ANNUAL REPORT 2022

Scandinavian Real Heart AB (publ)

556729-5588

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 Has the Word

During 2021 we made the strategic decision to build competencies and to add experience to our already excellent and talented team. In 2022, we build on that momentum and expanded our R&D activities to Australia, giving us access to TAH experts as well as to additional R&D funding. We also added new board members with extensive cardiac device commercialization experience, including Oliver Voigt, the former General Manager of SynCardia Europe, and Patrick NJ Schnegelsberg, the former COO of Occlutech Holding AG.

Now, and looking back at 2022, I am extremely pleased at the impressive results and outcomes these investments have yielded and what the Realhart team has achieved. Most importantly, the design of the Realheart TAH has evolved dramatically and we now have the clinical version of Realheart TAH, the design that we plan to use in human clinical trials. Not only does clinical version have a dramatically different appearance compared to its V11.2 predecessor but it has built in, automatic physiological controls.

In addition, in collaboration with Hydrix, we have started the development of a clinical controller, a small wearable computer that the patient will interact with.

These changes and improvements have resulted in a better performing and safer device. For example, a comparison of our TAH against the market leading device confirmed earlier results using computational modeling and showed that the Realheart TAH reduces damage to human blood by more than 50% vs. the market leading device.

But, the Company's most significant achievement came towards the end of 2022, when sheep implanted with the clinical version, reached survival times in the same range as our European competitor, with no signs of blood-related side effects.

These advances did not go unnoticed. The three cardiac surgeons who implanted the new Realhart device in sheep conveyed that the automatic physiological control of it represents a major improvement. And one of the surgeons, together with our TAH, was prominently featured in a show documenting the journey of a patient to her new heart that aired on ZDF, one of Germany's major TV channels.

Dr Libera Fresiello, an expert advisor to the EU on medical devices and an assistant professor at University of Twente, published a paper in the Journal Artificial Organs describing that the physiological pulsatile blood flow generated by the Realheart TAH can be finetuned by the heart rate, stroke volume, and percent systole – like the human heart.

Finally, during the year we have communicated our blood and other data to the clinical community at six conferences in Germany, Austria, Sweden, and in China.

Despite our impressive 2022 R&D track record and Realheart securing €2 million in innovation grants and loans, as well as the issuance of two additional U.S. patents, our share price remained under pressure. While market sentiment played a role, news of the first genetically engineered pig heart transplantation has clearly been a major confounding factor.
Many investors perceived that there was no longer a need for total artificial hearts. This is of course not the case. In fact, if genetically engineered pig hearts would become available, this would increase the bridge-to-transplant market segment which is currently limited by the lack of supply of donated human hearts.

Finally, Göran Hellers, the Chairman of the Board of Realheart, passed away unexpectedly in 2022 and we miss him immensely, both as a leader and as a friend. The best way for us to honor his memory is to ensure that we bring Realheart TAH to the market for patients and doctors. Thus, for 2023 my focus will be the continuation and acceleration of the preclinical studies needed to gather the results for us to enter human clinical trials.

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 United States, this means 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 hospital stays leads to significant costs for society, with healthcare and other social costs estimated to reach $70 billion US by 2030 in the USA alone.

The best therapy is a new heart, but the problem is that there are only about 7,000 donated hearts available each year for transplantation worldwide. This is because the donor must have died under special circumstances, be listed in a donor register, and match the recipient's tissue type. In other words, a patient needs a lot of luck to find a matching human heart for transplantation.

Organ transplantation, which is dependent on one patient dying to save another, is not a sustainable solution. New potential forms of treatment need to be developed through continuous research, both in terms of basic research 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 aim is not only to save lives, but to provide a good quality of life. It goes without saying that one should be able to live a normal life with a total artificial heart, it should seamlessly integrate into social life and everyday life situations.

The human heart consists of two pumps, one on the left and one on the right. Each pump consists of an atrium and a chamber. 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) that is designed to mimic the structure and function of the human heart. Its unique, patented design with two atria, two chambers and one AV-plane makes it possible to pump and deliver blood to the body's various organs in a natural way, just like the human heart.

Realheart® TAH is intended to be a permanent solution for patients with severe heart failure, but it will also be able to keep patients alive until a donated human heart is available for transplantation. The benefits with an artificial heart is that it is available immediately off-the-shelf, and aside from 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 consist of an atrium, a chamber and two mechanical valves. Blood is pumped in the same way as in a human heart. The aim of the design is 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 system with two separate pumps, the placement of the pumps can be adjusted to match the patient's unique chest anatomy.

THE CONTROLLER - THE BRAIN OF THE SYSTEM

The controller is the brain of the system and controls the blood flow for the two pumps separately to maintain balance between circulation to the body and to the lungs. The control system also receives information from the pressure sensors located 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 is mounted on a belt together with two batteries, but it can also be carried in a bag. The overall weight of the controller and the battery belt is approximately 2.5 kg.

LONG BATTERY LIFE

The two batteries for the system are mounted on the same belt as the controller unit, and they have a combined battery life of up to 12 hours. The controller also has an internal emergency battery in case the patient accidentally disconnects both external batteries at the same time. The energy-efficiency of the system opens up the future possibility for use of wireless energy transfer via the skin as a follow-on product.

