



ANNUAL REPORT 2023

sequanamedical

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Disclaimer

This annual report may contain predictions, estimates or other information that might be considered forward-looking statements. Such forward-looking statements are not guarantees of future performance. These forward-looking statements represent the current judgment of Sequana Medical on what the future holds, and are subject to risks and uncertainties that could cause actual results to differ materially. Sequana Medical expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this annual report, except if specifically required to do so by law or regulation. You should not place undue reliance on forward-looking statements, which reflect the opinions of Sequana Medical only as of the date of this annual report. Certain monetary amounts and other figures included in this annual report have been subject to rounding adjustments. Accordingly, any discrepancies in any tables between the totals and the sums of amounts listed are due to rounding.

Regulatory Disclaimers

*The **alfapump**[®] system is currently not approved in the United States or Canada. In the United States and Canada, the **alfapump** system is currently under clinical investigation (POSEIDON Trial) and is being studied in adult patients with refractory or recurrent ascites due to liver cirrhosis. 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 therapy and ongoing investigations with the **alfapump** system in Europe, the United States or Canada.*

*Note: **alfapump**[®] and DSR[®] are registered trademarks.*

OUR STRATEGY & KEY OBJECTIVES

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

- Commercialize **alfapump**[®] in North America for the treatment of recurrent and refractory ascites due to liver cirrhosis, using our own specialty salesforce targeting liver transplant centers.
- Develop our proprietary DSR[®] product as a disease-modifying heart failure drug therapy tackling cardiorenal syndrome and establish a strategic partnership for late-stage clinical development and commercialization.

SEQUANA MEDICAL AT A GLANCE

We are pioneers in treating fluid overload, a serious and frequent clinical complication in patients with liver disease, heart failure and cancer. These patients can have up to 15 liters of extra fluid in their bodies, causing major medical issues including increased mortality, repeated hospitalizations, severe pain, difficult breathing and restricted mobility that severely impacts their daily life. Although diuretics are standard of care, they become ineffective, intolerable or exacerbate the problem in many patients. There are limited effective treatment options, resulting in poor clinical outcomes, high costs and a major impact on their quality of life. We are seeking to provide innovative treatment options for this large and growing “diuretic-resistant” patient population.

alfapump and DSR are our two proprietary platforms that work with the body to treat diuretic-resistant fluid overload and are protected by our strong intellectual property (IP) portfolio. Our **alfapump** is a fully implanted medical device that has a proven track record for treatment of recurrent and refractory liver ascites. DSR or Direct Sodium Removal has demonstrated clinical proof-of-concept as a disease-modifying heart failure drug therapy tackling cardiorenal syndrome.

The **alfapump**, a fully implanted, wirelessly charged device, automatically pumps fluid from the peritoneal cavity into the bladder, where it is naturally eliminated through urination. It is protected by a portfolio of patents granted in the US and Europe and more than 1,000 devices have been implanted to date.

In Europe, the **alfapump** has received CE mark for the treatment of refractory ascites due to liver cirrhosis and malignant ascites and has been included in key European treatment guidelines. In the US, our key growth market, the **alfapump** has been granted breakthrough device designation by the Food and Drug Administration (FDA) for the treatment of recurrent or refractory ascites due to liver cirrhosis. Our pivotal POSEIDON study met all primary efficacy endpoints with statistical significance, confirming the strong clinical and commercial profile of the **alfapump**. The Pre-Market Approval (PMA) application was filed with the US FDA in December 2023 and accepted for substantive review in January 2024, ahead of anticipated timing. We plan to commercialize the **alfapump** directly in the US, using a specialized in-house sales force targeting 90 liver transplant centers (covering 95% of adult liver transplants). The North American market for the **alfapump** is estimated at \$2.4 billion and forecast to grow at a CAGR of 9%, from over 78,000 patients in 2025, reaching more than 147,000 patients by 2032ⁱ, primarily driven by the increasing prevalence of Non-Alcoholic SteatoHepatitis / Metabolic dysfunction-Associated SteatoHepatitis (NASH / MASH).

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

ⁱ Based on US and Canada market assessment conducted by highly experienced international consulting group, forecasting over 147,000 patients with recurrent or refractory ascites in North America by 2032 and a target price of \$30,000 per **alfapump**

Heart failure is the leading cause of US hospitalizations in patients over 65 years old with over one million hospitalizations per yearⁱⁱ at a cost of over \$14 billionⁱⁱⁱ, and 90% of these admissions are due to fluid overload (AKA congestion). In the US alone, we anticipate an estimated 200,000 patients with chronic congestive heart failure requiring repeated hospitalization. DSR is expected to be complementary to existing heart failure therapies.

Extensive analysis of patients in the RED DESERT and SAHARA proof-of-concept studies shows the benefit from DSR therapy on i) volume status, ii) normalized diuretic response and dramatically reduced loop diuretic dosing, iii) improvement in kidney function, iv) neurohormonal status and signalling, as well as v) cardiovascular parameters. In these patients there were no congestion-related re-hospitalizations, a one class improvement in their New York Heart Association (NYHA)^{iv} status and a reduction of 75% in their predicated one-year mortality (based on the Seattle Heart Failure model^v).

We have commenced MOJAVE, a US Phase 1/2a study to confirm the results of RED DESERT and SAHARA. The non-randomized cohort (n=3) has been completed and in these patients DSR therapy was safe and well tolerated, virtually eliminated loop diuretic requirements three months after completion of DSR treatment and improved diuretic response by over 300%^{vi}. The independent Data Safety Monitoring Board approved the start of the randomized MOJAVE cohort of up to a further 30 patients, which is planned after **alfapump** PMA approval. Based on the results of the MOJAVE trial, we plan to partner DSR to leverage the strengths of an established heart failure player to realize commercial potential of DSR.

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

ⁱⁱ Costanzo et al., 2017

ⁱⁱⁱ Urbich et al., 2000

^{iv} NYHA stratifies severity of heart failure by patient-reported symptoms. Data collected outside study protocols of RED DESERT and SAHARA.

^v Predicted one-year survival analysis using Seattle Heart Failure Model of seven patients in RED DESERT and ten patients in SAHARA pre- and post-intensive DSR therapy. Analysis includes physician-assessed data collected post hoc.

^{vi} Mean increase of 324% in six-hour urinary sodium excretion after 4-week DSR therapy vs baseline

OUR BUSINESS

Achievements in 2023

North American alfapump liver program

- POSEIDON – one-year follow-up data from successful pivotal study in patients with recurrent or refractory ascites due to liver cirrhosis, confirms strong clinical profile of **alfapump**
 - Virtual elimination of needle paracentesis
 - Robust safety profile despite disease progression
 - Clinically meaningful improvement in patients’ quality of life maintained
 - Survival probability of 70% at 12 and 18 months post-implant
- Patient preference study indicates that US patients have a strong preference for the **alfapump** vs large volume paracentesis^{vii}
- Matched interim analysis of patients from NACSELD-III^{viii} registry indicates that **alfapump** safety profile is comparable to standard of care^{ix}
- PMA application submitted to the US FDA in December 2023

DSR heart failure program

- Successful completion of IND^x-enabling pre-clinical and Phase 1 studies of second-generation DSR product (DSR 2.0)
 - Data from GLP^{xi} studies in mice and sheep showed there was no difference in systemic and local toxic effects in animals treated repeatedly with DSR 2.0 compared to animals in the control group, concluding that DSR 2.0 had consistent safety with the standard peritoneal dialysis solution used in the control group
 - Data from the Phase 1 CHIHUAHUA study in stable peritoneal dialysis patients demonstrated that a single dose of DSR 2.0 was safe and well-tolerated and indicated a compelling dosing profile
- MOJAVE – all three patients from the non-randomized cohort in the US Phase 1/2a study of DSR 2.0 for treatment of congestive heart failure successfully treated with DSR 2.0, confirming the strong clinical outcomes seen in the RED DESERT and SAHARA proof-of-concept studies
 - Safe and effective maintenance of euvoemia without the need for loop diuretics

^{vii} Patient preference study using discrete-choice experiment methodology to elicit patient preference for attributes of an implantable pump as a novel interventional treatment for ascites, N=125 US patients with comparable patient profile to pivotal cohort in POSEIDON study

^{viii} NACSELD: North American Consortium for the Study of End stage Liver Disease

^{ix} Comparing outcomes in terms of death, hospitalization rate and liver transplant of POSEIDON pivotal cohort (6 months post-implant) to matched patient group from NACSELD registry with POSEIDON

^x IND: Investigational New Drug

^{xi} GLP: Good Laboratory Practice

- Durable improvement in cardio-renal health
- Dramatic improvement in diuretic response and at least 95% reduction in loop diuretic requirements up to almost four months after last DSR therapy
- Additional DSR patents granted in the US and China
 - Additional US patents granted in February 2023 covering among other, the expansion of the composition of matter and method for Sequana Medical's DSR therapy, including additional oncotic and osmotic agents and the use of an implantable pump system
 - Key composition of matter patent was granted in China in March 2023

Corporate

- Established Sequana Medical US Inc. with an office in Boston which has been certified according to ISO 13485:2016 and MDSAP^{xii} (USA and Canada) by BSI^{xiii}, in preparation of the US commercial launch of the **alfapump**
- Expanded Board of Directors with the appointment of Dr. Kenneth Macleod in June 2023 and Ids van der Weij in November 2023 as non-executive directors
 - Dr. Macleod is a partner at Rosetta Capital and brings more than 35 years' experience in the life science sector from his senior operating roles in healthcare companies and life science fund management
 - Mr. van der Weij is managing partner of Partners in Equity and brings more than 25 years' corporate investment experience
- Raised €15.8 million in gross proceeds in April 2023 by means of an equity placement via an accelerated book building offering
- Cash position of €2.6 million at the end of December 2023, compared to €18.9 million at the end of December 2022

2024 year-to-date

North American **alfapump** liver program

- The American Medical Association granted six new CPT^{xiv} category III reimbursement codes in January 2024, available for use by healthcare professionals and payors as of July 1st, 2024, for procedures related to the **alfapump** system, including implantation, revision, removal and programming of the pump system, replacement of the pump and the catheters
- PMA application for **alfapump** accepted by the US FDA for substantive review in January 2024, ahead of anticipated timing

^{xii} MDSAP: Medical Device Single Audit Program

^{xiii} BSI: British Standards Institution

^{xiv} CPT: Current Procedural Terminology

- Positive and active interaction with the FDA, working towards the completion of their review

DSR heart failure program

- The independent Data Safety Monitoring Board approved the start of the MOJAVE randomized cohort of up to 30 additional patients following review of data from non-randomized cohort in January 2024
- Three-month follow-up data from all three patients in the MOJAVE non-randomized cohort confirmed dramatic improvement in diuretic response and virtual elimination of loop diuretics following DSR therapy
- Strong data supporting DSR's role as potential treatment for cardiorenal syndrome based on results of RED DESERT and SAHARA proof-of-concept DSR studies presented during late-breaking session at leading international heart failure conference, [THT 2024](#) and published in [European Journal of Heart Failure](#)

Corporate

- Cash runway extended to end of Q3 2024
 - In February 2024, we announced a significantly reduced cash burn through 1) the focus on obtaining **alfapump** PMA approval, 2) postponing the start of the randomized cohort of the DSR MOJAVE study to after reaching **alfapump** PMA approval, and 3) halting all European commercial activities for **alfapump**
 - In February 2024, our lenders agreed to defer all debt service payments
 - Kreos Capital VII (UK) Limited agreed to a payment holiday: Suspension of the repayment of any principal or interest amounts under the Kreos Loan until the earlier of (i) three months following the date on which the Company has obtained a PMA decision for the alfapump by the US FDA (irrespective whether such decision is positive or otherwise), (ii) date on which the Company has obtained a PMA approval for the alfapump by the US FDA and has completed an equity raise of at least EUR 20.0 million, and (iii) 31 December 2024.
 - PMV-Standaardleningen NV, Belfius Insurance and Sensinnovat NV agreed to a rescheduling of the principal repayments under the relevant loan agreements so that the principal amount outstanding under the loans thereunder will be repaid in four equal monthly instalments starting on 30 September 2025.
 - In March 2024, we raised €11.5 million in gross proceeds by means of an equity placement via an accelerated book building offering. Following this equity placement, the €3.0 million convertible loan agreement entered in February 2024 by Partners in Equity and Rosetta Capital will be mandatorily converted into new shares.

Outlook for 2024

We are working towards FDA approval of the PMA application for our **alfapump**, a key value inflection point, with commercial scale-up and launch planned for 2025.

For the DSR heart failure program, we will start the randomized cohort of the US Phase 1/2a MOJAVE study after reaching PMA approval for our **alfapump**. The start of the randomized phase is currently anticipated in Q1 2025, including up to 30 additional diuretic-resistant heart failure patients, with up to 20 patients treated with DSR 2.0 and up to 10 patients treated with intravenous loop diuretics, and interim data are expected in H2 2025.

Proprietary alfapump & DSR technologies

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

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



Medical device for recurrent and refractory ascites due to liver cirrhosis

- Growth in NASH drives attractive commercial opportunity
- \$2.4bn market growing at 9% CAGR (2025-2032)^{xv}
- Standard of care has severe limitations, little innovation
- FDA breakthrough device status; approved in EU under MDR 2017/745
- Successful North American pivotal study – primary endpoints met, strong clinical & commercial profile
- PMA accepted for review by FDA, targeting commercial scale up and US launch in 2025
- Derisked reimbursement position, supporting price of \$30k at 80% gross margin



Novel drug treatment for cardiorenal syndrome in heart failure

- Targeting unmet clinical needs in cardiorenal syndrome
- Clinical proof-of-concept as disease-modifying drug therapy
- Dramatic and durable impact on disease-status
- Low development risk, favourable safety profile & strong IP
- US Phase 1/2a randomized controlled study underway – positive data from initial patient cohort
- Over \$9bn addressable market in the US^{xvi}
- Partnering based on US Phase 1/2a readout planned for 2026

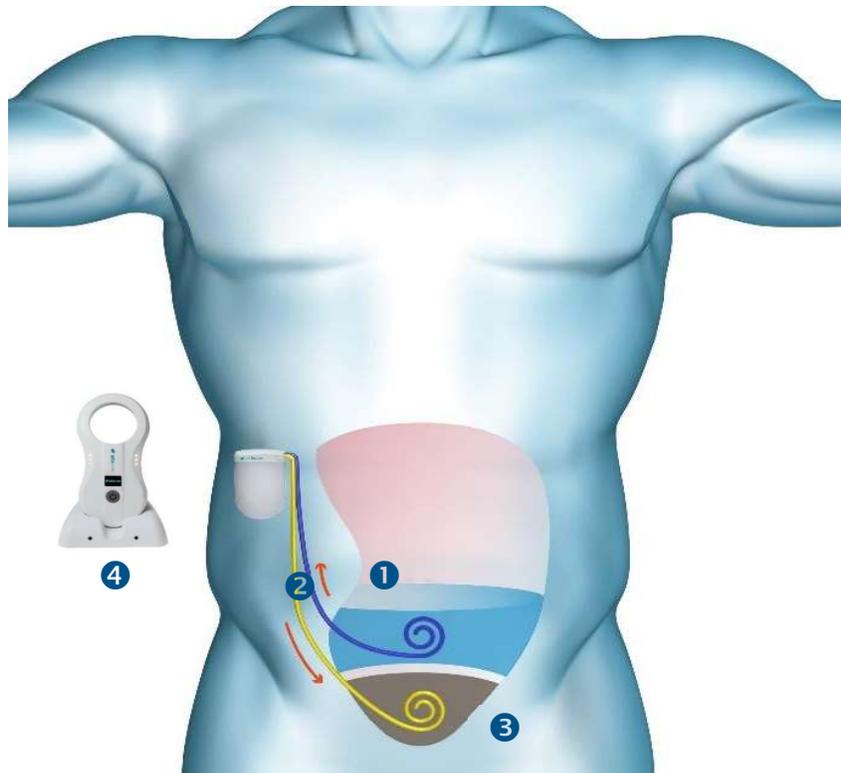
^{xv} Based on US and Canada market assessment conducted by highly experienced international consulting group, estimating 147,400 patients with recurrent or refractory ascites in North America by 2032 and based on an indicative price of \$30,000 per **alfapump**

^{xvi} Management estimate of ~200k chronically congested HF patients hospitalized per year in the US with a US annual HF hospitalization cost per patient of \$45,000



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

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



Fully implantable pump system

The **alfapump** is implanted under the patient's skin using minimally invasive surgery. It is a simple procedure taking approximately 60 -90 minutes that can be performed under local anaesthesia with sedation. In North America, we expect the procedure to be performed by interventional radiologists. Because the **alfapump** is fully implanted, patients are able to retain normal mobility and activity.

Once the **alfapump** has been implanted, it is programmed wirelessly by the physician to

ensure that the optimal amount of fluid is removed each day. The schedule can be designed to suit patients' individual daily routine.

In 2020, the **alfapump** surgical implantation technique was published in [Langenbeck's Archives of Surgery](#) by a group of experienced European implanting surgeons, providing the clinical community with their accumulated experience.

Wirelessly charged through the skin

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

While charging, performance data from the **alfapump** are transferred to the Smart Charger and transmitted wirelessly via the mobile phone network to secure servers using our proprietary DirectLink technology.

Remote pump performance monitoring

Using DirectLink technology, **alfapump** performance data are collected and transferred via the mobile phone network to secure servers for analysis – 24 hours a day, 7 days a week.

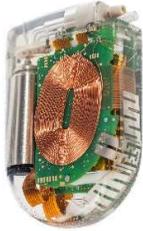
Our data specialists receive pump performance information (e.g. volume pumped and pump charging) and report this information to clinicians enabling them to manage patients more effectively through closer monitoring and notification of changes in pump performance data.



Components

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

alfapump



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

Catheters



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

Smart Charger



The Smart Charger is a hand-held charging device that charges the **alfapump** through the skin. While charging, performance data from the **alfapump** are transferred to the Smart Charger. When placed on the docking station, these data are transmitted 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 to the needs of each patient.

Supply Chain

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



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

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

Key principle

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



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



DSR approach

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



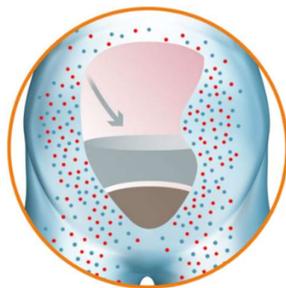
As a result, the body acts to restore the sodium concentration in the body by eliminating fluid through urination and osmotic ultrafiltration, resulting in a sustained level of fluid loss.



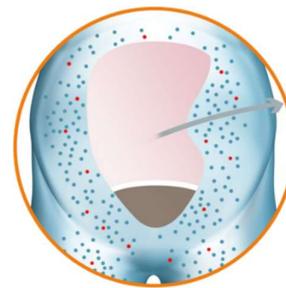
DSR therapy involves the use of the peritoneal cavity for the removal of sodium via diffusion. The peritoneal cavity, just like the lungs, has a large surface area, rich blood supply and thin walls, which makes it highly effective in removing soluble compounds from the blood stream. The utility of the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

How DSR works

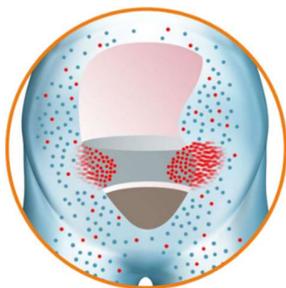
1 In DSR, the objective is to remove sodium. To do this, we administer our sodium-free DSR product to the peritoneal cavity and allow it to dwell for a pre-defined period.



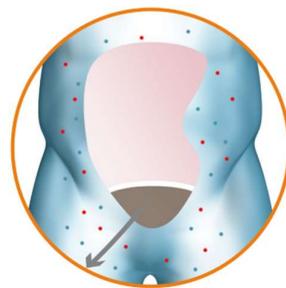
3 The DSR product and the extracted sodium are then removed, resulting in a removal of sodium from the body.



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



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



DSR therapy treatment overview

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

In the future we intend to replace the peritoneal catheter with our own proprietary subcutaneous port to improve treatment flexibility, reduce risk of infection and enhance patient convenience.

Extensive Intellectual Property Portfolio

Our patent portfolio consists of 71 patents being granted across 20 patent families and a further 18 patent applications pending for our **alfapump** and DSR. In addition to patents, we also rely on a combination of trade secrets, design rights, copyright laws, non-disclosure agreements and other contractual provisions and technical measures that help maintain and develop our competitive position with respect to intellectual property.

alfapump in liver disease and cancer

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

The **alfapump** provides an innovative treatment solution for the management of refractory ascites due to liver cirrhosis and cancer with proven safety, efficacy and quality of life benefits demonstrated in multiple clinical studies. By automatically and continuously moving ascites from the abdomen to the bladder where it is eliminated via urination, the **alfapump** prevents fluid build-up and possible complications, improving patients' quality of life and nutrition, and potentially reducing hospital visits and healthcare costs. To date, over 1,000 **alfapump** systems have been implanted.

In the US, the **alfapump** has been granted breakthrough device designation by the FDA for treatment of recurrent and refractory ascites due to liver cirrhosis. The North American pivotal study (POSEIDON) met all primary efficacy endpoints with statistical significance, confirming the strong clinical and commercial profile of the **alfapump**. The PMA application was filed with the US FDA in December 2023 and accepted for substantive review in January 2024, ahead of anticipated timing. Commencing in 2025, we plan to commercialize the **alfapump** directly in the US, using a specialized in-house sales force targeting 90 liver transplant centers (covering 95% of adult liver transplants). The North American market for the **alfapump** is estimated at \$2.4 billion and forecast to grow at a CAGR of 9%, from over 78,000 patients in 2025, reaching more than 147,000 patients by 2032^{xvii}, primarily driven by the increasing prevalence of NASH.

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

^{xvii} Based on US and Canada market assessment conducted by highly experienced international consulting group, estimating 147,000 patients with recurrent or refractory ascites in North America by 2032 and a target price of \$30,000 per **alfapump**

Market opportunity and limitations of existing therapies

Liver cirrhosis/NASH and refractory ascites

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

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

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

Approximately one-third of the US population is affected by NAFLD and approximately a quarter to one-third of NAFLD cases are classified as NASH^{xix}. NASH/MASH is a silent disease due to the difficulty in diagnosing it, making early-stage intervention challenging. It is estimated that about 10% of the NASH/MASH population will progress to liver cirrhosis in the near-to medium-term^{xx}, making the US NASH/MASH-related cirrhosis market an attractive market for the **alfapump**.

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

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

^{xviii} US Centers for Disease Control and Prevention

^{xix} Estes et al., 2018

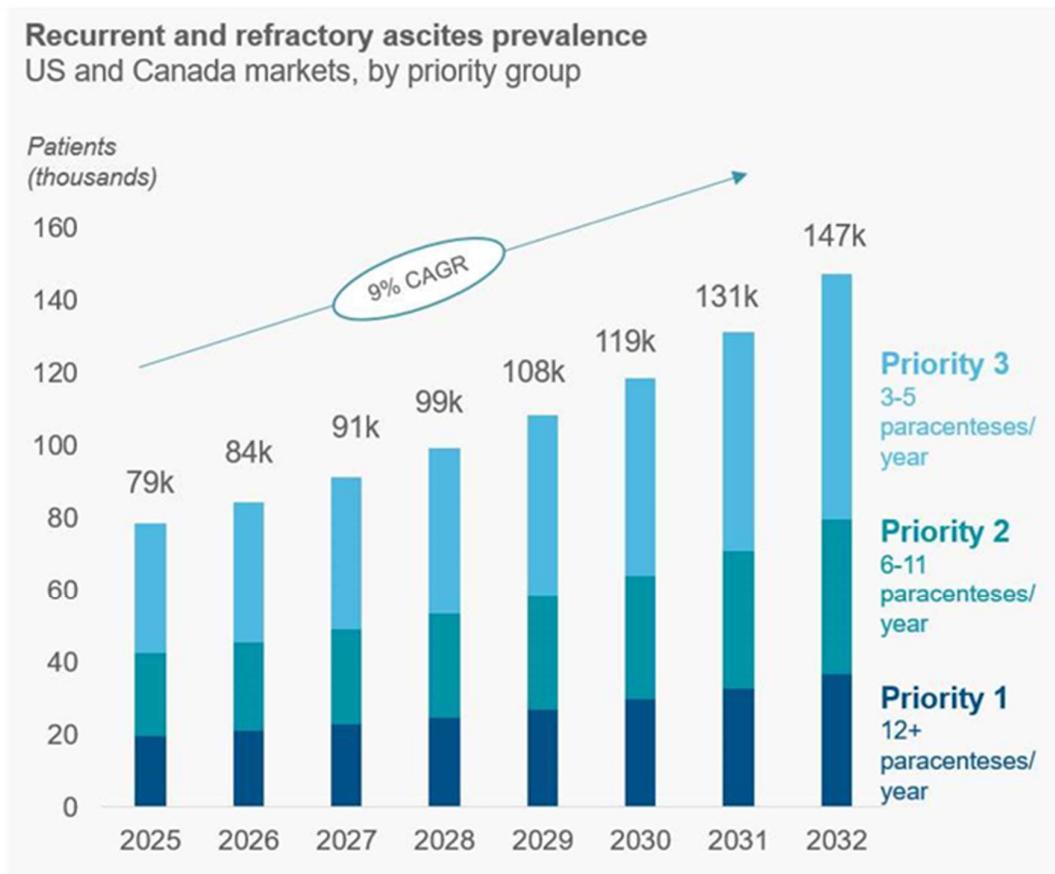
^{xx} Global Data NASH Epidemiology Forecast to 2026

^{xxi} Runyon et al., 2009

^{xxii} Ginès et al., 2004

Market assessment in the US and Canada

We engaged a highly experienced consulting group to conduct a market assessment in the US and Canada using claims analysis for commercial and CMS^{xxiii} patients who were diagnosed with liver disease and required at least three paracentesis procedures per year. In 2025, it is estimated that over 78,500 patients will be affected by recurrent or refractory ascites due to liver cirrhosis in the US and Canada, representing a total addressable market of approximately \$2.4 billion at launch^{xxiv}. The market is growing rapidly at an average annual growth rate of 9%, with NASH/MASH being the key driver of growth and alcoholic liver disease continuing to play an important role. About a quarter of these patients will require at least one paracentesis every month, our initial target population, representing an estimated priority one target market segment of approximately \$600 million.

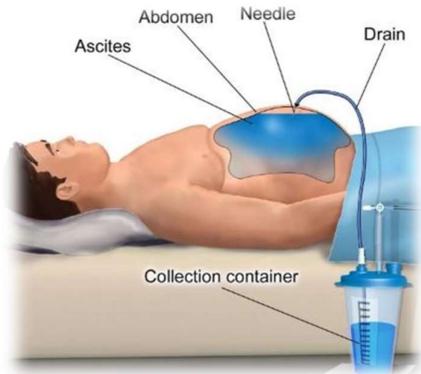


^{xxiii} CMS: Center for Medicare and Medicaid Services

^{xxiv} Based on US and Canada market assessment conducted by highly experienced international consulting group, estimating 147,000 patients with recurrent or refractory ascites in North America by 2032 and based on a target price of \$30,000 per **alfapump**

Existing therapies have severe limitations

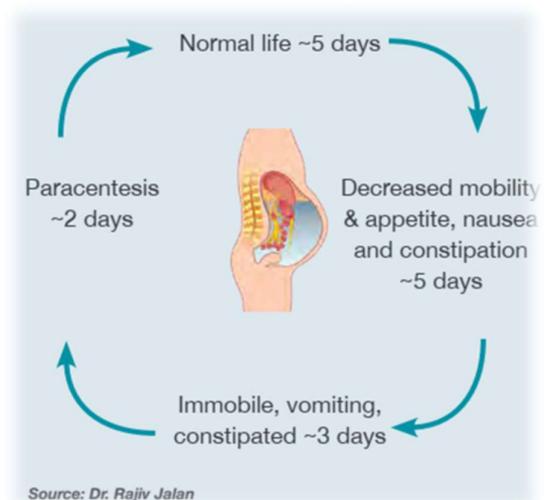
When drug therapy and dietary restriction are no longer effective, the common treatment of ascites is drainage (“*paracentesis*”).



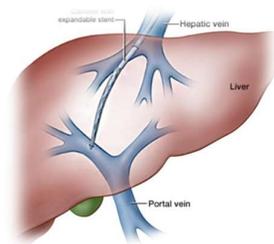
Paracentesis involves the insertion of a large needle into the peritoneal cavity to remove the ascitic fluid.

Drainage 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)*.



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

There are a wide variety of complications that can be encountered with TIPS, such as haemorrhage, hepatic encephalopathy (up to 50% of patients)^{xxv}, 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^{xxvi} and many patients with recurrent or refractory ascites due to NASH are forecast to exceed this age bracket, which we believe makes TIPS a less attractive treatment option for these patients. Furthermore, TIPS is not

^{xxv} EASL clinical practice guidelines, Journal of Hepatology, 2010, vol. 53. 397-417

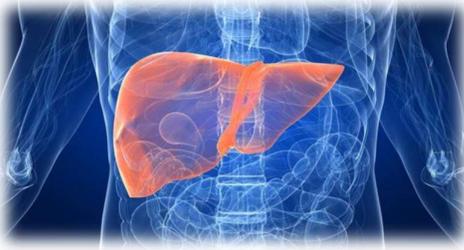
^{xxvi} Copelan et al., 2014

recommended in patients with heart failure, which is expected to represent a significant proportion of NASH/MASH patients.



The *peritoneal catheter system* facilitates drainage of ascites by use of an external catheter, which causes an increased risk for infections and blockage. As a result, it is generally used in patients with life expectancy of less than three months.

Liver transplantation remains the only curative treatment for liver disease. However, availability is extremely limited and transplants result in large healthcare costs. Furthermore, lifelong use of immunosuppressive drugs is required to reduce the risk that the recipient's body will reject the transplant. It is estimated that three out of four potential patients are not eligible for a liver transplant.



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.

Cancer and Malignant ascites

Ascites is also a common complication of certain late-stage cancers as a result of fluid accumulation in the peritoneal cavity due to a number of causes including draining of the lymph system. While life expectancy for many cancer patients with malignant ascites is short (less than 6 months), ovarian and breast cancer patients often have longer life expectancies^{xxvii}, making the **alfapump** a viable and attractive option.

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

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

The **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 physicians are able to conduct easy and regular liquid biopsies for therapy monitoring through the analysis of urine samples. These will contain significant material direct from the peritoneal cavity, including cancer cells.

^{xxvii} Ayantunde et al., 2017

^{xxviii} WHO International Agency for research on cancer, 2018

Proof-of-concept studies of alfapump in liver disease and cancer

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 and malignant ascites.

Name of Study	Description	Number of Patients
Recurrent or refractory ascites due to liver cirrhosis		
PIONEER Study	Prospective, multi-centre, open-label, uncontrolled study to assess the safety and performance of the 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 alfapump 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 alfapump 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
Retrospective Study at Hannover Medical School	Retrospective, single-centre study at Hannover Medical School to investigate the alfapump 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 US and Canada to assess the safety and efficacy of the alfapump in patients with recurrent or refractory liver ascites (completed in 2018).	30
POSEIDON (North American pivotal) Study	North American pivotal study including 40 Pivotal Cohort patients (and an additional 29 Roll-In Cohort patients) with recurrent or refractory liver ascites implanted with the alfapump to demonstrate safety and efficacy of the alfapump and support approval in the US and Canada (completed in 2024).	40
Malignant ascites due to cancer		
Retrospective Malignant Ascites Study	Retrospective open-label study in Europe to assess performance & safety of alfapump for treatment of malignant ascites (completed in 2017).	17

The key findings from clinical studies in recurrent or refractory liver ascites included significant reduction in the mean number of LVPs per month and clinically significant improvement in quality of life for patients treated with the **alfapump** versus patients treated with LVP standard of care.

