ANNUAL 2023 REPORT

Scandinavian Real Heart AB (publ)
556729-5588

This is only a translation of the statutory Swedish annual report. In the event of any differences in interpretation, the Swedish version shall prevail.

REALHEART

CONTENT

Realheart's mission is to use medical technology solutions to save as many heart failure patients as possible, and provide the best quality of life.

"Company" or "Realheart" refers to Scandinavian Real Heart AB with organization number 556729-5588.

Ina Laura Perkins
CEO, Realheart

The past year was characterised by successes both in our internal preclinical development work of Realheart® TAH and our strategic positioning externally with global opinion leaders in cardiology and implantable medical devices. In early 2024, we announced further successes in the safety studies of our artificial heart and a welcome recognition of the company's tireless efforts to highlight the need for new treatments for one of the world's most common heart diseases - heart failure.

Preclinical Development Taking Significant Steps Forward

Last year began with a successful implantation trial of Realheart® TAH, and since then the development of our total artificial heart has progressed at a rapid pace. On the advice of the US FDA, we designed a new test system to evaluate the mechanical impact of Realheart® TAH on human blood. In comparison with today's market-leading heart pump systems, Realheart® TAH measured an 80% lower rate of hemolysis. Because of the risks associated with blood damage, such as blood clots, low levels of haemolysis are a regulatory requirement for clinical trials.

This finding has since been confirmed in an in-depth study that will be presented at the scientific conference ASAIO 2024 this summer.

In the first quarter of this year, we conducted another successful implantation trial. The trial was attended by the company's surgical partner Göran Dellgren, Consultant Physician and Professor at the Transplantation Centre and Thorax Clinic at Sahlgrenska University Hospital, to get to know the technology for our upcoming clinical study. The trial generated several positive results and showed that Realheart® TAH gave rise to good cardiac output, proper blood pressure control and balance between the oxygen-poor and oxygen-rich side of the circulation. In addition, the study showed a hemolysis rate well below current regulatory requirements and an increased survival time, which we are very proud to have achieved as outcome measures are critical in the regulatory authorities' evaluation authorities' evaluation prior to clinical trials in patients.

To increase the speed of our implantation trials, we are evaluating the possibility of expanding our own trials to more veterinary centres, as well as carrying out the development with an experienced partner.

At present, our speed in conducting implantation trials is limited by the high workload of our supplier who is very reputable in the medical device industry. To finance the continued preclinical work, we are now conducting a partially underwritten issue, from which the majority of the proceeds will be dedicated to the continued implantation trials.

A Finely Tuned Business Model That Can Generate Great Value in the Near Term

We have made strategic recruitments to strengthen the company's management and board. In January, Ulf Kjellman, a former cardiac surgeon with over 35 years' experience, took up the role of Chief Medical Officer. In the autumn, Stuart McConchie, Magnus Öhman and Giovanni Lauricella joined the Board, bringing with them extensive experience and knowledge of the medical device industry. In early 2024, Magnus Öhman took on the role of Executive Chairman. From the outset, all these individuals provided important input into the strategic review of the company's business model. In November, we communicated a clarified commercial strategy for the company's business development in the short and medium term. In brief, this consists of addressing the need for bridge-to-transplant treatments for patients on the waiting list to receive a heart implant - a patient group that currently comprises at least 8,300 individuals in Europe and the United States alone. Each percentage point of patients currently on a waiting list for a heart transplant represents potential sales revenue of SEK 150 million. In the long term, however, the company's goal remains to offer Realheart® TAH as a broad treatment for heart failure, which corresponds to a global market worth billions of euros.

Successful Relationship Building at International Meetings

Positioning Realheart® TAH is a long-term endeavour that we undertake in close collaboration with clinical experts - surgeons, nurses and cardiologists. The interaction with these key people has been crucial in the development of our clinical controller, which forms the interface between the artificial heart and the patient or carer. Based on their, and patients', feedback, the controller has been slimmed down to a discreet solution that is easy to use and can be worn in a variety of ways, thus not being conspicuous.

To strengthen the relationship with potential development and commercialization partners, we have participated in several international meetings. During the summer, we were involved in a hearing in the European Parliament, organized by the Heart Failure Mission Initiative, where we were invited to discuss the societal challenges in the EU area linked to heart failure.

During the autumn, with the support of Business Sweden, we participated in the China International Import Expo (CIIE) - Mainland China's largest conference for foreign companies seeking to establish themselves in the country. We have also participated in several meetings with translational scientists and engineers in Germany, Italy, France and the United States, where Realheart has an obvious place as one of the leading companies in the world in the development of artificial hearts.

Grant Funding Provides Strong External Validation of the Potential of Realheart® TAH

At the end of the year, we received the second of three grant payments from the European Innovation Council (EIC). The payment of 750,000 EUR is an important complement to our core funding and represents an important external validation of our development project, as the award is conditional on us reporting progress to the agency. The grant from the EIC was one of several grants in 2023, we also received Almi's business development grant of 850,000 SEK, and a business development grant valued at 250,000 SEK from Business Sweden under their Catalyst programme. The three grants are a small sample of the soft funding we have received in recent years, and which continues to play an important role for the company. Earlier this year, we were awarded the title Innovator of the Year 2023 by Almi Guldstänk, an award given to recognize entrepreneurs and companies in the Mälar region. We see this honor as recognition of our ability to highlight the great need for new and innovative treatments for patients living with heart failure.

Preclinical Studies in 2024 Laying the Foundation for the Next Development Phase

We are focused on generating data from the preclinical study package that will form the basis of the company's application to conduct a clinical trial with Realheart® TAH in heart failure patients. Our convincing results so far in preclinical studies and implantation trials give us good scientific evidence that underlines the enormous potential of Realheart® TAH. Step by step, we are moving closer to our long-term goal - that no one should die of heart failure.

Ina Laura Perkins
CEO, Scandinavian Real Heart AB

Our **Vision**

No One Should Die of Heart Failure

A GLOBAL CLINICAL NEED COMPETES FOR MINIMAL RESOURCES

Around 64 million people worldwide suffer from heart failure. Half of all patients are expected to die within 5 years of diagnosis. In the US, this translates into 300,000 deaths annually. Heart failure occurs when the heart can no longer pump as much blood as the body needs.

The need for frequent hospitalization leads to significant costs to society, with healthcare and other social costs estimated at 70 billion $ by 2030 in the US alone.

The best treatment is a new heart, but the problem is that there are only around 8,000 donated hearts available for transplantation each year worldwide. This is because the donor must have died under specific circumstances, be listed in a donor registry and match the recipient's tissue type. In other words, a patient must be very lucky to find a matching human heart for transplant.

Organ transplantation, which relies on one patient dying to save another, is not a sustainable solution. New potential therapies need to be developed through continuous research, both in terms of basic and clinical research.

GOOD QUALITY OF LIFE WITH THE REALHEART® TAH

Realheart® TAH (Total Artificial Heart) will be used to save the lives of patients with advanced heart failure. However, the goal is not only to save lives, but also to provide a good quality of life. It goes without saying that a totally artificial heart should allow people to live a normal life, integrating smoothly into social life and everyday situations.

The human heart consists of two pumps, one on the left and one on the right. Each pump consists of an atria and a ventricle. The left pump supplies blood to the body, while the right pump supplies blood to the lungs. The blood is pumped out in pulses and continuously returns to the heart.

Realheart® TAH is the first total artificial heart (TAH) designed to mimic the structure and function of the human heart. Its unique, patented design with two atria, two ventricles and an AV plane allows it to pump and deliver blood to the body's various organs in a natural way, just like the human heart.

The Realheart® TAH is initially being developed as a bridge-to-transplant solution to keep patients alive until a donated human heart is available for transplantation.

Thereafter, the heart will be offered as a permanent solution to patients with severe heart failure. The benefits of an artificial heart are that it is available straight off the shelf, and in addition to keeping patients alive, it can also improve the health of patients who would otherwise not be suitable for transplantation.

Unique **Advantages** of Realheart® TAH

TWO SEPARATE PUMPS

Each of the two pumps consists of an atria, a ventricle and two mechanical valves. The blood is pumped around in the same way as in a human heart. The design aims to reduce the risk of stroke, bleeding and anemia. These side effects are common with existing heart pumps, which have an unnatural blood flow pattern. Thanks to Realheart's dual-pump system, the positioning of the pumps can be adjusted to match the patient's unique chest anatomy.

LONG BATTERY LIFE

The controller with its two integrated batteries weighs 1kg and provides a battery life of 5 hours. To this, the patient can the patient can connect an additional battery to increase the battery life to 12 hours. The controller has an internal emergency battery that the patient cannot disconnect, to always ensure patient safety. The energy efficiency of the system paves the way for the future use of wireless energy transfer via the skin as a follow-on product.

THE CONTROLLER - THE BRAIN OF THE SYSTEM

The controller is the brain of the system and controls the blood flow of the two pumps separately to maintain the balance between circulation to the body and to the lungs. The controller also receives information from the pressure sensors in the atria, allowing the amount of blood that needs to be pumped to be adjusted depending on the patient's activity level. The controller can be worn together with a spare battery on a belt, in a vest or bag. The total weight of the controller and the spare battery is about 2kg.