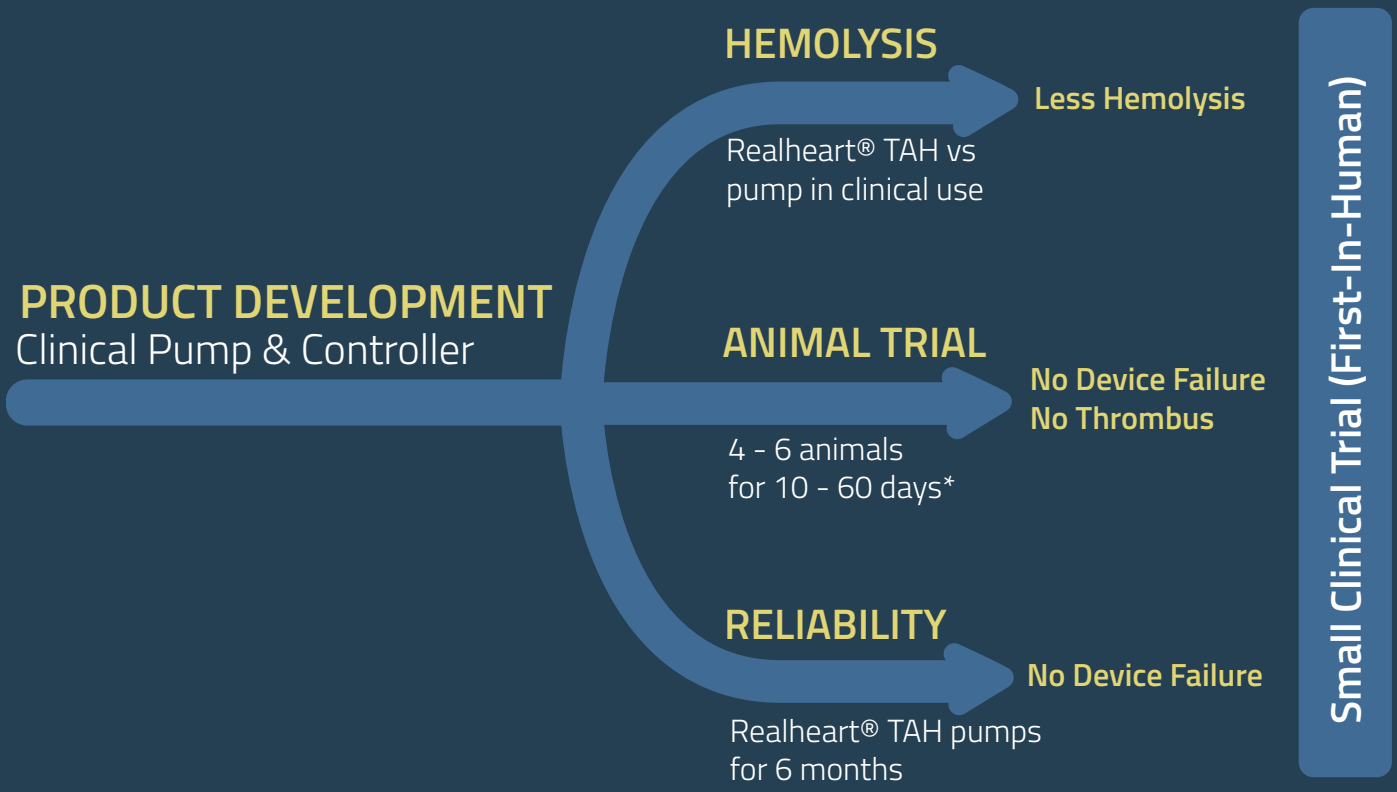
A THIN POWER CABLE

The power cable that connects the pumps to the controller is made of a soft, flexible material that allows natural body movements. The aim of having only one thin power cable is to minimize the risk of infection, which is a common complication during heart pump treatment.

Development Plan for Realheart

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



**Estimated lower ranges for EU and upper ranges for US*

2022

PRECLINICAL STUDIES
Blood tests, animal studies and endurance tests are performed on the clinical version of Realheart TAH.

2023

CLINICAL TRIAL PREPARATION
Completion of pre-clinical studies and documentation to obtain approval to conduct clinical trials.

2024

SMALL CLINICAL TRIAL (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. Interest received from physicians at clinics in Germany, Belgium, and Italy.

PRODUCT DEVELOPMENT
The results of clinical trials may result in modification of specific product components. Focus will also be on upscaling production to be able to produce many units in the future.

2025

BTT IDE (PMA) STUDY AND CE-MARK
An IDE (Investigational Device Exemtion) study on patients on the transplant waiting list (bridge to transplant: BTT) is initiated for the application for FDA approval for market launch.

The company estimates that a clinical trial including 10-20 patients would be suitable for the CE-mark.

2026

MARKET DEPLOYMENT ACTIVITIES
Initiate go-to-market activities, establish networks of international distributors and launch Realheart TAH 2026.

Dr. Oliver Voigt

”I Have Always Been Fascinated by the Concept of a Mechanical Heart”

Dr. Oliver Voigt joined Realheart’s Board of Directors in 2022, bringing 25 years of experience in the field of artificial hearts and mechanical circulation support systems. Oliver was the Managing Director in Europe for SynCardia (TAH) and successfully managed the US company’s international expansion as it introduced its TAH in Europe and the Middle East. Syncardia’s TAH was first approved in the US in 2004 as bridge to transplant for patients with end-stage biventricular heart failure. It has been used in over 2,000 patients worldwide.

> I decided to join Realheart because their innovative technology best mimics physiological function and their experienced and dedicated team can truly take TAH to the next level, improving the lives for many patients.