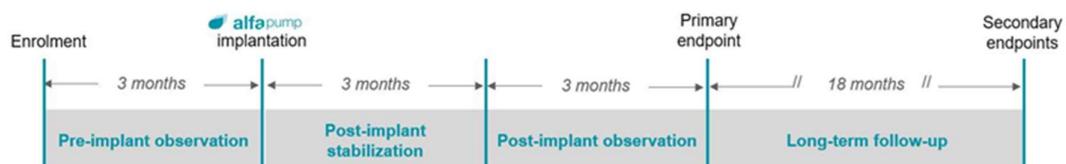
The retrospective study in patients with malignant ascites demonstrated that the **alfapump** was effective in palliative patients with malignant ascites and has the potential to improve quality of life and clinical outcomes for late-stage cancer patients.

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

POSEIDON – North American pivotal study to support approval of the alfapump in the US and Canada

Study design

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



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

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

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

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

Of the 71 patients enrolled in the Pivotal Cohort, 40 patients were implanted with the **alfapump** and have been evaluated for primary endpoint analysis at six months post-implantation. A further 29

patients were implanted with the **alfapump** in the Roll-In Cohort and are included in the overall safety analysis.

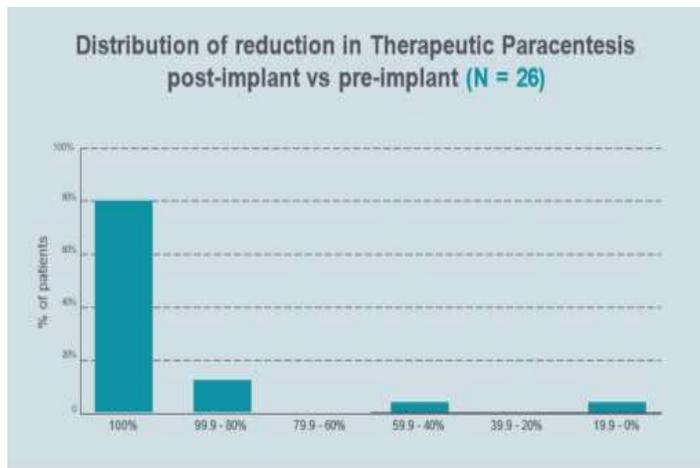
Looking at the underlying cirrhosis etiology of the 40 Pivotal Cohort patients (over one third had NASH or combined NASH etiology) and of the first 26 Roll-In patients (50% alcohol, 23% NASH, 4% NASH-alcohol, 4% hepatitis C and 19% other/mixed etiology), it is clear that NASH is already an important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

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

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

Pivotal Cohort N=40	% ^{xxix}	p-value ^{xxx}
1) Median per-patient ratio of frequency of TP	100% reduction	P<0.001
2) Proportion of patients with a 50% reduction in number of TP Post- vs. Pre-Implant	77% of patients	P<0.001

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



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

Of the six primary safety events, three were explants due to wound or skin erosion, and three were explants due to patient-reported discomfort (all patient-reported discomfort events were adjudicated

^{xxix} Using pre-specified imputation methods

^{xxx} As per primary effectiveness endpoint hypotheses. Per protocol, testing conducted using nonparametric methods for data that is not normally distributed

^{xxxi} These observed patient data are not part of the main primary effectiveness endpoint analysis.

by the independent Clinical Events Committee as moderate severity). At the time of the primary endpoint analysis, no UADE^{xxxii} occurred during the course of the POSEIDON study.

Sustained effective control of ascites and robust safety profile at 12 months post-implant

As in months 0-6 post implant, patients had a 100% median reduction in therapeutic paracentesis in the 7-12 month post-implant period vs the three month pre-implant period (n = 19). These data show that the **alfapump** has a sustained effect on controlling ascites, virtually eliminating the need for therapeutic paracentesis.

During the 7-12 month post-implant period, two patients had the **alfapump** explanted, one due to a urinary tract infection and one due to wound dehiscence and the number of Major Adverse Events (MAEs) and serious infections were in line with expectations. Importantly, creatine and eGFR levels of **alfapump**-treated patients over the 12-month follow-up indicated a stable renal function. Overall, these safety data indicate that the **alfapump** has a robust safety profile over long-term follow-up.

Quality of life, assessed through the physical component score of SF36 (a general health quality of life measure) and the Ascites Q score (a quality of life measure specific for patients with ascites), maintained a clinically meaningful improvement at 12 months post-implant vs three months pre-implant, despite disease progression.

The overall trend in survival in patients implanted with the **alfapump** remained positive over a longer term, with a Kaplan-Meier estimate indicating over 70% survival probability at 12 and 18 months post-implant. This compares favourably with the published literature reporting a predicted survival probability for refractory ascites patients with a similar MELD score^{xxxiii} and receiving paracentesis of approximately 17% at 12 months and 5% at 18 months^{xxxiv}.

Patient Preference study

The patient preference study was conducted by RTI Health Solutions, thought leaders in the field. The rigorous study design was pre-discussed with the FDA and utilizes a discrete-choice experiment (DCE^{xxxv}) methodology to elicit preferences of US patients with a physician-confirmed diagnosis of recurrent or refractory ascites due to liver cirrhosis for attributes of an implantable pump as a novel interventional treatment for ascites. Patients were surveyed for the risk of treatment-related adverse events they would be willing to accept (risk tolerance) to achieve specific improvements in treatment efficacy (desired benefits). In total, 125 US patients with a comparable patient profile as the Pivotal Cohort in the POSEIDON study, completed the survey.

^{xxxii} UADE: Unexpected Adverse Device Effects

^{xxxiii} MELD score: Model for End-Stage Liver Disease score is prognostic scoring system, based on laboratory parameters, used to predict 3-month mortality due to liver disease. MELD scores range from 6 to 40; the higher the score, the higher the 3-month mortality related to liver disease.

^{xxxiv} Salerno et al., *Gastroenterology* 2007; 133:825-834; predicted survival probability for refractory ascites patients with a MELD score of 15 and receiving paracentesis

^{xxxv} The DCE approach allows an analysis of individual stated preferences in response to hypothetical choices and enables the quantification of the relative importance of each attribute/level during the decision-making process.

Top-line results presented in the table below indicate that, on average, patients are willing to accept levels of risks greater than those observed in the POSEIDON study in exchange for improvements in treatment efficacy less than or equal to those observed in the POSEIDON study.

Risk tolerance (over 6 months)	Patient preference study Maximum acceptable risk	POSEIDON pivotal cohort Observed rate
Major surgery or death	>10%	0%
Minor procedure	>35%	20%
Serious infection or AKI resulting in hospitalization	>30%	20%

Desired benefits	Patient preference study	POSEIDON pivotal cohort
Reduction in frequency of paracentesis	100%	100% (median)
Additional ascites good health days each month	10	>10 (mean)

Reduction in paracentesis frequency and additional ascites good health days are important attributes for a novel interventional treatment for ascites. On average, patients responded with a 65% likelihood of selecting a treatment profile like the **alfapump** vs regular paracentesis procedures and no implanted pump.

These data support the premise that **alfapump** is a desirable treatment option for the majority of patients.

Matched interim analysis of NACSELD registry and POSEIDON pivotal cohort

The North American Consortium for the Study of End Stage Liver Disease (NACSELD) is a consortium of tertiary-care hepatology centers in North America formed to study patients with cirrhosis. NACSELD-III is an IRB^{xxxvi} approved registry of outpatients with cirrhosis which was initiated in 2019 at ten centers in North America.

A matched cohort analysis was conducted by an independent group comparing outcomes of decompensated cirrhosis patients from the NACSELD-III registry to those from the POSEIDON study. Forty decompensated ascites patients from NACSELD-III were matched to the forty patients from the Pivotal Cohort in the POSEIDON study, using baseline Ascites-Q score (reflecting burden of disease before **alfapump** implantation) and sex. Patients were also comparable for age and baseline MELD score after matching.

Results for all cause hospitalization and death within six months were similar between the NACSELD-III registry matched patients and the POSEIDON pivotal cohort.

^{xxxvi} IRB: Institutional Review Board

Six month data ^{xxxvii}	NACSELD-III Registry Matched Patients	POSEIDON Pivotal Cohort ^{xxxviii}
Any Death or Hospitalization	55.0% (22/40)	55.0% (22/40)
Death	12.5% (5/40)	12.5% (5/40)
Hospitalization	42.5% (17/40)	42.5% (17/40)
Median # of hospitalizations (min, max)	1 (0, 5)	1 (0, 4)
Liver Transplant	7.5% (3/40)	5.0% (2/40)

This analysis indicates that the safety profile of the **alfapump** is in line with expectations and comparable to standard paracentesis procedures.

Data from the matched cohort analysis together with the positive data from the POSEIDON study indicate that patients implanted with the **alfapump** benefit from significantly reduced number of paracentesis procedures and an improved quality of life without an increased risk of death or hospitalization compared to standard of care.

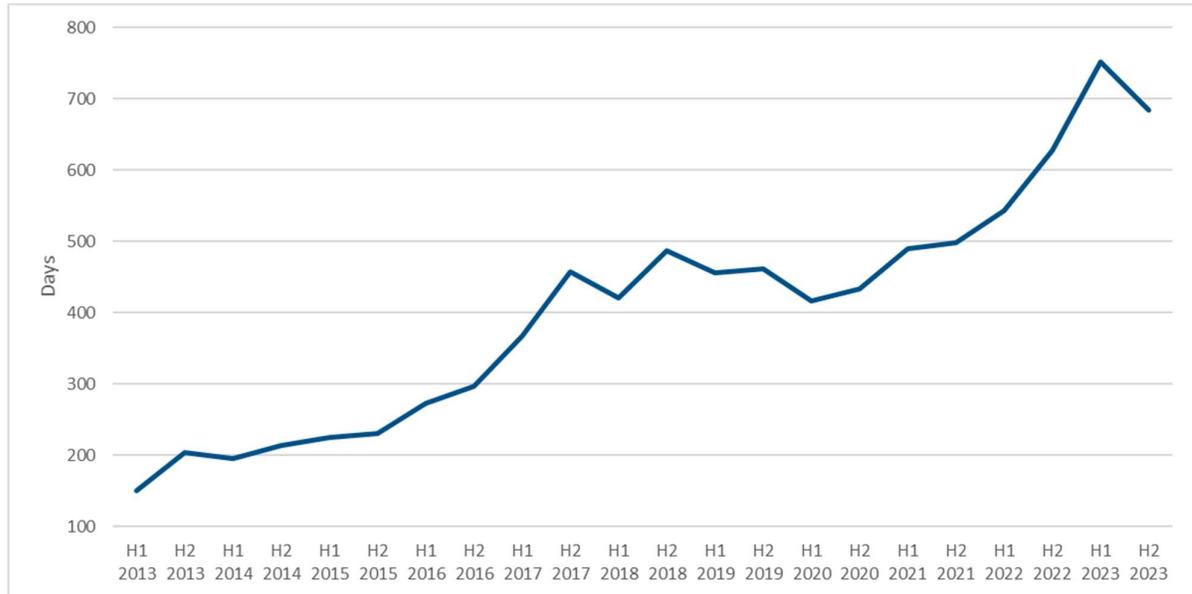
^{xxxvii} Deaths and serious adverse events (SAE) requiring hospitalization are presented hierarchically such that if a subject died and experienced an SAE requiring hospitalization, they are counted under “Death”

^{xxxviii} POSEIDON data are derived from adverse event data during six months post-implant

Dramatic improvement in duration of alfapump therapy

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

Average duration of alfapump therapy^{xxxix}



^{xxxix} Source: Sequana Medical internal statistical analysis of market feedback/implant duration

US commercialization – Going direct to 90 adult liver transplant centers

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

We have submitted a Premarket Approval (PMA) application to the US FDA in December 2023, which was accepted for substantive review in January 2024, ahead of anticipated timing. We are currently navigating through the approval process towards anticipated commercial launch in 2025.

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

For any company commercialising a novel treatment, it is essential that medical practitioners are supportive of the approach, the product and the clinical use. We have established strong relationships with KOLs in Europe and North America and we actively use our network of KOLs and patient advocacy groups to support the development and market adoption of the **alfapump**. In North America, we are working with the NACSELD-III registry to properly understand the cost and clinical impact of decompensated liver cirrhosis – building the links with the North American hepatology community.

In the US, the **alfapump** will be reimbursed through Current Procedural Terminology (CPT) codes for the physician services and bundled Diagnosis Related Group (DRG) payments for the hospital services. ICD-10 diagnosis and procedure codes, and severity of patients’ condition during their stay are bundled into the DRGs. The American Medical Association granted six new CPT category III reimbursement codes in January 2024, available for use by healthcare professionals and payors as of July 1st, 2024, for procedures related to the **alfapump** system, including implantation, revision, removal and programming of the pump system, replacement of the pump and the catheters. This is an important step in facilitating reimbursement for our innovative medical device for the treatment of recurrent or refractory ascites due to liver cirrhosis.

We were granted ICD-10 procedure codes for the **alfapump**, and these result in DRG code for “Other hepatobiliary or pancreas O.R. procedures”, including DRG 423 with major complications or comorbidities. FDA-designated breakthrough devices, such as the **alfapump** that meet certain cost criteria are eligible for incremental reimbursement through the New Technology Add-on Payment (NTAP), an initiative from CMS. If approved, NTAP can provide 65% of costs not covered by DRG payment. Based on the existing US hospital DRG payment enhanced by NTAP, we currently target a price for the **alfapump** of \$30,000 which represents a gross margin of 80%.

CMS is also working on an alternate pathway to coverage for new and innovative medical technologies, called Transitional Coverage for Emerging Technologies (TCET). An expedited coverage

process through TCET would help ensure that Medicare beneficiaries, who will be our principal patient population, have timely access to breakthrough devices such as the **alfapump** once approved by the FDA while real-world evidence continues to emerge.

DSR in heart failure

A disease-modifying heart failure drug therapy tackling cardiorenal syndrome

Fluid overload in heart failure, also known as congestion, is a key driver of morbidity and hospitalization in heart failure patients with a significant healthcare cost burden and limited effective treatments. Our DSR (Direct Sodium Removal) drug-based approach directly tackles the key clinical problem of sodium overload in heart failure patients by removing the excess sodium from the body, causing the kidneys to step in and eliminate free water to maintain the correct sodium concentration in the body.

Cardiorenal syndrome (CRS) is a key clinical challenge in heart failure and results from the combined vicious cycle of dysfunction of the heart and kidney. The resultant clinical profile is thought to manifest as a self-reinforcing negative feedback cycle characterized by decreased glomerular filtration, increased renal sodium retention, and congestion, despite escalating diuretic doses. No current therapies have been shown to improve patient outcomes in this complex and poorly understood indication. Reducing fluid overload is a key element of therapy but loop diuretics exacerbate many of the core mechanisms thought to underly CRS. Results of our RED DESERT and SAHARA proof-of-concept studies in heart failure support DSR's mechanism of action as breaking the vicious cycle of cardiorenal syndrome. Through effective control of the volume status for an extended period of time, and thereby avoiding the need for and negative consequences of loop diuretics, DSR has the potential to break the negative feedback cycle of CRS.

Extensive analysis of patients in our RED DESERT and SAHARA clinical studies shows the benefit from DSR therapy on i) volume status, ii) normalized diuretic response and dramatically reduced loop diuretic dosing, iii) improvement in kidney function, iv) neurohormonal status and signalling, as well as v) cardiovascular parameters. In these patients there were no congestion-related re-hospitalizations, a one class improvement in their NYHA status and a reduction of 75% in their predicated one-year mortality (based on the Seattle Heart Failure model). These results have been presented during the late-breaking session at a leading international heart failure conference, [THT 2024](#), and published in [European Journal of Heart Failure](#).

We have initiated MOJAVE, a US randomized controlled multi-center Phase 1/2a clinical study to confirm the strong clinical outcomes seen in the RED DESERT and SAHARA studies. All three patients from the non-randomized cohort of MOJAVE, have been successfully treated with DSR, resulting in a dramatic improvement in diuretic response and virtual elimination of loop diuretic requirements. The independent Data Safety Monitoring Board approved the start of the randomized MOJAVE cohort of up to a further 30 patients, which is planned after **alfapump** US PMA approval

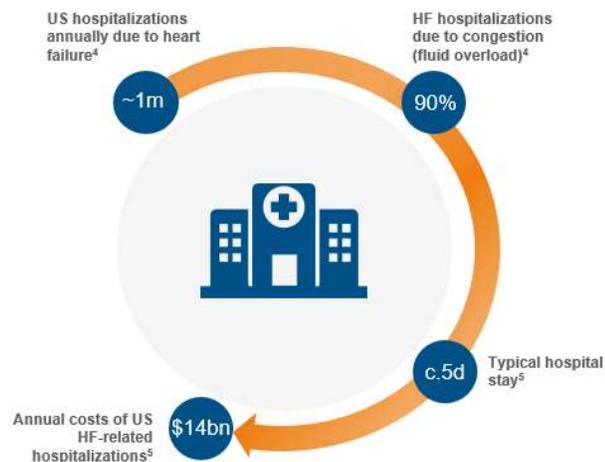
Based on the results from the MOJAVE study, we plan to establish a strategic partnership for further clinical development and commercialization of our DSR therapy. This will enable us to leverage the strengths of an established heart failure player to realize the strong commercial potential of our DSR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

Market opportunity and limitations of current therapies

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

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

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



We estimate that there are about 200,000 chronically congested heart failure patients hospitalized per year in the US and a similar number in Europe, which cause a major burden on the healthcare systems, payors and patients. This creates a total addressable market in the US of more than \$9 billion, when taken into account an annual hospital cost of \$45,000 for these patients and the potential for premium pricing of DSR through reduced hospitalization and improved survival rates.

^{xl} Benjamin et al., 2013

^{xli} Costanzo et al., 2007

^{xliii} Urbich et al., 2020

^{xliiii} US Department of Health & Human Services

^{xliv} Chen et al., 2013

^{xlv} Ross et al., 2010

^{xlvi} Testani et al., 2016

Existing therapies have severe limitations

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

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

^{xlvii} Costanzo et al., 2017

Pre-clinical and clinical studies of DSR 1.0

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

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

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

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

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

^{xlviii} NT-proBNP: N-terminal pro B-type natriuretic peptide, a key cardiac function parameter.

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

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

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

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

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

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

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

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

^{xlix} eGFR: estimated Glomerular Filtration Rate, a measure of kidney function

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

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

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

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

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

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



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

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

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

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

^{li} Seven patients from RED DESERT and ten patients from SAHARA pre- and post-intensive DSR therapy; analysis includes physician-assessed data collected post hoc

Pre-clinical and clinical studies of DSR 2.0

Following clinical proof-of-concept of our DSR therapy using DSR 1.0, we developed our proprietary second-generation DSR product (DSR 2.0), a sodium-free dextrose/icodextrin solution, for which composition of matter and method patents have been granted in the US, Europe and China, and which are under review elsewhere in the world. The intention is to deliver a product with a superior therapeutic profile and a favourable safety profile that will be better positioned for broad commercial acceptance with high margin recurring revenues. Pre-clinical and Phase 1 clinical studies using DSR 2.0 have been successfully completed. A US randomized controlled Phase 1/2a study (MOJAVE) is currently ongoing to confirm the strong clinical outcomes seen in the RED DESERT and SAHARA.

Name of Study	Description	Number
Pre-clinical studies		
GLP study in mice	Repeated dose, controlled study in healthy mice evaluating safety of DSR 2.0 compared to standard peritoneal dialysis (PD) solution, following chronic exposure of 30 days (completed in 2023).	30
GLP study in sheep	Repeated dose, controlled study in healthy sheep evaluating safety of DSR 2.0 compared to standard PD solution, following chronic exposure of up to 45 days (completed in 2023).	18
Clinical studies		
Phase 1 study in Mexico (CHIHUAHUA)	Interventional, single-centre, single-arm, single-dose study in stable PD patients to evaluate safety and tolerability of DSR 2.0 over a 24-hour dwell period (completed in 2023).	10
Phase 1 study in Canada (YUKON)	Interventional, single-centre, single-arm, single-dose study in stable PD patients to evaluate safety and tolerability of DSR 2.0 over an 8-hour dwell period (completed in 2023).	10
Phase 1/2a study in US (MOJAVE)	Randomized controlled Phase 1/2a US study in diuretic-resistant chronic heart failure patients with persistent congestion to evaluate safety and efficacy of up to four weeks of DSR 2.0 therapy on top of usual care vs. usual care alone (ongoing).	33

MOJAVE – US multi-center randomized controlled Phase 1/2a clinical trial in diuretic-resistant chronic heart failure patients with persistent congestion

Study design

The study started with a non-randomized cohort of three patients treated with DSR 2.0 on top of optimized usual care for congestive heart failure for up to four weeks, followed by a three-month safety follow-up period (with an initial review after 30 days). Following review and approval of the non-randomized cohort data by the independent Data and Safety Monitoring Board (DSMB), up to a further 30 patients will be enrolled in the multi-center randomized cohort. The intention is for up to 20 patients to be treated with DSR 2.0 on top of optimized usual care for congestive heart failure for up to four weeks, and for up to ten patients treated with intravenous loop diuretics alone as part of maximized usual care for congestive heart failure.

Primary and secondary safety and efficacy endpoints include the rate of adverse and serious adverse events and the improvement in diuretic response (measured as a six-hour urine sodium output) from baseline through the end of the treatment period. Exploratory endpoints measured from baseline through the end of the treatment period include change in weight (volume status), creatinine (a marker of renal function), natriuretic peptides (a marker of heart failure) and New York Heart Association (NYHA) functional class; and the number of heart failure related re-hospitalizations.

All three patients non-randomized cohort successfully treated with DSR 2.0

All three patients treated in the non-randomized cohort of the MOJAVE study had heart failure with preserved ejection fraction (HFpEF) and severe diuretic resistance at baseline (mean furosemide equivalent dose of 1,227 mg per day). At the start of the study treatment period, loop diuretics were withheld, and patients were treated with DSR 2.0 up to daily for four weeks, followed by a three-month safety follow-up period. All three patients successfully completed the three-month safety follow-up period.

Dramatic improvement in diuretic response and stable kidney function: During the four-week DSR treatment period, all three patients maintained euolemia without the need of loop diuretics. After the four-week DSR treatment period, patients' diuretic response^{lii} nearly normalized with a mean increase of 324% in their six-hour urinary sodium excretion vs baseline, and this was maintained at three months after the last DSR treatment. Throughout the study, patients' kidney function also remained stable as measured by eGFR and blood urea nitrogen.

Loop diuretics virtually eliminated: The need for loop diuretics was dramatically reduced or even completely eliminated, with a reduction in furosemide equivalent dose of 97%, 100% and 95% vs baseline at three months after the last DSR treatment.

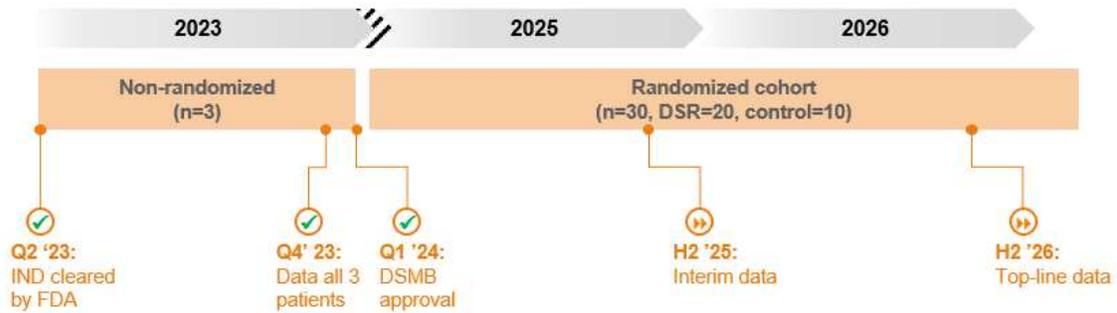
Safe and well tolerated: No clinically relevant changes in serum sodium levels or progressive hyponatremia were observed and none of the patients needed to be hospitalized for congestion throughout the study. There were only two serious adverse events, one short-term hypertension and one non-ST-elevation myocardial infarction, both adjudicated as non-related to DSR therapy. These events occurred during the three-month safety follow-up period and are often seen in this very sick patient population.

^{lii} Diuretic response assessed by 6-hour excretion of sodium after IV administration of 40mg furosemide

In January 2024, the independent DSMB approved the start of the randomized MOJAVE cohort following review of the safety data reported from the non-randomized cohort. The randomized phase is planned after receiving US market approval of our **alfapump**.

Clinical data package for partnering

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



Investor Relations

The shares in 2023

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

On 31 December 2023, the share capital of the Company amounted to €2,921,010.22 represented by 28,191,733 shares.

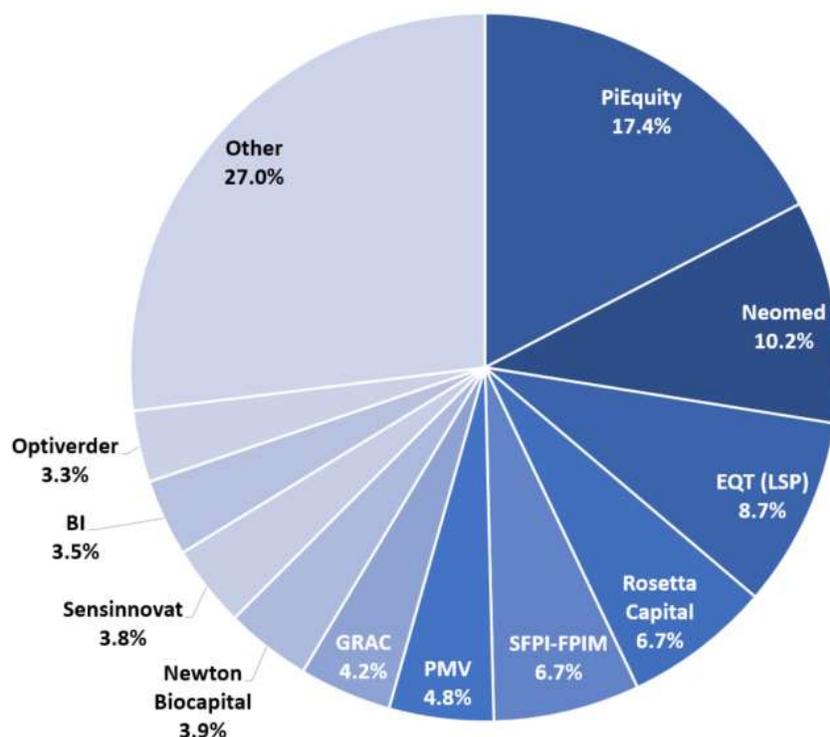
In addition to the outstanding shares, the total number of outstanding subscription rights on 31 December 2023 amounted to 4,145,008, entitling their holders (if exercised) to subscribe to 3,905,321 new shares with voting rights in total.

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



Major Shareholders

Sequana Medical has an international shareholder base and is supported by experienced life sciences investors and industry experts, and a broad base of local retail investors. Based on the number of shares as at 31 December 2022 and the transparency notifications received until that date, the shareholder structure of the Company **as per 31 December 2023** was as follows:



Analyst coverage

Sequana Medical was covered by five analysts at the end of 2023

Broker	Analyst
Degroof Petercam	Laura Roba
Edison Investment Research	Pooya Hemami
H.C. Wainwright	Yi Chen
KBC Securities	Jacob Mekhael
Van Lanschot Kempen	Luísa Morgado

Investor Relations Contact

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

CORPORATE GOVERNANCE

1. Report of the Board of Directors

This report of the Board of Directors has been prepared in accordance with the Articles 3:5, 3:6, §1 and 3:32, §1 of the Belgian Companies and Associations Code of 23 March 2019 (as amended) (the "**Belgian Companies and Associations Code**" or "**BCAC**") and relates to the position of Sequana Medical NV, a company domiciled and incorporated in Belgium (the "**Company**" or "**Sequana Medical**"), and together with its subsidiaries, the "**Sequana Medical Group**"), and the Company's annual accounts for the financial year ended on 31 December 2023.

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

1.1.1 *Operational review in the year 2023*

North American alfapump liver program

- POSEIDON – one-year follow-up data from successful pivotal study in patients with recurrent or refractory ascites due to liver cirrhosis, confirms strong clinical profile of **alfapump**
 - Virtual elimination of needle paracentesis
 - Robust safety profile despite disease progression
 - Clinically meaningful improvement in patients' quality of life maintained
 - Survival probability of 70% at 12 and 18 months post-implant
- Patient preference study indicates that US patients have a strong preference for the **alfapump** vs large volume paracentesis^{liii}
- Matched interim analysis of patients from NACSELD^{liv} registry indicates that **alfapump** safety profile is comparable to standard of care^{lv}
- PMA application submitted to the US FDA in December 2023

DSR heart failure program

- Successful completion of IND^{lvi}-enabling pre-clinical and Phase 1 studies of second-generation DSR product (DSR 2.0)
 - Data from GLP^{lvii} studies in mice and sheep showed there was no difference in systemic and local toxic effects in animals treated repeatedly with DSR 2.0 compared to animals in the control group, concluding that DSR 2.0 had consistent safety with the standard peritoneal dialysis solution used in the control group

^{liii} Patient preference study using discrete-choice experiment methodology to elicit patient preference for attributes of an implantable pump as a novel interventional treatment for ascites, N=125 US patients with comparable patient profile to pivotal cohort in POSEIDON study

^{liv} NACSELD: North American Consortium for the Study of End stage Liver Disease

^{lv} Comparing outcomes in terms of death, hospitalization rate and liver transplant of POSEIDON pivotal cohort (6 months post-implant) to matched patient group from NACSELD registry with POSEIDON

^{lvi} IND: Investigational New Drug

^{lvii} GLP: Good Laboratory Practice

- Data from the Phase 1 CHIHUAHUA study in stable peritoneal dialysis patients demonstrated that a single dose of DSR 2.0 was safe and well-tolerated and indicated a compelling dosing profile
- MOJAVE – all three patients from the non-randomized cohort in the US Phase 1/2a study of DSR 2.0 for treatment of congestive heart failure successfully treated with DSR 2.0, confirming the strong clinical outcomes seen in the RED DESERT and SAHARA proof-of-concept studies
 - Safe and effective maintenance of euolemia without the need for loop diuretics
 - Durable improvement in cardio-renal health
 - Dramatic improvement in diuretic response and at least 95% reduction in loop diuretic requirements up to almost four months after last DSR therapy
- Additional DSR patents granted in the US and China
 - Additional US patents granted in February 2023 covering among other, the expansion of the composition of matter and method for Sequana Medical's DSR therapy, including additional oncotic and osmotic agents and the use of an implantable pump system
 - A key composition of matter patent was granted in China in March 2023

Corporate

- Established Sequana Medical US Inc. with an office in Boston which has been certified according to ISO 13485:2016 and MDSAP^{lviii} (USA and Canada) by BSI^{lix}, in preparation of the US commercial launch of the **alfapump**
- Expanded Board of Directors with the appointment of Dr. Kenneth Macleod in June 2023 and Ids van der Weij in November 2023 as non-executive directors
 - Dr. Macleod is a partner at Rosetta Capital and brings more than 35 years' experience in the life science sector from his senior operating roles in healthcare companies and life science fund management
 - Mr. van der Weij is managing partner of Partners in Equity and brings more than 25 years' corporate investment experience
- Raised €15.8 million in gross proceeds in April 2023 by means of an equity placement via an accelerated book building offering
- Cash position of €2.6 million at the end of December 2023, compared to €18.9 million at the end of December 2022

^{lviii} MDSAP: Medical Device Single Audit Program

^{lix} BSI: British Standards Institution

1.1.2 *Commentary on the consolidated annual accounts*

Consolidated statements of profit and loss

Revenue

Revenue decreased from €0.92 million in 2022 to €0.71 million in 2023 due to the decision to scale back European commercial activities in April 2023.

