Total	745,312

# CONDENSED STATUTORY FINANCIAL STATEMENTS OF SEQUANA MEDICAL NV

### 1. Statutory Income Statement

In EUR	2018	2017(1)
Operating income	1,029,171	1,303,975
Operating charges	(14,487,939)	(8,394,021)
Operating loss	(13,458,768)	(7,090,046)
Financial result	(881,366)	(788,560)
Loss for the period before taxes	(14,340,134)	(7,878,606)
Income taxes	(3,315)	(3,508)
Loss for the period	(14,343,450)	(7,882,114)

<sup>(1)</sup> Sequana Medical NV has been registered in Belgium on October 1st, 2018. Proforma comparable data for 2017 represents Sequana Medical AG, registered in Switzerland.

### 2. Statutory Balance Sheet

In EUR	2018	2017(1)
Assets	3,544,378	3,977,506
Fixed assets	270,905	275,283
Tangible assets	183,696	205,426
Financial fixed assets	57,758	41,495
Participating interests	29,450	28,362
Current assets	3,273,473	3,702,223
Inventory	1,235,426	1,270,803
Amounts receivable within one year	697,136	724,203
Deferred charges and accrued income	116,372	13,358
Cash and cash equivalents	1,224,539	1,500,585
Own shares		193,275
Equity and liabilities	3,544,378	3,977,506
Equity	(18,588,252)	(4,061,489)
Capital	887,977	954,577
Treasury shares	-	-
Share premium	64,963,284	64,954,597
Reserves	449,182	574,581
Accumulated losses	(84,888,695)	(70,545,245)
Provisions	792,225	818,583
Amounts payable	21,340,404	7,220,413
Amounts payable after more than one year	2,582,087	4,577,761
Financial debt	2,582,087	4,577,761
Amounts payable within one year	15,973,468	2.240.619
Financial debt	12,257,049	-
Trade debts	2,726,702	2,001,691
Taxes, remuneration and social security	989,716	238,928
Other amounts payable	-	0
Accruals and deferred income	2,784,850	402,033

I Sequana Medical NV has been registered in Belgium on October 1st, 2018. Proforma comparable data for 2017 represents Sequana Medical AG, registered in Switzerland.

### **SOURCES**

- (I) U.S. Centers for Disease Control and Prevention (https://www.cdc.gov/nchs/fastats/liver-disease.htm).
- (2) Estes C, Razavi H, Loomba R, Younossi Z, Sanyal AJ. Modeling the epidemic of nonalcoholic fatty liver disease demonstrates an exponential increase inburden 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.
- (3) Estes et al. (2018).
- (4) GlobalData NASH Epidemiology Forecast to 2026.
- (5) Runyon et al. (2009).
- (6) Ginès et al. (2004) (stating refractory ascites occurs in 5 to 10 percent of patients with ascites).
- (7) Management estimate using historical liver cirrhosis mortality rates based on Mokdad AA, Lopez AD, Shahraz S, Lozano R, Mokdad AH, Stanaway J, Murray CJ, Naghavi M. Liver cirrhosis mortality in 187 countries between 1980 and 2010: a systematic analysis. BMC Med. 2014;12:145 and the estimated percentage of cirrhosis patients that die each year per expert feedback.
- (8) GlobalData NASH Epidemiology Forecast to 2026; Runyon et al. (2009); Ginès et al. (2004)
- (9) European Association for the Study of the Liver. EASL clinical practice guidelines on the management of ascites, spontane bacterial peritonitis, and hepatorenal syndrome in cirrhosis. Journal of Hepatology. 2010 vol. 53. 397-417. p. 402.
- (10) 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.
- (II) Ayantunde et al. (2007).
- (12) 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))
- (13) Ayantunde et al. (2007).
- (14) Benjamin et al. (2013).

- (15) Savarese et al. (2017).
- (16) Ziaeian B, Fonarow GC.Nat Rev Cardiol. 2016 Jun;13(6):368-78. doi: 10.1038/nrcardio.2016.25.
- (17) GlobalData Heart Failure Epidemiology Forecast to 2026
- (18) 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.
- (19) Costanzo et al. (2007).
- (20) Kilgore et al. (2017); Ambrosy et al. (2014).
- Chen J, Dharmarajan K, Wang Y, Krumholz HM. National Trends in Heart Failure Hospitalization Rates, 2001–2009. Journal of the American College of Cardiology. 2013;61(10):1078-1088. doi:10.1016/j.jacc.2012.11.057.
- (22) Ross et al. (2010).
- (23) U.S. Centers for Disease Control and Prevention (www.cdc.gov)

### **GLOSSARY**

Abbreviation	Significance
DRG	Diagnosis Related Group
DSR	Direct Sodium Removal
EASL	European Association for the Study of the Liver
FDA	Food and Drug Administration
IPO	Initial Public Offering
KOL	Key Opinion Leader
LVP	Large Volume Paracentesis
NAFLD	Non-Alcoholic Fatty Liver Disease
NASH	Non-Alcoholic Steatohepatitis
NICE	National Institute for Health and Care Excellence
NUB	Neue Untersuchungs- und Behandlungsmethode (temporary add-on payment to the German DRG for new treatment methods)
NYHAFC	New York Heart Association Functional Classification
PMSR	Post Marketing Surveillance Registry
QOL	Quality of Life
RCT	Randomised Controlled Trial
TIPS	Transjugular Intrahepatic Portosystemic Shunt

### **INVESTOR RELATIONS**

#### **Financial Calender**

23 May 2019 Annual General Meeting 2019 4 September 2019 Publication half year results 2019

#### **Investor Relations Contact**

For all your investor relations questions, please contact us at IR@sequanamedical.com or use the contact details below.

Lies Vanneste Director IR

Direct: +32 9 298 2864 Mobile: +32 498 053579

Sequana Medical NV Technologiepark 122 9052 Ghent, Belgium