What inspired you to pursue a career in the field of artificial hearts and mechanical circulation support, and what have been some of the highlights of your career so far?

I was always fascinated by the concept of a mechanical heart. While I was studying Biomedical Engineering, I saw in Star Trek (TNG) that Captain Jean-Luc Picard had an artificial heart. I was surprised that other organs there were healed or rebuilt, but not the heart. My university was next to the German Heart Institute Berlin and during an open house I met Prof. Bücherl - a true pioneer and inventor of the Berlin TAH. After I finished university, I took the chance to work at the German Heart Institute as Clinical Support Engineer for a new project where the renowned heart surgeon Dr. DeBakey and David Saucier from NASA had co-developed a new type of an artificial heart or more precisely, a left ventricular assist device (LVAD). I worked closely with the NASA engineers and supported the implants in Europe to achieve CE approval. Afterwards I became in charge of the European clinical support.

Within the following years I pursued an MBA and also got involved in Business Development. The biggest highlight in my career, however, was when I got involved in SynCardia - the US-based manufacturer of the Total Artificial Heart. I was given the opportunity to expand their international business, meaning that I was able to work actively to make this technology available to more patients in need of a TAH. I founded and managed the European subsidiary and successfully expanded the business internationally. By the way, the artificial heart from Cpt. Picard was made of duritanium.

What are your hopes for the future of artificial heart technology, and how do you see Realheart contributing to this?

To date, the SynCardia TAH accounts for more than 95% of all TAH Implants ever done globally or for 98% of total patients' time on support. The development started in the early 1970's when Dr Willem Kolff had moved to Utah, and it was first implanted in 1982. Since then, its design has not changed. The concept of organ perfusion and recovery with pulsatile flow has been proved. I would like to use my knowledge and experience for a modern TAH that has improved quality of life and durability. The Realheart TAH is the most promising device in development right now.

What are some of the challenges with bringing the Realheart TAH to market?

The focus now is on pre-clinical studies to pave the way for the regulatory approval process. We are currently conducting animal studies, testing the function and safety of the heart while surgeons are also presented with an opportunity to get acquainted with the procedure. Thereafter we need to demonstrate that our TAH is safe and effective in clinical trials before we can receive approval to sell it to hospitals and other healthcare providers.
Another important factor that is a bit out of the limelight right now, is serial production, which allows increased production to meet the needs of patients waiting for a TAH. All in all, there are many factors that need to be addressed, but I am convinced that we are well equipped to get all pieces in place.

How will Realheart approach the market, once the TAH has received market approval?

In those countries where it is possible, Realheart plans to sell directly through regional sales representatives, who are trained cardiovascular sales specialists supported by an in-house support team. Clinical specialists will conduct educational seminars, assist during implantations, and resolve any clinical questions. In other regions, we will work with qualified agents and distributors.

How will surgeons learn to perform the TAH implantation procedure, and what training and support will be provided to ensure successful outcomes?

Surgeons will learn the procedure through training programs and hands-on experience. Realheart will provide training to surgeons on the implantation procedure, and will also assist with support during implantations, an area in which I personally have a lot of experience in and look forward contributing to.

How long do you anticipate it will take for surgeons to become familiar with the TAH implantation procedure?

The successful implantation of a TAH is a team effort. Realheart TAH was designed to be easier to implant than marketed TAHs, so that surgeons will learn the technique in a short period of time. We will also provide proctor support if requested. Others in the team, those who operate the driver/console and manage the patient post-op on the ICU, will be trained on a simulator. A TAH allows to fully control hemodynamic functions whereas an LVAD for instance, is dependent on proper right heart function. We will ensure that everyone involved will get adequate training to ensure good patient outcomes.

Milestones During the Year

Realheart's CEO Elected to the **ISMCS - Board of Trustees**

Realheart's CEO Ina Laura Perkins was during the year elected to the Board of Trustees of the International Society for Mechanical Circulatory Support (ISMCS). The announcement was made at the society's annual conference in Hannover, Germany, May 24 to 27.

Beeing part of the ISMCS Board is a great opportunity for Ina Laura and Realheart to be among these extremely knowledgeable people and to represent Swedish research in general and her own lessons learned in developing Realheart® TAH specifically, in this context.

> It is our pleasure to welcome Ina Laura Perkins to the Board. We look forward to her being a bridge between the industry and research field with her outstanding experience and knowledge in developing a total artificial heart and joining us in promoting the mechanical circulatory support field throughout the world.
>
> Professor Toru Masuzawa,
> President of the ISMCS

Realheart Hosted an **International** Conference on **Artificial Hearts**

On June 15, Realheart hosted an international conference on artificial hearts to share the research results generated within the company and its network of scientists during the development of the Realheart TAH. The conference took place in Västerås, where the company has its headquarters and development labs.

The conference was multidisciplinary, and participants range from engineers specializing in electronics, computer systems and mechanics to medical professionals such as biomedical analysts, nurses, perfusionists and surgeons. In addition, there are investors within the life science industry who can bring a financial perspective to the discussions. Students, graduate students, professors, and senior industry executives also participated. With 40% of female speakers, the conference also contributes to the company's work towards the UN's sustainability goals by striving to increase women's influence in technology in general and the heart pump industry specifically.

Australian **Subsidiary**

In the first quarter of 2022, Realheart set up a subsidiary in Australia to take advantage of the knowledge and financial benefits offered by the Australian market related to product development and clinical trials.