Cost of goods sold

Cost of goods sold decreased from €0.21 million in 2022 to €0.16 million in 2023 in line with the decrease in revenue.

Operating expenses

Total operating expenses remained broadly unchanged from €29.34 million in 2022 to €30.04 million in 2023 and are mainly related to the preparations of the submissions for marketing approval of the **alfapump** in the US.

Sales and marketing expenses decreased from €2.24 million in 2022 to €1.80 million in 2023 due to the decision to scale back European commercial activities.

Clinical expenses decreased from €9.77 million in 2022 to €6.95 million in 2023 mainly as a result of lower costs related to the North American pivotal POSEIDON study of the **alfapump** and the completion of the SAHARA DSR proof-of-concept study in 2022, partially compensated by pre-clinical and clinical development work required for the Company's IND filing for its proprietary DSR product and commencement of the MOJAVE study in the US.

Quality and Regulatory expenses increased from €3.63 million in 2022 to €5.59 million in 2023, mainly driven by external advice solicited for the preparation of the submissions for marketing approval of the **alfapump** in the US.

Supply chain expenses increased from €3.16 million in 2022 to €4.72 million in 2023 largely driven by additional staffing and external advice for the preparation of the submissions for marketing approval of the **alfapump** in the US and higher production costs.

Engineering expenses increased from €3.85 million in 2022 to €4.04 million in 2023, largely driven by test samples required for the preparations of the submissions for marketing approval of the **alfapump** in the US.

General and administration expenses remained broadly unchanged, from €6.69 million in 2022 to €6.94 million in 2023.

Other income remained broadly unchanged from €0.53 million in 2022 to €0.63 million in 2023.

EBIT^{lx}

Earnings before interest and taxes (EBIT) remained broadly unchanged from a loss of €28.09 million in 2022 to a loss of €28.86 million in 2023.

Total net finance expenses

^{lx} EBIT is defined as revenue less cost of goods sold and operating expenses

Net finance cost increased from €2.28 million in 2022 to €3.24 million in 2023, mainly resulting from the valuation of the Investor Warrants (non-cash item) and debt related interest expenses compensated by the valuation of the Bootstrap Warrants and Kreos Subscription Rights (both non-cash items).

Income tax expense

Income tax expense remained broadly unchanged from €0.39 million in 2022 to €0.47 million in 2023.

Net loss for the period

As a result of the above, the net loss increased from €30.76 million in 2022 to €32.56 million in 2023.

Basic losses per share (LPS)

Basic losses per share decreased from €1.35 in 2022 to €1.22 in 2023.

Consolidated balance sheet**Net debt**

Net debt^{lxi} at 31 December 2023 increased by €16.22 million compared to 31 December 2022.

Working Capital

Working capital^{lxii} in 2023 decreased by €0.32 million compared to 2022, mainly as a result of a decrease in trade payables and other payables.

Consolidated statement of cash flows

Net cash outflow from operating activities was €29.06 million in 2023 compared to €27.48 million in 2022. The outflow was mainly driven by higher net loss of the period.

Cash flow from investing activities resulted in a net outflow of €0.72 million in 2023, compared to a net outflow of €0.65 million in 2022.

Cash flow from financing activities resulted in a net inflow of €13.46 million in 2023, mainly as a result of the proceeds from the equity placement in H1 2023 partially compensated by repayments of financial debt and interest. In 2022, the net inflow of €37.32 million was mainly a result of the proceeds from the equity placement in H1 2022, and the €10 million loan facility with Kreos Capital secured in H2 2022.

The Company ended 2023 with a total cash and cash equivalents amount of €2.58 million (2022: €18.87 million).

^{lxi} Net debt is calculated by adding short-term, long-term financial and lease debt and deducting cash and cash equivalents.

^{lxii} The components of working capital are inventory + trade receivables + other receivables and prepaid expenses - trade payables - other payables - accrued liabilities and provisions.

1.1.3 Information regarding major risks and uncertainties

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

Risks relating to global events

- The ongoing conflicts in Eastern Europe and the Middle East could have a destabilising impact on Sequana Medical's operations, both directly as a result of potential impacts on Sequana Medical's supply chain and indirectly due to the impact on global macroeconomic conditions.

Risks relating to Sequana Medical's financial situation

- Sequana Medical has incurred operating losses, negative operating cash flows and an accumulated deficit since inception and may not be able to achieve or subsequently maintain profitability.
- Sequana Medical does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months as of the date of this Annual Report and will require additional funds beyond this period in order to meet its capital and expenditure needs.
- Changes in currency exchange rates could have a material negative impact on the profitability of Sequana Medical.

Risks relating to clinical development

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

Legal and regulatory risks

- Seeking and obtaining regulatory approval for medical devices and drugs can be a long, expensive and uncertain process. Strict or changing regulatory regimes, government policies and legislation in any of Sequana Medical's target markets may delay, prohibit or reduce potential sales.
- Once pre-market approval ("PMA") of the alfapump has been granted by the US FDA, Sequana Medical intends to further develop a proprietary DSR product, which will require approval as a drug by the FDA and likely by regulatory authorities in other jurisdictions where Sequana Medical intends to market the DSR[®] product.

- Sequana Medical is and will be subject to certain post-approval regulatory obligations in relation to the alfapump® and, when relevant, the DSR® product.
- Sequana Medical's manufacturing facility and those of its third party suppliers are subject to significant regulations and approvals. If Sequana Medical or its third-party manufacturers or suppliers fail to comply with these regulations or maintain these approvals, Sequana Medical's business will be materially harmed.
- Sequana Medical is subject to the risk of product liability claims or claims of defectiveness, which could result in uninsured losses for Sequana Medical or recalls of the relevant product.
- Compliance with regulations and standards for quality systems for medical device and drug companies is complex, time consuming and costly. Sequana Medical may be found to be non-compliant, for example as a result of future changes in or interpretation of the regulations regarding quality systems in certain jurisdictions.
- The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about medical devices and drugs. If Sequana Medical is found to have made false or misleading claims about the alfapump® the DSR® product and/or any future products, or otherwise have violated promotion or advertising restrictions, it may become subject to significant fines and/or other liabilities.
- Sequana Medical is subject to healthcare fraud and abuse and other laws applicable to Sequana Medical's business activities. If Sequana Medical is unable to comply with such laws, it could face substantial penalties.
- Sequana Medical faces risks related to environmental matters and animal testing activities.

Risks relating to the Sequana Medical's dependence on third parties as well as retention and hiring of key personnel

- Sequana Medical depends on third party suppliers for services, components and pharmaceutical ingredients used in the production and operation of the alfapump® and, when relevant, DSR® product and some of those services, components and pharmaceutical ingredients are supplied from a single source. Disruption of the supply chain, unavailability of third party services required for the production of the alfapump® and, when relevant, DSR® product, component modifications or failure to achieve economies of scale could have a material adverse effect on Sequana Medical.
- Sequana Medical relies on third parties to conduct its clinical studies, perform data collection and analysis, and provide regulatory advice and other services that are crucial to its business.
- Sequana Medical relies on retaining its key personnel as well as the hiring of additional personnel to conduct its planned activities, including scale up of US commercial and manufacturing.

Risks relating to commercialisation and reimbursement

- Sequana Medical's success is largely contingent on third party payment from government providers, healthcare insurance providers or other public or private sources and it could fail to achieve or maintain reimbursement levels sufficient to support commercialisation on a large scale.
- Sequana Medical's future financial performance will depend on the commercial acceptance of the alfapump®, when relevant, the DSR® product, and/or any future products in target markets.

- The success of the alfapump[®], when relevant, the DSR[®] product, and/or any future products depends on their acceptance and adoption by physicians.
- Sequana Medical may not be able to manufacture or outsource manufacturing of the alfapump[®], when relevant, the DSR[®] product and/or any future products in sufficient quantities, in a timely manner or at a cost that is economically attractive.
- If Sequana Medical is unable to expand its sales, marketing and distribution capabilities for the alfapump[®], when relevant, the DSR[®] product, and/or any future products, whether it be with internal infrastructure or an arrangement with a commercial partner, Sequana Medical may not be successful in commercialising the alfapump[®], DSR[®] product and/or any future products in its target markets, if and when they are approved.

Risks relating to intellectual property

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

Risks relating to business activities

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

Risks relating to surgical procedures

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

Risks relating to the market in which Sequana Medical operates

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

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

- An active market for the Company's shares may not be sustained.
- The market price of the Company's shares may fluctuate widely in response to various factors and the market price of the shares may be adversely affected by such factors.
- Future sales of substantial amounts of the Company's shares, or the perception that such sales could occur, could adversely affect the market value of the Company's shares.

- The Company will likely not be in a position to pay dividends in the near future and intends to retain all earnings.
- Certain significant shareholders of the Company may have different interests from the Company and may be able to control the Company, including the outcome of shareholder votes.
- Any future capital increases by the Company could have a negative impact on the price of the Company's shares and could dilute the interests of existing shareholders.

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

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

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

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

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

The following R&D programs have been undertaken in the course of 2023 with the objective to further develop the **alfapump** and the **DSR®** product:

North American alfapump liver program

- POSEIDON – one-year follow-up data from successful pivotal study in patients with recurrent or refractory ascites due to liver cirrhosis, confirms strong clinical profile of **alfapump**
 - Virtual elimination of needle paracentesis
 - Robust safety profile despite disease progression
 - Clinically meaningful improvement in patients' quality of life maintained
 - Survival probability of 70% at 12 and 18 months post-implant
- Patient preference study indicates that US patients have a strong preference for the **alfapump** vs large volume paracentesis^{lxiii}
- Matched interim analysis of patients from NACSELD^{lxiv} registry indicates that **alfapump** safety profile is comparable to standard of care^{lxv}
- PMA application submitted to the US FDA in December 2023

DSR heart failure program

^{lxiii} Patient preference study using discrete-choice experiment methodology to elicit patient preference for attributes of an implantable pump as a novel interventional treatment for ascites, N=125 US patients with comparable patient profile to pivotal cohort in POSEIDON study

^{lxiv} NACSELD: North American Consortium for the Study of End stage Liver Disease

^{lxv} Comparing outcomes in terms of death, hospitalization rate and liver transplant of POSEIDON pivotal cohort (6 months post-implant) to matched patient group from NACSELD registry with POSEIDON

- Successful completion of IND^{lxvi}-enabling pre-clinical and Phase 1 studies of second-generation DSR product (DSR 2.0)
 - Data from GLP^{lxvii} studies in mice and sheep showed there was no difference in systemic and local toxic effects in animals treated repeatedly with DSR 2.0 compared to animals in the control group, concluding that DSR 2.0 had consistent safety with the standard peritoneal dialysis solution used in the control group
 - Data from the Phase 1 CHIHUAHUA study in stable peritoneal dialysis patients demonstrated that a single dose of DSR 2.0 was safe and well-tolerated and indicated a compelling dosing profile
- MOJAVE – all three patients from the non-randomized cohort in the US Phase 1/2a study of DSR 2.0 for treatment of congestive heart failure successfully treated with DSR 2.0, confirming the strong clinical outcomes seen in the RED DESERT and SAHARA proof-of-concept studies
 - Safe and effective maintenance of euvolemia without the need for loop diuretics
 - Durable improvement in cardio-renal health
 - Dramatic improvement in diuretic response and at least 95% reduction in loop diuretic requirements up to almost four months after last DSR therapy
- Additional DSR patents granted in the US and China
 - Additional US patents granted in February 2023 covering among other, the expansion of the composition of matter and method for Sequana Medical's DSR therapy, including additional oncotic and osmotic agents and the use of an implantable pump system
 - A key composition of matter patent was granted in China in March 2023

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

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

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

We refer to section 2.6 in the Corporate Governance Statement.

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

We refer to section 2.13 in the Corporate Governance Statement.

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

We refer to section 2.16 in the Corporate Governance Statement.

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

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

^{lxvi} IND: Investigational New Drug

^{lxvii} GLP: Good Laboratory Practice

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

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

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

The Consolidated Statement of Financial Position as at 31 December 2023 shows a negative equity in the amount of EUR 19.5 million and ending cash balance of EUR 2.6 million. The Company will continue to require additional financing in the near future and in that respect already executed a EUR 3.0 million Investor Loan Agreement in February 2024 with Partners in Equity and Rosetta Capital and raised EUR 11.5 million gross proceeds in March 2024 in a private equity placement via an accelerated book-build offering disclosed in note 14 "*Events after the reporting period in the Notes to Consolidated Financial Statements*". Together with existing cash resources, the net proceeds from these financing activities are expected to extend the current cash runway of the Company to the end of Q3 2024.

Based on the above condition, the Executive Management and the Board of Directors made an assessment of the Company's ability to continue as a going concern. Several measures have already been carried out in order to reduce expenditures, including:

- alfapump program: The Board of Directors strongly believes that pre-market approval ("PMA") approval of the alfapump is a key value inflection point for the Company and has decided to prioritize its resources on reaching this important milestone. A number of other alfapump-related activities have been delayed or halted, including termination of all commercial activities in Europe, which resulted in a significant reduction in personnel in all countries, and
- Heart Failure/DSR: Delaying the randomized phase of the MOJAVE clinical study until after the alfapump pre-market approval ("PMA") approval.

The Company is also assessing to what extent partnerships or licensing arrangements could be entered into regarding its alfapump and DSR programs in order to support development and commercialisation. While on the date hereof no concrete plans are on the table, the Company continuously engages with potential partners, which could also provide further funding to the Company's business.

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

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

We refer for more details about the additional financing to note 14 *“Events after the reporting period in the Notes to Consolidated Financial Statements”*.

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

On 4 October 2023, the board of directors of the Company convened before a notary public to resolve to approve the increase of the share capital of the Company in the framework of the authorised capital by the issuance of 51,020 new shares to the benefit of certain non-executive independent directors in the framework of the so-called "Restricted Share Units" (RSU) remuneration component (as set out in the remuneration policy approved by the extraordinary general meeting of the Company on 10 February 2023). The conflicts of interests procedure of Articles 7:96 of the Belgian Companies and Associations Code was applied during the aforementioned board meeting. In accordance with the Articles 7:96 and 3:6 of the Belgian Companies and Associations Code, the sections below contain the relevant parts of the aforementioned board decision.

Extract of the Minutes of the Meeting of the Board of Directors of 4 October 2023

[...]

Prior declaration by Pierre Chauvineau, WIOT BV (with Wim Ottevaere as permanent representative), Douglas Kohrs and Alexandra Taylor Clyde

Prior to the deliberation and resolutions of the board of directors, Pierre Chauvineau, WIOT BV (with Wim Ottevaere as permanent representative), Douglas Kohrs and Alexandra Taylor Clyde, each a director of the Company, declared, insofar as necessary and applicable, to have a conflicting interest within the meaning of article 7:96 of the Belgian companies and associations code with regard to the resolutions of the board of directors (since they are all beneficiaries of the capital increase and issuance of shares referred to in the agenda above). Subsequently, Pierre Chauvineau, WIOT BV (with Wim Ottevaere as permanent representative), Douglas Kohrs and Alexandra Taylor Clyde do not longer participate in the further deliberation and resolutions of the board of directors with regard to the capital increase and issuance of shares.

Prior declarations by the other directors

None of the other directors declared to have an interest in the capital increase that would require the application of the procedure of the provisions of article 7:96 of the Belgian companies and associations code.

Considerations by the board of directors with respect to the prior declarations

The other members of the board of directors have taken note of the prior declarations by Pierre Chauvineau, WIOT BV (with Wim Ottevaere as permanent representative), Douglas Kohrs and Alexandra Taylor Clyde.

The board of directors points out that the resolutions of the board of directors would not require the application of the procedure of article 7:97 of the Belgian companies and associations code since article 7:97, §1, 3° of the Belgian companies and associations code states that such procedure does not have to be applied for resolutions relating to the remuneration of the directors (which is the case since the new shares are issued within the framework of the remuneration policy which was approved by the Company's extraordinary general meeting, on the recommendation of the nomination- and remuneration committee, on February 10, 2023; as further described in the report of the board of directors referred to in item 1 of the agenda).

[...]

After this explanation and after deliberation, the board of directors of the Company requests the notary public to authenticate that the board of directors has unanimously resolved what follows:

FIRST RESOLUTION: Approval of the report of the board of directors

The board of directors resolves to approve the report prepared according to article 7:198 juncto articles 7:179 and 7:191 of the Belgian companies and associations code of March 23, 2019, as amended (the "Belgian companies and associations code") with regard to the proposition of the Company's board of directors to, within the framework of the authorized capital, (i) increase the capital of the Company in cash by an amount not exceeding EUR 15,892.36 (including issue premium) through the issuance of maximum 144.476 new shares at an issue price of EUR 0.11 per new share, to the benefit of members of the personnel within the meaning of article 1:27 of the Belgian companies and associations code, in particular independent non-executive directors Pierre Chauvineau, WIOT BV (with Wim Ottevaere as permanent representative), Douglas Kohrs and Alexandra Taylor Clyde (the "Beneficiaries"), and (ii) in this respect, in the interest of the Company, disapply the legal preferential subscription right of the existing shareholders of the Company and, insofar as necessary, of the existing holders of subscription rights (share options) of the Company, to the benefit of the Beneficiaries.

The board of directors of the Company establishes that, insofar as necessary and applicable, according to article 3:63, §5 of the Belgian companies and associations code, the members of the audit committee consent that the assignment to prepare the statutory auditor's report referred to in item 2 of the agenda, according to the rules and conditions which are necessary for such report, was given to the Company's statutory auditor.

SECOND RESOLUTION: Submission of the report of the statutory auditor

The board of directors submits the report of the statutory auditor of the Company prepared according to article 7:198 juncto articles 7:179 and 7:191 of the Belgian companies and associations code with regard to the proposition of the board of directors of the Company to, within the framework of the authorized capital, (i) increase the capital of the Company in cash by an amount not exceeding EUR 15.892.36 (including issue premium) through the issuance maximum 144,476 new shares at an issue price of EUR 0.11 per new share to the benefit of the Beneficiaries, and (ii) in this respect, in the interest of the Company, disapply the preferential subscription right of the existing shareholders of the Company and, insofar as necessary, the legal preferential right of the existing shareholders of the Company and, to the extent necessary, of the existing holders of subscription rights (share options) of the Company, to the benefit of the Beneficiaries.

[...]

THIRD RESOLUTION: Resolution to issue new shares within the framework of the authorized capital

The board of directors resolves to, within the framework of the authorized capital as provided for in article 8 of the Company's articles of association, increase the capital of the Company in cash by an amount not exceeding fifteen thousand eight hundred and ninety-two euros and thirty-six cents (EUR 15,892.36) (including issue premium) through the issuance of maximum hundred forty-four thousand four hundred and seventy-six (144,476) new shares, in the manner described in the report of the board of directors referred to in item 1 of the agenda.

All new shares to be issued within the framework of the capital increase in cash shall have no nominal value, shall be of the same nature as the existing and outstanding shares of the Company, and shall have the same rights and benefits as, and shall in all aspects have the same (*pari passu*) rank, including dividends and other entitlement rights, as the existing and outstanding shares of the Company at the time of their issuance and shall have the right to dividends and other entitlements for which the relevant registration date or maturity date is on or after the date of issuance of the new shares.

The aforementioned capital increase is made immediately in the amount of a cash contribution of five thousand six hundred and twelve euro twenty cents (EUR 5,612.20) (including issue premium) through the issuance of fifty-one thousand twenty-one (51,020) new shares. The remaining part of the capital increase, namely the cash contribution of an amount not exceeding ten thousand two hundred and eighty euro sixteen cents (EUR 10,280.16) (including issue premium) through the issuance of maximum ninety-three thousand four hundred and fifty-six (93.456) new shares, occurs under the conditions precedent set out in the report of the board of directors referred to in item 1 of the agenda,

and will be determined at a later date by the board of directors according to article 7:198 juncto article 7:186 of the Belgian companies and associations code.

FOURTH RESOLUTION: Confirmation of subscription to a part of the capital increase

The board of directors confirms that (i) a capital increase has occurred for a total amount of EUR 5,612.20 by issuance of fifty-one thousand twenty-one (51,020) new shares, whereby an amount of five thousand two hundred eighty-five euro sixty-eight cents (EUR 5,285.68) will be booked as capital and an amount of three hundred and twenty-six euro fifty-two cents (EUR 326.52) will be booked as issue premium, (ii) such capital is fully and unconditionally subscribed to and fully paid up, and (iii) as a result of such capital increase, all the existing and outstanding shares of the Company (including the new shares issued to the benefit of the Investors) have the same fractional value of zero comma one zero three six euros (EUR 0.1036) per share.

As mentioned above, certain new shares may be issued at a later time (to the extent that the applicable conditions precedent have been met; as further described in the report of the board of directors referred to in item 1 of the agenda) and the subscription to such capital increase (and confirmation thereof) may be established at that time.

[...]

No other events took place in 2023 that required the application of the provisions foreseen in article 7:96 and/or 7:97 BCAC.

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

Neither the Company nor any person acting in his own name but on behalf of the Company has acquired shares of the Company during the financial year 2023.

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

At 27 April 2023, the Company announced that in the context of the capital increase that was announced on 24 April 2023 and completed on 27 April 2023 by means of a private placement through an accelerated book building procedure of 4,445,205 new shares (being approximately 18.72% of the Company's outstanding shares at that time) at an issue price of EUR 3.55 per share. Its share capital increased from EUR 2,460,487 to EUR 2,921,010 and the number of issued and outstanding shares has increased from 23,746,528 to 28,191,733 ordinary shares. Of the 4,445,205 new shares, 2,276,192 were immediately admitted to listing and trading on the regulated market of Euronext Brussels upon their issuance (on the basis of applicable listing prospectus exemptions), while 2,169,013 shares were not immediately admitted to listing and trading on the regulated market of Euronext Brussels upon their issuance (as their admission to listing and trading was subject to the approval of a listing prospectus). The remaining shares have been admitted to trading and listing on the regulated market of Euronext Brussels after the approval of a listing prospectus by the FSMA on 26 July 2023. As a result of this transaction, the Board of Directors of the Company increased the share capital of the Company (on 27 April 2023 and 10 May 2023 in the framework of the authorised capital with the issuance of

4,445,205 new shares, with dis-application of the preferential subscription right of the shareholders of the Company and, in so far as required, of the holders of subscription rights (stock options) of the Company, that were offered to a broad group of Belgian and foreign institutional, qualified, professional and/or other investors, in and outside of Belgium, on the basis of applicable private placement exemptions, in the framework of a private placement through an accelerated bookbuilding procedure. In this context, the Board of Directors prepared a report in accordance with Article 7:198 juncto Article 7:179, 7:180 and 7:191 of the Belgian Companies and Associations Code in relation to the transaction, providing notably (i) a justification of the transaction, including notably a justification of the issue price of the new shares, (ii) a description of the consequences of the transaction for the financial and shareholder rights of the shareholders of the Company, (iii) a justification of the proposed dis-application of the statutory preferential subscription right of the shareholders and, in so far as required, of the holders of subscription rights (stock options) in connection with the proposed increase of the share capital in the framework of the transaction, and (iv) a description of the consequences of the dis-application of the preferential subscription rights for the financial and shareholder rights of the shareholders. This board report must be read together with the report prepared by the Company's statutory auditor, PwC Bedrijfsrevisoren BV, a private company with limited liability organised and existing under the laws of Belgium, with registered office at Culliganlaan 5, 1830 Machelen, Belgium, represented by Mr. Peter D'hondt, auditor.

As mentioned above, on 4 October 2023, the board of directors of the Company issued 51,020 new shares in the framework of the authorised capital to the benefit of certain non-executive independent directors in the framework of the so-called "Restricted Share Units" (RSU) remuneration component (as set out in the remuneration policy approved by the extraordinary general meeting of the Company on 10 February 2023). The Company's share capital has increased from EUR 2,921,010 to EUR 2,926,296 and the number of issued and outstanding shares has further increased from 28,191,733 to 28,242,753 ordinary shares, through the issuance of a total of 51,020 new shares that were subscribed for in the capital increase. In this context, the Board of Directors prepared a report in accordance with Article 7:198 juncto Articles 7:179 and 7:191 of the Belgian Companies and Associations Code in relation to the transaction. This board report must be read together with the related report prepared by the Company's statutory auditor.

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

2. Corporate Governance Statement

2.1 Introduction

This Corporate Governance Statement is included in the Company's report of the Board of Directors on the statutory accounts for the financial year ended on 31 December 2023 (dated 19 April 2024) in accordance with Article 3:6, §2 of the Belgian Companies and Associations Code of 23 March 2019 (as amended) (the "**Belgian Companies and Associations Code**").

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

On 23 April 2020, the Board of Directors approved an amended and restated version of the Company's Corporate Governance Charter to align it with the provisions of the 2020 Belgian Corporate Governance Code and the Belgian Companies and Associations Code. The current version of the Company's Corporate Governance Charter was approved by the Company's board of directors on 21 April 2023. The board of directors of the Company will review this charter from time to time and make such changes as it deems necessary and appropriate.

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

2.2 Corporate Governance Charter

The Company applied a Corporate Governance Charter that was in line with the 2020 Belgian Corporate Governance Code. The Company's Board of Directors approved the last version of this charter on 21 April 2023. The Corporate Governance Charter described the main aspects of the Corporate Governance of the Company, including its governance structure, the terms of reference of the Board of Directors and its committees and other important topics. The Corporate Governance Charter had to be read together with the Company's articles of association.

2.3 Deviations from the 2020 Belgian Corporate Governance Code

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

- Pursuant to Article 7:91 of the Belgian Companies and Associations Code and provision 7.11 of the 2020 Belgian Corporate Governance Code, shares should not vest and share options should not be exercisable within three years as of their granting. Insofar as necessary, it is recalled that following the extraordinary shareholders' meeting of 28 May 2020, it has been expressly provided in the articles of association that the Board of Directors is explicitly authorised to deviate from the provisions of Article 7:91 of the Belgian Companies and Associations Code, for all persons who fall within the scope of these provisions (whether directly or pursuant to Articles 7:108 and 7:121 of the Belgian Companies and Associations Code, or otherwise). The Company is of the opinion that this allows for more flexibility when structuring share-based awards. For example, it is customary for option plans to provide for a vesting in several instalments over a well-defined period of time, instead of vesting after three years only. This seems to be more in line with prevailing practice.

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

qualified as variable remuneration, the Board of Directors is of the opinion that such bad leaver provisions sufficiently protect the Company's interests and that it is therefore currently not necessary to provide for additional contractual provisions that give the Company a contractual right to reclaim any (variable) remuneration from the members of the Executive Management.

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

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

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

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

2.4.1. Board of Directors

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

Name	Age	Position	Start of Current Term	End of Current Term
Mr Pierre Chauvineau	60	Chair, Independent Non-Executive Director	2021	2025
Mr Ian Crosbie	56	CEO, Executive Director	2021	2025
Dr Rudy Dekeyser	63	Non-Executive Director	2021	2025
Mr Wim Ottevaere^{lxviii}	68	Independent Non-Executive Director	2021	2025
Mrs Jackie Fielding	60	Independent Non-Executive Director	2022	2026
Mr Doug Kohrs	66	Independent Non-Executive Director	2023	2026
Mrs Alexandra Clyde	60	Independent Non-Executive Director	2023	2026
Mr Kenneth Macleod	64	Non-Executive Director	2023	2027
Mr Ids van der Weij	57	Non-Executive Director	2023	2027

Mr Pierre Chauvineau is an independent non-executive director and the chair of the Company's Board of Directors. Mr Chauvineau has over 31 years of international business leadership in corporate and start-up companies within the medical technology industry. He started his career with Medtronic where he spent 20 years before joining Cameron Health, a VC-funded medical device company based

^{lxviii} Acting as permanent representative of WIOT BV.

in California where he was responsible for commercialising their innovative implantable defibrillator across international markets. Cameron Health was acquired by Boston Scientific two years later in June 2012, after which Mr Chauvineau went on to lead Boston Scientific's largest European Business Unit for 5 years. Today, Mr Chauvineau continues to mentor and coach, he is also a non-executive board member with London based Rhythm AI and Lausanne based Comphya. He is also the chairman of Galway based Aurigen Medical. Pierre Chauvineau holds an MBA degree in International Management from the Monterey Institute of International Studies (Monterey, California, U.S.A.) and a BA degree from IPAG (Paris, France).

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

Dr Rudy Dekeyser is a non-executive director of the Company. He is partner at EQT and head of the EQT's Health Economics Funds. Besides serving on the Company's Board of Directors, Dr. Dekeyser currently also serves on the Board of Directors of Lumeon, Nobi and reMYND 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). Dr. Dekeyser was one of the founders of VIB and co-managing director of this leading life sciences research institute for 17 years, during which he was also responsible for all business development. Under his leadership VIB has built a patent portfolio exceeding 200 patent families, signed 800 R&D and license agreements, spun out 8 companies and laid the foundation for bio-incubators, bio-accelerators and the biotech association FlandersBio. Dr. Dekeyser is member of the advisory board of several foundations investing in life sciences innovation and has been one of the catalysts in the foundation of Oncode, a Dutch cancer research institute. Rudy holds a Ph.D in molecular biology from the University of Ghent.

Mr Wim Ottevaere (WIOT BV) is an independent non-executive director of the Company. Mr Ottevaere is currently active as a non executive board member/consultant for biotechs. He was the Chief Financial Officer of Biotalys from July 2020 until June 2023, a Belgian based Food and Crop Protection company that provides agricultural solutions. Mr Ottevaere was the Chief Financial Officer of Ablynx until September 2018, a Belgian biopharmaceutical company engaged in the development of proprietary therapeutic proteins based on single-domain antibody fragments. Ablynx was listed on Euronext Brussels and Nasdaq and acquired by Sanofi in June 2018. From 1992 until joining Ablynx in 2006, Mr Ottevaere was Chief Financial Officer of Innogenetics (now Fujirebio Europe), a biotech company that was listed on Euronext Brussels at the time. From 1990 until 1992, he served as Finance Director of Vanhout, a subsidiary of the Besix group, a large construction enterprise in Belgium. From 1978 until 1989, Mr Ottevaere held various positions in finance and administration within the Dossche group. Wim Ottevaere holds a Master's degree in Business Economics from the University of Antwerp, Belgium.