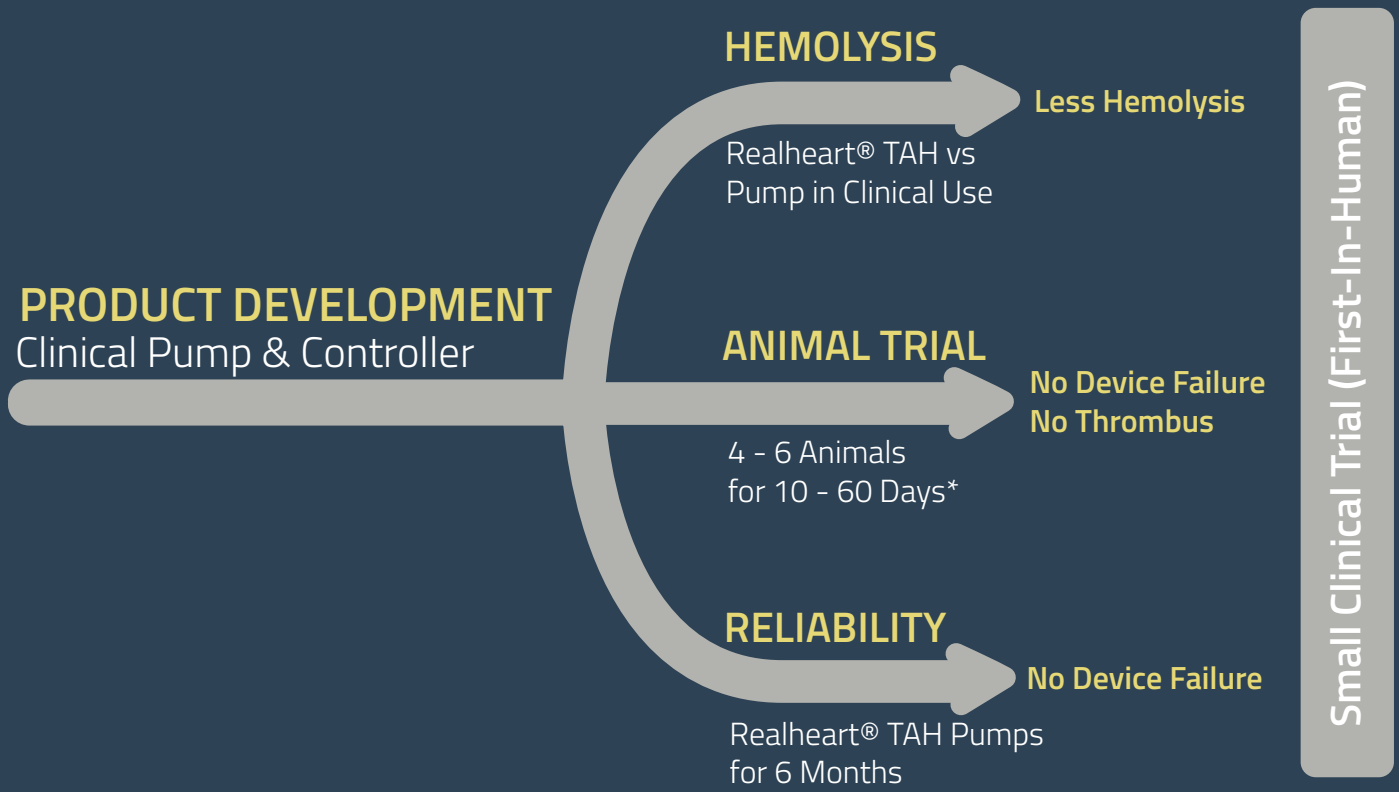
A THIN POWER CABLE

The power cable (drive cable) that connects the pumps to the controller is made of a soft, flexible material that allows natural body movements. The purpose of having only a thin power cable is to minimize the risk of infection, which is a common complication of heart pump therapy. In a Vinnova-funded collaboration with Swedish InvivoPower AB, we have developed a proof-of-concept for a wireless charging device. It shows that in the future, Realheart® TAH will be able to be used with wireless charging to further reduce the risk of infection and give patients more freedom in their daily lives.

Development Plan

The basic design of Realheart® TAHs is fully developed. To verify the design and its operation, preclinical results are needed from endurance tests, blood tests, and long-term studies on animals. These studies are conducted in parallel. The aim of the animal studies is to awaken the animal and observe it while it lives with the artificial heart. The length of time the animal needs to be kept alive is determined by the regulatory authorities.

The Path Towards Clinical Trials



PRECLINICAL STUDIES

Blood tests, animal studies and endurance tests are performed on the clinical version of Realheart® TAH. To date, Realheart® TAH has performed 80% lower hemolysis than the market leading product in blood tests; physiological blood flow and right-left balance in safety tests; and demonstrated good endurance at the component level, preparing for system testing.

PREPARATION FOR CLINICAL STUDY

Completion of preclinical studies and documentation to obtain authorisation to conduct clinical trials. Anatomy studies ongoing at Sahlgrenska University Hospital and Hannover Medical School to identify anatomical inclusion and exclusion criteria for clinical trials.

FIRST-IN-HUMAN

Early small-scale study to initially assess safety and gather information about the product. Estimated to include up to 4 patients at one clinic. Collaboration initiated with Sahlgrenska University Hospital to perform the first implantation in Sweden. Interest has been received from doctors at clinics in Germany, Belgium and Italy.

PRODUCT DEVELOPMENT

The results of clinical trials may lead to the modification of specific product components. The focus will also be on scaling up production to produce many units in the future.

BTT IDE (PMA) STUDY AND CE-MARK

An Investigational Device Exemption (IDE) study in patients on the transplant waiting list (bridge to transplant: BTT) is initiated to apply for FDA approval for market introduction. The company estimates that a clinical trial involving 10-20 patients would be suitable for CE marking.

ACTIVITIES FOR MARKET LAUNCH

Marketing, establishment of sales force and network of international distributors for the market launch of Realheart® TAH.

RESEARCH, DEVELOPMENT & COOPERATION

New Milestone Reached for Realheart® TAH

The animal studies conducted in autumn 2022 showed that animals implanted with Realheart® TAH survive for longer. Since the series of animal trials with the clinical version of the company's artificial heart began in 2022, Realheart has been able to gradually increase the survival time from the previous milestone of one day to the current four days.

In Addition to the Animal Being Able to Stand up and Eat After Implantation, Several Important Performance Criteria Were Confirmed, Including:

- **No damage to red blood cells** (hemolysis). Hemolysis caused by the red blood cells to mechanical stress in artificial hearts is crucial for the extent of side effects and survival of patients over time.
- **No thromboembolic events** (blood clots). Good blood flow and low mechanical stress in the TAH minimizes the risk of blood clots forming which can otherwise lead to very serious life-threatening consequences for patients, such as stroke.
- **High pumping capacity and good right-left balance.** The TAH can pump eight litres of blood per minute, which is significantly more than an adult human normally needs. The balance between blood flow from the right and left hemisphere is crucial for survival.
- **Short operating time.** The heart-lung machine used for the implantation has been disconnected after less than 2.5 hours. A long time of use of the heart-lung machine during open heart surgery poses risks for patients. Realheart is developing the TAH to shorten the time on the heart-lung machine and the total surgery time, thereby increasing patient safety.

”I am incredibly pleased with how much we have been able to achieve with just a few implantations. The fact that we see no signs of hemolysis or clot formation in combined with the fact that we can achieve good left-right balance and a pulsatile blood flow and natural blood pressure is extremely satisfactory. We are now moving with the aim of continuing to increase survival time by optimizing the surgical methodology.”

/Ina Laura Perkins, CEO at Realheart

Update on the Development of Realheart® TAH

At the end of the year, Realheart provided a strategy update on the development and commercialization of Realheart® TAH, which in initial testing has been shown to induce 80% less red blood cell damage (hemolysis) compared to the current market-dominant heart pump system. The update was based on a comprehensive analysis conducted under the guidance of the company's Board of Directors. Realheart will focus more clearly on the use of the product as a bridging therapy prior to organ transplantation and now believes that the product can be subsidized in the US already when used in clinical trials.

The update resulted in a more clearly defined commercialization strategy, where Realheart's goal is to significantly reduce mortality and increase quality of life for people waiting for a heart transplant by providing the first artificial heart that mimics a human heart and thus has the potential to minimize the risk of side effects.

After decades of research and development, Realheart® TAH is now undergoing functional and safety testing for its first clinical trial in patients. Realheart believes that the product is eligible for reimbursement in the US already for use in the upcoming clinical trials, which has the potential to generate early revenue streams for the company.

Future market approvals will create significant commercial potential - each percentage point of patients currently on the waiting list for heart transplantation in Europe and the US represents potential sales revenue of 150 MSEK. The use of Realheart® TAH in this area is the first important step towards the company's long-term vision - that broader patient groups have access to the product so that no one dies of heart failure.

As the global number of transplant centres is limited, it is possible to market Realheart® TAH with relatively limited resources. The company's business model is based on direct sales of the product in the US and Europe, with the addition of necessary services and support for clinical staff and patients.

Updated timeline and pre-clinical activities resulted in an application to initiate the first clinical study of Realheart® TAH expected be submitted to the relevant authorities by the end of 2024/beginning of 2025. This will require a comprehensive preclinical data package based on safety studies, blood tests and reliability studies.

The safety studies are being conducted in preclinical trial models to fulfil the regulatory requirements for the first study in patients. This work is progressing with very positive results so far.

The blood tests are performed in a laboratory setting and the company has recently established a preclinical test system that allows it to mimic blood flow throughout the body to more reliably evaluate red blood cell damage (hemolysis). Initial test results show that Realheart® TAH induces 80% lower rate of hemolysis compared to the current market dominant heart pump system.

Reliability studies of the individual components of the Realheart® TAH have already been carried out with favorable results and corresponding tests of the artificial heart as a whole will begin shortly.