Australia is one of the top five markets for artificial hearts. Several heart pumps including an artificial heart have been developed in the country and thus there is a large pool of knowledge among academic institutions, consultants, suppliers, and test centres. It was this, among other things, that led Realheart to choose Australia's Hydrix as their partner in developing the control unit for its artificial heart recently.

The subsidiary is led by Dr Marianne Hellers, who holds a degree in Microbiology from Stockholm University and has extensive experience in the Australian life science community as well as a large network that can be valuable for Realheart in taking advantage of the innovation support and research and development opportunities available in the region.

Oliver Voigt, Patrick Schnegelsberg and Solveig Bergström - Board Members of Realheart. At the conference in Västerås

> It was great to showcase Västerås and promote Sweden to researchers from countries that are strong in this field of research – and important markets for heart pumps – such as Belgium, Germany, Turkey, the UK, and the US.
>
> CEO Ina Laura Perkins

Recruitments

Lead System Engineer. Chief Financial Officer. Senior Mechanical Engineer. Clinical Strategist & Electronics Expert.

Realheart has made several important recruitments thorough the year. **Bruce Wedding** came from Texas to start as the **Lead Systems Engineer**. His most recent role was as a senior software engineer at LivaNova, PLC. Thanks to Bruce, the product development team has been strengthened. Bruce contribute with over 30 years of diverse software engineering and project management experience. He has been team leader in the development of a Class III implantable medical device and has experience from active implants, including cardiovascular applications. He has also been trained on regulatory requirements for software development, verification and validation of medical devices and other mission-critical applications.

Realheart also recruited **Jonas Caspari Bark** as its new **Chief Financial Officer**. He joined Realheart from a similar position with Ecokraft Sverige AB and has previously, among other things, worked in various roles within the ABB group. Jonas has previous experience of getting onboard at this phase of the development process and he hopes to be able to contribute to the company's success.

Erik Hammarstrand, an experienced lead mechanical engineer, has joined as a **Lead Mechanical Engineer** after working as a consultant for Realheart since 2020. With a diverse background in industries like GE Healthcare, Thermo Fisher Scientific, Westinghouse, and ABB, Erik brings strong expertise in CAD and agile methodologies. Alongside his technical skills, Erik is well-versed in regulatory compliance, ensuring his designs meet legal and safety requirements for reliable and safe products.

Other recruitments during 2022 was Australian **consultant Sara Diab**, with the role to support the company's regulatory and clinical strategy. Sara is a former IVA nurse who now works as a medical device specialist with over 10 years of experience in the development of artificial hearts. And also **electronics expert Nicolas Barabino**, aimed to support the development of the clinical control unit for the Realheart TAH. Nicolas is an expert in medical device innovations such as active implants and various forms of life support devices.

Realheart Receives **two More US Patents** for its Pump Concept

In may the company was granted a new US patent that protects the entire principle behind it through 2037. In addition, the company has obtained similar protection for its sternal prosthesis, a separate product designed to facilitate chest surgery.

This is extremely valuable as it provides a strong two-layer protection for the company's artificial heart in one of the world's most important markets and further strengthens the overall patent portfolio.

The second patent protects Realheart's sternal prosthesis, a zipper-like innovation that allows the chest to be reopened and closed if necessary after surgery. It is also intended to relieve pain. This patent too has already been approved in Europe. Both new patents are valid until 2037.

Grant Applications **Approved**

Vinnova
MSEK 4

Realheart and KTH have received a grant of SEK 4 million from Vinnova to jointly develop a Swedish hybrid simulator that will enable advanced testing of algorithms that control Realheart's artificial heart, but also will contribute to increasing Sweden's overall competitiveness in cardiovascular device innovation.

Eurostars 3
MSEK 10

Realheart and Berlin Heart have jointly been awarded approximately SEK 10 million in funding from the European program "Eurostars 3" to develop an automated production process of membranes, which are critical components of the Realheart total artificial heart.

Almi - Additional Loan
MSEK 7.6

Realheart has been granted an additional loan from Almi of SEK 7.6 million, which will aid in securing a continuos rapid product development targeting clinical trials. Not all companies qualify for this loan, and we are very greatful for the support from Almi.

Blood Results Achieved (In-Vitro)

Since 2019 the Realheart® TAH prototypes have been tested against clinical comparator devices and have been shown to cause less blood damage.

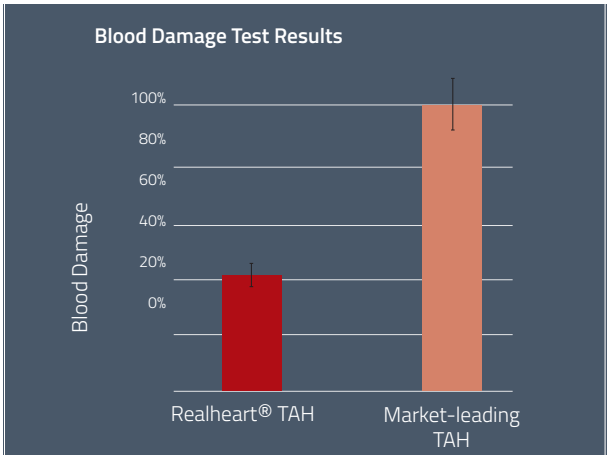
The early version of Realheart® TAH (V11C) performed better than both the large and small Reinheart TAH devices (competing solution in development) when tested with pig blood.