Mrs Jackie Fielding is an independent non-executive director of the Company. Mrs Fielding spent 28 years with Medtronic, most recently as Vice President UK / Ireland, where she was responsible for more than 700 staff and revenue of approximately \$750 million. She held a number of external posts alongside her role at Medtronic, including Chair of the BCIA (British Cardiovascular Intervention Association) and council member of the BCIS (British Cardiovascular Intervention Society). In 2010, she was elected to the Board of Directors of ABHI (Association of British HealthTech Industries) and in 2015 was appointed Vice Chair. Jackie has worked with the UK's NHS (National Health Service) Clinical Entrepreneur programme and was a member of the Ministerial Medical Technology Strategy Group. She is Non-Executive Director on the Boards of UK's NICE (National Institute for Health and Care Excellence), Insight Surgery, and Scottish Brain Sciences. She also held the position of Chair at Northumbria Primary Care for 2 years.

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

Mrs Alexandra Clyde is an independent non-executive director of the Company. She is an accomplished medical technology executive with deep expertise and experience in health policy, health economics, reimbursement and the global health care landscape. She spent 26 years at Medtronic in roles of increasing responsibility, most recently as Corporate Senior Vice President of Global Health Economics, Policy and Reimbursement. In this role, she led a global function of more than 300 professionals around the world and provided company-wide leadership on health and payment policy. She has been widely recognized for her industry-wide leadership and impact in designing and implementing coverage and payment mechanisms for new technology, as well as value-based strategies and policy initiatives. She has participated in various Centers for Medicare and Medicaid Services (CMS) technical advisory councils as well as other private and public sector multi-stakeholder initiatives to improve value in health care. Alex graduated from Colgate University with a B.A. in Economics and from Harvard University with a M.S. in Health Policy and Management.

Dr Kenneth Macleod is a Partner at Rosetta Capital, a venture capital firm focused on life sciences and medical devices. Dr Macleod has over 35 years' experience in the life sciences sector in a career combining senior operating roles in healthcare companies (Abbott Laboratories, Serono SA) and life science fund management (SV Health Investors, Paul Capital Partners, Visium Healthcare Partners). Dr

Macleod currently holds board positions at JenaValve Technology Inc. and Oxular Limited and has previously held board roles including at Pharming Group N.V. (NASDAQ:PHAR) and On-X Life Technologies, Inc., a mechanical heart valve company sold to Cryogenics Inc. (now NASDAQ:AORT). Dr Macleod received a BSc in Biological Sciences from the University of Manchester and a D.Phil. from the University of York.

Mr Ids van der Weij is Managing Partner of Partners in Equity V (“PiE V”), a private investment firm focusing on, among others, life sciences. Ids has spent more than 25 years of his career working in Private Equity and Venture Capital. Before PiE V, he was, among others, CEO of Friesland Bank Investments, Managing Partner of Ondernemend Oranje Kapitaal, board member of the Nederlandse Vereniging van Participatiemaatschappijen and member of the supervisory board of, among others, Arboned and Ophthec. Besides PiE V, he is currently a (non-executive) director at Diceris Therapeutics and member of the supervisory board of Micros B.V. He started his career at ABN AMRO NV, after completing his Business Administration studies at the University of Groningen.

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

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

- Erik Amble, as representative of Morningside SPV L.P., a shareholder of the Company;
- Maurizio Petitbon, as representative of Kreos Capital VII (UK) Limited, a debt provider of the Company.

2.4.2. Executive Management and Senior Management Team

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

Name	Age	Position
Mr Ian Crosbie	56	Chief Executive Officer
Mrs Kirsten Van Bockstaele ^{lxix}	49	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.

^{lxix} Acting as permanent representative of Fin-2K BV.

Mrs Van Bockstaele previously served as Chief Financial Officer for Arseus Dental & Medical Solutions, where she was instrumental in the coordination, support and control of financial activities in key European countries. Her previous roles include Financial Controller at Omega Pharma and Audit Manager at PwC. Kirsten Van Bockstaele has a degree in Business Economics from EHSAL and a degree in Financial and Fiscal Sciences from the University of Antwerp, Belgium.

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

Name	Age	Position
Dr Oliver Gödje^{lxx}	59	Chief Medical Officer
Dr. Gijs Klarenbeek	47	Senior Medical Advisor
Mr Timur Resch	41	Global Vice President QM/QA/RA
Dr. Andreas Wirth	55	Global Vice President Engineering
Mr Martijn Blom	49	Chief Commercial Officer
Mr Dragomir Lakic	41	Global Vice President Manufacturing

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

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

Mr Timur Resch is the Global Vice President QM/QA/RA and Person Responsible for Regulatory Compliance (PRRC) of Sequana Medical. Timur has over 10 years of experience within quality management and regulatory affairs in the regulated medical device industry. In 2010, he graduated as an engineer in medical technology from the University of Applied Sciences in Lübeck, Germany and

^{lxx} Dr. Oliver Gödje's employment will end as of May 2024.

began his professional career as a process and management consultant at Synspace AG. Thereafter, Timur continued as Head of Quality Management & Regulatory Affairs at Schaerer Medical AG and prior to joining Sequana Medical held the position of Manager & Team Leader Regulatory Affairs at Medela AG. His experience includes the establishment of quality management systems, auditing, international product registrations for Class I to Class III medical devices, ensuring compliance with applicable regulatory requirements as well as being the liaison to Notified Bodies and Health Authorities. Timur serves as member of quality and regulatory task forces and expert groups within Germany and Switzerland.

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

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

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

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

2.5. Board of Directors

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

shareholders' meeting by law or the Company's articles of association. The Board of Directors acts as a collegiate body.

Pursuant to the Company's Corporate Governance Charter (approved by the Board of Directors on 21 April 2023), the role of the Board of Directors is to pursue sustainable value creation by the Company, by determining the Company's strategy, putting in place effective, responsible and ethical leadership, and monitoring the Company's performance. The Board of Directors decides on the Company's values and strategy, its risk appetite and key policies.

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

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

Pursuant to the Belgian Companies and Associations Code and the Company's articles of association, the Board of Directors must consist of at least three directors. The Company's Corporate Governance Charter (approved by the Board of Directors on 21 April 2023), provides that the composition of the Board of Directors should ensure that decisions are made in the corporate interest. It should be determined so as to gather sufficient expertise in the Company's areas of activity as well as sufficient diversity of skills, background, age and gender. Pursuant to the 2020 Belgian Corporate Governance Code, at least half of the directors must be non-executive and at least three directors must be independent in accordance with the criteria set out in the Belgian Companies and Associations Code and in the 2020 Belgian Corporate Governance Code. By 1 January 2025, at least one third of the members of the Board of Directors must be of the opposite gender. On the date of this report, the composition of the Board of Directors complies with the aforementioned statutory rules on gender diversity.

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

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

The Board of Directors elects a chair from among its non-executive members on the basis of his knowledge, skills, experience and mediation strength. The chair should be a person trusted for his or her professionalism, independence of mind, coaching capabilities, ability to build consensus, and

communication and meeting management skills. The chair is responsible for the leadership and the proper and efficient functioning of the Board of Directors. He or she leads the meetings of the Board of Directors and ensures that there is sufficient time for consideration and discussion before decision-making.

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

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

During 2023, 27 meetings of the Board of Directors were held.

2.6. Committees of the Board of Directors

The Board of Directors has established two board committees which are responsible for assisting the Board of Directors and making recommendations in specific fields: the audit committee (in accordance with Article 7:99 of the Belgian Companies and Associations Code and provision 4.10 of the 2020 Belgian Corporate Governance Code) and the remuneration and nomination committee (in accordance with Article 7:100 of the Belgian Companies and Associations Code and provision 4.17 and 4.19 of the 2020 Belgian Corporate Governance Code). The terms of reference of these board committees are primarily set out in the Corporate Governance Charter of the Company (approved by the Board of Directors on 21 April 2023).

2.6.1. Audit Committee

The audit committee of the Company consists of three directors. According to the Belgian Companies and Associations Code, all members of the audit committee must be non-executive directors, and at least one member must be independent within the meaning of Article 7:87 of the Belgian Companies and Associations Code. The chair of the audit committee is to be appointed by the members of the audit committee. On the date of this report, the following directors are the members of the audit committee: Mr Wim Ottevaere (WIOT BV), Mr Pierre Chauvineau and Mrs Alexandra Clyde. The composition of the audit committee complies with the 2020 Belgian Corporate Governance Code, which require that a majority of the members of the audit committee are independent.

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

The role of the audit committee is to:

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

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

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

During 2023, 4 meetings of the audit committee were held.

2.6.2. Remuneration and Nomination Committee

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

are the members of the remuneration and nomination committee: Dr Rudy Dekeyser, Mr Doug Kohrs and Mrs Jackie Fielding.

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

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

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

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

- report regularly to the Board of Directors on the exercise of its duties.

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

In 2023, 2 meetings of the remuneration and nomination committee were held.

2.7. Activity Report and Attendance at Board and Committee Meetings during 2023

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

Name	Board Meeting ^{lxxi}	Audit	Nomination and remuneration ^{lxxii}
Mr Pierre Chauvineau	27 out of 27 meetings	4 out of 4 meetings	1 out of 2 meetings ^{lxxii}
Mr Ian Crosbie	27 out of 27 meetings	4 out of 4 meetings ^{lxxii}	2 out of 2 meetings ^{lxxii}
Mr Rudy Dekeyser ^{lxxiii}	27 out of 27 meetings	N/A ^{lxxiv}	2 out of 2 meetings
Mr Wim Ottevaere ^{lxxv lxxvi}	27 out of 27 meetings	4 out of 4 meetings	N/A ^{lxxiv}
Mrs Jackie Fielding	25 out of 27 meetings	N/A ^{lxxiv}	2 out of 2 meetings
Mrs Alexandra Clyde ^{lxxi}	26 out of 27 meetings	4 out of 4 meetings	N/A ^{lxxiv}
Mr Doug Kohrs ^{lxxvii}	26 out of 27 meetings	N/A ^{lxxiv}	2 out of 2 meetings
Dr Kenneth Macleod ^{lxxviii}	12 out of 27 meetings	N/A ^{lxxiv}	N/A ^{lxxiv}
Mr Ids Van der Weij ^{lxxix}	7 out of 27 meetings	N/A ^{lxxiv}	N/A ^{lxxiv}

^{lxxi} The extraordinary general shareholders' meeting of 10 February 2023 appointed Mrs. Alexandra Clyde as independent non-executive director. Prior to such appointment, Mrs. Alexandra Clyde already participated to certain board and committee meetings.

^{lxxii} The board member attended the meeting as an observer.

^{lxxiii} The board member is chairman of the Remuneration and Nomination Committee.

^{lxxiv} The board member is not a member of the specific committee.

^{lxxv} Acting as permanent representative of WIOT BV.

^{lxxvi} The board member is chairman of the Audit Committee.

^{lxxvii} The extraordinary general shareholders' meeting of 10 February 2023 appointed Mr Doug Kohrs as independent non-executive director. Prior to such appointment, Mr Doug Kohrs already participated to certain board and committee meetings.

^{lxxviii} The special general shareholders' meeting of 26 June 2023 appointed Dr. Kenneth Macleod as non-executive director.

^{lxxix} The extraordinary general shareholders' meeting of 10 November 2023 appointed Mr Ids Van der Weij as non-executive director. Prior to that, Mr. Ids Van der Weij was already member of the board of directors in a non-voting capacity (observer).

2.8 Independent Directors

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

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

10. Not being, in the Company or an affiliated company or person, a spouse, legal partner or close family member to the second degree, exercising a function as board member or executive or person entrusted with the daily management or employee of the senior management (as defined in Article 19,2° of the law of 20 September 1948 regarding the organisation of the business industry), or falling in one of the other cases referred to in the points 1 to 9 above, and as far as point 2 is concerned, up to three years after the date on which the relevant relative has terminated their last term.

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

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

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

2.9. Performance Review of the Board of Directors

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

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

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

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

2.10. Executive Management and Chief Executive Officer

2.10.1 Executive Management

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

The Executive Management is responsible for:

- being entrusted with the operational leadership of the Company;

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

2.10.2. Chief Executive Officer

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

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

2.11. Conflicts of Interest

Directors are expected to arrange their personal and business affairs so as to avoid conflicts of interest with the Company. Any director with a conflicting financial interest (as contemplated by Article 7:96 of the Belgian Companies and Associations Code) on any matter before the Board of Directors must bring it to the attention of both the statutory auditor and fellow directors, and take no part in any deliberation or voting related thereto. The Corporate Governance Charter of the Company (approved by the Board of Directors on 21 April 2023), contains the procedure for transactions between the Company and the directors which are not covered by the legal provisions on conflicts of interest. The Corporate Governance Charter (approved by the Board of Directors on 21 April 2023), contains a similar procedure for transactions between the Company and members of the Executive Management.

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

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

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

2.12. Dealing Code

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

2.13. Internal Control and Risk Management

2.13.1. Introduction

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

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

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

2.13.2. Control Environment

Three lines of defence

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

- First line of defence: line management is responsible for assessing risks on a day-to-day basis and implementing controls in response to these risks.
- Second line of defence: the oversight functions like Finance and Controlling and Quality and Regulatory oversee and challenge risk management as executed by the first line of defence.

The second line of defence functions provide guidance and direction and develop a risk management framework.

- Third line of defence: independent assurance providers such as external accounting and external audit challenge the risk management processes as executed by the first and second line of defence.

Policies, procedures and processes

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

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

Group-wide Financial System

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

2.13.3. Risk management

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

2.13.4. Control activities

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

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

2.13.5. Information and communication

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

- security of confidential information;
- clear communication about roles and responsibilities; and

- timely communication to all stakeholders about external and internal changes impacting their areas of responsibility.

2.13.6. Monitoring of control mechanisms

Monitoring helps to ensure that internal control systems operate effectively.

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

- **Quality and Regulatory:** Within the Quality Management System (QMS) according to ISO 13485:2016, MDSAP and MDR 2017/745, Sequana Medical has a systematic process for identifying hazards and hazardous situations associated with Sequana Medical devices and their use, estimating and evaluating the associated risks, controlling and documenting the risks, and monitoring the effectiveness of controls. This risk management process is based on the standard ISO 14971:2019. Sequana Medical's QMS is subject to internal audits by the Quality and Regulatory department and external audits by the Notified Body and Auditing Organization BSI. The suitability and effectiveness of the QMS will also be evaluated as part of the annual management review.
- **External Audit:** In Sequana Medical's review of the annual accounts, the statutory auditor focuses on the design and effectiveness of internal controls and systems relevant for the preparation of the financial statements. The outcome of the audits, including work on internal controls, is reported to management and the audit committee.
- **Audit Committee:** The Board of Directors and the audit committee have the ultimate responsibility with respect to internal control and risk management. For more detailed information on the composition and functioning of the audit committee, see section 2.6.1. of this Corporate Governance Statement.

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

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

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

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

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

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

An external financial calendar is planned in consultation with the Board and the Executive Management, and this calendar is announced to the external stakeholders. The objective of this

external financial reporting is to provide Sequana Medical Group stakeholders with the information necessary for making sound business decisions. The financial calendar can be consulted on <https://www.sequanamedical.com/investors/financial-information>.

2.14. *Principal Shareholders*

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

The table provides an overview of the shareholders that notified the Company of their shareholding in the Company pursuant to applicable transparency disclosure rules up to 31 December 2023.

It should be noted that the Company can have received updated transparency notifications after 31 December 2023, if any. The most recent update of principal shareholder overview, as well as the most recent transparency notifications, are available on Sequana Medical's website (<https://www.sequanamedical.com/investors/shareholder-information/>). Although the applicable transparency disclosure rules require that a disclosure be made by each person passing or falling under one of the relevant thresholds, it is possible that the information included in such transparency notifications in relation to a shareholder is no longer up-to-date.

		On a non-diluted basis
	Date of Notification	% of the voting rights attached to Shares^{lxxx}
Partners in Equity V B.V.	16 March 2022	15,31%
Société Fédérale de Participations et d'Investissement SA – Federale Participatie- en Investeringsmaatschappij NV / Belfius Insurance NV/SA	18 February 2020	12,70%
NeoMed IV Extension L.P. / NeoMed Innovation V L.P./ Erik Amble	6 February 2023	12,09%
LSP Health Economics Fund Management B.V.	19 February 2021	9,25%
Rosetta Capital Ltd	6 February 2023	5,97%
ParticipatieMaatschappij Vlaanderen NV	11 May 2023	4.80%
Newton Biocapital I SA	15 March 2022	4,64%
GRAC Société Simple	22 March 2022	4,25%
Sensinnovat BV	15 March 2022	3,79%
Optiverder BV	10 May 2023	3,29%

^{lxxx} The percentage of voting rights is calculated on the basis of the number of outstanding shares at the date of the relevant transparency notifications

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

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

2.15. Share Capital and Shares

On 31 December 2023, the share capital of the Company amounted to EUR 2,926,295.90 and was fully paid-up. It was represented by 28,242,753 ordinary shares, each representing a fractional value of (rounded) EUR 0.1036 and representing one 28,242,753th of the share capital. The Company's shares do not have a nominal value.

On the date of this report, the share capital of the Company amounted to EUR 3,720,562.60 and is fully paid-up. It is represented by 35,909,420 ordinary shares, each representing a fractional value of (rounded) EUR 0.1036 and representing one 35,909,420th of the share capital. The Company's shares do not have a nominal value.

In addition to the outstanding shares, the total number of outstanding subscription rights amounts to 5,032,452, which entitles their holders (if exercised) to subscribe to 4,792,765 new shares with voting rights in total, namely:

- Up to 261,895 new shares can be issued upon the exercise 90,780 share options that are still outstanding under the "Executive Share Options" plan for staff members and consultants of the Company, entitling the holder thereof to acquire ca. 2.88 shares when exercising one of his or her share options (the "Executive Share Options");
- Up to 956,868 new shares can be issued upon the exercise of 956,868 share options (each share option having the form of a subscription right) that are still outstanding under the "2018 Share Options" plan for directors, employees and other staff members of the Company and its subsidiaries, entitling the holder thereof to acquire one new share when exercising one of his or her share options (the "**2018 Share Options**");
- Up to 998,500 new shares can be issued upon the exercise of 998,500 share options (each share option having the form of a subscription right) that are still outstanding under the "2021 Share Options" plan for directors, employees and other staff members of the Company and its subsidiaries, entitling the holder thereof to acquire one new share when exercising one of his or her share options (the "**2021 Share Options**");
- Up to 1,000,000 new shares can be issued upon the exercise of 1,000,000 share options (each share option having the form of a subscription right) that are still outstanding under the "2023 Share Options" plan for directors, employees and other staff members of the Company and its subsidiaries, entitling the holder thereof to acquire one new share when exercising one of his or her share options (the "**2023 Share Options**");
- Up to 302,804 new shares can be issued to Bootstrap Europe S.C.SP. upon the exercise of 10 warrants (each warrant having the form of a subscription right) that are still outstanding (at the date of this report) that have been issued by the extraordinary shareholders meeting of 27 May 2022 (the "**Bootstrap Warrants**"); and
- Up to 161,404 new shares can be issued to Kreos Capital VII Aggregator SCSp. upon the exercise of 875,000 warrants (each warrant having the form of a subscription right) that are

still outstanding (at the date of this report) that have been issued by the extraordinary shareholders meeting of 10 February 2023 (the "**Kreos Subscription Rights**").

- Up to 1,111,294 new shares can be issued upon exercise of 1,111,294 subscription rights that are still outstanding that have been issued by the board of directors (within the framework of the authorized capital) on 27 April 2023 in the framework of the aforementioned private placement of new shares and new subscription rights (the "**2023 Investor Warrants**")

On 17 July 2020, the Company entered into a subordinated loan agreement with PMV Standaardleningen NV (formerly known as PMV/z-Leningen NV) (the "**PMV Loan**") for an aggregate principal amount of maximum EUR 4.3 million, of which a loan for a principal amount of EUR 0.8 million can be converted by PMV Standaardleningen NV for new ordinary shares of the Company in the event of a future equity financing or sale of the Company. The conversion can be carried out by means of a contribution in kind of the respective payable due by the Company under the loan (whether as principal amount or as interest) (the "**Convertible Loan Payable**") to the share capital of the Company. In December 2021, the Company entered into an amendment agreement, thereby (i) extending the duration of such loans, (ii) increasing the interest rates retroactively, and (iii) introducing payment by instalments. Consequently, the loans have a term of 60 months and are repayable in eight equal quarterly instalments between months 36 and 60. The convertible portion of the loan granted by PMV Standaardleningen NV bears an interest rate of 5.5% per annum. The price per share at which the Convertible Loan Payable can be converted through a contribution in kind in the event of an equity financing or sale of the Company will be equal to 75% of the price of the Company's shares as will be reflected in the relevant equity financing or sale. PMV Standaardleningen NV can exercise this right until 30 days as from the completion of such equity financing or sale of the Company. In March 2023, the Company entered into new amendment agreements, thereby (i) amending the repayments terms and (ii) further increasing the interest rates retroactively (+0.5%pt). Consequently, the loans had a term of 60 months and were repayable in four equal quarterly instalments on 30 September 2024, 31 December 2024, 31 March 2025 and 30 June 2025. In February 2024, the Company entered into further amendments in relation to (i) the aforementioned PMV Loan, (ii) the EUR 2,000,000 loan with Belfius Insurance NV (the "**Belfius Loan**"), and (iii) the EUR 400,000 loan with Sensinnovat BV (the "**Sensinnovat Loan**"). The main amendments to the PMV Loans, the Belfius Loan and the Sensinnovat Loan consist of (a) an extension of the final maturity date to 31 December 2025, (b) a rescheduling of the principal repayments under the relevant loan agreements so that the principal amount outstanding under the loans thereunder will be repaid in four equal monthly instalments starting on 30 September 2025, and (c) an increase of the applicable interest rates under each of the relevant loan agreements with 0.5% per annum.

2.15.1. Form and Transferability of the Shares

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

On 31 December 2023, all of the Company's shares have been admitted to trading on the regulated market of Euronext Brussels.

2.15.2. Currency

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

2.15.3. Voting Rights attached to the Shares

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

Voting rights can be mainly suspended in relation to shares:

- which are not fully paid up, notwithstanding the request thereto of the Board of Directors of the Company;
- to which more than one person is entitled or on which more than one person has rights in rem (zakelijke rechten/droits réels) on, except in the event a single representative is appointed for the exercise of the voting right vis-à-vis the Company;
- which entitle their holder to voting rights above the threshold of 3%, 5%, 10%, 15%, 20% and any further multiple of 5% of the total number of voting rights attached to the outstanding financial instruments of the Company on the date of the relevant general shareholders' meeting, in the event that the relevant shareholder has not notified the Company and the FSMA at least 20 calendar days prior to the date of the general shareholders' meeting in accordance with the applicable rules on disclosure of major shareholdings; and
- of which the voting right was suspended by a competent court or the FSMA.

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

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

- the approval of the annual financial statements of the Company;
- the distribution of profits (except interim dividends);
- the appointment (at the proposal of the Board of Directors and upon recommendation by the remuneration and nomination committee) and dismissal of directors of the Company;
- the appointment (at the proposal of the Board of Directors and upon recommendation by the audit committee) and dismissal of the statutory auditor of the Company;
- the granting of release from liability to the directors and the statutory auditor of the Company;
- the determination of the remuneration of the directors and of the statutory auditor for the exercise of their mandate;
- the advisory vote on the remuneration report included in the annual report of the Board of Directors, the binding vote on the remuneration policy (which was approved for the first time by the general shareholders' meeting held on 27 May 2021, and was amended by the general shareholders' meetings held on 27 May 2022 and 10 February 2023), and subsequently upon every material change to the remuneration policy and in any case at least every four years, and the determination of the following features of the remuneration or compensation of directors, members of the Executive Management and certain other executives (as the case may be): (i) in relation to the remuneration of executive and non-executive directors, members of the Executive Management and other executives, an exemption from the rule that share based awards can only vest after a period of at least three years as of the grant of

the awards, (ii) in relation to the remuneration of executive directors, members of the Executive Management and other executives, an exemption from the rule that (unless the variable remuneration is less than a quarter of the annual remuneration) at least one quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least two years and that at least another quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least three years, (iii) in relation to the remuneration of non-executive directors, any variable part of the remuneration (provided, however that no variable remuneration can be granted to independent non-executive directors), and (iv) any service agreements to be entered into with executive directors, members of the Executive Management and other executives providing for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration and nomination committee, eighteen (18) months' remuneration);

- the filing of a claim for liability against directors;
- the decisions relating to the dissolution, merger and certain other reorganisations of the Company; and
- the approval of amendments to the articles of association.

2.15.4. Dividends and Dividend Policy

All of the shares of the Company entitle the holder thereof to an equal right to participate in dividends (if any) in respect of the financial year ending 31 December 2023 and future years. All of the shares participate equally in the Company's profits (if any). Pursuant to the Belgian Companies and Associations Code, the shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the annual general shareholders' meeting, based on the most recent statutory audited financial statements, prepared in accordance with Belgian GAAP and based on a (non-binding) proposal of the Company's Board of Directors. In accordance with Belgian law, the right to collect dividends declared on shares expires five years after the date the board of directors has declared the dividend payable, whereupon the Company is no longer under an obligation to pay such dividends. The Belgian Companies and Associations Code and the Company's articles of association also authorise the Board of Directors to declare interim dividends without shareholder approval. The right to pay such interim dividends is, however, subject to certain legal restrictions.

The Company has never declared or paid any cash dividends on its shares. The Company does not anticipate paying cash dividends on its equity securities in the foreseeable future and intends to retain all available funds and any future earnings for use in the operation and expansion of its business.

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

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

Furthermore, the aforementioned loan agreements entered into with PMV Standaardleningen NV in July 2020, amended in December 2021, March 2023 and February 2024, also include restrictive covenants, which may limit the Company's ability (and require PMV Standaardleningen NV's prior consent) to make distributions by way of dividends or otherwise and this so long as any monies or obligations, actual or contingent, are outstanding under the aforementioned loan agreements. Under the loan facility agreement entered into with Kreos Capital VII (UK) Limited on 19 July 2022 (as amended), no distributions by way of dividend can be declared or made without consent of Kreos Capital VII (UK) Limited (other than the payment of a dividend to the Company by any of its directly or indirectly wholly owned subsidiaries)

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

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

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

- (i) The share capital (at the date of this report) of the Company amounts to EUR 3,720,562.60 and is fully paid-up. It is represented by 35,909,420 ordinary shares, each representing a fractional value of (rounded) EUR 0.1036 and representing one 35,909,420th of the share capital. The Company's shares do not have a nominal value.
- (ii) Other than the applicable Belgian legislation on the disclosure of significant shareholdings and the Company's articles of association, there are no restrictions on the transfer of shares.
- (iii) There are no holders of any shares with special control rights.
- (iv) There are no share option plans for employees other than the share option plans disclosed elsewhere in this report. These share option plans contain provisions on accelerated vesting in case of change of control.
- (v) Each shareholder of the Company is entitled to one vote per share. Voting rights may be suspended as provided in the Company's articles of association and the applicable laws and articles.
- (vi) There are no agreements between shareholders which are known by the Company that may result in restrictions on the transfer of securities and/or the exercise of voting rights, except transfer restrictions in relation to shares issuable upon exercise of the Executive Share Options, the 2018 Share Options, the 2021 Share Options and the 2023 Share Options (see also section 3.7 of the Remuneration Report).
- (vii) The rules governing appointment and replacement of board members and amendment to articles of association are set out in the Company's articles of association and the Company's Corporate Governance Charter.
- (viii) The powers of the Board of Directors, more specifically with regard to the power to issue or

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

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

- the employment agreement between the Company and Ian Crosbie (Chief Executive Officer) contains takeover provisions. Agreements concluded between the Company and certain of its employees also provide for compensation in the event of a change of control;
- the loan agreements entered into with PMV Standaardleningen NV, Sensinnovat and Belfius Insurance in July 2020, amended in December 2021, March 2023 and February 2024, contain change of control provisions.
- The Kreos Loan Agreement contains a change of control clause, which has been approved by the shareholders on the extraordinary general meeting held on 10 February 2023.
- the 'Warrant Agreement', dated 2 September 2016, that was entered into between the Company and Bootstrap, and that has been amended and supplemented by an amendment agreement dated 28 April 2017, a second amendment agreement dated 1 October 2018, an amendment letter dated 20 December 2018, and an agreement dated 1 September 2021 (the "Former Bootstrap Warrant"), also contains take-over provisions. The extraordinary general shareholders' meeting held on 27 May 2022 resolved to renew the Former Bootstrap Warrant through the issuance of ten new warrants represented by ten separate subscription rights (the "Bootstrap Warrants"), including the take-over provisions.
- In addition, the Company's subscription rights plans provide for an accelerated vesting of the subscription rights in case of a change of control event. These plans are described in more detail in the Remuneration Report below.

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

immediate effect and the Company shall then be required to make a payment in lieu of a notice equivalent to the basic salary only (but not the other benefits) to which the Chief Executive Officer would have been entitled. Furthermore, the agreements concluded between the Company and a few of its employees provide for compensation in the event of a change of control.

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

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

2.17. Diversity & Inclusiveness

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

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

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

3. REMUNERATION REPORT

3.1. Introduction

The Company has prepared this remuneration report relating to the remuneration of directors and the Executive Management of the Company. This remuneration report is part of the Corporate Governance Statement, which is part of the Company's annual report of the Board of Directors on the statutory accounts for the financial year ended on 31 December 2023 (dated 19 April 2024) in accordance with Article 3:6, §3 of the Belgian Companies and Associations Code of 23 March 2019 (as amended) (the "**Belgian Companies and Associations Code**"). The remuneration report will be submitted to the annual general shareholders' meeting on 23 May 2024 for approval.

3.2. Remuneration policy

On 16 May 2020 the new article 7:89/1 of the Belgian Companies and Associations Code, which provides that listed companies must establish a remuneration policy with respect to directors, other officers and delegates for day-to-day management, entered into force. This article details the objectives of, as well as the information that needs to be included in, the remuneration policy. The remuneration policy must be approved by a binding vote of the general shareholders' meeting and must be submitted to the general shareholders' meeting for approval whenever there is a material change and in any case at least every four years. In view hereof, in accordance with article 7:89/1 of the Belgian Companies and Associations Code, the nomination and remuneration committee prepared a remuneration policy which (most recent version) has been approved by the shareholders at the extraordinary general meeting held on 10 February 2023. The aforementioned remuneration policy can be consulted on the Company's website through the following link: <https://www.sequanamedical.com/wp-content/uploads/2023/03/20230207-Remuneration-Policy-ENG-final-with-votes.pdf>.

The revised remuneration policy will be submitted for approval to the annual shareholders' meeting of 23 May 2024.

3.3. Directors

3.3.1. General

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

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

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

performance criteria that have been determined in advance and that can be measured objectively over a period of at least three years;

- (iii) in relation to the remuneration of non-executive directors, any variable part of the remuneration (provided, however, that no variable remuneration can be granted to independent non-executive directors); and
- (iv) any service agreements to be entered into with executive directors providing for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration and nomination committee, eighteen months' remuneration).