In preparation for the first clinical study of Realheart® TAH, the company has established a collaboration with Professor Göran Dellgren, Consultant Physician at the Transplantation Centre and Thorax Clinic at Sahlgrenska University Hospital in Gothenburg. Several experimental and pre-clinical studies are being conducted within the framework of the collaboration, including to further evaluate different surgical methods and define the patient selection for the clinical study.

The first clinical trial, expected to be initiated in 2025, will be conducted in 2-4 patients awaiting heart transplantation. Assuming positive results, a further study in 10-20 patients is planned to confirm the performance and safety of Realheart® TAH in clinical use prior to market authorization applications.

The process towards market approval involves, In Europe, a process has been initiated with a notified body (an independent organization that ensures that manufacturers comply with EU regulations) to investigate the requirements for approval in the EU.

In addition, Realheart has an ongoing dialogue with the U.S. regulatory authority, the FDA, on the documentation necessary for marketing approval, and further meetings are planned to determine the specific application process that is most appropriate in the US.

New Preclinical Test System was Finalized

The company completed a preclinical test system that allows it to mimic blood flow throughout the body and more comprehensively evaluate red blood cell damage (hemolysis). Initial test results showed that the company's artificial heart, Realheart® TAH, induces 80% lower rate of hemolysis compared to the current market-dominant heart pump system.

The new test model used was developed by Realheart in response to a request from the US FDA. The development was time- and resource-intensive, but at the same time created a favorable environment for future regulatory activities. Realheart's CEO, Dr Ina Laura Perkins, actively participated in FDA committee meetings to contribute to the development of new regulatory standards for hemolysis tests.

Collaboration With Invivopower

Swedish Invivopower was awarded a grant of 900,000 SEK from Vinnova to further develop its patented transcutaneous energy transfer technology in collaboration with Realheart. The project started in June 2023 and runs until May 2024. In the short term, the schedule is not affected, but it gives the company a great head starts in developing the next generation of Realheart® TAH. It is much appreciated that Vinnova enables collaborations like this. Wireless energy transfer/charging is something that will be implemented in Realheart® TAH in the future, and through this project, the Company gains access to a prototype that is also based on its own technology.

All of today's artificial hearts and other heart pumps are powered by a cable that connects the implanted pump to an energy source outside the body (the driveline). Drive line infections are the most common type of heart pump-associated infections because the exit point of the drive line creates a channel for bacteria. Invivopower's solution instead relies on an energy link that transfers energy without breaking the protective skin barrier.

"We have now succeeded in establishing a test model that allows us to mimic the body's circulatory system in a completely new way to compare our artificial heart with other heart pump systems. The system strengthens our dialogue with cardiologists and investors who see the value in a model that can generate comparative performance data. The initial results indicate that Realheart® TAH produces only a low level of hemolysis and we now look forward to conducting similar tests with the clinical version of our unique artificial heart."

/ Ina Laura Perkins

"Realheart is one of the most advanced companies in the world in developing an artificial heart. This project gives us a unique opportunity to put our technology in the hands of a potential customer early on and gain invaluable feedback that will allow us to focus on the right things in developing a competitive product."

/Bengt Bern, CEO and Founder of Invivopower

The First Patient Simulator

Together with KTH Royal Institute of Technology, Realheart developed a patient simulator to test the algorithm that controls the company's artificial heart and makes the heart adapt to the body's needs.

The simulator is a digital model of the human heart, lungs and blood vessels connected to a mechanical test rig that can be used to model and measure the performance of Realheart® TAH. The collaboration between Realheart and KTH to develop the simulator (scientific term: 'hybrid simulator') began in 2022 following a grant of SEK 4 million from Vinnova Smart Elektronik.

Vinnova's mission is to strengthen Swedish competitiveness. A patient simulator in Sweden gives Realheart and other Swedish companies a significant cost advantage as they no longer need to travel to Europe and the US to access the simulators available there to test their products. Realheart has previously developed an MRI-compatible version of Realheart® TAH in collaboration with Linköping University. The patient simulator now brings together two areas of research that contribute to increased patient safety in clinical trials and reduce the need for animal testing.

There is a lot going on in medical sensors and cardiovascular medical technology in Sweden right now and this will increase the innovative potential of the research area.

"I am proud to have built such a complex system during my first year in Sweden as an assistant professor at KTH, Royal Institute of Technology, and to be able to contribute to fewer animal experiments."

/Dr Seraina Dual

Scientific Conferences

Participating in various scientific conferences is a very good way to highlight and disseminate outstanding research results, and Realheart presented at no less than three different scientific conferences in Europe - the European Society for Artificial Organs (ESAO) in Bergamo, BDW in Rostock and EUMS in Paris - where many future customers and partners are participating. Among other things, the company highlighted its experience with non-animal methods in its development work and challenged the industry to move away from animals.

Despite the FDA Modernization Act 2.0, passed last year, which frees the pharmaceutical industry from animal testing requirements, there is still a strong focus on chronic animal studies in medical technology development. We believe that our industry needs to modernize as well and would like to highlight non-animal methods and present our experience with them.

"We call for collaboration within our field to develop more lab tests based on available clinical data from already authorized products, in order to reduce animal testing in the development of new heart pumps."

/Ina Laura Perkins, vd på Realheart

Cooperation With Sahlgrenska

Scandinavian Real Heart AB initiated a collaboration with senior physician and professor Göran Dellgren at the Transplantation Center and Thorax Clinic at Sahlgrenska University Hospital. The collaboration is part of the preparations for the clinical studies with the company's artificial heart that are planned to start when everything is ready. The intention is that Sahlgrenska University Hospital will eventually participate in the clinical trial.

Several experimental and pre-clinical studies will be conducted as part of the collaboration, including further investigation of surgical methodology and patient selection.

Professor Göran Dellgren has a long history of working with patients with severe heart failure and has performed several heart transplants and implants of mechanical pumps. Since 2016, as part of a Swedish research group, he has been running one of the largest studies in Sweden on patients with severe heart failure, comparing drug treatment with mechanical circulatory support for the heart, the study is called the SweVAD study.

Publication of Scientific Results

Artificial Organs

Research results show that the company's Realheart® (TAH) prototype V11C, has lower hemolysis compared to published data from studies of Reinheart's large and small TAH. The peer-reviewed study titled "In Vitro Hemolytic Performance of the Realheart V11C TAH Prototype with Porcine Blood" was published online in the Journal of Artificial Organs.

The article summarizes the work of an international research team led by Dr Ina Laura Perkins and Dr Azad Najar, in collaboration with researchers at Swansea University Medical School in the UK. High hemolysis requiring repeated and frequent blood transfusions is a major factor limiting the use of the artificial hearts currently available. In addition, hemolysis testing is a regulatory requirement for all new products intended to treat patients with heart failure. In this study, the so-called 'Aachen Rig' was used as a step towards creating a golden standard for testing pulsatile flow blood pumps.

Scientific Reports

Realheart has several international collaborations with researchers and PhD students in the development of the world's first four-chamber heart. One of these is Joseph Bornoff, a PhD student at the University of Bath in the UK. Bornoff has developed an advanced computational fluid dynamics (CFD) model of the Realheart® TAH to study blood flow in the pump and optimize its operation. The work, co-authored with Realheart collaborators, was published in the Springer Nature journal Scientific Reports.

The model of the Realheart® TAH can be simulated in a wide range of operational conditions where variations in heart rate and stroke volume were investigated. The model was validated using Assistant Professor Libera Fresiello's hybrid simulator, a work published in the scientific journal Artificial Organs 2022 and showed excellent agreement between simulation and experimental results. The computational model builds on Joseph's previous work in which he developed a fluid-structure interaction method to simulate complex valve movements.

Based on detailed descriptions of the background, methodology and results, Joseph concluded that the risk of blood damage was low, thanks to the low levels of shear stress in the pump. In addition, the excellent flow of blood through the pump during operation was comparable to other similar devices examined, suggesting a low risk of blood clot formation.

Computer Methods in Biomechanics and Biomedical Engineering

Realheart and the University of Bath published the world's first combined Computational Fluid Dynamics (CFD) and Fluid Structure Interaction (FSI) method for simulating mechanical heart valves in series. The paper "Overset meshing in combination with novel blended weak-strong fluid-structure interactions for simulations of a translating valve in series with a second valve" is the result of an international collaboration between researchers at Realheart and researchers at the University of Bath (UK) and was published in the scientific journal "Computer Methods in Biomechanics and Biomedical Engineering".

International Trademark Protection

Realheart has had its trademark registration of Realheart approved in key international markets, in addition to the protection it already enjoys in Sweden. This allows the brand to be developed to exclusively support the company's artificial heart.

"Many respond well to drug treatment but there are also patients who do not, and eventually the situation also worsens for many heart failure patients with traditional treatment. For them, heart transplantation remains as a last resort or a mechanical heart pump. However, there is a shortage of organs, and pumps are not generally offered to heart failure patients who are not suitable for transplantation. Evidence is insufficient."

/Dr Göran Dellgren

INTERNATIONAL **MARKETING**

Swiss Nordic Bio Healthcare

For the second year in a row, CEO Ina Laura Perkins was present at Swiss Nordic Bio Healthcare, to present Realheart to interested potential investors.

Ina Laura noted that artificial hearts are paving the way for a paradigm shift in the care of patients with severe heart disease. Saving lives and reducing healthcare costs go hand in hand. During the conference, there was an increased interest in the potential of total artificial hearts (TAH) and interest in Realheart specifically was much higher this year, compared to 2022.