The following version (V11.2) showed better results than the market leader SynCardia (see graph on the below), meaning that Realheart® TAH hemolysis was less than half of SynCardia's[1] when tested with human blood.

The innovative Realheart® TAH concept is thus gentler to the blood than other devices in current clinical use.

That the Realheart concept should be good at handling blood we already knew from computer simulations by University of Bath of the early Realheart V11C version, but in 2022 the first study of the follow-on version V11.2 was completed against the market leading device using human blood. The outcome: less than half the blood damage, which was communicated to the clinical community at 6 conferences in Germany, Austria, Sweden, and China.

[1] *Clinical comparator/Market leading TAH*



Faisal Zaman, Biomedical Engineer, in Realheart's blood lab at Karolinska University Hospital in Stockholm.

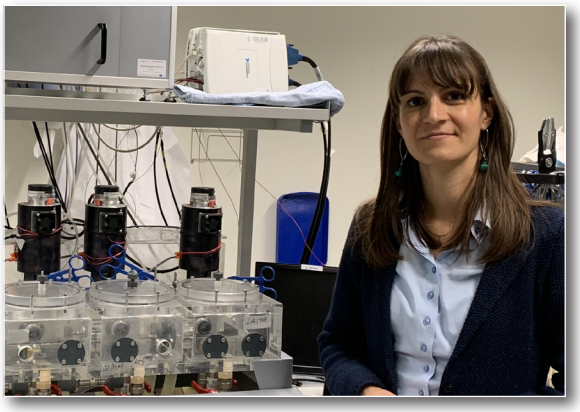
Libera Fresiello's Research Presented in the Journal Artificial Organs

Realheart is collaborating with a number of international researchers to develop the world's first four-chamber artificial heart. One is Professor Libera Fresiello at Katholieke Universiteit Leuven and University of Twente. The results of her study of the Realheart® TAH in a hybrid simulator has now been published by the journal Artificial Organs.

The outcome of her studies shows that the Realheart® TAH produces physiological pulsatile blood flow that can be finetuned by the heart rate, stroke volume, and percent systole – like the human heart. The two artificial ventricles work independently and if controlled properly, they can attain a right-left balance.

This is exactly what the company aim to achieve. This research will therefore be of great importance in its work. The fact that it is now also presented in a scientific journal such as Artificial Organs will further contribute to greater awareness, trust, and interest in Realheart's artificial heart.

> "When the company asked me to challenge the automatic control and try to break it, I tried, and I couldn't break it. I must say I am impressed.
>
> Prof. Libera Fresiello



Professor Libera Fresiello & the Hybrid Simulator. Katholike Universiteit Leuven in Belgium and University of Twente in the Netherlands.

Animal Studies (In-Vivo) Update

At the end of 2022, Realheart achieves a new milestone in animal studies - from 24 hours until 4-days survival. In addition, several important performance criteria can be confirmed[1].

After the last implantation, the animal was able to stand up and eat. In addition, Scandinavian Real Heart was able to confirm key TAH performance criteria, including:

No Haemolysis (damage to red blood cells)
Haemolysis due to mechanical stress caused by artificial hearts on blood cells is a major cause of severe side effects impacting survival of artificial heart patients over time.

No Thromboembolic Events (blood clots)
Good blood flow and low mechanical stress in the TAH minimise the risk of very serious, and life-threatening consequences for patients, including stroke.

High Pumping Capacity and Good Right-left Balance
The TAH can pump eight litres of blood per minute. This is significantly more capacity than what an adult human needs. The balance between blood flow from the right and left ventricles is crucial for survival.

Short Procedure
A heart-lung machine used during the implantation of the TAH was disconnected after less than 2.5 hours. The extended use of a heart-lung machine during open heart surgeries poses considerable safety risks to patients. Realheart is developing its TAH to reduce time on a heart-lung machine and overall procedure times, therefore improving overall safety.

[1]This is communicated early 2023, when all results have been analyzed and compiled.

During second quarter the company announces that the production of the clinical version of Realheart's artificial heart – the one that will eventually be used by human patients – is almost completed. and will now be tested in a series of animal trials.

This is a major step forward in the development process and the company has therefore strengthened the operating team. There are now three highly experienced cardiac surgeons working together: Professor Bart Meyns, Dr Dilek Gürsoy and Dr Joeri van Puyvelde.

The veterinary protocol has also been updated and an expanded animal care team, with ten years of experience in the care of animals with artificial hearts, is now present, responsible for the selection, preparation and aftercare, including medication.

The animal studies can be described as a team effort with many people involved where everything needs to flow smoothly between surgeons, the person operating the heart-lung machine, engineers, veterinarians, and animal caretakers all the way from preparation to aftercare.

> "I am incredibly pleased with how much we have been able to achieve after just a few implantations of our TAH. The fact that we see no signs of haemolysis or blood clots, combined with the fact that we can achieve good left-right balance, a pulsatile blood flow, and natural blood pressure, is extremely satisfying.
>
> CEO Ina Laura Perkins

Realheart **International Marketing**

During the year, Realheart has appeared at several international arenas to present the company and the results achieved. Here are some of the most relevant ones.