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

- The general shareholders' meeting approved that share options issued pursuant to the Company's existing share option plans (for further information, see section 3.7 of this Remuneration Report) can, under certain conditions, vest earlier than three years as of their grant, as referred to in paragraph (i) above. Notably, pursuant to the Company's articles of association, the Board of Directors is explicitly authorised to deviate from the rule of Article 7:91 of the Belgian Companies and Associations Code in connection with share-based incentive plans, compensation, awards or issues to employees, directors and service providers of the Company and/or its subsidiaries. The Company is of the opinion that this allows for more flexibility when structuring share-based awards. For example, it is customary for option plans to provide for a vesting in several instalments over a well-defined period of time, instead of vesting after three years only. This seems to be more in line with prevailing practice.
- The general shareholders' meeting approved that the existing share options under the respective existing share option plans will not qualify as variable remuneration nor as annual remuneration for the purpose of the application of the rule set out in paragraph (ii) above under the former Belgian Companies Code of 7 May 1999.

The remuneration and compensation of the non-executive directors for the 2023 financial year, which has been determined by the general shareholders' meeting, is as follows:

- Annual fixed fees:
 - The chair of the Board of Directors receives an annual fixed fee of €60,000.
 - The chair of the audit committee receives an annual fixed fee of €15,000.
 - The chair of the remuneration and nomination committee receives an annual fixed fee of €15,000.
 - The non-executive independent directors (other than the chair of the board of directors) are entitled to an annual fixed fee of €34,000, plus €1,750 per meeting of the board of directors attended in person (pro rata temporis).
 - The members of the audit committee and the remuneration and nomination committee (other than the chair of such committees) are entitled to an additional annual fixed fee of €11.500 (pro rata temporis). The aforementioned remuneration of the non-executive directors can be reduced pro rata temporis depending on the

duration of the director's mandate, the mandate of chair or the membership of a committee during a given year. All amounts are exclusive of VAT and similar charges.

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

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

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

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

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

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

The revised remuneration policy will be submitted for approval to the annual shareholders' meeting of 23 May 2024.

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

3.3.2. Remuneration and compensation in 2023

During 2023, the non-executive independent directors were entitled to the following compensation, based on the approved fees in 3.3.1.

	Gross amount (in €) ^{lxxxii}	Share options awarded	Number of RSUs awarded and accepted ^{lxxxiii}
Pierre Chauvineau	71.500	-	36.119
Wim Ottevaere (WIOT BV)	52.500	-	36.119
Jackie Fielding	49.000	-	36.119
Doug Kohrs	45.500	-	36.119
Alexandra Clyde	49.000	-	36.119

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

3.4. Executive Management

3.4.1. General

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

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

^{lxxxii} The amounts are prorated to the term that the director is part of a committee, if applicable.

^{lxxxiii} (2) Of the number of RSUs awarded and accepted in 2023, 12,755 underlying RSU shares (relating to the first reference year 2022-2023) have been issued on 4 October 2023. The remaining 23,364 underlying RSU shares (relating to the second reference year 2023-2024) will have to be issued on or prior to 21 June 2024.

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

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

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

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

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

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

The members of the Executive Management have a variable remuneration (*i.e.* remuneration linked to performance criteria) amounting to up to 50% of the base salary/fee for on target performance.

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

The Chief Executive Officer is entitled to pension benefits. The contributions by the Company to the pension scheme amount to 5% of the annual salary.

The Chief Financial Officer is not entitled to pension benefits.

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

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

3.4.2. Remuneration and compensation in 2023

In 2023, the following remuneration, compensation and other benefits were paid to the two members of the Executive Management. All amounts included in the table are gross amounts.

	Chief executive officer (€)		Other member of the Executive Management (€)	
	Amount ^{lxxxiii}	%	Amount ^{lxxxiv}	%
Annual base salary	310,765	71%	291,312	82%
Pension plan ^{lxxxv}	15,538	4%	N/A	N/A
Insurance plan ^{lxxxvi}	1,156	0%	N/A	N/A
Car lease/transport allowance	11,037	3%	N/A	N/A
Medical plan	6,792	2%	N/A	N/A
Bonus plan ^{lxxxvii}	95,282	22%	64,671	18%
Total	440,569	100%	355,983	100%

^{lxxxiii} The amount is paid in GBP to the CEO. The conversion applied to EUR is performed on the average GBP/EUR rate of 2023 of the ECB.

^{lxxxiv} Acting as permanent representative of Fin-2K BV

^{lxxxv} The pension plan amounts to 5% of the annual base salary of the CEO.

^{lxxxvi} The Company pays a life insurance plan for the CEO.

^{lxxxvii} The bonus has been paid in cash.

In 2023, the Board of Directors has decided to establish the Company's performance at 65% (reflecting the level of achievement of the Company's 2022 objectives based on the progress made in our clinical programs and the financial performance). In function thereof, variable remuneration (in the form of a cash bonus) has been paid out in the course of 2023 to the members of the Executive Management.

In 2023, 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 €91,606.

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

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

	2019		2020		2021		2022		2023	
	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year
Directors and executive managers	834,090	42%	901,035	8%	919,714	2%	1,026,109	12%	1,067,552	4%

Note:

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

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

	2019		2020		2021		2022		2023	
	EUR	% vs prior year								
Employees	109,695	-4%	109,886	0%	112,481	2%	117,388	4%	132,626	13%

Note:

- In 2019 and onwards, some key positions are fulfilled by persons working via a consulting agreement, who are not included in the above average remuneration of employees.
- The remuneration is dependent on the fluctuation of the exchange rate of GBP/EUR and CHF/EUR.

Evolution of the performance of the Company

Performance Criteria	2019		2020		2021		2022		2023	
	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year	EUR	% vs prior year
Net loss for the period	- 14,977,445	7%	-19,106,205	28%	-23,615,081	24%	-30,763,083	30%	-32,563,574	6%
Total Equity	925,932	-105%	112,761	-88%	-786,919	-798%	-2,153,252	174%	-19,465,174	804%
Paid dividends	0	0	0	0	0	0	0	0	0	0
Market capitalisation at 31 December	78,950,494	NA	186,305,079	136%	140,442,710	-25%	142,479,168	1%	112,971,012	-21%

The ratio between the highest and lowest remuneration in 2023 was equal to 7 in the European Union and 6 outside the European Union. The remuneration is dependent on the fluctuation of the exchange rate of GBP/EUR and CHF/EUR.

3.4.4. Claw-back right relating to variable remuneration

In accordance with provision 7.12 of the Belgian Corporate Governance Code, the Board of Directors should include provisions in the contracts of the members of the Executive Management that would

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

3.4.5. Payments upon termination

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

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

breach or violation by a party of any of its covenants, obligations or duties under the agreement, or any wilful or serious neglect of or refusal to perform any of such covenants, obligations or duties.

3.5. Indemnification and Insurance of Directors and Executive Management

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

3.6. Description of share option plans

The Company, as per 31 December 2023, has a number of outstanding options that are exercisable into ordinary shares, consisting of:

- 261,895 new shares can be issued upon the exercise of 90,780 share options that are still outstanding under the "Executive Share Options" plan for staff members and consultants of the Company, entitling the holder thereof to acquire ca. 2.88 shares when exercising one of his or her share options (the "**Executive Share Options**"); and
- 984,138 new shares can be issued upon the exercise of 984,138 2018 share options that are still outstanding under the "2018 Share Options" plan for staff members and consultants of the Company, entitling the holder thereof to acquire one share when exercising one of his or her share options (the "**2018 Share Options**").
- 997,600 new shares can be issued upon the exercise of 997,600 share options (each share option having the form of a subscription right) that are still outstanding under the '2021 Share Options' plan for directors, employees and other staff members of the Company and its subsidiaries, entitling the holder thereof to acquire one new share when exercising one share option (the "**2021 Share Options**").
- 1,000,000 new shares can be issued upon the exercise of 1,000,000 share options (each share option having the form of a subscription right) that are still outstanding under the '2023 Share Options' plan for directors, employees and other staff members of the Company and its subsidiaries, entitling the holder thereof to acquire one new share when exercising one share option (the "**2023 Share Options**").

The table below provides an overview of the number of shares which each member of the Executive Management is entitled to acquire upon exercise of the outstanding and granted Executive Share Options, 2018 Share Options and 2021 Share Options that are held by him or her on 31 December 2023.

Number of share options

Name	Executive Share Options	2018 Share Options	2021 Share Options
Ian Crosbie	216,442	135,809	173,005
Kirsten Van Bockstaele ^{lxxxviii}	6,226	70,419	59,747

In financial year 2023, 115,656 share options lapsed as a result of the termination of a number of employment contracts.

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

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

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

^{lxxxviii} Acting as permanent representative of Fin-2K BV.

breach of contract or breach of director responsibilities, shall automatically and immediately lapse and become null and void.

- The terms of the Share options are governed by the laws of Belgium.

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

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

serious cause, breach of contract or breach of director responsibilities, shall automatically and immediately lapse and become null and void.

- The 2018 Share Option Plan is governed by the laws of Belgium.

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

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

serious cause, breach of contract or breach of director responsibilities, shall automatically and immediately lapse and become null and void.

- The 2021 Share Option Plan is governed by the laws of Belgium.

The key features of the 2023 Share Options can be summarised as follows:

- The 2023 Share Options are subscription rights in registered form.
- The 2023 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 2023 Share Options that have vested prior to the time of death can be transferred.
- Each 2023 Share Option can be exercised for one new ordinary share.
- If a 2023 Share Option which is not exercisable or which cannot be exercised pursuant to the issuance conditions (as determined in the 2023 Share Option Plan or in the relevant sub-plan and/or share option agreement) becomes prematurely exercisable on the basis of the provisions of Article 7:71 of the Belgian Companies and Associations Code (or any other provision having the same purport) and is also exercised pursuant to said provision, the shares obtained by exercising the 2023 Share Options shall not be transferable, unless explicitly agreed upon by the Board of Directors, until the time the underlying 2023 Share Options would have become exercisable in accordance with the 2023 Share Option Plan, the relevant sub-plan or share option agreement.
- The exercise price of the 2023 Share Options shall be determined by the Board of Directors of the Company, taking into account applicable laws.
- The 2023 Share Options are granted for free, *i.e.* no consideration is due upon the grant of the 2023 Share Options, unless the grant agreement provides otherwise.
- Pursuant to Belgian company law, the 2023 Share Options have a maximum term of 10 years as of their issuance.
- Unless stipulated otherwise in the grant agreement, one third of the 2023 Share Options granted to a beneficiary shall vest on the first anniversary of the date of grant, the remaining two thirds will vest in 8 equal instalments, whereby on each first calendar day of the 8 quarters following first anniversary of the date of grant falls, 1/8 of the total number of unvested 2023 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 2023 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 2023 Share Options and determine the conditions of such accelerated vesting.
- The 2023 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 2023 Share Option Plan is governed by the laws of Belgium.

3.8. *Shareholding and Share Options*

As per 31 December 2023, the directors of the company have the following holding of shares and share options

Holding per 31/12/2023				
	Ordinary shares	Ordinary shares resulting from exercised RSU	RSU	Share Options
Pierre Chauvineau	7,664	12,755	23,364	10,192 ^{lxxxix}
Wim Ottevaere (WIOT BV)	23,000	12,755	23,364	10,192 ^{lxxxix}
Doug Kohrs	0	12,755	23,364	0
Alexandra Clyde	0	12,755	23,364	0

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

^{lxxxix} In 2019 (before the entry into force of the Belgian Companies and Associations Code), 2018 Share Options have been granted to non-executive directors Mr Wim Ottevaere (10,192) and Mr Pierre Chauvineau (10,192). No share options were granted to non-executive directors since 2020.

CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2023 AND 2022

1. Statement of the Board of Directors

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

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

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

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

Pierre Chauvineau

Chairman

Ian Crosbie

CEO

Kirsten Van Bockstaele

CFO

2. Statutory auditor's report

STATUTORY AUDITOR'S REPORT TO THE GENERAL SHAREHOLDERS' MEETING SEQUANA MEDICAL NV ON THE CONSOLIDATED ACCOUNTS FOR THE YEAR ENDED 31 DECEMBER 2023

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

We have been appointed as statutory auditor by the general meeting *d.d.* 27 May 2021, following the proposal formulated by the board of directors and following the recommendation by the audit committee. Our mandate will expire on the date of the general meeting which will deliberate on the annual accounts for the year ended 31 December 2023. We have performed the statutory audit of the Company's consolidated accounts for 6 consecutive years.

1. Report on the consolidated accounts

1.1. Unqualified opinion

We have performed the statutory audit of the Group's consolidated accounts, which comprise the consolidated statement of financial position as at 31 December 2023, the consolidated income statement, consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended, and notes to the consolidated financial statements, including a summary of significant accounting policies and other explanatory information, characterised by a consolidated balance sheet total of EUR 10.101.034, and a consolidated income statement showing a consolidated loss for the year of EUR 32.563.574.

In our opinion, the consolidated accounts give a true and fair view of the Group's net equity and consolidated financial position as at 31 December 2023, and of its consolidated financial performance and its consolidated cash flows for the year then ended, in accordance with International Financial Reporting Standards as adopted by the European Union and with the legal and regulatory requirements applicable in Belgium.

1.2. Basis for unqualified opinion

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

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

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

1.3. Material Uncertainty Related to Going Concern

We draw attention to Note 4 in the consolidated accounts, which indicates that the Company is still in the development phase for its alfapump and DSR programs, including the execution of clinical trials and submission / review of applications in order to achieve regulatory marketing approvals for these products. This entails various risks and uncertainties, including but not limited to the uncertainty of the development and regulatory review process and the timing of achieving profitability. The Company's ability to continue operations also depends on its ability to raise additional capital and to refinance existing debt, in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows. The impact of macroeconomic conditions and the geopolitical situation on the Company's ability to secure additional financing rounds or undertake capital market transactions remain unclear at this point in time. The Consolidated Statement of Financial Position as at 31 December 2023 shows negative equity in the amount of EUR 19.5 million and ending cash balance of EUR 2.6 million.

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

1.4. Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the consolidated accounts of the current period. These matters were addressed in the context of our audit of the consolidated accounts as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. We have determined there were no other matters to be considered as key audit matters to be communicated in our report, in addition to the matter described in the "Material Uncertainty Related to Going Concern" section.

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

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

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

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

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

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

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

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

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

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

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

2. Other legal and regulatory requirements

2.1. Responsibilities of the board of directors

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

2.2. Statutory auditor's responsibilities

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

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

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

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

2.4. Statement related to independence

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

2.5. European Uniform Electronic Format (ESEF)

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

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

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

Since Sequana Medical NV does not prepare digital consolidated financial statements in English we are unable to express an opinion on these. However, we refer to our report on the consolidated financial statements for the year ended 31 December 2023 in Dutch. This contains our opinion on the official Dutch version of the digital consolidated financial statements of Sequana Medical NV which have been prepared in accordance with the ESEF requirements under the Delegated Regulation.

3. Other statements

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

Antwerp, 19 April 2024

The statutory auditor

PwC Bedrijfsrevisoren BV/PwC Reviseurs d'Entreprises SRL
Represented by

Peter D'hondt*
Bedrijfsrevisor/Réviser d'entreprises

*Acting on behalf of Peter D'hondt BV

3. Consolidated Income Statement

EUR	Notes	2023	2022
Revenue	6	712,173	922,687
Costs of goods sold		(164,124)	(204,597)
Gross Margin		548,049	718,090
Sales & Marketing		(1,798,813)	(2,240,029)
Clinical		(6,946,987)	(9,772,874)
Quality & Regulatory		(5,585,728)	(3,631,681)
Supply Chain		(4,723,619)	(3,157,666)
Engineering		(4,041,014)	(3,853,153)
General & administration		(6,943,361)	(6,687,346)
Total Operating Expenses	7.1	(30,039,522)	(29,342,749)
Other income	7	629,268	530,174
Earnings before interests and taxes (EBIT)		(28,862,205)	(28,094,484)
Finance income	7	1,052,196	450,553
Finance cost	7	(4,287,957)	(2,732,522)
Net Finance Cost		(3,235,761)	(2,281,970)
Income Tax Expense	8	(465,608)	(386,629)
Net loss for the period		(32,563,574)	(30,763,083)
Attributable to Sequana Medical shareholders		(32,563,574)	(30,763,083)
Basic loss per share	8	(1.22)	(1.35)

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

4. Consolidated Statement of Comprehensive Income

EUR	Notes	2023	2022
Net loss for the period		(32,563,574)	(30,763,083)
Items that will not be reclassified to profit or loss:			
Remeasurements of defined benefit plans	8.9	(355,896)	413,370
Items that may be reclassified subsequently to profit or loss:			
Currency translation adjustments		(64,193)	726,751
Total other comprehensive income/(loss)-net of tax		(420,089)	1,140,121
Total comprehensive income		(32,983,663)	(29,622,962)
Attributable to Sequana Medical shareholders		(32,983,663)	(29,622,962)

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

5. Consolidated Statement of Financial Position

EUR	Notes	December 31, 2023	December 31, 2022
Property, plant and equipment	8.4	2,316,290	2,067,958
Financial assets		100,440	85,746
Other non-current assets	8.5	1,387,979	782,207
Total non-current assets		3,804,708	2,935,911
Trade receivables	8.2	43,075	113,871
Other receivables and prepaid expenses		1,373,450	1,479,294
Other receivables	8.2	312,871	292,330
Prepaid expenses	8.2	1,060,578	1,186,964
Inventory	8.3	2,295,673	2,621,197
Cash and cash equivalents	8.1	2,584,128	18,874,959
Total current assets		6,296,326	23,089,321
TOTAL ASSETS		10,101,034	26,025,232

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

Consolidated Statement of Financial Position

EUR	Notes	December 31, 2023	December 31, 2022
Share Capital	8.6	2,926,296	2,460,487
Share premium	8.6	185,644,420	170,324,139
Reserves		(2,896,178)	(2,425,934)
Loss brought forward		(206,021,958)	(173,458,384)
Cumulative Translation Adjustment		882,246	946,440
Total equity		(19,465,174)	(2,153,252)
Long term financial debts	8.7	8,968,649	12,192,829
Long term lease debts	8.7	464,231	609,458
Retirement benefit obligation	8.9	667,797	228,194
Total non-current liabilities		10,100,677	13,030,481
Short term financial debts	8.7	7,818,288	4,482,914
Short term lease debts	8.7	268,604	306,952
Other current financial liabilities	8.8	2,767,350	1,568,784
Trade payables and contract liabilities		2,906,877	3,391,783
Trade payables	8.10	2,736,617	3,227,290
Contract liabilities	5.0	170,260	164,492
Other payables	8.8	2,256,685	1,811,940
Accrued liabilities and provisions		3,447,728	3,585,631
Provision warranty	8.10	79,988	71,088
Accrued liabilities	8.10	3,367,740	3,514,543
Total current liabilities		19,465,531	15,148,003
TOTAL EQUITY AND LIABILITIES		10,101,034	26,025,232

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

6. Consolidated Statement of Changes in Equity

EUR	Notes	Share capital	Share premium	Reserves	Loss brought forward	Currency translation differences	Total shareholder equity
Balance at 1 January 2022		1,924,932	142,432,715	(2,668,955)	(142,695,301)	219,689	(786,919)
Net loss for the period					(30,763,083)		(30,763,083)
Other comprehensive income				413,370		726,751	1,140,121
March 2022 Equity Placement	8.6	535,329	27,884,645				28,419,974
Capital increase Share Options	8.6	226	6,779				7,005
Transaction costs for equity instruments	7.2			(734,789)			(734,789)
Share-based compensation	9			564,440			564,440
December 31, 2022		2,460,487	170,324,139	(2,425,934)	(173,458,384)	946,440	(2,153,252)
Balance at 1 January 2023		2,460,487	170,324,139	(2,425,934)	(173,458,384)	946,440	(2,153,252)
Net loss for the period					(32,563,574)		(32,563,574)
Other comprehensive income	8.5			(355,896)		(64,193)	(420,089)
April 2023 Equity Placement	8.6	460,523	15,319,955				15,780,478
Capital increase 10/23	8.6	5,286	327				5,612
Transaction costs for equity instruments	7.2			(678,215)			(678,215)
Share-based compensation	9			563,866			563,866
December 31, 2023		2,926,296	185,644,420	(2,896,178)	(206,021,958)	882,246	(19,465,174)

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

7. Consolidated Statement of Cash Flows

EUR	Notes	2023	2022
Net loss for the period		(32,563,574)	(30,763,083)
Income tax expense	7.5	465,608	386,629
Financial result	7.4	3,271,053	1,923,083
Depreciation	8.4	661,280	311,514
Change in defined benefit plan	8.9	(50,493)	(102,110)
Share-based compensation	8.9	563,866	564,440
Changes in trade and other receivables	8.2	(542,792)	(456,622)
Changes in inventories	8.3	482,766	42,417
Changes in trade and other payables / accrued liabilities	8.10	(905,207)	989,998
Taxes paid	7.5	(445,853)	(378,111)
Cash flow used for operating activities		(29,063,346)	(27,481,845)
Investments in tangible fixed assets	8.4	(710,754)	(676,736)
Investments in financial assets		(10,617)	23,644
Cash flow used for investing activities		(721,372)	(653,092)
Proceeds from capital increase	8.6	15,786,090	28,419,974
(Repayments) from leasing debts	8.7	(414,042)	(407,217)
(Repayments) from financial debts	8.7	(982,417)	-
Proceeds from financial debts	8.7		9,626,085
Interest paid	8.7	(928,914)	(314,516)
Cash flow generated from/used in (-) financing activities		13,460,718	37,324,326
Net change in cash and cash equivalents		(16,324,000)	9,189,389
Cash and cash equivalents at the beginning of the period		18,874,959	9,600,412
Net effect of currency translation on cash and cash equivalents		33,169	85,158
Cash and cash equivalents at the end of the period		2,584,128	18,874,959

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

8. Notes to the Consolidated Financial Statements

1. Corporate Information

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

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

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

Sequana Medical NV is a pioneer in treating drug-resistant fluid overload, a serious and frequent clinical complication in patients with liver disease, heart failure and cancer. Fluid overload is a well-recognized problem in these growing diseases, causing severe problems for the large number of patients for whom current medicines are no longer effective. These patients can have up to 15 liters of extra fluid in their bodies, causing major medical issues including increased mortality, repeated hospitalizations, severe pain, difficult breathing and restricted mobility that severely impacts daily life.

alfapump[®] and **DSR**[®] are our proprietary platforms that work with the body to remove this excess fluid, delivering major clinical and quality of life benefits for patients and reducing costs for healthcare systems.

Group information

Information about the subsidiaries

The consolidated financial statements of Sequana Medical Group include:

Company	Purpose	Share capital	Investment 2023	Investment 2022
Sequana Medical NV	Holding/Sales	EUR 2,926,296	n/a	n/a
Sequana Medical NV branch (Switzerland)	Production and research	n/a	n/a	n/a
Sequana Medical GmbH (Germany)	Distribution	EUR 25,000	100 %	100 %
Sequana Medical US Inc. (USA)	Administration	USD 0	100 %	n/a
Sequana Medical Inc (USA)	Administration	USD 0	100 %	100 %

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

The holding company

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

Shareholder structure

The shareholder structure of the Company based on the transparency declarations, received in the period up to December 31, 2023, is as follows:

Shareholder	Shares	%
Partners in Equity V B.V.	4,903,968	17.4%
NeoMed IV Extension L.P. / NeoMed Innovation V L.P	2,871,854	10.2%
LSP Health Economics Fund Management B.V.	2,451,275	8.7%
Rosetta Ltd	1,896,007	6.7%
Société Fédérale de Participations et d'Investissement SA - Federale Participatie- en Investeringsmaatschappij NV	1,885,806	6.7%
Participatiemaatschappij Vlaanderen NV	1,346,074	4.8%
GRAC Société Simple	1,191,431	4.2%
Newton Biocapital I Pricav Privée SA	1,102,529	3.9%
Sensinnovat BV	1,061,332	3.8%
Belfius Insurance SA	995,893	3.5%
Optiverder BV	922,535	3.3%
Total threshold	20,628,704	73.0%
Other	7,614,049	27.0%

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

2 Basis of preparation of the Consolidated Financial Statements

2.1 Basis of preparation

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

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

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

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

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

Clinical Affairs expenses relate to the expenses made for clinical studies to demonstrate the safety and efficacy of the **alfapump**[®] and **DSR**[®].

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

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

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

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

The Consolidated Financial Statements were approved for issue by the Board of Directors on 19 April 2024.

2.2 Principles of consolidation

The Consolidated Financial Statements of Sequana Medical NV 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 2023 are prepared using uniform accounting policies.

2.3 Significant accounting policies, judgments and estimates

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

2.3.1 Application of critical accounting policies

2.3.1.1. Revenue recognition

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

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

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

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

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

2.3.1.2 Other income

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

2.3.1.3 Sales tax

Expenses and assets are recognized net of the amount of sales tax, except when the sales tax incurred on a purchase of assets or services is not recoverable from the taxation authority, in which case, the sales tax is recognized as part of the cost of acquisition of the asset or as part of the expense item, as applicable. VAT on lease payments is not included in the right-of-use asset as described in note 2.3.1.188 Leases.

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

2.3.1.4 Foreign currency translation

The Group's Consolidated Financial Statements are presented in EUR. For each entity, the Group determines the functional currency and items included in the financial statements of each entity are measured using that functional currency. Consequently, the functional currency of the subsidiaries does not necessarily correspond to the functional currency of the parent. The functional currencies as per 31 December 2023 are as follows:

Sequana Medical NV : EUR

Sequana Medical NV branch : CHF

Sequana Medical GmbH : EUR

Sequana Medical Inc : USD

Sequana Medical US Inc : USD

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

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

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

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

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

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

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

The following foreign exchange rates, which were applied for the Consolidated Financial Statements at 31 December 2023 and the comparative periods to translate the following currencies into EUR, are as follows:

Currency	December 31, 2023		December 31, 2022	
	Year-end	Average Rate	Year-end	Average Rate
Swiss Franc (CHF)	0.9260	0.9718	0.9847	1.0047
US Dollar (USD)	1.1050	1.0813	1.0666	1.0530

2.3.1.5 Income tax

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

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

Deferred tax

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

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

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

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

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

2.3.1.6 Property, plant and equipment

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

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

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

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

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

2.3.1.7 Internally generated intangible assets

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

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

- a) the technical feasibility of completing the intangible asset so that it will be available for use or sale ;
- b) its intention to complete the intangible asset and use or sell it;
- c) its ability to use or sell the intangible asset;
- d) how the intangible asset will generate probable future economic benefits. Among other things, the entity can demonstrate the existence of a market for the output of the intangible asset or the intangible asset itself or, if it is to be used internally, the usefulness of the intangible asset;
- e) the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset;

- f) its ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for internally generated intangible assets is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria listed above. When no internally generated intangible asset can be recognized, development expenditures are recognized in the Consolidated Income Statement in the period in which they are incurred.

Subsequent to initial recognition, internally generated intangible assets are reported at cost less accumulated amortization and accumulated impairment losses.

Due to uncertainties inherent to the development and registration with the relevant healthcare authorities of its products, Sequana Medical NV estimates the conditions for capitalization are not met until the regulatory procedures required by such healthcare authorities have been finalized.

The Company currently has no development expenditures that have been capitalized.

2.3.1.8 Trade receivables

In accordance with IFRS 9, trade receivables are classified and measured at amortised cost. The measurement bases are contractual terms, payment history and other sales evidence. Adjustments for doubtful receivables are only allowed to the extent losses are expected in the future or individually determinable. Any losses caused by amortization of receivables are booked in income statements.

The Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables. To measure the expected credit losses, trade receivables have been grouped based on shared credit risk characteristics and the days past due. The historical loss rates are adjusted to reflect current and forward-looking information on macroeconomic factors affecting the ability of the customers to settle the receivables.

2.3.1.9 Other non-current assets

Other non-current assets are measured at amortized cost. They mainly consist of R&D incentives receivables. These receivables are future expected tax deductions or refunds resulting from tax incentives on research and development expenses. The non-current portion of these receivables are discounted over the period until maturity date according to appropriate discount rates. In the event the receivable (or part of) becomes current, it (the current part) is classified in current assets on the Consolidated Statement of Financial Position. The R&D incentives are accounted for in line with IAS12.

2.3.1.10 Inventory

Inventories are valued at the lower of initial cost and net realizable value. The cost of inventories shall comprise all costs of purchase (based on first-in, first- out method), costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

The net realisable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and the estimated costs necessary to make the sale.

2.3.1.11 Cash and cash equivalents

Cash and cash equivalents consists of cash on hand and cash equivalents. The cash is held with bank and financial institutions which have as a minimum an A rating.

2.3.1.12 Share capital

Financial instruments issued by the Group are classified as equity only to the extent that they do not meet the definition of a financial liability or financial asset. Ordinary shares are classified as equity.

Incremental costs directly attributable to the issue of new ordinary shares are presented in equity as a deduction, net of tax, from the proceeds.

2.3.1.13 Provisions

Provisions are recognized when:

- 1) the Group has a present legal or constructive obligation as a result of past events;
- 2) it is probable that an outflow of resources will be required to settle the obligation; and
- 3) the amount has been reliably estimated.

Provisions are measured at the present value of the expenditures expected to be required to settle the obligation using a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the obligation. The increase in the provision due to passage of time is recognized as finance cost.

If the Group has an onerous contract, it will be recognized as a provision.

Provisions are not recognized for future operating losses.

A provision for restructuring is only recorded if the Group demonstrates a constructive obligation to restructure at the date of the statement of financial position. The constructive obligation should be demonstrated by:

- a) A detailed formal plan identifying the main features of the restructuring; and
- b) Raising a valid expectation to those affected that it will carry out the restructuring by starting to implement the plan or by announcing its main features to those affected.

2.3.1.14 Employee benefits

Short-term employment benefits

Short-term employee benefits are recorded as an expense in the income statement in the period in which the services have been rendered. Any unpaid compensation is included in 'Other payables' in the Consolidated Statement of Financial Position.

Post-employment benefits

The Group has both defined contribution plans and defined benefit plans.

In the case of defined contribution plans, contributions are paid to publicly or privately administered pension plans on a statutory, contractual, or voluntary basis. The Belgian defined contribution plan contains a legally guaranteed minimum return, which is payable by the employer. The contributions are recognized as personnel expenses.

Defined benefit plans require the Group to contribute to individual plans, for which the ultimate benefit to the employee is based on a defined benefit, e.g., based on a final salary level, defined performance of the plan, etc. For defined benefit plans, the Group obtains actuarial valuations to determine the required defined benefit pension obligation.

General

Wages, salaries, social security contributions, paid annual leave and sick leave, bonuses, and non-monetary benefits are accrued in the year in which the associated services are rendered by employees of the Company.

Pension obligations

The cost of providing benefits under the defined benefit plan is determined using the projected unit credit method.

Remeasurements, comprising of actuarial gains and losses, the effect of the asset ceiling, excluding net interest and the return on plan assets (excluding net interest), are recognized immediately in the statement of financial position with a corresponding debit or credit to retained earnings through OCI in the period in which they occur. Re-measurements are not reclassified to profit or loss in subsequent periods.

Past service costs are recognized in profit or loss on the earlier of:

- the date of the plan amendment or curtailment; and
- the date that the Company recognizes restructuring-related costs.