Swiss Nordic Bio Healthcare was a great opportunity for the company to showcase Realheart® TAH to MedTech investors and spread the word about an upcoming paradigm shift in the care of patients with severe heart disease. With current treatment methods, patients suffer from long-term health problems and hospitalizations. This means personal suffering and high burden and costs for the healthcare system. With the company's TAH on the market, the lives of heart failure patients will be saved, while helping to reduce healthcare costs for society.

The pool of potential patients for Realheart is unfortunately unlimited and the supply of heart transplants is nowhere near matching the need for new hearts. Today, 9 million people die annually from cardiovascular disease and stroke, which together are the leading cause of death globally. The company's French competitor forecasts sales of over 100 MSEK in 2023, the first year they are fully commercialized in the TAH market. Realheart believes that the market for Realheart® TAH will only be limited by the number of devices that can be manufactured. An advantage of the company's heart is that it does not consist of any biological tissues, but only pure mechanics and a modular construction. This means that there are no limitations when it comes to mass production.

"It is great that that knowledge of the opportunities offered by a new generation of TAH's is spreading. We see it not only in the the range of trade fairs and conferences, but also in the growth of our network of surgeons and other specialists, resulting in the recruitment of highly qualified staff with extensive experience in heart pumps and thoracic surgery."

/Ina Laura Perkins, CEO at Realheart

”We are very pleased that the unique benefits of Realheart® TAH, have been so widely adopted around the world. The conference in Dubai is of great importance as it is organized by local innovators in the UAE, which opens for meetings with new interest groups, beyond the medical researchers, surgeons and doctors that we have previously presented to in the past. Our strategy is to reach out to several major markets in the world simultaneously.”

/Azad Najar, Founder & Innovator, Realheart

”Scandinavian Real Heart is one of Sweden’s most exciting and innovative MedTech companies. With Scandinavian Real Heart Sweden could develop into a leading Life Science nation. We are proud that the Company chooses to to work with Business Sweden and look forward to supporting them in their global growth.”

/Jonas Thulin Program Manager, Business Sweden

Azad Najar Keynote Speaker at AI Congress in Cairo & at Innovation Conference in Dubai

Realheart’s founder and innovator, Azad Najar, presented the company’s artificial heart as keynote speaker at a congress in Cairo. The main theme of the congress was Artificial Intelligence (AI) and was organized by the Ministry of Youth and Sports. The congress brought together 125 participants from 25 countries and was aimed primarily at young researchers in the field of applied artificial intelligence, including healthcare. Azad Najar presented his thoughts on how AI could be used in artificial organs in the future. Specifically, he discussed how AI can help improve patient safety in heart pump patients.

Najar was also a keynote speaker at the ‘Future of Innovation’ conference in Dubai. The conference, organized by the Innovation Association of Dubai, brought together innovators, hospital management, scientists, and representatives from the government of Dubai as well as other states in the UAE.

Interest in Realheart and Azad Najar’s innovation work has long been recognized and known in the Middle East and now Azad had the chance to once again present the company’s artificial heart to an interested audience.

Realheart Selected for Business Sweden Catalyst Program

Realheart was one of the companies selected for Business Sweden’s scale-up program Catalyst, which aims to create international growth. The program, which targets Sweden’s most innovative and promising companies, provided participants with a tailored market entry project plan valued at 250,000 SEK and opportunities to network in the market, among investors and other experts.

Dilek Gürsoy Talks About Artificial Hearts and Realheart® TAH at Impact LECH

Cardiac surgeon Dilek Gürsoy was one of several first-class speakers at Impact LECH in Austria. Dr. Gürsoy spoke about artificial hearts in general and about the Realheart artificial heart specifically. She also participated in a panel discussion on the theme "Man and machine in medicine".

Dr. Gürsoy was the first female surgeon in Europe to implant an artificial heart and she is one of several prominent cardiac surgeons involved in Realheart's animal studies. Dr. Gürsoy has nearly 20 years of experience in cardiac surgery and has specialist expertise in the field of artificial hearts.

China Heart Congress

The China Heart Congress (CHC), one of the largest cardiovascular conferences in the Asia-Pacific region, attracted over 8,000 participants. CEO Ina Laura Perkins was invited by one of China's leading cardiac surgeons, Mr. Shenshou Hu, President of Fuwai Hospital in Beijing. With 15,000 cardiovascular surgeries and 50,000 interventional procedures annually, Fuwai Hospital is one of the world's largest cardiovascular hospitals.

"Artificial heart treatment and artificial heart research is important and therefore I am happy to share my long experience in this field at Impact LECH on June 17, 2023. Realheart's pump is very good, I really believe in it."

/Dr Dilek Gürsoy

China International Import Expo (CIIE)

At the sixth China International Import Expo (CIIE) 2023, Realheart qualified for the semi-final finals in the CIIE medical device track. Realheart was one of a few Swedish companies that had the opportunity to present to the forum including local government representatives, companies from the health sector and investors.

Realheart's Chief Medical Officer (CMO) Dr. Ulf Kjellman presented the Company's artificial heart and highlighted the unique benefits of Realheart® TAH and the promising preclinical results in terms of blood damage and stroke risk.

"CHC is a great opportunity for Realheart to make contacts and create awareness of our artificial heart in China and Southeast Asia. A better introduction to the market is hard to imagine."

/CEO Ina Laura Perkins

Leading German Cardiac Surgeon on the Market Need for Artificial Hearts

Leading German cardiac surgeon Professor Jan Schmitto estimated that the number of patients with end-stage heart failure in Germany, with a population of 82 million, was around 40-60,000 per year. While not all of these patients meet the criteria for a transcatheter artificial heart (TAH), the market for a company that can provide a good one is huge.

In Germany, thousands of patients are waiting in line, but fewer than 300 heart transplants are performed each year. In high-income countries, cardiovascular disease is the leading cause of death globally and, with current treatment methods, patients suffer long-term health problems and hospital stays. This causes personal suffering and a high burden and cost to the health system.

Realheart and Industry Stakeholders on Market Needs

Industry players and Realheart estimated that the market potential for total artificial hearts (TAHs) is over 200,000 units per year in Europe and the US. Realheart believes it is well positioned to capture significant market share with its four-chamber artificial heart.

An important factor in production is the Eurostars 3 grant of 10 MSEK that Realheart received together with Berlin Heart for the automation of the membrane production process. The membranes themselves are a critical component of the artificial heart and must be manufactured with high precision and unwavering repeatability. The best way to achieve this is to automate the manufacturing process. Therefore, the collaboration between Realheart and Berlin Heart was initiated, who are experts in the field of development and manufacturing of membrane technologies successfully used in their external heart pumps.

According to the WHO and several other stakeholders, cardiovascular disease is now the leading cause of death globally in high-income countries, and the number of people affected is increasing, as is the number of years patients can live with their disease. All in all, this means a significant increase in the burden and cost of healthcare. According to research [1], the global bill will increase from 346 billion USD in 2012 to 400 billion USD in 2030. Heart failure is a type of cardiovascular disease in which the heart is no longer able to pump the amount of blood the body needs.

Approximately 300,000 Swedes [2] have heart failure and around 64 million [3] people are affected globally.

New treatment options are needed, and an artificial heart may be a near-term option for patients with severe heart failure. Adequate TAH can help reduce the suffering of those affected, while also having the potential to reduce the costs of treating heart failure.

[1] Lippi, Giuseppe; Sanchis-Gomar, Fabian. 2020. Global epidemiology and future trends of heart failure. AME Medical Journal.

[2]https://janusinfo.se/lakemedelskommitte/lok/artiklar/lakemedelsbehandlingvidkroniskhjartsvikt.5.6b0ce-c9617a2d3d28f8699b5.html

[3] (1): Savarese G, Lund LH. Global Public Health Burden of Heart Failure a comprehensive and updated review of epidemiology, https://pubmed.ncbi.nlm.nih.gov/28785469/

Direkt Studios Trading Direct Healthcare

During the year, Realheart's Chief Medical Officer Dr. Ulf Kjellman was a guest on Direkt Studios Trading Direkt Healthcare. The current episode had the theme of artificial hearts and with more than 30 years of experience in heart surgery and artificial hearts, Dr. Kjellman gave a clear picture of why artificial hearts need to become available as an alternative to heart transplants.

During the interview, Dr. Kjellman took us back to 1969 - the year when the first artificial heart was implanted in a patient in the United States - an important milestone that made it clear that a very sick person can survive until transplantation thanks to the bridging of an artificial heart. He further explained what an artificial heart is and how it works. He particularly highlighted the difference between a temporary and a permanent solution and emphasized the importance of the patient's quality of life.

”Sales are likely to be limited only by how many artificial hearts we have the capacity to produce. We have great advantages with our TAH because we have started to automate parts of the production process at an early stage of development. That said, we have no long-term limitations on volume production.”

/CEO Ina Laura Perkins

” In Germany alone, with a population of 82 million, estimates show that 40-60 000 patients with severe heart failure could potentially benefit from a new heart every year. However, the shortage of organ donors only allows for around 300 heart transplants per year in Germany. With a good TAH on the market, many of these patients’ lives could potentially be saved, while providing them with a good quality of life. Better treatment options could also contribute significantly to reducing society’s healthcare costs.”

/Professor Jan Schmitto

TEAM & RECRUITMENTS

Ulf Kjellman and Bart Meyns Strengthen Realheart's Medical Advisory Board

During the year, Realheart further strengthened the expertise of its Medical Advisory Board with the addition of Dr. Ulf Kjellman and cardiac surgeon Bart Meyns. Dr. Kjellman brings many years of experience in advanced surgical treatment of heart failure and was the surgeon who performed the first implantation in Scandinavia in 2008. Bart Meyns is a professor at the Faculty of Medicine at KU Leuven University in Belgium and one of the surgeons on the Realheart team in the ongoing animal study.