Fokus Patient Forum

Realheart's CEO Ina Laura Perkins was invited to give a presentation entitled "When organs are not enough" in a section covering the future of organs and organ donation, at the "Transplantation Forum" organised by Fokus Patient in collaboration with Livet som Gåva and the European Society of Organ Transplantation, ESOT. The Transplantation Forum was part of a three-day forum where healthcare professionals, patients, companies, and other interested parties could get an overview of developments and discuss current issues in the field of transplantation in Sweden and internationally. Participants included Dr Bartley Griffith, the American surgeon who performed a high-profile pig heart transplant for a human.

European Society of Artificial Organs (ESAO/yESAO)

Three of the company's engineers were presenting their research at the conference. CEO Ina Laura Perkins and CTO Thomas Finocchiaro were attending to make contacts and represent the company. Joseph Bornoff and Faisal Zaman were awarded the 2022 yESAO Exchange Award and received this at the conference. yESAO Exchange Awards is a stipend for young researchers with the aim of building international networks and producing advancements in the field of research.

Blood Injury Conference

In september Realhearts biomedical engineer Faisal Zaman was attending a conference on blood damage in heart pumps, organised by the University of Rostock in Germany. Faisal presented the company's work on developing methods to measure blood damage in pulsating pumps. One part is measuring haemolysis, i.e. the leakage of haemoglobin from red blood cells, and here they want to achieve the lowest possible value. Faisal presented the results of these tests, the most important of which is that the Realheart® TAH haemolysis value is less than half that of the leading product on the market today.

International Society for Mechanical Circulatory Support (ISMCS)

CEO Ina Laura Perkins was holding a presentation at the annual meeting for the International Society for Mechanical Circulatory Support in Hannover. She gave an update on the developing process and also shared the results achieved so far through blood tests. Blood testing is a key activity in Realheart's development work, as the aim is to achieve as low blood damage as possible to move away from the side effects that have so far hampered the use of artificial hearts as a treatment option.

International Conference of Pharmacy and Medicine (ICPM)

Realheart's founder Dr Azad Najar was a speaker at the ICPM conference in the United Arab Emirates. ICPM stands for International Conference of Pharmacy and Medicine and this is the second time Azad Najar has been invited to speak. Azad, who is from Iraqi Kurdistan, has received a lot of attention for his innovation in this region. in the Middle East, people are falling ill at a younger age and should have many more years to live.

Critical Heart Disease Congress (CHDC) in China

Realheart is proud to have been invited to speak at the 2022 Annual Meeting of Chinese Mechanical Circulatory Support, the 3rd Critical Heart Disease Congress (CHDC) in China.

CEO Ina Laura Perkins presented the Company at the conference's parallel forum. On the same occasion, she also gave an introduction to the ISMCS - International Society for Mechanical Circulatory Support (ISMCS). The conference shared experiences, knowledge and cutting-edge research in the field of cardiovascular disease in general and artificial hearts specifically.

German Documentary

Realheart's artificial heart was featured in a German TV documentary about heart disease and new scientific developments, broadcasted on ZDF. The documentary, entitled "Horst Licther: Mein Herz, mein Motor", follows a heart failure patient on the waiting list for a transplant. It also highlights the shortage of donor hearts and the need for new technology in artificial hearts.

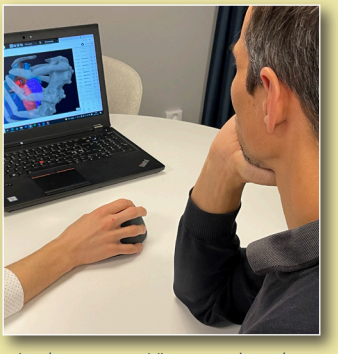
Both Realheart's founder Dr Azad Najar and Dr Dilek Gürsoy, who is part of the company's surgical team for the ongoing animal studies, are interviewed in the programme. The general interest in the company's artificial heart is high among patients, doctors and investors alike, and this kind of media coverage further helps to raise awareness of the prevalence of heart failure today, as well as the need for better medical devices to treat patients. It's very important for Realheart to be able to showcase the TAH in this kind of context.

Joseph Bornoff, University of Bath and Faisal Zaman, Realheart.

Virtual Patients

Realheart has been pilot testing the German Virtonomy web platform v-Patients containing 3D anatomical models of heart failure patients for some time. Now the company is moving forward with a full license and more patients to test the clinical version of its artificial heart virtually and collect data in preparation for human clinical trials and the subsequent market launch. This will bring significant commercial benefits. The generated data can not only be used in the application for approval to start clinical trials but also presented in scientific contexts to continue building interest in Realheart TAH. In addition, the collaboration will allow the company to connect with clinicians, hospitals and specialists who may be potential future customers.

Virtonomy, based in Munich, Germany, helps companies shorten the time to market for medical products by allowing them to conduct data-driven studies on virtual patients in a database continuously increased by new patients reflecting anatomical variability, demographic diversity, and pathological conditions. Digital test methods can speed up the pre-clinical and clinical phase, a process supported by the FDA and corresponding EU institutions.



Oliver Chu and Thomas Finocchiaro, learning how to use Virtonomy's web platform v-Patients, containing 3D anatomical models of heart failure patients.

The Best Controller & the Most **Suitable Sheep**

The controller that Realheart has used so far to test and refine the design in bench and animal trials was developed in-house, but to move to humans, a more advanced one is needed as it will be used by the patients themselves without supervision from healthcare professionals or experts.