Net interest is calculated by applying the discount rate to the net defined benefit liability or asset and is disclosed in the respective expense by function.

The Group recognizes the service costs comprising current service costs, past-service costs, gains and losses on curtailments and non-routine settlements in the net defined benefit obligation under the respective expenses by function.

2.3.1.15 Loans and borrowings

After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortized cost using the effective interest method. Gains and losses are recognized in profit or loss when the liabilities are derecognized as well as through the effective interest amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest method. The amortization is included as finance costs in the Consolidated Income Statement.

The convertible loans are hybrid instruments and contain a liability as well as an embedded derivative (conversion option). They can also be compound instruments and in case of Sequana Medical NV, these are the EUR denominated loans in particular. There are two methods with respect to the accounting treatment for hybrid instruments (liability with an embedded derivative i.c. the conversion option). The instrument as a whole can either be accounted for as follows:

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

or

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

The Group has elected to apply the method 1):

The entire instrument has been designated at fair value through profit or loss (FVTPL) on initial recognition and as such, the embedded conversion feature is not separated. The consideration received corresponds to the fair value at inception of the whole instrument.

Financial liabilities at fair value through profit or loss (FVTPL) (including derivatives that are liabilities) are subsequently measured at fair value at each year-end. A gain or loss resulting from this measurement shall be presented as follows (IFRS 9, 5.7.7):

- a) The amount of change in the fair value of the financial liability that is attributable to changes in the credit risk of that liability shall be presented in other comprehensive income, and
- b) the remaining amount of change in the fair value of the liability shall be presented in profit or loss unless the treatment of the effects of changes in the liability's credit risk described in (a) would create or enlarge an accounting mismatch in profit or loss (in which case paragraph 5.7.8 applies).

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

Fair value measurement of financial instruments

a. Fair value hierarchy

This note presents the judgements and estimates made by the Group in determining fair values of the financial instruments recognized and measured at fair value in the financial statements. To provide an indication about the reliability of the inputs used in determining fair value, the Group has classified its financial instruments into the three levels prescribed under the accounting standards.

Recognized fair value measurements:

Level 1: The fair value of financial instruments traded in active markets is based on quoted market prices at the end of the reporting period.

Level 2: The fair value of financial instruments that are not traded in an active market is determined using valuation techniques, which maximize the use of observable market data and rely as little as possible on entity-specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.

Level 3: If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3. This is the case for unlisted debt securities.

There were no transfers between levels for recurring fair value measurements during last year.

The Group's financial instruments measured at fair value on a recurring basis are classified as level 3 (refer to the table). This is due to the market interest rate, on which basis the valuation of the financial liabilities was performed, being based on the most current loans with related parties.

The following table presents the Group's financial liabilities measured and recognized at fair value:

Description	Note	Level	At 31	At 31
			December 2023 (EUR)	December 2022 (EUR)
EUR denominated convertible loans at fair value through PL	8.6	3	979,453	934,779
Bootstrap Warrant	8.8.1	3	447,850	1,103,277
Kreos Subscription Rights	8.8.2	3	323,740	465,508
2023 Investor Warrant	8.8.3	3	1,995,760	-

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

b. Valuation techniques used to determine fair values

The fair value of the company's convertible loans is determined using discounted cash flow analysis, based on a market yield around 20% for similar loans, which is deemed to be the best indicator of the market interest rate for loans without conversion features for Sequana Medical NV. With respect to the valuation of the embedded derivative, the Company assumed that the conversion option will be exercised within the requirements set in the agreements.

For more details on valuation techniques used to determine fair values of Bootstrap Warrants, Kreos Subscription Rights and 2023 Investor Warrants, refer to notes 8.8.1, 8.8.2 and 8.8.3.

c. Valuation inputs and relationships to fair value

Description/Financial statement	Liability component of convertible bond denominated in EUR including the conversion option
Class of subsequent measurement	Fair value through profit or loss
Fair value at 31 December 2023	979,453
Unobservable inputs	Discount rate / market rate
Yield	20%
Relationship of unobservable inputs to fair value	An increase/decrease of the market interest rate of +2%pts/-2%pts would change the fair value of the liability by EUR +55,511/- 55,511

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

Decription/Financial statement	Bootstrap warrants	Kreos Subscription rights	2023 Investor Warrant
Class of subsequent measurement	Fair value through profit or loss	Fair value through profit or loss	Fair value through profit or loss
Fair value at 31 December 2023	447,850	323,740	1,995,760
Unobservable inputs	Market rate	Market rate	Market rate
Relationship of unobservable inputs to fair value	An increase/decrease of the market interest rate of +2%pts/-2%pts would change the fair value of the liability by EUR + 17,006/ - 16,975	An increase/decrease of the market interest rate of +2%pts/-2%pts would change the fair value of the liability by EUR + 16,581/ - 16,667	An increase/decrease of the market interest rate of +2%pts/-2%pts would change the fair value of the liability by EUR + 98,619/ - 98,398

d. Valuation processes

The only level 3 inputs by the Group in measuring the fair value of financial liabilities are market interest rates. The inputs are derived and evaluated by recent comparable bonds having no conversion rights at the issue date.

2.3.1.16 Trade payables

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

2.3.1.17 Share-based compensation transactions

The Group has offered equity-settled, share-based compensation plans to its employees, Executive Management and specific consultants. The cost with respect to the employee services received in compensation for the grant of these warrants is recognized as an expense on a pro rata basis over the vesting period. 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 estimated 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.

The Company has also offered equity-settled Restricted Share Units ("RSU") to its non-executive independent directors. The cost with respect to the director services received in compensation for the grant of these RSUs is recognized as an expense on a pro rata basis over the vesting period. The total amount of the expense is recognized over the vesting period and determined on the basis of the fair value of the RSUs at grant date. As the vesting period of the RSUs is one year, the fair value of each RSU is estimated as the difference between share price at grant date and the subscription price to be paid. The total cost is initially estimated on the basis of the number of RSUs that will become automatically vested (and settled into shares) at the end of the vesting period. At each balance date, the Group revises its estimated number of RSUs that will become vested. The impact of the revision is recognised in the income statement over the remaining vesting period with a corresponding

adjustment to equity. When the RSUs are vested and settled into shares, the proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium.

2.3.1.18 Leases

The Group leases various company cars and buildings. Rental contracts for the cars are typically made for fixed periods of 3 to 5 years and the rental contracts for the offices are typically made for 2 to 9 years. The contracts may have extension options. Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. The lease agreements do not impose any covenants, but leased assets may not be used as security for borrowing purposes.

Leases are recognised as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Group. Each lease payment is allocated between the liability and finance cost. The finance cost is charged to profit and loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period. The right-of-use asset is depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments, if material:

- Fixed payments (including in-substance fixed payments), less any lease incentives receivable;
- Variable lease payment that are based on an index or a rate;
- Amounts expected to be payable by the lessee under residual value guarantees;
- The exercise price of a purchase option if the lessee is reasonably certain to exercise that option; and
- Payments of penalties for terminating the lease, if the lease term reflects the lessee exercising that option.

The lease payments are discounted using the interest rate implicit in the lease. If that rate cannot be readily determined, which is the case for leases in the Group, the lessee's incremental borrowing rate is used, being the rate that the individual lessee would have to pay to borrow the funds necessary to obtain an asset of similar value in a similar economic environment with similar terms and conditions. The Group uses the incremental borrowing rate as its discount rate. The discount rates applied range between 3.1% and 12%.

Right-of-use assets are measured at cost comprising the following:

- The amount of the initial measurement of lease liability;
- Any lease payments made at or before the commencement date less any lease incentives received;
- Any initial direct costs (if material); and
- Restoration costs (if material).

Payments associated with short-term leases and leases of low-value assets are recognised on a straight-line basis as an expense in profit or loss. Short-term leases are leases with a lease term of 12 months or less. Low-value assets comprise IT-equipment and small items of office furniture.

2.3.1.19 Earnings/(loss) per share

Basic net profit/(loss) per share is computed on the basis of the weighted average number of ordinary shares outstanding during the period, excluding treasury shares.

Diluted net profit/(loss) per share is computed based on the weighted-average number of ordinary shares outstanding including the dilutive effect of warrants and bonds. During 2023 and 2022 due to the losses incurred by the Group, these instruments had an anti-dilutive effect on the loss per share. Instruments that can be converted into ordinary shares shall only be treated as dilutive when their conversion into ordinary shares would decrease earnings per share or increase loss per share from continuing operations.

2.3.2 Significant accounting judgments, estimates and assumptions

For the preparation of the Consolidated Financial Statements it is necessary to make judgments, estimates and assumptions to form the basis of presentation, recognition and measurement of the Group's assets, liabilities, items of income statements, accompanying disclosures and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

In the process of applying Sequana Medical NV's accounting policies, management has made various judgments. Those which management has assessed to have the most significant effect on the amounts recognized in the Consolidated Financial Statements have been discussed in the individual notes of the related financial statement line items.

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial years, are also described in the individual notes of the related financial statement line items.

The Group based its assumptions and estimates on parameters available when the Consolidated Financial Statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond the control of the Group. Such changes are reflected in the assumptions when they occur.

Sequana Medical NV is subject to risks and uncertainties, which may lead to actual results differing from these estimates, both positively and negatively. Sequana Medical's specific estimates including pension liabilities, fair value of financial instruments or share-based compensation are discussed in the relevant sections of the management's review and in the notes.

Significant estimates and judgments of the Group include:

- **Pensions (IAS 19) – key assumptions for measuring defined benefit for measuring post-employment benefit expense for a period and the defined benefit obligation at the period end;**
- **Share-based compensation;**
- **Accounting for research and development expenses**
- **Accounting for R&D tax credit**
- **Recognition deferred taxes**
- **Going concern**

2.3.2.1 Post-employment benefits

The aggregate of the present value of the defined benefit obligation and the fair value of plan assets for each plan is recognized in the Consolidated Financial Position as a net defined benefit liability or net defined benefit asset. The defined benefit obligation is determined annually by independent actuaries using the projected unit credit method. Employee contributions are recognized in the period in which the related service is rendered. Plan assets are not available to the creditors of the Group.

Pension costs consist of three elements: service costs, net interest, and re-measurements of employee benefits.

- Service costs are part of personnel expenses and consist of current service costs, past service costs (gains/losses from plan amendments or curtailments), and gains/losses from plan settlements.
- Net interest is recorded in the financial result and is determined by applying the discount rate to the net defined benefit liability or net defined benefit asset that exists at the beginning of the year.
- Gains and losses resulting from the actuarial valuation are recorded in other comprehensive income (OCI) as re-measurements of employee benefits. The return on plan assets (excluding interest based on the discount rate) and any change in the effect of an asset ceiling are also recorded in OCI.

Significant other non-current employee benefits (mainly jubilee benefits) are also measured using the projected unit credit method, however re-measurements are recorded in the Consolidated Income Statement.

Detailed information about the assumptions and measurement of post-employment benefits are included in note 09.

Termination benefits are recognized on the date on which the Group can no longer withdraw the offer of this type of benefit or on which restructuring provisions are recorded.

2.3.2.2 Share-based payments

The Group used the Black & Scholes model for share-based payment calculation purposes for the Executive share-based option plan, implemented early October 2018. The volatility parameter has been based on the volatility of peer shares, listed on the STOXX Medtech stock exchange.

The share price considered is EUR 9.25 and is the lowest based on the expected gross amount of IPO proceeds of EUR 30.0 million, whereas probability weighted scenarios between EUR 9.25 and EUR 10.50 per share have been applied. For more information refer to note 9.1.

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

The Group used as well the Black & Scholes model for share-based payment calculation purposes for the 2018 Share Option plan, approved by the extra-ordinary shareholders meeting of 18 January, 2019. The volatility parameter has been based on the volatility of peer shares, listed on the STOXX Medtech stock exchange.

The weighted average share price considered is calculated as the average of the historical actual share prices for the thirty days period prior to the grant of the options. For more information refer to note 9.2.

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

The Group used as well the Black & Scholes model for share-based payment calculation purposes for the 2021 Share Option plan, approved by the extra-ordinary shareholders meeting of May, 27 2021. The volatility parameter has been based on Company's shares.

The weighted average share price considered is calculated as the average of the historical actual share prices for the thirty days period prior to the grant of the options. For more information refer to note 9.3.

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

The Group has established, after approval of the board of directors dated 6 November 2023, a 2023 Share Option Plan. As at 31 December 2023, none of the 1,000,000 2023 Share Options have been granted.

2.3.2.3 Accounting for research and development expenses

Due to uncertainties inherent to the development and registration with the relevant healthcare authorities of its products, Sequana Medical NV estimates the conditions for capitalization are not met until the regulatory procedures required by such healthcare authorities have been finalized.

The Company currently has no development expenditures that have been capitalized.

2.3.2.4 Accounting for R&D tax credit

The tax credit is calculated as a percentage of qualifying investments in research and development; it can be offset against corporate income tax and is refunded to us in cash after four years to the extent it could not be offset.

2.3.2.5 Recognition deferred taxes

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. Please refer to note 7.5 for more information.

2.3.2.6 Going concern

The accompanying consolidated financial statements have been prepared on a going concern basis. Please refer to note 4 for the detailed explanation of the going concern.

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

The following amendments to standards are mandatory for the first time for the financial year beginning 1 January 2023 and have been endorsed by the European Union and have no material impact on the Group's Consolidated Financial Statements:

- ✓ **Amendments to IAS 1 Presentation of Financial Statements and IFRS Practice Statement 2: Disclosure of Accounting policies (effective 1 January 2023).** The amendments aim to improve accounting policy disclosures and to help users of the financial statements to distinguish between changes in accounting estimates and changes in accounting policies. The IAS 1 amendment requires companies to disclose their material accounting policy information rather than their significant accounting policies. Further, the amendment to IAS 1 clarifies that immaterial accounting policy information need not be disclosed. To support this amendment, the Board also amended IFRS Practice Statement 2, 'Making Materiality Judgements', to provide guidance on how to apply the concept of materiality to accounting policy disclosures. The amendments are effective for annual reporting periods beginning on or after 1 January 2023. Earlier application is permitted (subject to any local endorsement process).
- ✓ **Amendments to IAS 8 Accounting policies, Changes in Accounting Estimates and Errors: Definition of Accounting Estimates (effective 1 January 2023).** The amendment to IAS 8, 'Accounting Policies, Changes in Accounting Estimates and Errors', clarifies how companies should distinguish changes in accounting policies from changes in accounting estimates. The amendments are effective for annual reporting periods beginning on or after 1 January 2023. Earlier application is permitted (subject to any local endorsement process).

- ✓ **Amendments to IAS 12 Income Taxes: Deferred Tax related to Assets and Liabilities arising from a Single Transaction (effective 1 January 2023 but immediate application permitted).** The amendments clarify how companies account for deferred tax on transactions such as leases and decommissioning obligations. The main change in the amendments is an exemption from the initial recognition exemption of IAS 12.15(b) and IAS 12.24. Accordingly, the initial recognition exemption does not apply to transactions in which equal amounts of deductible and taxable temporary differences arise on initial recognition. The amendments are effective for annual reporting periods beginning on or after 1 January 2023. Early adoption is permitted.
- ✓ **Amendments to IAS 12 'Income Taxes': International Tax Reform – Pillar Two Model Rules (effective 1 January 2023).** The IASB has issued these amendments introducing:
 - a. a temporary exception to the requirements to recognise and disclose information about deferred tax assets and liabilities related to Pillar Two income taxes; and
 - b. targeted disclosure requirements for affected entities.

The following new standards and amendments have been issued, are not mandatory for the first time for the financial year beginning 1 January 2023 but have been endorsed by the European Union and have no material impact on the Group's Consolidated Financial Statements:

- ✓ **Amendments to IFRS 16 'Leases': Lease Liability in a Sale and Leaseback (effective 1 January 2024).** The amendments explain how an entity accounts for a sale and leaseback after the date of the transaction, specifically where some or all the lease payments are variable lease payments that do not depend on an index or rate. They state that, in subsequently measuring the lease liability, the seller-lessee determines 'lease payments' and 'revised lease payments' in a way that does not result in the seller-lessee recognising any amount of the gain or loss that relates to the right of use it retains. Any gains and losses relating to the full or partial termination of a lease continue to be recognised when they occur as these relate to the right of use terminated and not the right of use retained.

The following amendments have been issued, but are not mandatory for the first time for the financial year beginning 1 January 2023 and have not been endorsed by the European Union and are currently not expected to have a material impact on the Group's Consolidated Financial Statements:

- **Amendments to IAS 1 'Presentation of Financial Statements: Classification of Liabilities as current or non-current' (effective 01/01/2024),** affect only the presentation of liabilities in the statement of financial position — not the amount or timing of recognition of any asset, liability income or expenses, or the information that entities disclose about those items. They:
 - Clarify that the classification of liabilities as current or non-current should be based on rights that are in existence at the end of the reporting period and align the wording in all affected paragraphs to refer to the "right" to defer settlement by at least twelve months and make explicit that only rights in place "at the end of the reporting period" should affect the classification of a liability;
 - Clarify that classification is unaffected by expectations about whether an entity will exercise its right to defer settlement of a liability; and make clear that settlement refers to the transfer to the counterparty of cash, equity instruments, other assets or services.

- Clarify how conditions with which an entity must comply within 12 months after the reporting period, such as covenants, affect the corresponding liability's classification.
- **Amendments to IAS 7 'Statement of Cash Flows' and IFRS 7 'Financial Instruments: Disclosures': Supplier Finance Arrangements (effective 1 January 2024).** The amendment describes the characteristics for which reporters will have to provide additional disclosures regarding the impact of supplier finance arrangements on liabilities, cash flows and exposure to liquidity risk.
- **Amendments to IAS 21 'The Effects of Changes in Foreign Exchange Rates: Lack of Exchangeability' (effective 1 January 2025).** IAS 21 previously did not cover how to determine exchange rates in case there is long-term lack of exchangeability and the spot rate to be applied by the company is not observable. The narrow scope amendments add specific requirements on:
 - Determining when a currency is exchangeable into another and when it is not;
 - Determining the exchange rate to apply in case a currency is not exchangeable;
- Additional disclosures to provide when a currency is not exchangeable.

The Group is continuously assessing the impact of the upcoming standards. The Group expects currently no material impact on the Sequana Medical Group consolidated financial statements.

There were no other standards, interpretations or amendments that are not yet effective and that would be expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

2.3.4 Changes in accounting policies

New standards or interpretations applicable from 1 January 2023 do not have any significant impact on the Sequana Medical Group Consolidated Financial Statements.

3 *Financial instruments and financial risk management*

The nature of Sequana Medical NV's business and its global presence exposes the Group to market risks and liquidity risks. The Board of Directors is responsible for overseeing the Group's internal control system, which addresses risks to which the Group is exposed. These systems provide appropriate security against significant inaccuracies and material losses. Management is responsible for identifying and assessing risks that are of significance for the respective country.

3.1 *Market risk*

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. The market risks consist primarily of foreign currency risks and, to a lesser degree, interest rate risks. Main currency exposures are the Swiss franc and the Euro. The Group is not hedging any of these risks.

3.1.1 *Foreign currency risks*

Foreign currency risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate due to changes in foreign exchange rates. The group identifies two main types of foreign currency risk: foreign currency transaction risk and foreign currency translation risk.

The Group incurs foreign currency transaction risk on accounts receivable, accounts payable and other monetary items that are denominated in a currency other than the Company's functional currency. Foreign currency transaction risk in the Group's operations also arises from the variability of cash flows in respect of forecasted transactions. The foreign currency transaction risk is not significant.

Foreign operations which do not have the Euro as their functional currency give rise to a translation risk. The Group operates internationally and is exposed to foreign exchange risks arising from currency exposures, primarily with respect to the Swiss Franc (CHF).

The carrying amounts of the Group's main foreign currency denominated assets and liabilities in CHF at the end of the reporting period are as follows:

CHF	31 December 2023	31 December 2022
Assets		
Inventory	2,125,800	2,581,381
Cash and cash equivalents	617,310	1,462,972
Liabilities		
Non-current liabilities	(618,382)	-
Current liabilities	(2,906,946)	-

The carrying amounts of the Group's main foreign currency denominated assets and liabilities in USD at the end of the reporting period are as follows:

USD	31 December 2023	31 December 2022
Assets		
Inventory	-	-
Cash and cash equivalents	299,772	-
Liabilities		
Non-current liabilities	(3,368,729)	-
Current liabilities	-	-

The Group has exposures to the Swiss Franc (CHF) and the US dollar (USD) due to their net investments in foreign operations.

Foreign exchange exposures are currently not hedged.

The following table shows the sensitivity to foreign exchange rate changes (CHF / EUR and USD / EUR), with all other variables held constant, of the Group's income statement and equity:

As of 31 December 2023, if the EUR had weakened 5% against the CHF with all other variables held

As at 31 December 2023	
EUR	Impact on income statement
5% decrease of average foreign exchange rate (CHF)	(417,529)
5% increase of average foreign exchange rate (CHF)	418,054
5% decrease of average foreign exchange rate (USD)	(330,645)
5% increase of average foreign exchange rate (USD)	330,777

As at 31 December 2022	
EUR	Impact on income statement
5% decrease of average foreign exchange rate (CHF)	(328,731)
5% increase of average foreign exchange rate (CHF)	328,702
5% decrease of average foreign exchange rate (USD)	(397,114)
5% increase of average foreign exchange rate (USD)	396,949

constant, the loss for the period would have been EUR 417,529 higher (2022: EUR 328,731). Conversely, if the EUR had strengthened 5% against the CHF with all other variables held constant, the loss of the period would have been EUR 418,054 lower (2022: EUR 328,702).

As of 31 December 2023, if the EUR had weakened 5% against the USD with all other variables held constant, the loss for the period would have been EUR 330,645 higher (2022: EUR 397,114). Conversely, if the EUR had strengthened 5% against the USD with all other variables held constant, the loss of the period would have been EUR 330,777 lower (2022: EUR 396,949).

As at 31 December 2023	
EUR	Impact on equity
5% decrease of average foreign exchange rate	3,210
5% increase of average foreign exchange rate	(3,210)

As at 31 December 2022	
EUR	Impact on equity
5% decrease of average foreign exchange rate	36,338
5% increase of average foreign exchange rate	(36,338)

As of 31 December 2023, if the EUR had weakened 5% against the CHF and against the USD with all other variables held constant, the equity for the period would have been EUR 3,210 lower (2022: EUR -36,338). Conversely, if the EUR had strengthened 5% against the CHF and the USD with all other variables held constant, the equity of the period would have been EUR 3,210 higher (2022: EUR 36,338).

3.1.2 Interest rate risks

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

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

As at 31 December 2023 and 31 December 2022, the Group interest rates applied on material interest-bearing assets and liabilities are contractually fixed and therefore the above sensitivity is highly unlikely to materialise.

As at 31 December 2023		As at 31 December 2022	
EUR	Impact on income statement and equity	EUR	Impact on income statement and equity
50 basis points increase / decrease	+/- 13,878	50 basis points increase / decrease	+/- 9,822

3.2 Liquidity risk

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

EUR	Cash outflows			
	Carrying amount			
	31.12.2023	Up to 1 year	1 to 3 years	More than 3 years
Trade payables	2,906,877	2,906,877	-	-
Other payables	2,989,519	2,525,288	234,687	229,544
Financial debt at amortized cost	15,807,484	7,418,288	8,389,196	-
Financial debt at FVTPL	979,453	400,000	579,453	-
Total	22,683,333	13,250,453	9,203,336	229,544

EUR	Cash outflows			
	Carrying amount			
	31.12.2022	Up to 1 year	1 to 3 years	More than 3 years
Trade payables	3,391,783	3,391,783	-	-
Other payables	2,728,350	2,118,892	300,485	308,973
Financial debt at amortized costs	15,740,964	4,282,914	11,458,050	-
Financial debt at FVTPL	934,779	200,000	734,779	-
Total	22,795,876	9,993,588	12,493,314	308,973

3.3 Capital management

Management presently monitors its capital structure based on its legal, statutory requirements for stand-alone entities and, in particular, for the holding company. The Group's policy is to maintain sufficient capital to continue as a going concern, and sustain the future development of the business (see note 4 regarding the assessment of the going concern).

Management monitors rolling forecasts of the Group's liquidity reserve and cash and cash equivalents on the basis of expected cash flows for the next 12 months. This is carried out in accordance with practice and limits set by management and in accordance with the statutory capital requirements of the holding company. In addition, the Group's liquidity management policy involves projecting cash flows in EUR, CHF and GBP and considering the level of liquid assets necessary to meet these, monitoring balance sheet liquidity ratios against internal requirements and maintaining debt-financing plans.

No changes were made in the objectives, policies or processes for managing capital during the years ended 31 December 2023 and 2022.

3.4 General business risks

Over the years 2023 and 2022 the macroeconomic environment have been affecting businesses globally, including Sequana Medical NV. We refer to the risk factors defined in our Report of the Board of Directors (1.1.3 Information regarding major risks and uncertainties).

On 24 February 2022, Russia launched a full-scale invasion of Ukraine. As at the date of this Annual Report, the conflict remains ongoing. While the Group does not have any operations in Russia or Ukraine, it previously conducted its SAHARA clinical study in Georgia, which borders Russia. Although no delays were experienced as a result of the conflict and Sequana Medical NV does not have any plans for further studies in the region, if this were to change, these studies could encounter difficulties. DSR® product production will also be based in Romania, which borders Ukraine. Moreover, the conflict has had and could continue to have an adverse impact on global macroeconomic conditions generally, including due to the increase in oil and gas prices resulting from the conflict. This could in turn result

in suppressed demand for the **alfapump**[®], the **DSR**[®] product and/or any future products, although Sequana Medical NV has not experienced any such impact to date. Finally, the conflict may in the longer term result in issues for Sequana Medical NV in procuring sub-components for the **alfapump**[®], particularly since neon and palladium are often sourced from Ukraine, although it has not experienced material issues thus far.

3.5 Effects of climate-related matters on financial statements

In view of climate related matters, the Group's operations are not likely to be impacted by extreme weather conditions such as droughts, earthquakes or floods. Consequently, the Group does not expect any significant indicators for impairment of any assets nor understatement of any liabilities.

4 Going concern

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

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

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

The Consolidated Statement of Financial Position as at 31 December 2023 shows a negative equity in the amount of EUR 19.5 million and ending cash balance of EUR 2.6 million. The Company will continue to require additional financing in the near future and in that respect already executed a EUR 3.0 million Investor Loan Agreement in February 2024 with Partners in Equity and Rosetta Capital and raised EUR 11.5 million gross proceeds in March 2024 in a private equity placement via an accelerated book-build offering disclosed in note 14 "*Events after the reporting period in the Notes to Consolidated Financial Statements*". Together with existing cash resources, the net proceeds from these financing activities are expected to extend the current cash runway of the Company to the end of Q3 2024.

Based on the above condition, the Executive Management and the Board of Directors made an assessment of the Company's ability to continue as a going concern. Several measures have already been carried out in order to reduce expenditures, including:

- **alfapump** program: The Board of Directors strongly believes that pre-market approval ("PMA") approval of the **alfapump** is a key value inflection point for the Company and has decided to prioritize its resources on reaching this important milestone. A number of other **alfapump**-related activities have been delayed or halted, including termination of all commercial activities in Europe, which resulted in a significant reduction in personnel in all countries, and

- Heart Failure/DSR: Delaying the randomized phase of the MOJAVE clinical study until after the alfapump pre-market approval (“PMA”) approval.

The Company is also assessing to what extent partnerships or licensing arrangements could be entered into regarding its alfapump and DSR programs in order to support development and commercialisation. While on the date hereof no concrete plans are on the table, the Company continuously engages with potential partners, which could also provide further funding to the Company’s business.

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

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

We refer for more details about the additional financing to note 14 *“Events after the reporting period in the Notes to Consolidated Financial Statements”*.

5 Revenues from customers

The Group generates sales solely from the sale of **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	2023	2022
Trade receivables	43,075	113,871
Contract liabilities (relating to customers' advance payments)	170,260	164,492

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	2023	2022
Revenue recognized in the period (included in contract liability at the beginning of the period)	-	-
Increases due to cash received as advance payment	-	-
Effect of currency translation	5,768	4,263

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

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

6 Segment information

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

Based on the Group's structure Sequana Medical NV's only entity (branch), 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 Medical NV constitutes only one reportable segment, which is represented by the whole Group.

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

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

EUR	2023	2022
Germany	553,500	692,650
France	95,000	114,375
Switzerland	43,673	85,662
Rest of the world	20,000	30,000
Total revenue	712,173	922,687

Revenue decreased from EUR 0.92 million in 2022 to EUR 0.71 million in 2023 due to the decision to scale back European commercial activities in April 2023.

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

The Swiss branch is the sole operating entity within the Group, 40% of the assets are located in Switzerland compared to 24% last year. There are no significant concentrations of credit risk through exposure to individual customers.

7 Detailed information on profit or loss items

7.1 Breakdown of expenses by nature

EUR	2023	2022
Personnel costs	10,975,997	10,078,399
Clinical Studies	5,277,339	7,706,860
External consultancy	2,136,981	3,485,913
External accounting & legal services	947,947	849,405
Travel & Lodging	790,732	703,274
Rent & infrastructure expenses	336,441	289,312
Intellectual Property	297,213	295,671
Insurance & IT	920,711	834,986
Marketing	71,956	95,743
Depreciation and amortization (1)	661,280	812,483
Quality Audits / Regulatory Fees	2,397,278	1,435,554
Other	5,225,648	2,755,150
Total operating expenses	30,039,522	29,342,749

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

7.2 Operating Expenses – general and administration

Expenses (EUR)	2023	2022
Capital increase related expenses	365,397	343,778

The total amount of known and accrued capital raise related expenditure for 2023 is EUR 1,043,612, of which EUR 365,397 has been recognized in the Consolidated Income Statement as G&A expenses and EUR 678,215 has been reported under equity. The capital raise expenditure accounted for in equity relate to the issuance of equity instruments and represent the incremental costs attributed to new shares. They mainly consist of lawyer fees, audit fees, consulting fees and notary fees.

The total amount of known and accrued capital raise related expenditure for 2022 is EUR 1,078,568, of which EUR 343,778 has been recognized in the Consolidated Income Statement as G&A expenses and EUR 734,789 has been reported under equity. The capital raise expenditure accounted for in equity relate to the issuance of equity instruments and represent the incremental costs attributed to new shares.

7.3 Other Income

EUR	2023	2022
R&D Incentives	627,292	510,222
Other	1,977	19,952
Total Other income	629,268	530,174

Other income increased from EUR 0.53 million in 2022 to EUR 0.63 million in 2023.

The R&D incentives income was predominantly composed of:

- Income from Belgian R&D incentives (tax credit) with regard to incurred R&D expenses amounting to EUR 607,663 in 2023 (2022: EUR 442,390).
- Reduction on payroll withholding taxes of R&D qualified employees in Belgium amounting to EUR 19,629 in 2023 (2022: EUR 67,832).