Ulf Kjellman new Chief Medical Officer

Cardiac surgeon Ulf Kjellman, who recently joined Realheart's Medical Advisory Board, later accepted the position as the company's Chief Medical Officer. Kjellman, who has many years of experience in advanced cardiac surgery, became clinically responsible for the company's preclinical and clinical studies.

" Bart Meyns is one of the most skilled and experienced surgeons in the field of heart pump implantation. He has been invaluable at the operating table during our animal trials, and I am delighted to be able to bring him even closer to us. His knowledge will be a very valuable addition to our expert medical advice."

/Ina Laura Perkins, CEO at Realheart

"For me, it was an easy decision to take on the role of Chief Medical Officer at Realheart. Realheart's TAH is an extremely interesting concept and a paradigm shift in artificial hearts. As a product, it fills a gap in the care of heart failure patients, with the potential to save lives in the future and provide patients with a continued good quality of life."

/Ulf Kjellman, Chief Medical Officer, Realheart

Three new Recruitments to the Board

During the year, Realheart made three very competent and experienced recruitments to its Board. All have long and solid experience from the medical device industry and will be very valuable additions to the Company.

Magnus Öhman has extensive experience from the medical technology industry in general and pacemaker development specifically, including as CEO of St. Jude Medical's Swedish subsidiary in Cardiac Rhythm Management.

Giovanni Lauricella is currently Managing Partner at Lifeblood Inc, a company specializing in recruitment and fundraising for medical device companies.

Stuart McConchie has held senior positions in global medical device companies for more than 25 years, guiding companies from research to product commercialization.

"Realheart has a unique artificial heart solution with significant clinical benefits for the patient that has the potential to radically change clinical care."

/Magnus Öhman

”Realheart is developing solutions that will change the artificial heart (TAH) industry for patients with advanced heart failure who need a transplant.”

/Giovanni Lauricella

”Realheart is now making progress towards offering heart failure patients an alternative to heart transplantation and I am eager to follow them all the way.”

/Stuart McConchie

BOARD OF DIRECTORS

Magnus Öhman

Chairman

Holding: -

Azad Najar

Board Member

Holding: 3 272 635 shares

Ulf Grape

Board Member

Holding: 10 000 shares

Oliver Voigt

Board Member

Holding: 3 236 shares

Christer Norström

Board Member

Holding: 8 555 shares

Solveig Bergström

Board Member

Holding: -

Stuart McConchie

Board Member

Holding: -

Giovanni Lauricella

Board Member

Holding: -

Board of Director's Report

General Information About the Business

Scandinavian Real Heart AB (publ) shares are listed on Nasdaq First North Growth Stockholm with the ticker symbol HEART.

The Company's business shall be to conduct sales and development of medical products and services and services and related activities. The parent company has its registered office in Västerås and conducts its main business. The subsidiary Scandinavian Realheart Pty is based in the state of Victoria, Australia. Its task is to be responsible, in cooperation with Hydrix Pty, for the development of the control unit (external and implants). 2022 is the first year that the company reports its operations in a consolidated format and therefore has no comparative figures for previous years.

The company is developing an artificial heart that mimics the function of a natural heart, a so-called total artificial heart (TAH). The patented solution of the Realheart® TAH is developed to mimic the blood flow pattern and function of the natural human heart, which creates the possibility of a long-term solution for patients diagnosed with advanced heart failure. Research and development of the concept has been conducted since 2000 in collaboration with leading specialists in thoracic surgery and related specialties. The pump principle has been patented in many countries and additional patent applications have been filed. In terms of the company's R&D, the costs associated with the product development are balanced. If there is general research not linked to product development, it is not balanced. The work on developing the heart pump for clinical studies on humans is in progress through pre-clinical studies on animals, research and material development. In 2023 R&D amounted to 21.2 MSEK or 60% of the cost base before balancing of costs.

Development of the Company's Operations, Results and Position

Group

Amount KKR	2023-12-31	2022-12-31
Balance sheet total	102 638	119 816
Equity ratio	80%	81%
Cash liquidity	321%	71%

Definitions: see note 17

2022 is the first year that the company has a subsidiary and consolidated accounts.

Parent Company

Amounts in KSEK	2023-12-31	2022-12-31	2021-12-31	2020-12-31	2019-12-31
Balance sheet total	103 222	111 229	117 815	78 045	66 614
Equity ratio	80%	88%	95%	92%	89%
Cash liquidity	309%	95%	1032%	667%	603%

Definitions: see note 17

Significant Events During the Financial Year

Research and Development Activities

The work of further developing the heart pump for long-term animal tests and, by extension, clinical studies, establishing new supplier and partner collaborations and continuing to work on the authorities' specifications continues. In 2023, work on in vivo studies, blood studies and sustainability studies continued.

In the animal studies, the target survival time of four days was achieved, and the analysis shows that the animals did not suffer from hemolysis (damage to the cell membrane of red blood cells so that the hemoglobin leaks out) or blood clots. In addition, high pumping capacity was maintained continuously, and the development of the surgical technique significantly shortened the operation time.

The continued blood studies show that Realheart's prototype continues to have a significantly lower hemolysis rate than similar products. 80% lower hemolysis rate compared to today's market-dominant heart pump systems in tests performed with human blood in whole body circulation.

Component-level durability tests have been carried out with good results and work on test equipment to prepare for system-level tests is ongoing.

In 2023, the subsidiary Scandinavian Real Heart Pty. located in Australia has continued its operations. The subsidiary is responsible for the development of the control unit (external and implanted electronics) in collaboration with Hydrix Pty. Hydrix is a world leader in the development of control units for medical devices. Work on the controller continues with a new lighter design. A further reason for the presence in Australia is a favorable R&D tax incentive where up to 43.5% of the investment can be recouped.

During the year, the company's board of directors was strengthened with highly experienced individuals such as Magnus Öhman, Stuart McConchie and Giovanni Lauricella. All three have many years of experience in MedTech and the commercialization of advanced products focused on the treatment of cardiovascular diseases.

The company further strengthened its expertise when cardiac surgeons Bart Meyns and Ulf Kjellman joined the company's Medical Advisory Board. Ulf has also taken over the role of Chief Medical Officer (CMO).

Scandinavian Real Heart AB initiates a collaboration with Chief Physician and Professor Göran Dellgren at the Transplant Center and Thorax Clinic at Sahlgrenska University Hospital. The collaboration is part of the preparations for the clinical studies with the Company's artificial heart.

Impairment of Intangible Fixed Assets

The value of all the Group's intangible assets is tested annually or when indications of significant changes in assumptions are identified. In connection with the work on the 2023 financial statements, a careful analysis was made of the book values of the Group's operating assets, including goodwill, in relation to current WACC requirements. Due to a sharp increase in the interest rate level in 2023, which increases the requirements for WACC, and previously communicated delays in the commercialization process, the Board decided to write down the value of intangible assets of -50.1 MSEK. The write-down does not affect cash flow. An impairment of the value of intangible assets means that the requirement for future amortization decreases, which will give a better future result.

Government Relations

In 2023, the company continued to work to meet the requirements of the US Food and Drug Administration (FDA) and participated in standards committee meetings to update standards related to preclinical testing for heart pumps.

Financing
Warrants of series TO1 were closed, which provided the company with approximately 4.2 MSEK before issue costs.

During the year, the company received 42.2 MSEK after issue costs through a preferential and directed issue to the European Innovation Council (EIC), which will be the company's largest owner. The company is nominated by EIC for investment of up to 15 MEUR and the directed issue was the first investment from that pot.

Realheart is also part of a Vinnova collaboration for cordless TAH technology. The company InVivopower has been awarded a grant of 0.9 MSEK from Vinnova to further develop its patented technology for wireless energy transfer through the skin in collaboration with Scandinavian Real Heart. The project runs from June 2023 to May 2024.

Realheart has been awarded a business development grant of 850,000 SEK from the Swedish Agency for Economic and Regional Growth and Region Västmanland for digitization, green transition, internationalization and verification.

Realheart was selected for Business Sweden's Scale-up Program Catalyst, which aims to create international growth. In the program, which is aimed at Sweden's most innovative and promising companies, participants receive a tailor-made project plan for market entry valued at 250,000 SEK and opportunities to build networks in the market, among investors and other experts.

The Board believes that the funding is sufficient for continued operations in 2024 and that liquidity will last into the first quarter of 2025.

Patent Protection
The company has patents granted on the pumping principle in the EU, the US, China, India, the UK, Australia, and Japan. In addition, the company has filed a further series of patent applications in recent years. In total, this represents eight patent families. During the year, the company was granted two additional patents in the US.

During the year, trademark registration of Realheart was approved in key international markets including Australia, the EU, Canada, Japan, Norway, Switzerland, the UK and the US. This is in addition to the protection the brand already has in Sweden. This allows the brand to be developed to exclusively support the company's artificial heart.

Expected Future Development

Expected future developments and significant risks and uncertainties
Realheart's focus remains on getting through the preclinical phase (hemolysis, safety studies and endurance tests) to be able to start clinical studies. This means that the company must finalize the version of both the controller and the heart pump to be included in these tests. Realheart is also continuing discussions with the Notified Body in the EU and with the FDA to ensure the fastest and safest route for the product to market.