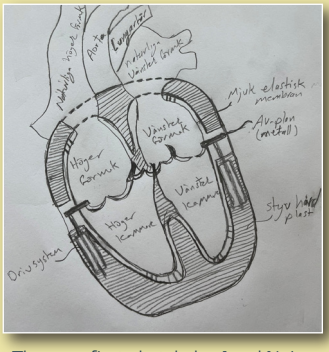
During 2021, Realheart started a collaboration with the Australian company Hydrix, which specialises in the development of control systems for heart pumps. Realheart has decided to equip patients in the first clinical trial with the full version of the controller – a kind of remote control – instead of a simpler version as previously envisaged. This will benefit patients and shorten the overall development time of the controller but will delay the human trial.

In spring 2022, Realheart was conducting a series of implantations in sheep to test the newly developed clinical version of its artificial heart. However, in preparation for the first surgery, it was discovered that the sheep made available at the lab did was not suitable for the surgery. The first surgery was therefore postponed until early June to prepare a new animal. It was during a preliminary test operation in a virtual environment that the team discovered that the intended animal was not suitable to undergo the surgery. Virtual implantation techniques are widely used prior to artificial heart treatment in humans, precisely because we all look different inside.

Realheart Initiates Collaboration With Researchers at KTH

Realheart has initiated collaborations with Lisa Prahl Wittberg and Seraina Dual, both researchers with expertise in heart pumps at the Royal Institute of Technology, KTH, in Stockholm. These collaborations has brought additional expertise to the company in the areas of blood testing and evaluation of the control unit for the clinical version of the Realheart TAH, as well as in the company's research on new products. Through these new collaborations, the company aims to strengthen Sweden's international competitiveness in research and development of heart pumps. It is therefore an advantage if students learn about artificial hearts and the specialist skills required in this field early on in their education.

Realheart has collaborated with KTH before. When founder Azad Najar began sketching what would become Realheart in 1999, the basic idea was to develop an artificial heart that mimics the human heart. This idea was based on flow analyses conducted by Professor Said Zahrai at KTH.



The very first sketch, by Azad Najar.

Realheart® TAH today.

> "At present we recruit mostly internationally to find the skills we need for our growth, but it would be beneficial to be able to find them at home in the future.
>
> We want to strengthen Sweden's international competitiveness in research and development of heart pumps. It is therefore an advantage if students learn about artificial hearts and the specialist skills required in this field early on in their education.
>
> Ina Laura Perkins, CEO

Realheart Hires **Investment Advisor** in the UAE

Realheart has partnered with an experienced investment advisor in the UAE, who will help the company meet the high level of interest in the product and the company in the Middle East. There is particularly strong interest in the Middle East. This is partly due to the attention given to the inventor and founder of Realheart, Azad Najar, who himself was born and raised in Iraqi Kurdistan. Another contributing factor is that heart failure affects many in the region – and often at a younger age than in the West – while few transplants are performed.

New **Key Roles** at Realheart

Jonas Caspari Bark,
Chief Financial Officer

> Realheart's artificial heart is a super exciting product that will help save a lot of lives in the future. I am really looking forward to being involved in the work towards commercialisation.

Jonas Caspari Bark is the company's new Chief Financial Officer (CFO).

What was your position before you came to Realheart?
I had similar position at Ecokraft Sverige AB and I have, among other things, worked in various roles within the ABB group.

What will be your contribution to the company?
I have previous experience of getting onboard at this phase of the development process and I really hope to be able to contribute to the company's success.

What do you see as the company's biggest challenge going forward?
Like all other Medtech companies, financing will most likely be a challenge until we have revenues from sales.

Bruce Wedding,
Lead Systems Engineer

> When I learned about the great work Realheart is doing, developing the world's first four-chamber heart, I had to be a part of it. I've helped develop many medical devices which make people's lives better but none more important than Realheart's artificial heart. I am excited to contribute to the team with my experience architecting and designing safe, robust, Class III medical device software and firmware.

Bruce Wedding is the company's new Lead Systems Engineer.

What was your role before you came to Realheart?
My most recent role was as a senior software engineer at LivaNova, PLC. So I moved from Texas to Sweden, to start my work at Realheart.

What experience do you have, that will be valuable for the company?
I have more than 30 years of diverse software engineering and project management experience. In my career, I've been part of teams that have taken implantable and other Class III medical devices through the entire product life cycle, from R&D to shipped products approved for use worldwide.

I have experience and understanding of regulatory requirements for software development, verification and validation of medical devices and other mission-critical applications.

Why did you chose Realheart?
I can't think of a more important mission than that of RealHeart. While my years in medical device has benefitted the lives of tens of thousands of people, there is just something special about giving a new heart to people dying of heart failure. The Realheart TAH will not only give life back to these people, but will give them a life with freedom and mobility. I can't think of a better calling.

Figures and Facts 2022

2 037
Realheart has patent protection on the heart pump construction in several important markets until 2037.

5
Combined expertise from five other artificial heart projects.

33 183 461
Total number of shares in the Company at the end of the year.

2
During the year, the company was granted two additional patents in the US. In total, this constitutes eight patent families.

64 million
The number of people in the world that are suffering from heart failure.

4 279
Number of shareholders in the Company at the end of the year.

7
Number of collaborating academic institutions.

8 000
So few transplants are available annually worldwide.

Board of Directors' Report

The Board of Directors and the CEO of Scandinavian Real Heart AB (publ), 556729-5588, with its registered office in Västerås, hereby submit an annual report for the financial year 2022-01-01 - 2022-12-31.