7.4 Financial result

The financial result is split into the following categories:

EUR	2023	2022
Finance income	1,052,196	450,553
Interest income	1,978	131
Remeasurement at FVTPL on convertible loans	13,815	
Foreign exchange gains	239,209	274,292
Remeasurement at FVTPL on subscription rights	797,195	176,129
Finance cost	(4,287,957)	(2,732,522)
Interest costs	(1,931,585)	(816,348)
Interest costs leasing	(58,738)	(63,608)
Remeasurement at FVTPL on convertible loans	(58,489)	(58,653)
Remeasurement at FVTPL on subscription rights	-	(1,103,277)
FV correction tax credit receivable	(1,891)	(124,043)
FV correction investor warrants	(1,995,760)	-
Foreign exchange losses	(241,495)	(566,593)
Net financial result	(3,235,761)	(2,281,970)

The remeasurement at FVTPL on subscription rights is relating to the Bootstrap Warrant, the Kreos subscriptions rights and 2023 Investor Warrants as further disclosed in note 8.8.

The increase in interest costs is mainly relating to the Secured loan facility agreement with Kreos as further disclosed in note 8.7.2.

7.5 Income taxes

Income tax expense

EUR	2023	2022
Current income taxes	(465,608)	(386,629)
Total income tax expense	(465,608)	(386,629)

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

EUR	2023	2022
Loss before tax	(32,097,966)	(30,376,454)
Tax rate	25%	25%
Income tax expense at the calculated tax rate	(8,024,491)	(7,594,114)
Effect of non-recognition of tax losses in current	(7,558,883)	(7,207,485)
Effective income tax expense	(465,608)	(386,629)

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

Taxes on unremitted earnings

At 31 December 2023 and 2022, there was no recognized deferred tax liability for taxes that would be payable on the unremitted earnings of certain of the Group's subsidiaries. The Group does not expect any distribution of retained earnings to the parent company within the next twelve months.

Deductible temporary differences and available tax loss carry – forwards

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

EUR	31 December 2023	31 December 2022
Deductible temporary differences for which no deferred tax asset has been recognised	-	-
Belgium	99,073,526	75,003,294
Switzerland	-	-
USA	785,954	983,723
Total unused tax losses	99,859,480	75,987,017

As of 2019, the unused tax losses are mainly incurred by the Belgian company. As the Company did not generate any taxable profits in the past and due to the fact that there is an uncertainty about the realization of future taxable profits the Company has decided to not recognize a deferred tax asset on the tax losses carried forward. The unused tax losses have no expiration date.

The Group obtained a tax ruling with the Swiss tax authorities. In this tax ruling, it has been agreed that the Swiss branch will be taxable on a cost-plus basis. The cost-plus percentage is 10%. The 2023 estimated tax amount, amounting to CHF 442,256 or EUR 440,575 has been accrued for in the statement of financial position, Other payables.

7.6 Loss per share

The calculation of the basic earnings per share is based on the loss/profit attributable to the holders of ordinary shares and the weighted average number of ordinary shares outstanding during the period.

The Group offers its employee's share-based compensation benefits (see note 9), which may have a dilutive effect on the basic earning per share.

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

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

EUR, except number of shares	2023	2022
Net loss attributable to shareholders	(32,563,574)	(30,763,083)
Weighted average number of shares - basic	26,774,116	22,769,576
Basic loss per share	(1.22)	(1.35)

8 Detailed information on statement on financial position items

8.1 Cash and cash equivalents

The Group held cash and cash equivalents of EUR 2,584,128 at 31 December 2023 (2022: EUR 18,874,959).

The cash is held with bank and financial institutions which are rated A as a minimum. All investments are highly liquid.

8.2 Trade receivables, other receivables and prepaid expenses

EUR	31 December 2023	31 December 2022
Trade receivables	43,075	113,871
Other receivables	312,871	292,330
Prepaid expenses	1,060,578	1,186,964

Other receivables mainly consist of VAT.

The total amount of Prepaid expenses in the statement of financial position amounts to EUR 1,060,578 (in 2022: EUR 1,186,964). For 2023 this is mainly related to prepayments for Clinical Research Organisations.

The following provides information about the exposure to credit risk and expected credit loss for trade receivables:

The counterparties are in most transactions hospitals in the public sector in Germany, Switzerland or France. Therefore, there were no credit losses in the past and the expected credit loss is close to nil.

The ageing of trade receivables at 31 December 2023 and 2022 past due, but not impaired, are as follows:

2023 (EUR)	Not past due	Total past due	0-90 days	90-180 days	180-360 days	More than 360 days
Trade receivables	19,000	24,075	24,075	-	-	-
Weighted average loss rate						
2022 (EUR)	Not past due	Total past due	0-90 days	90-180 days	180-360 days	More than 360 days
Trade receivables	68,931	44,940	44,940			
Weighted average loss rate						

8.3 Inventories

Inventories are categorized as follows:

EUR	31 December 2023	31 December 2022
Finished goods	322,090	500,634
Subassembly	321,229	174,671
Components	1,652,354	1,945,892
Total	2,295,673	2,621,197

No significant inventory write-down have been recorded nor any reversal of previous inventory write-downs. No write-downs of inventories to net realisable value have been recorded.

8.4 Property, plant and equipment

Reconciliation of beginning and ending balance by classes of assets:

EUR				Fully owned
	Installation & machinery	Furniture, fixtures & vehicles	Other tangible fixed assets & AUC (1)	Total
Acquisition value				
1 January 2022	143,060	755,469	75,379	973,909
Additions	-	395,196	472,204	867,400
Disposals	-	-	-	-
Transfers	-	38,329	(38,329)	-
Currency translation effects	35,191	156,304	1,370	192,864
31 December 2022	178,251	1,345,298	510,624	2,034,173
Additions	2,472	72,991	681,842	757,305
Disposals	-	-	-	-
Transfers	-	-	-	-
Currency translation effects	11,420	75,547	4,361	91,328
31 December 2023	192,143	1,493,836	1,196,827	2,882,806
Depreciations				
1 January 2022	65,588	391,580	23,151	480,319
Additions	13,496	262,681	31,704	307,882
Disposals	-	-	-	-
Currency translation effects	15,859	92,716	342	108,917
31 December 2022	94,943	746,977	55,198	897,118
Additions	13,943	301,791	39,931	355,665
Disposals	-	-	-	-
Currency translation effects	6,707	57,219	2,239	66,165
31 December 2023	115,593	1,105,987	97,368	1,318,948
Net book value 31 December 2022	83,308	598,320	455,426	1,137,055
Net book value 31 December 2023	76,550	387,848	1,099,459	1,563,858

(1) AUC = Assets Under Construction

The increase in fully owned P,P&E is largely driven by the expenses incurred for the future implementation of a new ERP-system.

EUR	Right-of-use		
	Land & building	Furniture, fixtures & vehicles	Total
Acquisition value			
December 31, 2021	1,064,000	354,157	1,418,157
Additions	450,542	47,917	498,459
Disposals	-	(61,147)	(61,147)
Currency translation effects	-	-	-
December 31, 2022	1,514,542	340,927	1,855,469
Additions	68,532	88,737	157,269
Disposals	-	(278,288)	(278,288)
Currency translation effects	-	-	-
December 31, 2023	1,583,074	151,376	1,734,451
Depreciations			
December 31, 2021	476,376	167,032	643,409
Additions	218,005	93,509	311,514
Disposals	-	(30,357)	(30,357)
Currency translation effects	-	-	-
December 31, 2022	694,381	230,184	924,565
Additions	230,782	75,862	306,644
Disposals	-	(249,192)	(249,192)
Currency translation effects	-	-	-
December 31, 2023	925,163	56,854	982,017
Net book value 31 December 2022	820,161	110,743	930,904
Net book value 31 December 2023	657,911	94,523	752,434

The increase in right-of-use assets is largely driven by new and renewed leasing contracts in office and production area.

8.5 Other non-current assets

Other non-current assets are composed of R&D incentives, which the Group has applied for starting in 2021. The R&D incentives receivables are future expected tax deductions or refunds resulting from tax incentives on research and development expenses in Belgium. The non-current R&D incentives receivables are discounted over the period until maturity date and therefore reported at net present value. The discount rate applied in 2023 embeds a Belgian OLO rate of 2.18% (2022: 2.82%).

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

31 December 2023					
Maturity date					
EUR	2025	2026	2027	2028	Total
Non-current R&D incentives receivables (discounted)	167,010	271,009	405,318	544,641	1,387,979
Total Other non-current assets	167,010	271,009	405,318	544,641	1,387,979

31 December 2022				
Maturity date				
EUR	2026	2027	2028	Total
Non-current R&D incentives receivables (discounted)	155,857	252,872	373,479	782,208
Total Other non-current assets	155,857	252,872	373,479	782,208

8.6 Share capital and Share Premium

The share capital of the Company is EUR 2,926,295.90 and is represented by 28,242,753 ordinary shares. The share capital is fully paid-in. During 2023, several capital increases took place.

EUR, except number of shares	Shares	Share capital	Share premium	Total
December 31, 2021	18,577,078	1,924,932	142,432,715	144,357,647
Capital increase ESOP 21/01/2022	2,182	226	6,779	7,005
March 2022 Equity Placement	5,167,268	535,329	27,884,645	28,419,974
December 31, 2022	23,746,528	2,460,487	170,324,139	172,784,626
April 2023 Equity Placement	4,445,205	460,523	15,319,955	15,780,478
Capital increase RSU 10/23	51,020	5,286	327	5,612
December 31, 2023	28,242,753	2,926,296	185,644,420	188,570,716

At 27 April 2023, the Company announced that in the context of the capital increase that was announced on 24 April 2023 and completed on 27 April 2023 by means of a private placement through an accelerated book building procedure of 4,445,205 new shares (being approximately 18.72% of the Company's outstanding shares) at an issue price of EUR 3.55 per share. Its share capital increased from EUR 2,460,487 to EUR 2,921,010 and the number of issued and outstanding shares has increased from 23,746,528 to 28,191,733 ordinary shares. Of the 4,445,205 new shares, 2,276,192 were immediately admitted to listing and trading on the regulated market of Euronext Brussels upon their issuance (on the basis of applicable listing prospectus exemptions), while 2,169,013 shares were not immediately admitted to listing and trading on the regulated market of Euronext Brussels upon their issuance (as their admission to listing and trading was subject to the approval of a listing prospectus). The remaining shares have been admitted to trading and listing on the regulated market of Euronext Brussels after the approval of a listing prospectus by the FSMA.

At 4 October 2023, the Company announced that, in the framework of the "restricted share unit" or "RSU" plan for non-executive independent directors as approved by the Company's extraordinary shareholders' meeting of 10 February 2023, the Company's share capital has increased from EUR

2,921,010 to EUR 2,926,296 and the number of issued and outstanding shares has further increased from 28,191,733 to 28,242,753 ordinary shares, through the issuance of a total of 51,020 new shares that were subscribed for in the capital increase.

The new shares issued within the framework of the capital increases are common shares with the same rights and benefits, and in all respects a grade equivalent, including dividend rights, as the existing and outstanding shares of the Company at the time of their issue.

As of 31 December 2023 the Company does not hold any Treasury shares.

Authorised capital

The Extraordinary General Meeting on November 10, 2023 decided to grant the Board of Director's authorisation to increase the authorised share capital, such within the limits of the existing authorisation as set out in Article 8 of the Articles of Association, in one or more rounds by a maximum amount of EUR 2,926,295.90, such within a period of five years from the date of announcing such a decision in the Annexes of the Belgian Bulletin of Acts, Orders and Decrees.

8.7 Financial debts / net debt

8.7.1 Subordinated loan agreements

In July 2020, the Company entered into subordinated loan agreements with PMV/z Leningen NV ("PMV/z" later "PMV Standaardleningen"), Sensinnovat BV ("Sensinnovat") and Belfius Insurance NV ("Belfius Insurance"), for an aggregate principal amount of EUR 7.3 million, of which loans for a principal amount of EUR 1.4 million could be converted for new shares in the event of an equity financing or sale of the Company.

In March 2021, as a result of the equity raising by the Company that took place on 15 February 2021, Sensinnovat and Belfius Insurance converted their convertible loans for an aggregate amount of EUR 618,916.67 (representing principal and interests) into an aggregate of 97,084 new Shares in accordance with the terms of the convertible loans, thereby settling the convertible portion of their loans through a contribution in kind of their payables due by the Company under the relevant loans.

In December 2021, the Company entered into amendment agreements related to the outstanding subordinated loan agreements with the lenders, thereby (i) extending the duration of such loans, (ii) increasing the interest rates retroactively, and (iii) introducing payment by instalments. Consequently, the loans have a term of 60 months and are repayable in eight equal quarterly instalments between months 36 and 60. The loans bear an interest rate of 6.5% per annum, except that the convertible portion of the loan granted by PMV/z bears an interest rate of 5.5% per annum. The loans with PMV/z, Belfius Insurance and Sensinnovat allow the Company to prepay the relevant loans together with all accrued interest, provided that the Company pays a termination indemnity equal to six months of interest on the prepaid loan.

In March 2023, the Company entered into new amendment agreements, thereby (i) amending the repayments terms and (ii) further increasing the interest rates retroactively. Consequently, the loans have a term of 60 months and are repayable in four equal quarterly instalments of EUR 1,675,000 on 30 September 2024, 31 December 2024, 31 March 2025 and 30 June 2025. The Subordinated Loan Agreements bear an interest rate of 7.0% per annum, except that the convertible portion of the loan

granted by PMV-Standaardleningen bears an interest rate of 6.0% per annum. The loans with PMV-Standaardleningen, Belfius Insurance and Sensinnovat allow the Company to prepay the relevant loans together with all accrued interest, provided that the Company pays a termination indemnity equal to six months of interest on the prepaid loan. The convertible portion of the loan granted by PMV-Standaardleningen can be converted in the event of an equity financing or sale of the Company, at a price per share that is equal to 75% of the price of the Company's shares as will be reflected in the relevant equity financing or sale.

The amendments to the loan agreements were treated as a loan modification.

All subordinated loan agreements described in this section have been concluded with similar terms and conditions on an at arm's length basis.

The Company considers no material changes have occurred in its own credit risk that would significantly impact the fair value of the convertible loans as at 31 December 2023.

8.7.2. Secured loan facility agreement Kreos

The Company entered into a secured loan facility agreement with Kreos (the "Kreos Loan Agreement") in the amount of EUR 10.0 million and pursuant to which the Company is permitted to request an increase of the facilities in the amount of a maximum of EUR 10.0 million on an uncommitted basis. The loan facility has been drawdown for an amount of EUR 10.0 million. During the initial period of six months from the first drawdown (extendable by mutual agreement), the Company only pays interest, with the loans amortising in equal monthly instalments of principal and interest until maturity. The loan matures on 30 September 2025. The main elements of the Kreos Loan Agreement can be summarised as follows:

- *Interest:* The loans under the facility accrue interest at a fixed rate of 9.75% per annum.
- *Fees:* A number of fees will be payable to Kreos Capital, principally consisting of (i) a transaction fee equal to 1.25% of the total loan facility amount and (ii) an end of loan payment, payable upon final repayment of the loan, corresponding to 1.25% of the amount drawn.
- *Board observer:* Kreos Capital will be entitled to appoint a board observer to attend meetings of the Company's board of directors in a non-voting capacity.
- *Collateral:* The loans are secured by the Company's bank accounts, receivables and movable assets, including IP rights.
- *Change of control:* The Kreos Loan Agreement contains a change of control clause and requires such clause to be approved by the Company's general shareholders' meeting. The Extraordinary General Meeting, dated 10 February 2023 approved the related clause.
- *Contractual restrictions:* The Kreos Loan Agreement does not contain financial covenants, but does contain other customary restrictions on the business of the Company and its subsidiaries (such as limitations on future disposals, limitations on the incurrence of financial indebtedness, security and acquisitions, subject to certain carve-outs and limitations) and on the ability of the Company to distribute dividends as long as loans are outstanding.

In April 2023, the Company has obtained an amendment to its debt financing with Kreos Capital VII (UK) Limited. The amended agreement is subject to a number of conditions. If the Company succeeds in securing equity financing, of at least EUR 15,000,000 and no later than 30 June 2023, capital repayments will be reduced by 75% until 31 December 2023. The end date of the reduced capital repayments may be extended to 31 March 2024 if the company succeeds in starting up the first clinical site of its MOJAVE study no later than 31 December 2023. If the Company succeeded in completing an additional equity financing (additional to the previously described equity financing no later than 30

June 2023) of at least EUR 20,000,000 no later than 31 December 2023, the capital repayments would have been reduced by 50% for an additional period of 6 months.

The agreement is subject to a number of conditions as described before, including an increase of the end of loan payment from 1.25% to 1.75%.

Given the April 2023 Equity placement, the capital repayments have been reduced by 75% until 31 December 2023. In July 2023, the Company succeeded the startup of the first clinical site of its MOJAVE study resulting in an extension of the reduced capital repayments until 31 March 2024. The amendment to the loan agreement was treated as a loan modification.

In the framework of the Kreos Loan Agreement, the Company and Kreos Capital VII Aggregator SCSp entered into a subscription rights agreement in July 2022 (the "Kreos Subscription Rights Agreement") pursuant to which the Company agreed to issue and allocate subscription rights to Kreos Capital VII Aggregator SCSp (the "Kreos Subscription Rights") to subscribe to new shares of the Company. Refer to section 8.8.2. Kreos subscription rights for more information.

The table below contains an analysis of the net financial debt and the relevant movements for the periods presented. The amounts disclosed in the table are not substantially different to the undiscounted contractual cash flows.

in EUR	2023	2022
Cash and cash equivalents	2,584,128	18,874,959
Borrowings - repayable within one year	(7,818,288)	(4,482,914)
Borrowings - repayable after one year	(8,968,649)	(12,192,829)
Net financial debt	(14,202,809)	2,199,216

EUR	Cash and cash equivalents	Borrowings due within 1 year	Borrowings due after 1 year
Net financial debt as per 31 December 2021	9,600,412	-	7,324,834
Cash flows	9,189,389	-	9,626,085
Fair value adjustment at inception date (non-cash item)	-	-	(766,637)
Paid interest (cash item)	-	-	(314,516)
Interest expenses accrued on non-convertible loans (non-cash item)	-	-	747,324
Transfer (non-cash item)	-	4,482,914	(4,482,914)
Converted to equity (non-cash item)	-	-	-
Remeasurement at FVTPL on convertible loans (non-cash item)	-	-	58,653
Foreign exchange impact (non-cash item)	85,158	-	-
Net financial debt as per 31 December 2022	18,874,959	4,482,914	12,192,829
Net financial debt as per 31 December 2022	18,874,959	4,482,914	12,192,829
Cash flows	(16,324,000)	(982,417)	-
Fair value adjustment at inception date (non-cash item)	-	-	-
Paid interest (cash item)	-	-	(928,914)
Interest expenses accrued on non-convertible loans (non-cash item)	-	-	1,978,073
Transfer (non-cash item)	-	4,317,792	(4,317,792)
Remeasurement at FVTPL on convertible loans (non-cash item)	-	-	44,453
Foreign exchange impact (non-cash item)	33,169	-	-
Net financial debt as per 31 December 2023	2,584,128	7,818,289	8,968,649

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

EUR	31 December 2023	31 December 2022
Fair value of convertible loans issued at recognition date	800,000	800,000
Conversion convertible loan to shares	-	-
Cumulative remeasurement at FVTPL on convertible loans	179,453	134,779
Total convertible loans	979,453	934,779
Fair value of non-convertible loans	15,133,363	15,133,363
<i>Subordinated loan agreements</i>	<i>5,900,000</i>	<i>5,900,000</i>
<i>Kreos loan agreement</i>	<i>9,233,363</i>	<i>9,233,363</i>
Cumulative interest expenses accrued on non-convertible loans (amortized cost)	2,291,466	1,296,032
Paid interest Kreos loan agreement	(1,243,430)	(314,516)
Advance payment Kreos loan agreement	(373,915)	(373,915)
Total non-convertible loans	15,807,484	15,740,964
Total short term and long term financial debt	16,786,937	16,675,743

8.7.3 Leases

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

EUR	31 December 2023	31 December 2022
Long term lease debts	464,231	609,458
Short term lease debts	268,604	306,952
Total	732,835	916,410

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

Leases	
Buildings	230,782
Vehicles	73,002
IT equipment	2,860
Total	306,644

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

8.8 Other current financial liabilities

	Bootstrap warrants	Kreos subscription rights	2023 Investor Warrants
Number of warrants granted	10	161,405	1,111,294
Fair value / warrant (in EUR)	1.48	2.02-1.95	1.80
Share price (in EUR)	3.43	4.00	4.00
Exercise price (in EUR)	3.21	5.31 - 5.77	5.10
Expected volatility	63%	63%	63%
Lifetime (in years)	3	6	4
Risk-free interest rate	2.18%	2.30%	2.16%
Expected dividends	0%	0%	0%

8.8.1 Bootstrap warrants

The extraordinary general shareholders' meeting of the Company dd. 27 May 2022 approved the issuance of 10 new subscription rights for shares of the Company, named the "Bootstrap Warrants", to the benefit of Bootstrap Europe S.C.Sp. ("Bootstrap"), as initially stipulated in the Bootstrap Loan Agreement dd. 2 September 2016 (as amended over time).

The Bootstrap Warrants give Bootstrap the right to subscribe upon exercise of the 10 Bootstrap Warrants for an aggregate of up to 302,804 new shares of the Company at an issue price of EUR 3.21 per underlying new share, in whole or in part, at one or several occasions (the 'Cash Exercise'). The conditions also provide for a 'Cashless Exercise' and, in case of specific sale events, a 'Net Issuance Exercise' mechanism. The number of shares to be issued upon exercise of the Bootstrap is subject to certain adjustments in case of certain dilutive corporate actions, it being understood that transactions or operations approved by the general shareholders' meeting of the Company or which are implemented or occur on the basis of an authorization that was provided or approved by the general

shareholders' meeting (such as, but not limited to, the authorized capital) shall not lead to such adjustments.

It is at the sole discretion of Bootstrap to apply for a Cash Exercise or a Cashless Exercise.

The exercise price of the Bootstrap Warrants depends on the applicable exercise mechanism:

- In the event of a Cash Exercise, the Bootstrap Warrants can be exercised at a price of EUR 3.21 per new share. This exercise price is subject to certain adjustments in case of certain dilutive corporate actions, it being understood that transactions or operations approved by the general shareholders' meeting of the Company or are implemented or occur on the basis of an authorisation that was provided or approved by the general shareholders' meeting (such as, but not limited to, the authorised capital) shall not lead to adjustments;
- In the event of a Cashless Exercise, the Bootstrap Warrants can be exercised at a price equal to the fractional value of the shares of the Company, i.e., currently rounded EUR 0.1036 per share; and
- In the event of a Net Exercise, no exercise price should be paid by Bootstrap.

The Bootstrap Warrants have a term commencing on 27 May 2022 and ending on 11:59 p.m. (Belgian time) on 2 September 2026.

Bootstrap shall be entitled to transfer or assign the Bootstrap Warrants, except to an entity that is a customer, competitor or supplier of the Company, or an entity that holds 20% or more of the Company's share capital of any such customer, competitor or supplier.

The Bootstrap Warrants are accounted for in accordance with 'IAS 32 - *Financial Instruments: Presentation*' (measurement category: derivative financial instruments at FVTPL) and are classified in the Condensed Consolidated Statement of Financial Position as '*Other current financial liabilities*'. The fair value of the Bootstrap Warrants as at 31 December 2023: 447,850 (2022: EUR 1,103,277) has been reported as '*Finance cost*' in the Condensed Consolidated Statement Income Statement.

The fair value of the Bootstrap Warrants as at 31 December 2023 has been calculated using the Black & Scholes model with parameters as described in the table.

The expected volatility is based on the volatility of the Company's shares.

The share price is calculated, in line with the terms and conditions of the Bootstrap Warrants, as the average of the closing price of the Company's shares on Euronext Brussels over the 30 calendar day period ending 3 days prior to the balance sheet date.

8.8.2 Kreos subscription rights

In the framework of the Kreos Loan Agreement, the Company and Kreos Capital VII Aggregator SCSp entered into a subscription rights agreement in July 2022 (the "Kreos Subscription Rights Agreement") pursuant to which the Company agreed to issue and allocate subscription rights to Kreos Capital VII Aggregator SCSp (the "Kreos Subscription Rights") to subscribe to new shares of the Company. Notably, subject to approval by the Company's extraordinary general shareholders' meeting at the latest at the date of the annual shareholders' meeting of the Company to be held in 2023, Kreos Capital shall receive, free of charge, (a) subscription rights for new shares in an aggregate amount of EUR 650,000, at an exercise price per new Share equal EUR 5.31 (based on the arithmetic average of the daily volume weighted average price of the Shares traded on Euronext Brussels during the period of 30 consecutive tradings ending on (and including) the third trading days prior to the date of signing of

the Kreos Loan Agreement), and (b) further subscription rights for new Shares for an aggregate amount of up to EUR 225,000 pro rata to the drawdowns under the initial facility, at an exercise price per new Share equal to the arithmetic average of the daily volume weighted average price of the Shares traded on Euronext Brussels during the period of 30 consecutive tradings ending on (and including) the third trading days prior to the date of the relevant drawdowns. The subscription rights have an initial term which expires five years after the date of the Kreos Loan Agreement or (if earlier) the completion of (i) a public takeover bid with respect to the Shares and other outstanding voting securities of the Company or securities granting access to voting rights, or (ii) a sale of the entire issued share capital of the Company to a bona fide third party on arm's length terms for cash consideration (a "Share Sale"). If at the end of the initial five-year period the subscription rights have not been fully exercised and no Share Sale has yet taken place, the Company will issue new subscription rights on similar terms for an additional period of two years (or until the completion of a Share Sale, if earlier).

The Extraordinary General Meeting, dated 10 February 2023 approved the related clause.

The Kreos subscription rights are accounted for in accordance with 'IAS 32 - *Financial Instruments: Presentation*' (measurement category: derivative financial instruments at FVTPL) and are classified in the Condensed Consolidated Statement of Financial Position as '*Other current financial liabilities*'. The fair value of the Kreos subscription rights as at 31 December 2023: EUR 323,740 (2022: EUR 465,508) has been reported as '*Finance income*' in the Condensed Consolidated Statement Income Statement.

The fair value of the Kreos subscription rights as at 31 December 2023 has been calculated using the Black & Scholes model with parameters as described in the table.

The expected volatility is based on the volatility of the Company's shares.

The share price is calculated, in line with the terms and conditions of the Kreos subscription rights, as the average of the closing price of the Company's shares on Euronext Brussels over the 30 calendar day period ending 3 days prior to the balance sheet date.

8.8.3 2023 Investor Warrants

At 27 April 2023, the Company announced that it successfully raised an amount of EUR 15.78 million in gross proceeds by means of a private placement of new shares and subscription rights (the "2023 Investor Warrants"), at a ratio of one (1) new subscription right per four (4) new shares, via an accelerated bookbuild offering of 4,445,205 new shares (being approximately 18.72% of the Company's current outstanding shares) at an issue price of EUR 3.55 per new share and 1,111,294 new subscription rights (if exercised into 1,111,294 new shares, representing approximately 4.68% of the Company's current outstanding shares) at an exercise price of EUR 5.10 per underlying new share. For more information, refer also to note 9.2 Share capital and Share Premium. The 2023 Investor Warrants are accounted for in accordance with 'IAS 32 - *Financial Instruments: Presentation*' (measurement category: derivative financial instruments at FVTPL) and are classified in the Consolidated Statement of Financial Position as '*Other current financial liabilities*'.

The fair value of the 2023 Investor Warrants has been calculated using the Black & Scholes model.

The fair value of the 2023 Investor Warrants as at 31 December 2023 has been determined at EUR 1,995,760 and has been reported as '*Finance cost*' in the Consolidated Statement Income Statement. The expected volatility is based on the volatility of the Company's shares. The share price applied aligns with the closing price of the Company's shares on Euronext Brussels on the balance sheet date.

8.9 Post-employment benefits

The Group operates different employee benefit plans. The plans for all three countries, Switzerland, Germany and Belgium, remained unchanged compared to end of 2022.

8.9.1 Pension plan in Switzerland

This pension plan is governed by the Swiss Federal Law on Occupational Retirement, Survivor's and Disability Pension Plans (BVG), which states that pension plans are to be managed by independent, separate legal entities. It also stipulates that a pension plan's most senior governing body (Board of Trustees) must be composed of equal numbers of employee and employer representatives.

Plan participants are insured against the financial consequences of old age, disability and death. The insurance benefits are subject to regulations, with the BVG specifying the minimum benefits that are to be provided. The employer and employees pay contributions to the pension plan. If a plan is underfunded, various measures can be taken, such as a reduction of the interests or compensation premiums by the employees.

The Group has entered into an agreement with PKG Joint Foundation. PKG is responsible for the governance of the plan; the Board is composed of an equal number of representatives from the employers and employees chosen from all affiliated companies. PKG has set up investment guidelines, defining in particular the strategic allocation with margins. PKG has taken out reinsurance for the pure risk benefits, like disability pension, spouse and orphans pension as well as lump sum in case of death.

Related plan assets are measured at fair value.

Reconciliation of the amount recognised in the statement of financial position at the end of period	2023	2022
Defined benefit obligation	4,347,759	2,950,140
Fair value of plan assets	3,679,969	2,721,955
Deficit	667,791	228,185
Net defined benefit liability	667,791	228,185

The net defined benefit liability increased from EUR 228,185 in 2022 to EUR 667,797 in 2023, mainly as a result of the decreased discount rate.

Components of defined benefit cost in profit or loss	2023	2022
Current service cost (employer)	261,352	309,366
Plan amendment / Past Service Cost	55,981	-
Interest expense on defined benefit obligation	72,178	12,398
Interest income on plan assets	(66,860)	(10,629)
Administration cost excl. cost for managing plan assets	13,254	11,624
Defined benefit cost recognised in profit or loss	335,904	322,760
thereof service cost and administration cost	330,586	320,990
thereof net interest on the net defined benefit liability (asset)	5,318	1,770

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

Defined benefit obligation (DBO)^{xc}

The difference between the reconciliation and the valuated defined benefit obligation as of 31 December 2023 corresponds to an actuarial loss of EUR 547,606. The changes in financial assumptions led to an actuarial loss of EUR 503,387. The changes in demographic assumptions led to an actuarial loss of 44,220. The changes in experience adjustments had not impact. These three components led to a total actuarial gain of EUR 547,606.

The plan assets are carried forward until 31 December 2023 taking into consideration employees' and employer's contributions as well as paid benefits and are compared with the assets of the pension fund. The difference between the carried forward plan assets and the plan assets as of 31 December 2023 corresponds to an actuarial loss of EUR 161,782.

The total actuarial loss of EUR 385,825 (loss on defined benefit obligations of EUR 547,606 and gain on plan assets of EUR 161,782) have been recognized in OCI.

Components of defined benefit cost in OCI	2023	2022
Actuarial (gain) / loss on defined benefit obligation	547,606	(627,485)
Return on plan assets excl. interest income	(161,782)	241,222
Defined benefit cost recognised in OCI	385,825	(386,263)

Components of actuarial gain/losses on obligations	2023	2022
Actuarial (gain) / loss arising from changes in financial assumptions	503,387	(634,757)
Actuarial (gain) / loss arising from changes in demogr. assumptions	44,220	-
Actuarial (gain) / loss arising from experience adjustments	-	7,272
Actuarial (gain) / loss on defined benefit obligation	547,606	(627,485)

Reconciliation in net defined benefit liability	2023	2022
Net defined benefit liability at 1.1.	228,185	491,775
Defined benefit cost recognised in profit or loss	335,904	322,760
Defined benefit gain recognised in OCI	367,639	(386,263)
Contributions by the employer	(298,446)	(226,179)
Currency translation adjustments	-	26,092
Net defined benefit liability at 31.12.	636,315	228,185

^{xc} Immaterial rounding differences are possible between the underlying actuarial tables and the statement of financial position information due to the foreign currency translation of the source actuarial tables, which are initially prepared in CHF, to EUR.