The company is continuously working on measures to minimize delays. Furthermore, the continued product development requires that we can continue to solve the financing. The Board of Directors is continuously working on various scenarios to ensure the company's future operations. With a maintained high rate of development, current liquidity is sufficient to finance the company into the first quarter of 2025. To solve the company's longer-term financing needs, Realheart is continuously working to evaluate options for further capitalization of the Company. One possibility is to be able to finance the Company in the future through equity from financially strong additional owners and from other sources such as EU support and non-profit foundations.

Ownership of Parent Company

Name	Numbers of Shares	Votes (%)	Capital (%)
European Innovation Council Accelerator	18 300 000	18.9	18.9
Eskilstunahem Fastighets AB	7 900 018	8.1	8.1
Avanza Pension	4 333 808	4.5	4.5
Azad Najar	3 372 635	3.5	3.5
Nordnet Pensionsförsäkring	1 603 244	1.7	1.7
Gilbert Raux	1 125 902	1.2	1.2
Jonas Rudberg	1 028 932	1.1	1.1
BigBear Holding AB	907 500	0.9	0.9
Abbe Dikmen	775 000	0.8	0.8
Swedbank Försäkring	618 269	0.6	0.6
Others	56 703 295	58.7	58.7
Total	96 994 446	100.0	100.0

Shareholder's Equity

Group	Share Capital	Other Contributed Capital	Other Equity incl. net Income
Opening balance 2023-01-01	3 318 346	165 057 256	-70 730 380
Changes directly in equity			
Translation differences			-422 822
Transactions with owners			
New share issue	6 381 099	46 440 397	
Options, repayment		-28 630	
Transfer between equity items			
Profit for the year			-67 977 292
Total Shareholders's Equity 2023-12-31	**9 699 445**	**211 469 023**	**-139 130 494**

Parent Company	Share Capital	Fund for Development Costs	Share Premium Account	Retained Earnings	Profit for the Year
Opening balance 2022-01-01 (3 318 346 shares)	3 318 346	68 409 773	164 712 421	-114 666 829	-10 483 500
Provision for development fund		13 816 417		-13 816 417	
Options			344 835		
Diposition according to AGM decision				-10 483 500	10 483 500
Profit for the year					13 810 029
Total Shareholders's Equity 2022-12-31	**3 318 346**	**82 226 190**	**165 057 256**	**138 966 746**	**13 810 029**
Opening balance 2023-01-01	3 318 346	82 226 190	165 057 256	-138 966 746	-13 810 029
Provision for development fund		-43 871 434		43 871 434	
New share issue	6 381 099		46 440 397		
Warrants			-28 630		
Diposition according to AGM decision				-13 810 029	13 810 029
Profit for the year					-67 678 901
Total Shareholders's Equity 2023-12-31	**9 699 445**	**38 354 756**	**211 469 023**	**-108 905 341**	**-67 678 901**

Proposal for Allocation of the Company's Profit or Loss

The Board of Directors proposes that unrestricted equity, SEK 34,884,781, be appropriated so that SEK 34,884,781 is carried forward. No dividend is proposed.

	Amounts in SEK
Share premium account	211 469 023
Loss brought forward	-108 905 341
Profit for the year	-67 678 901
Total for the year	34 884 781

As regards the Group's and the Parent Company's results and position in general, reference is made to the following income statements and balance sheets with accompanying notes.

Income Statement Group

Amounts in SEK	Note	2023-01-01-2023-12-31	2022-01-01-2022-12-31
Operating Income			
Net turnover		-	10 000
Other operating income	3	902 882	657 589
		902 882	667 589
Operating Expenses			
Purchased services		-3 041 053	-8 884 613
Other external expenses		-18 639 649	-15 632 223
Personnel costs	4	-13 740 093	-10 041 161
Capitalized expenses for own account		17 192 235	21 161 883
Depreciation and impairment of tangible and intangible fixed assets	5	-50 217 319	-115 366
Other operating expenses	6	-469 509	-1 006 742
Operating profit/loss		**-68 012 506**	**-13 850 633**
Result From Financial Items			
Interest income and similar items		607 240	423
Interest expense and similar income and expense items	7	-572 026	-137 701
Profit After Financial Items		**-67 977 292**	**-13 987 911**
Profit Before Taxes		**-67 977 292**	**-13 987 911**
Profit for the Year		**-67 977 292**	**-13 987 911**

Balance Sheet Group

Amounts in SEK	Note	2023-12-31	2022-12-31
ASSETS			
Fixed Assets			
Intangible fixed assets			
Capitalized expenditure on development,			
patents, licences, and trademarks	8	56 143 419	105 051 108
		56 143 419	105 051 108
Tangible fixed assets			
Equipment, tools and installations	10	707 510	46 068
		707 510	**46 068**
Total Fixed Assets		**56 850 929**	**105 097 176**
Current Assets			
Current receivables			
Other receivables		801 267	1 936 905
Prepayments and accrued income	12	1 683 371	1 523 136
		2 484 638	**3 460 041**
Cash and bank		**43 302 712**	**11 259 038**
Total Current Assets		**45 787 350**	**14 719 079**
TOTAL ASSETS		**102 638 279**	**119 816 255**

Balance Sheet Group

Amounts in SEK	Note	2023-12-31	2022-12-31
SHAREHOLDER'S EQUITY AND LIABLITIES			
Shareholder's Equity			
Share capital		9 699 445	3 318 346
Other contributed capital		211 469 023	164 712 421
Other equity incl. profit for the year		-139 130 494	-70 385 545
Total Equity		**82 037 974**	**97 645 222**
Non-Current Liabilities			
Liabilities to credit institutions	13	6 352 920	1 552 795
		6 352 920	**1 552 795**
Current Liabilities			
Liabilities to credit institutions		1 896 706	621 118
Advances from customers		8 157 140	7 960 800
Accounts payable		1 789 333	10 331 385
Tax liabilities		217 885	118 582
Other current liabilities		473 091	397 679
Accured expenses and deferred income	14	1 713 230	1 188 674
		14 247 385	**20 618 238**
TOTAL SHAREHOLDER'S EQUITY AND LIABILITIES		**102 638 279**	**119 816 255**

Cash Flow Statement Group

Amounts in SEK	Note	2023-12-31	2022-12-31
Operating Activities Result after financial items		-67 977 292	-13 987 911
Adjustments for items not included in the cash flow, etc.		49 794 499	113 453
Cash Flow From Operating Activities Before Changes in Working Capital		**-18 182 793**	**-13 874 458**
Cash flow from changes in working capital			
Change in current receivables		975 403	-535 941
Change in accounts payable		-8 542 052	6 846 065
Change in current liabilities		699 270	184 185
Cash Flow from Operating Activities		**-25 050 172**	**-7 380 149**
Investing Activities Investments in intangible assets		-1 016 568	-23 757 229
Acquisitions of tangible fixed assets		-758 164	
Cash Flow from Investing Activities		**-1 774 732**	**-23 757 229**
Financing Activities Warrants		-28 630	344 834
Rights issue		52 821 495	-
Change in loans		7 600 000	-
Repayment of loan liabilities		-1 524 287	-621 118
Cash Flow from Financing Activities		**58 868 578**	**-276 284**
Cash Flow for the Year		**32 043 674**	**-31 413 662**
Cash and Cash Equivalents at Beginning of the Year		**11 259 038**	**42 672 700**
Cash and Cash Equivalents at End of the Year		**43 302 712**	**11 259 038**

Notes to Cash Flow Statement Group

Note Other Disclosures to the Cash Flow Statement

	2023-12-31	2022-12-31
Adjustment for Items not Included in the Cash Flow etc.		
Depreciation and amortization	155 210	115 366
Unrealized exchange rate differences	50 062 109	-
Exchange rate differences	-422 820	-1 913
	49 794 499	113 453

Investments in Intangible Aassets

	2023-12-31	2022-12-31
Expenses for the year	-18 581 473	-37 579 990
Acquisition of patents	-506 495	-1 483 507
Activated R&D grants	17 875 060	7 345 468
Change in prepaid contributions	196 340	7 960 800
	-1 016 568	**-23 757 229**
Prepaid grants	10 985 870	15 335 336
Tax refund attributable to accrued expenses	6 873 498	-

Income Statement Parent Company

Amounts in SEK	Note	2023-01-01- 2023-12-31	2022-01-01- 2022-12-31
Operating Income			
Net turnover		-	10 000
Other operating income	3	902 882	657 589
		902 882	**667 589**
Operating Expenses			
Purchased services		-3 041 053	-8 884 613
Other external costs		-18 262 817	-15 454 340
Personnel cost	4	-13 740 093	-10 041 161
Capitalized expenses on own account		17 192 235	21 161 883
Depreciation and impairment of tangible and intangible fixed assets	5	-50 217 319	-115 366
Other operating expenses	6	-469 509	-1 006 743
Operating Profit/Loss		**-67 635 674**	**-13 672 751**
Result From Financial Items			
Interest income and similar items		528 799	423
Interest expenses and similar items	7	-572 026	-137 701
Profit/Loss after Financial Items		**-67 678 901**	**-13 810 029**
Profit/Loss Before Taxes		**-67 678 901**	**-13 810 029**
Net Income for the Year		**-67 678 901**	**-13 810 029**

Balance Sheet Parent Company

Amounts in SEK	Note	2023-12-31	2022-12-31
ASSETS			
Fixed Assets			
Intangible fixed assets			
Capitalized expenditure for development work			
and similar work	8	45 209 571	88 633 000
		45 209 571	88 633 000
Tangible fixed assets			
Machinery and other technical equipment	10	707 510	46 068
		707 510	46 068
Financial Fixed Assets			
Shares in group companies	11	14 195 622	11 320 840
		14 195 622	**11 320 840**
Total Fixed Assets		**60 112 703**	**99 999 908**
Current Assets			
Current receivables			
Other receivables		652 100	747 123
Prepaid expenses and accrued income	12	455 266	232 901
		1 107 366	**980 024**
Cash and bank balances		**42 001 609**	**10 249 293**
Total Current Assets		**43 108 975**	**11 229 317**
TOTAL ASSETS		**103 221 678**	**111 229 225**