Reconciliation of defined benefit obligation	2023	2022
Defined benefit obligation at 1.1.	2,950,140	3,327,469
Interest expense on defined benefit obligation	72,178	12,398
Current service cost (employer)	261,352	309,366
Contributions by plan participants	298,446	226,179
Plan amendment / Past Service Cost	55,981	-
Benefits (paid) / deposited	(69,533)	(474,420)
Administration cost (excl. cost for managing plan assets)	13,254	11,624
Actuarial (gain) / loss on defined benefit obligation	521,796	(627,485)
Currency translation adjustments	-	165,008
Defined benefit obligation at 31.12.	4,103,613	2,950,140

Reconciliation of fair value of plan assets	2023	2022
Fair value of plan assets at 1.1.	2,721,955	2,835,694
Interest income on plan assets	66,860	10,629
Contributions by the employer	298,446	226,179
Contributions by plan participants	298,446	226,179
Benefits (paid) / deposited	(69,533)	(474,420)
Return on plan assets excl. interest income	154,157	(241,222)
Currency translation adjustments	-	138,916
Fair value of plan assets at 31.12.	3,470,332	2,721,955

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	2023	2022
Weighted average duration of DBO in years	18.0	17.3

There are no retired plan participants for the years 2023 and 2022.

For the reporting year 2024, employer contributions of EUR 285,773 are expected.

Significant actuarial assumptions:

Actuarial assumptions	2023	2022
Discount rate (DR) at 1.1.	2.30%	0.35%
Discount rate (DR) at 31.12.	1.50%	2.30%
Interest rate on retirement savings capital (IR) at 31.12.	2.00%	2.30%
Future salary increases (SI) at 31.12.	1.75%	1.75%
Future pension increases (PI) at 31.12.	0.00%	0.00%
Future inflation at 31.12.	~1.50%	~1.50%
Mortality tables	BVG 2020 GT	BVG 2020 GT
Date of last actuarial valuation	31-12-23	31-12-22

Sensitivities of significant actuarial assumptions

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

Sensitivity	2023	2022
DBO = Defined benefit obligation, SC = Service cost (employer)		
DBO at 31.12. with DR -0.25%	4,535,596	3,060,322
DBO at 31.12. with DR +0.25%	4,163,562	2,806,593
DBO at 31.12. with IR -0.25%	4,267,407	2,876,967
DBO at 31.12. with IR +0.25%	4,420,389	2,982,434
DBO at 31.12. with SI -0.25%	4,389,011	2,896,485
DBO at 31.12. with SI +0.25%	4,297,683	2,962,206
DBO at 31.12. with life expectancy +1 year	4,437,633	2,999,154
DBO at 31.12. with life expectancy -1 year	4,445,603	3,003,533
SC of next year with DR +0.25%	355,008	215,892
SC of next year with IR +0.25%	394,403	258,087

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

8.9.2 Pension plan in Belgium

According to IAS 19, Defined Contribution plans are those, which do not bear any financial or actuarial risks. All the plans, which do not meet this definition, are Defined Benefit Plans.

Article 24 of the Belgian WAP/LPC obliges employers to ensure that plan members receive, when leaving the plan, at least the amount of the contributions capitalized at the statutory guaranteed minimum rate. As a result, the Belgian Defined Contribution plans do not meet the definition of Defined Contribution plans as stated in IAS-19 and should, by default, be classified as Defined Benefit plans.

According to IAS 19, the net (i.e. before taxes and social security contributions) total pension obligation at valuation date is equal to the Defined Benefit Obligation (DBO). For a given participant, the DBO "retirement" is the maximum between the individual vested reserves at valuation date and the discounted value of future pension obligations, taking into account the assumptions made.

According to IAS 19, the net total obligation must be compared to the plan assets at the same date, namely the vested mathematical reserves of the participants increased by the assets of the financing fund at AXA if any. The comparison of these amounts gives the amount of the net Defined Benefit Liability (DBL), which represents the net deficit at the valuation date, according to IAS 19:

Net DBL = - (DBO - Assets)

The gross Defined Benefit Liability is equal to the net Defined Liability increased by the Belgian tax of 4,40% and the Belgian social security contribution of 8,86%, namely a total of 13,26%.

Per 31 December 2023, the Net Defined Benefit Liability equals to EUR 0 (2022: EUR 0).

As per 31 December 2023, there are 6 employees in the plan.

Funded status and recognised/unrecognised amounts	2023	2022
Defined Benefit Obligation at end of year	212,391	176,625
Fair value assets at end of year	212,391	176,625
Funded status: plan assets above/(below) DBO	-	-
Unrecognised net (gain)loss	-	-
Unrecognised past service costs	-	-
Unrecognised net transition obligation/(asset)	-	-
Unrecognised balance sheet asset (because of limit)	-	-
Defined benefit Liability at end of year	-	-

The contributions recognised in 2023 for the defined contribution plan in Belgium amounted to EUR 38,780 (2022: 48,439).

For the reporting year 2024, employer contributions of EUR 30,417 are expected.

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

8.9.3 Pension plan in Germany

The contributions paid to the defined contribution plan in Germany amounted to EUR 5,033 (2022: EUR 5,033).

8.10 Trade payables, other payables and accrued liabilities

EUR	31 December 2023	31 December 2022
Trade payables	2,736,617	3,227,290
Other payables	2,256,685	1,811,940
Accrued liabilities	3,447,728	3,585,631
<i>Provision warranty</i>	<i>79,988</i>	<i>71,088</i>
<i>Accrued liabilities</i>	<i>3,367,740</i>	<i>3,514,543</i>

Other payables mainly consist of salary related provisions, VAT, income taxes payable, social security, employee insurances and other employee provisions (e.g. holiday pay and bonus).

The total amount of Accrued Liabilities in the Consolidated Statement of Financial Position amounts to EUR 3,447,728 (in 2022: EUR 3,514,543) and are mainly accruals related to clinical expenses and other liabilities.

9. Share-based compensation

The following table sets forth a summary of subscription rights outstanding and exercisable on 31 December 2023 per subscription right plan:

Subscription right plan	Grant date	Expiry date	Exercise price (€) - (1)	Outstanding per 1 January 2023	Granted during the year	Exercised during the year	Forfeited during the year	Expired during the year	Outstanding per 31 December 2023	Exercisable per 31 December 2023
Executive share options - CEO (2)	27-09-18	27-09-28	0.92	75,025	-	-	-	-	75,025	75,025
Executive share options - other (2)	30-09-18	30-09-28	9.19	15,755	-	-	-	-	15,755	15,755
2018 Share Options	13-02-19	13-02-29	7.46	175,904	-	-	5,096	-	170,808	170,808
2018 Share Options	24-05-19	13-02-29	6.22	15,288	-	-	5,096	-	10,192	10,192
2018 Share Options	20-08-19	13-02-29	6.78	5,096	-	-	5,096	-	-	-
2018 Share Options	30-07-20	13-02-29	6.19	286,966	-	-	37,068	-	249,898	251,902
2018 Share Options	05-01-21	13-02-29	8.61	50,000	-	-	-	-	50,000	45,828
2018 Share Options	23-03-21	13-02-29	8.38	251,200	-	-	33,600	-	217,600	204,480
2018 Share Options	29-07-21	13-02-29	7.88	20,000	-	-	-	-	20,000	14,996
2018 Share Options	22-03-22	13-02-29	6.21	247,770	-	-	29,700	-	218,070	127,877
2021 Share Options	22-03-22	27-05-31	6.21	5,030	-	-	-	-	5,030	2,933
2021 Share Options	07-07-23	27-05-31	3.17	-	810,130	-	-	-	810,130	-
2018 Share Options	11-09-23	13-02-29	3.67	-	6,000	-	-	-	6,000	-
Subtotal Executive Share Options				90,780	-	-	-	-	90,780	90,780
Subtotal 2018 Share Options				1,052,224	6,000	-	115,656	-	942,568	826,083
Subtotal 2021 Share Options				5,030	810,130	-	-	-	815,160	2,933

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

(2) one share option of the Executive share options plan entitles the holder thereof to acquire ca. 2.88 shares when exercising one of his or her share options

9.1 Executive Share Options

Early October 2018, Sequana Medical NV implemented an option plan for a certain group of employees and granted 111,177 share options, which each entitle the holder for a subscription of one share. The options are accounted for as equity-settled share-based payments.

The Group used the Black & Scholes model for share-based payment calculation purposes in order to determine the fair value of the Executive share-based option plan. The volatility parameter has been based on the volatility of relevant peer shares, listed on the STOXX Medtech stock exchange.

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

The effect of the share-based payment transactions on the 2023 Consolidated Income Statement of the Group is an expense of EUR 0. The same amount goes through reserves in equity so that the net effect on the Group's equity is zero.

One share option of the Executive Share Options plan entitles the holder thereof to acquire ca. 2.88 shares when exercising one of his or her share options.

Presented below is a summary of subscription right activities for the reported periods.

Executive Share Options

	Subscription rights	Weighted average exercise price (EUR)
Granted during the year	-	-
Forfeited during the year	-	-
Exercised during the year	756	9.19
Expired during the year	-	-
Outstanding on 31 December, 2022	90,780	2.36
Exercisable on 31 December, 2022	90,780	2.36
Granted during the year	-	
Forfeited during the year	-	
Exercised during the year	-	
Expired during the year	-	
Outstanding on 31 December, 2023	90,780	2.36
Exercisable on 31 December, 2023	90,780	2.36

9.2 2018 Share Option Plan

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

The Group used the Black & Scholes model for share-based payment calculation purposes in order to determine the fair value of the Executive share-based option plan. The volatility parameter has been based on the volatility of relevant peer shares, listed on the STOXX Medtech stock exchange.

The effect of the share-based payment transactions on the 2023 Consolidated Income Statement of the Group is an expense of EUR 48,026. The same amount goes through reserves in equity so that the net effect on the Group’s equity is zero.

Presented below is a summary of subscription right activities for the reported periods.

2018 Share Options

	Subscription rights	Weighted average exercise price (EUR)
Granted during the year	263,170	6.21
Forfeited during the year	66,644	7.09
Exercised during the year	-	-
Expired during the year	-	-
Outstanding on 31 December, 2022	1,052,224	7.08
Exercisable on 31 December, 2022	595,362	7.25
Granted during the year	6,000	3.67
Forfeited during the year	115,656	6.91
Exercised during the year	-	-
Expired during the year	-	-
Outstanding on 31 December, 2023	942,568	7.08
Exercisable on 31 December, 2023	826,083	7.16

9.3 2021 Share Option Plan

The Extraordinary General Meeting of 27th of May 2021 approved the new Share options for directors, employees and other staff members of Sequana Medical NV (the “2021 Share Options”). There was no obligation for the holders of the 2011 Share Options and Executive Share Options to exercise the Share options prior to the closing of the Offering. The number of options is equal to 10% of the total number of New Shares outstanding after the closing of the Offering and after the allocation of the over-allotment option.

The Group used the Black & Scholes model for share-based payment calculation purposes in order to determine the fair value of the Executive share-based option plan. The volatility parameter has been based on the Company’s shares.

The effect of the share-based payment transactions on the 2023 Consolidated Income Statement of the Group is an expense of EUR 189,734. The same amount goes through reserves in equity so that the net effect on the Group’s equity is zero.

Presented below is a summary of subscription right activities for the reported periods.

2021 Share Options

	Subscription rights	Weighted average exercise price (EUR)
Granted during the year	5,030	6.21
Forfeited during the year	-	-
Exercised during the year	-	-
Expired during the year	-	-
Outstanding on 31 December, 2022	5,030	6.21
Exercisable on 31 December, 2022	-	-
Granted during the year	810,130	3.17
Forfeited during the year	-	-
Exercised during the year	-	-
Expired during the year	-	-
Outstanding on 31 December, 2023	815,160	3.19
Exercisable on 31 December, 2023	-	-

Below is an overview of the parameters used in relation to the determination of the fair value of the grants during 2023:

Stock options granted in	July 2023	September 2023
Subscription right plan	2021 Share	2018 Share
Number of options granted	810,130	6,000
Fair value of options (in €)	0.69	0.55
Share price (in €)	3.10	3.23
Exercise price (in €)	3.17	3.67
Expected volatility	40%	40%
Expected option life (in	7.89	7.71
Risk-free interest rate	3.11%	2.96%
Expected dividends	-	-

Below is an overview of the parameters used in relation to the determination of the fair value of the grants during 2022:

Stock options granted in	March 2022	March 2022
Subscription right plan	2018 Share	2021 Share
Number of options granted	263,170	5,030
Fair value of options (in €)	1.67	1.67
Share price (in €)	6.44	6.44
Exercise price (in €)	6.21	6.21
Expected volatility	48%	48%
Expected option life (in	6.90	9.19
Risk-free interest rate	0.77%	0.77%
Expected dividends	-	-

9.4 2023 Share Option Plan

The Group has established, after approval of the board of directors dated 6 November 2023, a 2023 Share Option Plan. As at 31 December 2023, none of the 1,000,000 2023 Share Options have been granted.

10 Contingencies and arbitrations

At present there are no significant contingencies and arbitrations.

11 Commitments

11.1 Capital commitments

The Group has no material contracted expenditures for the acquisition of property, plant and equipment at 31 December 2023.

11.2 Asset pledges

The Kreos secured loan facility is secured by the Company's bank accounts, receivables and movable assets, including IP rights. The Company has no other meaningful pledges as per December 31, 2023.

12 Transactions with related parties

Related parties primarily comprise members of Executive Management, members of the Board of Directors and significant shareholders. There are no significant transactions with related parties except for:

- 1) the remuneration and reimbursement of expenses paid, if any, to the members of Board of Directors and Executive Management in fulfilling their responsibilities as disclosed in notes 12.3, 12.4 and 12.5.
- 2) the subordinated loan agreements concluded with amongst others PMV/z-Loans as described in notes 8.7.1 and 12.2.

12.1 Consolidated companies

We refer to note 1 Corporate Information for the list of subsidiaries.

12.2 Relations with the shareholders

We refer to notes 8.6 Share Capital and Share Premium and 8.7 Financial debts / net debt for the changes in the relations with the shareholders.

There exist no other relations with the shareholders as those described in the sections above.

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

The non-executive directors earned the following compensation (gross), based on the approved fees:

EUR	2023	2022
Pierre Chauvineau	71,500	70,750
Wim Ottevaere (WIOT BV)	52,500	55,500
Jackie Fielding	49,000	43,750
Alexandra Clyde	49,000	18,331
Doug Kohrs	45,500	20,037

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

On 10 February 2023, the extraordinary general meeting of the Company (the "EGM"), upon the recommendation of the nomination and remuneration committee, decided to amend the remuneration policy to allow non-executive independent directors ("INEDs") to receive remuneration in the form of shares of the Company in addition to their fixed remuneration in cash. Since the Company does not have distributable reserves (and therefore does not meet the legal requirements to conduct a share buy-back and subsequent allocation), the remuneration policy provides for the Company to grant so-called "Restricted Share Units" (the "RSUs") to INEDs. In implementation of the abovementioned EGM resolution, the Company proposed in September 2023 to grant RSUs to the then current INEDs. Ultimately, Pierre Chauvineau, WIOT BV (with Wim Ottevaere as permanent representative), Douglas Kohrs and Alexandra Taylor Clyde accepted to be awarded RSUs. The particular terms of the grant (e.g., the number of RSUs granted (retroactively) and the applicable reference period and price) were set forth in written "RSU Award Agreements" and can be summarized as follows:

- Each INED is granted, in relation to each reference year during which the relevant INED exercises his or her mandate as an INED and provided that the grant conditions (as contractually defined) are still met in relation to such reference year, a number of RSUs. The number of RSUs granted annually to the relevant INED is calculated by dividing an amount of EUR 75,000.00 by the volume weighted average price of the Company's shares on Euronext Brussels during a period of 30 calendar days preceding the start of a reference year (where a reference year starts on the date of the annual general meeting).
- Each RSU represents the contractual obligation of the relevant INED to subscribe for one new underlying share of the Company at a subscription price of EUR 0.11 per new share (regardless of the share's market price at that time) (the "RSU Shares") after the expiry of a specified time period. The RSU is not an option that leaves the director discretion as to whether or not to exercise it. Upon expiration of the specified time period, the relevant INED must subscribe for the new RSU Shares.

On 4 October 2023, the following RSU Shares relating to the first reference year 2022-2023 were issued resulting in an increase in share capital from EUR 2,921,010.22 to EUR 2,926,295.90 and the number of issued and outstanding shares has further increased from 28,191,733 to 28,242,753 ordinary shares, through the issuance of a total of 51,020 new RSU Shares that were subscribed for in the capital increase.

Reference year 2022-2023

Name independent director	RSU Reference Price (EUR)	# RSUs	# Underlying RSU Shares	Subscription price paid (EUR)
Pierre Chauvineau	5.88	12,755	12,755	1,403
Wim Ottevaere (WIOT BV)	5.88	12,755	12,755	1,403
Alexandra Clyde	5.88	12,755	12,755	1,403
Doug Kohrs	5.88	12,755	12,755	1,403

With respect to the second reference year (26 May 2023 till 23 May 2024), the following RSU shares have been granted, which will vest on 23 May 2024.

Reference year 2023-2024

Name independent director	RSU Reference Price (EUR)	# RSUs	# Underlying RSU Shares	Subscription price paid (EUR)
Pierre Chauvineau	3.21	23,364	23,364	2,570
Wim Ottevaere (WIOT BV)	3.21	23,364	23,364	2,570
Alexandra Clyde	3.21	23,364	23,364	2,570
Doug Kohrs	3.21	23,364	23,364	2,570

The RSUs have been accounted for in accordance with IFRS 2 Share Based Payments and resulted into a cost of EUR 326.106 in 2023.

For more information regarding the RSUs, the underlying RSU Shares and the RSU Award Agreements, reference is made to the most recent version of the Company's remuneration policy, as well as the report of the board of directors dated 4 October 2023 prepared in accordance with article 7:198 juncto articles 7:179 and 7:191 of the Belgian Companies and Associations Code, in each case as available on the Company's website.

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:

2023 Executive Management compensation				
EUR (except number of share options)	Short-term Employee benefits	Post-employment benefits	Number of share options	
Ian Crosbie	425,031	15,538	525,256	
Kirsten Van Bockstaele	355,983	-	136,392	

2022 Executive Management compensation				
EUR (except number of share options)	Short-term Employee benefits	Post-employment benefits	Number of share options	
Ian Crosbie	448,938	14,658	357,281	
Kirsten Van Bockstaele	354,144	-	76,645	

13 Belgian GAAP disclosures

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

The consolidated financial statements of Sequana Medical Group include:

Company	Purpose	Share capital	Investment 2023	Investment 2022
Sequana Medical NV	Holding/Sales	EUR 2,926,296	n/a	n/a
Sequana Medical NV branch (Switzerland)	Production and research	n/a	n/a	n/a
Sequana Medical GmbH (Germany)	Distribution	EUR 25,000	100 %	100 %
Sequana Medical US Inc. (USA)	Administration	USD 0	100 %	n/a
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

	2023	2022
Average number of employees	62	60

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

EUR (except number of share options)	2023	2022
Short term employee benefits	425,031	448,938
Post-employment benefits	15,538	14,658
Number of share options	525,256	357,281

14 Events after the reporting period

Restructuring program

In February 2024, several additional measures have been carried out in order to reduce expenditures, including:

- **alfapump program:** The Board of Directors strongly believes that pre-market approval ("PMA") approval of the alfapump is a key value inflection point for the Company and has decided to prioritize its resources on reaching this important milestone. A number of other alfapump-related activities have been delayed or halted, including termination of all commercial activities in Europe, which resulted in a significant reduction in personnel in all countries, and
- **Heart Failure/DSR:** Delaying the randomized phase of the MOJAVE clinical study until after the alfapump pre-market approval ("PMA") approval.

Additional secured investor financing of EUR 3.0 million

In February 2024, the Company has obtained a Convertible Loan provided by major shareholders Partners in Equity and Rosetta Capital (each a "Lender") and is for an aggregate principal amount of EUR 3.0 million. The maturity date of the Convertible Loan is 30 September 2024. The principal amount and interest of the Convertible Loan can be converted by the Lenders for new shares of the Company at any time prior to the maturity date, at a conversion price equal to the lower of (i) arithmetic average of the daily volume weighted average trading price per share of the Company's shares traded on Euronext Brussels during the period of twenty (20) consecutive trading days ending on (and including) the third trading day before the date on which the Company has received the optional conversion exercise notice, minus a discount of 45%, and (ii) the issue price of the new shares issued by the Company at the occasion of the most recent future equity financing before receipt of the optional conversion exercise notice, minus a discount of 45%. The principal amount and interest of the Convertible Loans are mandatorily converted in the event of a future equity financing transaction by the Company for at least EUR 7.0 million. In case of a mandatory conversion, the conversion occurs at a conversion price equal to the issue price of the new shares in equity financing transaction, minus a discount of 45%. If the Company enters into a new convertible loan for a value of at least EUR 7.0 million and such new convertible loan includes conversion rights equivalent to the mandatory and optional equity conversion rights in the Convertible Loan (but with a discount of at least 25% instead of 45%), all amounts outstanding under the Convertible Loan, plus a conversion fee of 33% of all amounts owed under the Convertible Loan, will be converted into the new convertible loan. In the event that the conditions for conversion for shares or for a new convertible loan have not been fulfilled

by the maturity date, the loans will be repayable in cash (subject to certain subordination provisions). The loans bear interest of 15% per annum, which shall be compounded on a monthly basis. In case of conversion, the minimum amount to be converted for new shares or a new convertible loan will in any event be EUR 300,000. The proceeds from the loan will be used to finance general working capital requirements.

As a consequence of the equity placement on 25 March 2024 (see below for more details), the aggregate principal amounts and interests under this loan agreement will be mandatorily converted at the date of the annual shareholders' meeting into new shares (through a contribution in kind of payables) at a conversion price per share equal to the issue price in said equity financing transaction, minus a discount of 45%.

Amendments to the existing loan agreements

The Company's lenders have also agreed to a number of measures to support the goal of obtaining PMA approval through enabling the focus of the Company's cash resources on alfapump PMA approval instead of debt service payments. These measures include the postponement of all repayments under the existing loan agreements and a new conversion feature for 30% of the outstanding loans of funds and accounts managed by BlackRock, Inc. and its affiliates ("BlackRock").

Amendment to the senior debt agreements with Kreos Capital VII (UK) Limited

In February 2024, the Company also entered into an agreement in relation to the amendment of certain repayment and other terms of the EUR 10,000,000 loan with Kreos Capital VII (UK) Limited (together with its affiliates "Kreos", and the "Kreos Loan").^{xci}

Subject to finalization of definitive agreements, the main amendments to the Kreos Loan can be summarized as follows:

- **Payment holiday:** Suspension of the repayment of any principal or interest amounts under the Kreos Loan until the earlier of (i) three months following the date on which the Company has obtained a PMA decision for the alfapump by the US FDA (irrespective whether such decision is positive or otherwise), (ii) date on which the Company has obtained a PMA approval for the alfapump by the US FDA and has completed an equity raise of at least EUR 20.0 million, and (iii) 31 December 2024.
- **Maturity date extension:** If the Company (i) completes an equity raise resulting in additional cash proceeds of the higher of: (x) EUR 30.0 million, and; (y) such amount as required to provide the Company with cash runway until 31 March 2026 determined by reference to a budget approved by the board at the time of such equity raise, and (ii) receives a PMA approval for alfapump before the payment resumption date, the maturity date of the Kreos Loan would be extended from 30 September 2025 to March 2026.
- **Interest rate increase:** The applicable interest rate of the Kreos Loan would increase from 9.75% per annum to 11.5% per annum (counting as of 1 February 2024).
- **New restructuring fee:** Kreos will be entitled to a certain restructuring fee equal to 1.5% of the principal amount outstanding as at 1 February 2024 and accrued interest outstanding as at 31 January 2024, which shall accrue interest of 11.5% per annum until payment.
- **Increase of the end of loan fee:** The applicable end of loan fee due at expiration of the Kreos Loan would increase from 1.75% to 2.25% of the total principal amount of the Kreos Loan or, if earlier, on prepayment in full of the relevant amount.

^{xci} BlackRock Inc. announced the completion of its acquisition of Kreos, a leading provider of growth and venture debt financing to companies in the technology and healthcare industries, on 2 August 2023.

- **Convertibility feature:** 30% of the principal amounts outstanding under the Kreos Loan as at 31 January 2024 will be convertible into new shares of the Company (through a contribution in kind of receivables) at the option of Kreos against a conversion price equal to the lower of (i) the applicable loan conversion price under the Convertible Loan agreement with Partners in Equity and Rosetta Capital, and (ii) the issue price in any other future equity or equity linked investment in the Company completed prior to the conversion of the Kreos Loan.
- **Kreos warrants amendment:** The Company agreed to submit a proposal to amend the exercise price of the subscription rights (warrants) issued by the Company's extraordinary shareholders' meeting to the benefit of Kreos on 10 February 2023. The amended exercise price would be equal to the lower of (i) the applicable loan conversion price under the Convertible Loan agreement with Partners in Equity and Rosetta Capital, and (ii) the issue price in any other future equity or equity linked investment in the Company completed prior to the exercise of the relevant warrants.
- **Contractual restrictions:** The amendments set out in the agreement with Kreos are conditional upon, among other things, the Company's plans to focus on the alfapump business and to pause the DSR product.

Amendment to the subordinated debt agreements with PMV/z-leningen (currently known as PMV-Standaardleningen), Belfius Insurance and Sensinnovat NV

The Company also entered into amendments in relation to (i) the EUR 4,300,000 partially convertible loan with PMV Standaardleningen NV (formerly known as PMV/z Leningen NV) (the "PMV Loan"), (ii) the EUR 2,000,000 loan with Belfius Insurance NV (the "Belfius Loan"), and (iii) the EUR 400,000 loan with Sensinnovat BV (the "Sensinnovat Loan"). The main amendments to the PMV Loans, the Belfius Loan and the Sensinnovat Loan consist of (a) an extension of the final maturity date to 31 December 2025, (b) a rescheduling of the principal repayments under the relevant loan agreements so that the principal amount outstanding under the loans thereunder will be repaid in four equal monthly instalments starting on 30 September 2025, and (c) an increase of the applicable interest rates under each of the relevant loan agreements with 0.5% per annum.

Equity placement

The Company successfully raised an amount of EUR 11.5 million in gross proceeds by means of a private placement of new shares via an accelerated bookbuild offering of 7,666,667 new shares (being approximately 27.15% of the Company's current outstanding shares) at an issue price of EUR 1.50 per new share (the "Offering").

As a consequence, the Company's share capital has increased on 25 March 2024 from EUR 2,926,295.90 to EUR 3,720,562.60 and the number of issued and outstanding shares has increased from 28,242,753 to 35,909,420 shares, through the issuance of a total of 7,666,667 new shares.

Partners in Equity V B.V. ("Partners in Equity"), Rosetta Capital VII, LP ("Rosetta Capital"), LSP HEF Sequana Holding B.V. ("EQT"), Marc Nolet's family through its investment company ("Nolet"), as well as certain other investors (together, the "Pre-Committing Investors"), pre-committed to submit subscription orders for new shares in the Offering for an aggregate amount of approximately EUR 8.5 million.

2,000,789 of the new shares (representing ca. 7.08% of the currently outstanding shares of the Company already admitted to listing and trading on the regulated market of Euronext Brussels) were

immediately admitted to listing and trading on the regulated market of Euronext Brussels. The Pre-Committing Investors received new shares that were not immediately admitted to listing and trading upon their issuance. The Company has undertaken to apply to the regulated market of Euronext Brussels for the admission to trading and listing of those unlisted new shares, as soon as practicable after their issuance, which will be subject to the preparation of a listing prospectus.

The new shares issued have the same rights and benefits as, and rank *pari passu* in all respects, including as to entitlement to dividends and other distributions, with, the existing and outstanding shares of Sequana Medical at the moment of their issuance, and are entitled to dividends and other distributions in respect of which the relevant record date or due date falls on or after the date of issue of the new shares.

15 Audit fees

EUR	2023	2022
Fees of the independent auditor with the respect to the statutory audit mandate for the Company and the group (Belgium)	85.397	81.330
Additional Services rendered by the auditor's mandate:	65.300	35.000
<i>Audit related fees</i>	-	-
<i>Tax advisory & compliance services</i>	-	-
<i>Due diligence fees</i>	-	-
<i>Other Services</i>	65.300	35.000
Subtotal	150.697	116.330
Fees of independent auditor's network with respect to a statutory audit mandate at the level of the Group (foreign operations)	-	-
Additional Services rendered by the auditor's mandate:	-	-
<i>Audit related fees</i>	-	-
<i>Tax advisory & compliance services</i>	-	-
<i>Due diligence fees</i>	-	-
<i>Other Services</i>	-	-
Subtotal	-	-
Total	150.697	116.330

9. Condensed Statutory Financial Statements of Sequana Medical NV

1 Statutory Income Statement

EUR	2023	2022
Operating income	10,839,227	13,057,906
Operating charges	(38,747,738)	(36,198,200)
Operating loss	(27,908,511)	(23,140,294)
Financial result	(1,433,466)	(1,274,930)
Loss for the period before taxes	(29,341,977)	(24,415,225)
Income taxes	(441,255)	(369,938)
Loss for the period	(29,783,232)	(24,785,163)

2 Statutory Balance Sheet

EUR	2023	2022
Intangible assets	13,075,655	11,926,220
Tangible assets	1,479,365	1,077,518
Financial fixed assets	100,440	85,746
Participating interests	25,000	25,000
Non current-assets	14,680,460	13,114,483
Amounts receivable after more than one year	1,387,979	782,207
Inventory	1,811,345	2,294,111
Amounts receivable within one year	950,435	1,212,434
Deferred charges and accrued income	1,056,588	1,186,964
Cash and cash equivalents	2,286,958	18,356,178
Current assets	7,493,305	23,831,895
TOTAL ASSETS	22,173,765	36,946,378
Capital	2,926,296	2,460,487
Share premium	185,644,420	170,324,139
Reserves	686,404	1,321,184
Accumulated losses	(193,086,827)	(163,303,595)
Total Equity	(3,829,707)	10,802,215
Provisions	667,797	228,194
Amounts payable after more than one year	9,597,366	12,807,500
<i>Financial debt</i>	9,597,366	12,807,500
Amounts payable within one year	12,339,931	9,588,189
<i>Financial debt</i>	7,263,550	4,482,914
<i>Trade debts</i>	2,864,181	3,375,796
<i>Taxes, remuneration and social security</i>	2,212,200	1,729,479
Accruals and deferred income	3,398,378	3,520,281
Amounts payable	25,335,675	25,915,969
TOTAL EQUITY AND LIABILITIES	22,173,765	36,946,378

The full version of the accounts (including the auditor's report) is available on the company's website and can be obtained free of charge.