Balance Sheet Parent Company

Amounts in SEK	Note	2023-12-31	2022-12-31
SHAREHOLDER'S EQUITY AND LIABILITIES			
Shareholder's Equity			
Restricted equity			
Share capital (96 944 446 aktier)		9 699 445	3 318 346
Fund for development expenditure		38 354 756	82 226 190
		48 054 201	**85 544 536**
Unrestricted Equity			
Share premium reserve		211 469 023	164 712 421
Retained earnings		-108 905 341	-138 621 911
Result for the year		-67 678 901	-13 810 029
		34 884 781	**12 280 481**
Total Shareholder's Equity		**82 938 982**	**97 825 017**
Long-Term Liabilities			
Other liabilities	13	6 352 920	1 552 795
		6 352 920	**1 552 795**
Current Liabilities			
Liabilities to credit institutions		1 896 706	621 118
Advances from customers		8 157 140	7 960 800
Accounts payable to suppliers		1 471 725	1 564 560
Tax liabilities		217 885	118 582
Other current liabilities		473 091	397 679
Accrued expenses and deferred income	14	1 713 229	1 188 674
		13 929 776	**11 851 413**
TOTAL SHAREHOLDER'S EQUITY AND LIABILITIES		**103 221 678**	**111 229 225**

Cash Flow Statement Parent Company

Amounts in SEK	Note	2023-12-31	2022-12-31
Cash Flow From Operations			
Result after financial items		-67 678 901	-13 810 029
Adjustment for non-cash items		50 217 319	115 366
		-17 461 582	**-13 694 663**
Cash Flow from Operations Before Changes in Working Capital		**-17 461 582**	**-13 694 663**
Changes in Working Capital			
Change in current receivables		-127 342	668 019
Change in accounts payable		-92 835	-644 704
Change in current liabilities		699 270	184 186
Cash Flow from Operating Activities		**-16 982 489**	**-13 487 162**
Investing Activities			
Shareholders' contributions paid		-2 874 782	-11 320 840
Investments in intangible assets		-6 500 828	-7 339 121
Investment in tangible fixed assets		-758 164	-
Cash flow from investing activities		-10 133 774	-18 659 961
Financing Activities			-
New share issue		52 821 496	
Warrants		-28 630	344 834
Loans raised		7 600 000	-
Repayment of loans		-1 524 287	-621 118
Cash Flow From Financing Activities		**58 868 579**	**-276 284**
Cash Flow for the Year		**31 752 316**	**-32 423 407**
Cash and Cash Equivalents at the Beginning of the Year		**10 249 293**	**42 672 700**
Cash and Cash Equivalents at the End of the Year		**42 001 609**	**10 249 293**

Notes to the Cash Flow Statement Parent Company

Note Other Disclosures to the Cash Flow Statement

	2023-12-31	2022-12-31
Adjustment for Items not Included in the Cash Flow etc.		
Depreciation	155 210	115 366
Impairment losses/reversal of impairment losses	50 062 109	
	50 217 319	115 366
Investments Intangible Assets		
Expenses for the year	-17 192 235	-21 161 882
Acquired patents	-506 495	-1 483 507
Activated R&D grants	11 001 562	7 345 468
Prepaid grants	196 340	7 960 800
	-6 500 828	**-7 339 121**
Contributions Paid	**10 985 870**	**15 335 336**

Notes

Note1 Accounting Principles

Amounts in SEK unless otherwise stated.

General Accounting Principles
The annual report has been prepared in accordance with the Annual Accounts Act and the Swedish Accounting Standards Boards general advice BFNAR 2012:1 Annual Report and Consolidated Accounts (K3).

Consolidated Acounts

Subsidiaries
Subsidiaries are companies in which the parent company directly or indirectly holds more than 50% of the voting rights or otherwise has a controlling interest. Control is the power to govern the financial and operating policies of an entity so as to obtain benefits from its activities.

The cost of subsidiaries is measured as the aggregate of the fair values of assets given, liabilities incurred and assumed, and equity instruments issued, costs directly attributable to the business combination and any contingent consideration. From the date of acquisition, the consolidated financial statements include the acquiree's revenue and expenses, identifiable assets and liabilities, and any goodwill or negative goodwill arising.

Valuation Principles, etc.
Assets, provisions and liabilities have been valued at cost unless otherwise stated below.

Government Grants
A government grant that is not conditional on future performance is recognized as revenue when the conditions for receiving the grant are met. A government grant that is conditional on future performance is amortized over the period to which it relates and reduces the value of the intangible asset.

Intangible Assets

Research and Development Expenditure

The cost of capitalized expenditure includes the expenditure incurred in developing the asset. Directly attributable expenditure includes staff costs incurred in the development process. The corresponding amount has been transferred to the Development Expenditure Fund.

Internally generated intangible assets are stated at cost less accumulated amortization and impairment losses and grants received during the period. Patents are amortized over the life of the patent; patents acquired by the entity are stated net of accumulated amortization and impairment losses.

Tangible Fxed Assets

Property, plant and equipment are stated at cost less accumulated depreciation and impairment losses. Cost includes the purchase price and expenditure directly attributable to the acquisition.

Amortization

Depreciation is calculated using the straight-line method over the estimated useful life of the asset. Depreciation is recognized as an expense in the income statement. Capitalized development expenditure is amortized when the developed product is ready for use.

	Group (%)	Parent Company (%)
Patents	12,5	12,5
Equipment, tools and installations	20	20

Testing for Impairment of Intangible and Tangible Assets

At each balance sheet date, an assessment is made as to whether there is any indication that the value of an asset is lower than its carrying amount. See note 2.

Leasing - Lessees

All leases have been classified as finance or operating leases. A finance lease is a lease lease under which the risks and rewards incidental to ownership of an asset are substantially transferred from the lessor to the lessee. An operating lease is a lease that is not a finance lease.

Operating Leases

Lease payments under operating leases, including increased initial rentals but excluding charges for services such as insurance and maintenance, are recognized as an expense on a straight-line basis over the lease term.

Foreign Currency

Foreign Currency Items

Monetary items denominated in foreign currency are translated at the closing rate. Non-monetary items are not translated but are translated at the exchange rate at the date of acquisition.

Cash Flow Statement

The cash flow statement is prepared using the indirect method. The reported cash flows include only transactions that have resulted in cash receipts or payments.

The entity classifies bank balances as cash and cash equivalents.

Equity Capital

Equity of the enterprise consists of the following items:
Share capital representing the nominal value of issued and registered shares. share premium account, which includes any premium received on the issue of new share capital. Any transaction costs associated with the issue of new shares are deducted from the share premium account, taking into account any income tax effects. The development expenditure fund is increased annually by the amount capitalized in respect of the company's own development work.

The fund is reduced annually by the amortization of the capitalized development work. Retained Earnings/Accumulated Loss and Net Profit for the Year, i.e. all retained earnings and share-based payments for the current and previous periods, as well as acquisitions of own shares. Other equity is the development expenditure fund, retained earnings and profit for the year.

Note 2 Estimates and Judgments

The preparation of the financial statements requires the Board of Directors and the Managing Director to make certain estimates, judgments and assumptions that affect the recognition and measurement of assets, provisions, liabilities, income and expenses in accordance with the applicable accounting policies. The areas in which such estimates and judgments may have a significant effect on the company, and which may therefore affect the profit and loss accounts and balance sheets in the future, are described below.

Significant Judgments

The following significant judgments have been made in applying the entity's accounting policies that have the most significant effect on the financial statements.

Capitalization of Intangible Assets

To assess any impairment of the intangible asset, a recoverable amount is calculated based on the expected future cash flow with an expected start of sales in 2027. We have also calculated an appropriate discount rate (WACC) based on market conditions and by comparing with other similar companies, to discount the cash flow. In the calculation of the recoverable amount. In this assessment, which extends a number of years into the future (up to 2033), there are uncertainties about future cash flows and the appropriate discount rate. The sales price we have assigned to the product is in line with the only similar product currently on the market but which, in our assessment, is based on old technology and cannot really be compared with our product in terms of user-friendliness, reliability and mobility. Our assessment is based on available information and is based on our commercialization plan. The risks we assess are if there would be delays in approvals from medical authorities in the EU and the US and thus our own commercialization process.

Note 3 Other Operating Income

	2023-01-01- 2023-12-31	2022-01-01- 2022-12-31
Group		
Exchange rate gains on operating receivables/liabilities	38 795	649 929
Sick pay	864 149	5 235
Refund of surplus from insurance companies	-	2 425
Others	-62	-
Total	**902 882**	**657 589**
Parent Company		
Exchange gains on operating receivables/liabilities	38 795	649 929
Grants received	864 149	5 235
Sick pay	-	2 425
Others	-62	-
Total	**902 882**	**657 589**

Note 4 Employees, Staff Costs and Directors' Fees

Average Number of Employees

	2023-01-01-2023-12-31	Of which men	2022-01-01-2022-12-31	Of which men
Parent Company Sweden	13	10	11	8
Total Parent Company	13	10	11	8
Of which CEO	1	-	1	-
Of which board members	-	-	-	-
Subsidiary Australia	-	-	-	-
Total Group	**13**	**10**	**11**	**8**

The Executive Board consists of 1 employed CEO (1 year) and 6(6) remunerated members.

Salaries and Other Remuneration Broken Down by Country and Between Directors etc. and Other Employees

	2023-01-01-2023-12-31 Board and CEO	2023-01-01-2023-12-31 Others employees	2022-01-01-2022-12-31 Board and CEO	2022-01-01-2022-12-31 Others employees
Parent Company Sweden	1 806 743	7 727 538	1 239 049	5 758 689
Of which CEO	1 278 603		1 139 049	
Of which board fees	528 140		100 000	
Total Parent Company	**1 806 743**	**7 727 538**	**1 239 049**	**5 758 689**
Subsidiary Australia	-	-	-	-
Total Subsidiary	-	-	-	-
Total Group	**1 806 743**	**7 727 538**	**1 239 049**	**5 758 689**

Social security costs SEK 4,594,085 (2,993,687), of which pension costs SEK 1,716,564 (820,966).

Note 5 Depreciation, Amortization and Impairment of Tangible and Intangible Fixed Assets

	2023-01-01- 2023-12-31	2022-01-01- 2022-12-31
Group		
Depreciation according to plan broken down by asset		
Concessions, patents, licenses, trademarks	58 488	70 485
Equipment, tools and installations	96 722	44 881
	155 210	**115 366**
Impairment losses broken down by asset:		
Capitalized expenditure on research and development and similar activities	50 062 109	-
	50 062 109	-
	50 217 319	**115 366**

Parent Company		
Depreciation according to plan broken down by asset		
Concessions, patents, licenses, trademarks	58 488	70 485
Equipment, tools and installations	96 722	44 881
	155 210	**115 366**
Impairment losses broken down by asset:		
Capitalized expenditure on research and development and similar activities	50 062 109	-
	50 062 109	-
	50 217 319	**115 366**

Note 6 Other Operating Expenses

	2023-01-01- 2023-12-31	2022-01-01- 2022-12-31
Group		
Exchange losses on operating receivables/liabilities	234 977	529 047
Exchange rate difference	234 532	477 695
Total	**469 509**	**1 006 742**
Parent Company		
Exchange losses on operating receivables/liabilities	234 977	529 047
Exchange rate difference	234 532	477 695
Total	**469 509**	**1 006 742**

Note 7 Interest Expense and Similar Items

	2023-01-01- 2023-12-31	2022-01-01- 2022-12-31
Group		
Interest expense	570 891	136 238
Interest expense, accounts payable	546	1 426
Interest expense for taxes and duties	589	37
	572 026	**137 701**
Parent Company		
Interest expense	570 891	136 238
Interest expense, accounts payable	546	1 426
Interest expense for taxes and duties	589	37
	572 026	**137 701**

Note 8 Capitalized Expenditure for Development Work

	2023-12-31	2022-12-31
Group		
Accumulated acquisition values:		
- At the beginning of the year, development work	109 627 288	72 047 298
- New acquisitions	18 581 472	37 579 990
- Activated R&D grants	-18 347 030	-7 345 468
- Tax refund on development costs	-6 873 498	-
- Patents at the beginning of the year	6 802 488	5 318 981
- Year acquisitions patents	506 495	1 483 506
	110 297 215	**109 084 307**

Accumulated amortization and impairment losses:		
- At the beginning of the year	-3 637 521	-3 637 521
- Depreciation for the year	-50 062 109	
- Reclassification of patents IB	-395 678	-325 193
- Amortization of patents for the year	-58 488	-70 485
	-54153 796	**-4 033 199**
Carrying Amount at the End of the Year	**56 143 419**	**105 051 108**
Parent Company		
Accumulated acquisition values:		
- At the beginning of the year, development work	93 209 180	72 047 298
- New acquisitions	17 192 234	21 161 882
- Activated R&D grants	-18 347 030	-7 345 468
- Patents at the beginning of the year	6 802 488	5 318 981
- Year Acquisitions patents	506 495	1 483 506
	99 363 367	**92 666 199**
Accumulated amortization and impairment losses:		
- Amortization at beginning of year, capitalized expenditure	-3 637 521	-3 637 521
- Depreciation for the year	-50 062 109	-
- Amortization of patents at beginning of year	-395 678	-325 193
- Amortization of patents for the year	-58 488	-70 485
	-54 153 796	**-4 033 199**
Carrying Amount at the End of the Year	**45 209 571**	**88 633 000**

Note 9 Concessions, Patents, Licenses, Trademarks and Similar Rights

	2023-12-31	**2022-12-31**
Parent Company		
Accumulated acquisition values:		
- At the beginning of the year	-	5 318 962
- Reclassifications	-	-5 318 962
Accumulated amortization:		
- At the beginning of the year	-	-325 193
Reclassifications	-	325 193
Carrying Amount at the End of the Year	**-**	**-**

In 2022, patents have been moved to be included in the item Capitalized development expenditure.

Note 10 Machinery and Other Technical Installations

	2023-12-31	2022-12-31
Group		
Accumulated acquisition cost:		
-At the beginning of the year (Parent Company)	840 309	840 309
-New acquisitions	758 164	-
-At the end of the year	1 598 473	840 309
Accumulated depreciation:		
-At the beginning of the year	-794 241	-749 360
-Depreciation for the year	-96 722	-44 881
-At the end of the year	-890 963	-794 241
Carrying Amount at the End of the Year	**707 510**	**46 068**

Parent Company		
Accumulated acquisition cost: -At the beginning of the year	840 309	840 309
-New acquisitions	758 164	-
-At the end of the year	1 598 473	840 309
Accumulated acquisition cost: -At the beginning of the year	-794 241	-749 360
-Depreciation for the year	-96 722	-44 881
-At the end of the year	-890 963	-794 241
Carrying Amount at the End of the Year	**707 510**	**46 068**

Note 11 Shares in Group Companies

	2023-12-31	2022-12-31
Accumulated acquisition cost: -Company formation	78	78
Shareholder contributions	14 195 544	11 320 762
Carrying Amount at the End of the Year	**14 195 622**	**11 320 840**

Specification of the Parent Company's and Group's Holdings of Shares in Group Companies

Ownership share of the capital is referred to, which also corresponds to the share of the votes for the total number of shares. The parent company has assessed that a controlling influence exists in Subsidiaries as the company is 100% owned.

Subsidiary / Company name / Registered office	Number of shares	in %	2023-12-31 Carrying amount
Scandinavian Real Heart Pty, orgnr 629303788	2 018 264	100	14 195 622
Victoria, Austalia			
			14 195 622

Note 12 Prepaid Expenses and Accrued Income

	2023-12-31	2022-12-31
Group Prepaid rent	127 877	
Prepaid. leasing fees	70 000	12 500
Prepayment of insurance	9 648	9 374
Förutbetald kostnad Hydrix	1 228 105	1 276 056
Other interim charges	247 741	225 206
	1 683 371	**1 523 136**
Parent Company Prepaid rent	127877	
Prepaid. leasing fees	70 000	12 500
Prepayment of insurance	9 648	9 374
Other interim charges	247 741	211 027
	455 266	**232 901**

Note 13 Other Liabilities to Credit Institutions

	2023-12-31	2022-12-31
Group		
Maturity date, 2-5 years from balance sheet date	6 034 023	1 552 795
Maturity date, later than five years from the balance sheet date	318 897	-
	6 352 920	1 552 795
Parent Company		
Maturity date, 2-5 years from balance sheet date	6 034 023	1 552 795
Maturity date, later than five years from the balance sheet date	318 897	-
	6 352 920	**1 552 795**

Note 14 Accrued Expenses and Deferred Income

	2023-12-31	2022-12-31
Group		
Accrued vacation pay	1 133 215	633 461
Social security holiday pay liability	349 075	199 033
Other items	230 940	356 180
	1 713 230	1 188 674
Parent Company		
Accrued vacation pay	1 133 215	633 461
Social security holiday pay liability	349 075	199 033
Other items	230 939	356 180
	1 713 229	**1 188 674**

Note 15 Pledged Assets and Contingent Liabilities Group

Collateral Pledged

	2023-12-31	2022-12-31
Group		
Company mortgages	10 000 000	4 200 000
Total colleteral pledged Group	10 000 000	4 200 000
Parent Company	10 000 000	4 200 000
Company mortgages		
Total collateral pledged Parent Company	**10 000 000**	**4 200 000**

Note 16 Significant Events After the end of the Financial Year

Organizational Change

Magnus Öhman has taken over as Executive Chairman of the Board. Christer Norström remains on the Board as a member. Giovanni Lauricella and Stuart McConchie are also new members of the Board.

Note 17 Key Figure Definitions

Balance sheet total:
Total assets.

Equity ratio:
(Total equity + 79.4% of untaxed reserves) / Total assets.

Cash liquidity:

Current assets excluding stocks and work in progress / current liabilities.

Signatures

Västerås

Magnus Öhman
Chairman of the Board of Directors

InaLaura Perkins
Chief Executive Officer

Oliver Voigt
Member of the Board of Directors

Ulf Grape
Member of the Board of Directors

Azad Najar
Member of the Board of Directors

Christer Norström
Member of the Board of Directors

Solveig Bergström
Member of the Board of Directors

Giovanni Laruricella
Member of the Board of Directors

Stuart McConchie
Member of the Board of Directors

Our audit report was submitted on

GrantThornton Sweden AB Joakim Söderin Authorized Public Accountant.

The consolidated income statement and balance sheet and the parent company's income statement and balance sheet are subject to adoption at the annual general meeting.

REALHEART