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 the blood flow pattern and function of the natural human heart, which creates the possibility of a long-term 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 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 to 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 2022, 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 Overview

Amounts in KSEK	2022-12-31
Balance sheet total	119 816
Equity ratio	81%
Cash liquidity	71%

Definitioner: se not 17

Parent Company Overview

Amounts in KSEK	2022-12-31	2021-12-31	2020-12-31	2019-12-31	2018-12-31
Balance sheet total	111 229	117 815	78 045	66 614	27 425
Equity ratio	88%	95%	92%	89%	70%
Cash liquidity	95%	1 032%	667%	603%	111%

Definitions see note 17

Significant Events During the Financial Year

Research and Development Activities
Work on further developing the heart pump for long animal tests, establishing new supplier and partner collaborations and partnerships and to continue to work with the FDA's requirement specification. 2022 has been dominated by a series of dominated by a series of animal trials with the clinical version of the company's artificial heart where Realheart gradually increased the survival time from the previous milestone of one day to four days.

In 2022, the subsidiary Scandinavian Realheart Pty. located in Australia has started its operation. The subsidiary's task is to, in collaboration with Hydrix Pty, be responsible for the development of the control unit (external and implant). Hydrix is a world leader in the development of control units for medical devices. Australia also has a favorable tax incentive for R&D where up to 43.5% of the of the investment can be recovered.

During the year, Realheart has, together with KTH, developed a patient simulator that will allow for enable advanced tests of the control algorithm that controls Realheart's artificial heart, but also contribute to increase Sweden's competitiveness when it comes to assistive devices for cardiovascular disease in general.

Realheart and Berlin Heart have started a joint project that will develop an automated manufacturing process for the production of membranes. This will enable future serial production in large in large volumes with extremely tight tolerances.

During the year, the company has recruited Jonas Bark, CFO, Bruce Wedding, Lead Systems Engineer and Erik Hammarström, Senior Mechanical Engineer in order to increase the pace of development work.

Government Relations

In 2022, the company has continued discussions with the Notified Body that specializes in class III medical technology to meet EU requirements for clinical studies. The work to meet the requirements of the US authority FDA's requirements continues in parallel.

Patent Protection

The company has granted patents on the pump principle in the EU, USA, China, India, UK, Australia, and Japan. In addition, the company has filed a further series of patent applications in recent years.

In total, this constitutes eight patent families. During the year, the company was granted two additional patents in the US.

Financing

As part of securing continued development, the company was granted an additional loan from Almi of 7.6 MSEK, which will be paid out in 2023.

Realheart and Berlin Heart were together granted approximately 10 MSEK in grants from the EU program ''Eurostars 3'' for a joint project that will develop an automated manufacturing process for the production of membranes, a critical component of Realheart's artificial heart. The grant will be paid out during the period May 2022 - April 2024.

Realheart and KTH were awarded a grant of 4 MSEK from Vinnova to jointly develop a Swedish hybrid simulator. The grant will be paid out during the period July 2022 - December 2023.

Significant Events After the end of the Financial Year

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

Financing
Warrants of series TO1 were also exercised, which provided the company with approximately 4.2 MSEK before issuing costs.

Expected Future Development

Expected Future Development and Significant Risks and Uncertainties
Realheart's focus is now on getting through the pre-clinical phase (Hemolysis, GLP studies in animals and endurance tests) to be able to start clinical studies. This means that the company must finalize the the version of both the controller and the heart pump that will be included in these tests. Realheart must also conduct parallel 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 is continuously working with different scenarios to ensure the company's future operations. With a maintained high rate of development the current liquidity is sufficient to finance the company into the second quarter of 2023, but depending on the development, the company can quickly adjust its cost base and activities so that the liquidity is sufficient until the end of 2023.

In order to solve the company's more long-term financing needs, Realheart is continuously working to evaluate alternatives for further capitalization of the Company. One possibility is to finance the Company via equity from financially strong investors as well as from other sources such as EU grants and non-profit foundations.

Ownership

Shareholders	Numbers of Shares	Votes (%)	Capital (%)
Najar Medical & Invention AB	3 262 635	9.83	9.83
Eskilstunahem Fastighets AB	1 650 006	4.97	4.97
Avanza Pension	1 478 568	4.46	4.46
Ålandsbanken ABP (Finland) Svensk filial SEBP6	801 710	2.42	2.42
Najar, Bilend	516 263	1.56	1.56
Forslund, Lars	489 474	1.48	1.48
Nordnet Pensionsförsäkring AB	468 216	1.41	1.41
Smartgroup Holding AB	417 316	1.26	1.26
Ewerth, Staffan	350 000	1.05	1.05
Raux, Gilbert	314 756	0.95	0.95
Others	23 434 517	70.61	70.61
Total	**33 183 461**	**100.00**	**100.00**

Amounts in SEK

Equity

GROUP	Share capital	Other contributed capital	Other equity including profit for the year
Opening balance 2022-01-01, parent company	3 318 346	164 712 421	-56 740 556
Changes directly against equity			
Translation differences			-1 913
Transactions with owners			
Stock options		344 835	
Transfer between items in equity			
Profit for the year			-13 987 911
Equity at 2022-12-31	**3 318 346**	**165 057 256**	**-70 730 380**

Equity

PARENT COMPANY	Share capital	Fund for development costs	Share premium reserve	Retained earnings	Profit for the year
Opening balance 2021-01-01 (22 558 459 shares)	2 255 846	50 062 104	115 695 766	-87 498 488	-8 820 671
Provision for development fund		18 347 669		-18 347 669	
New share issue	1 062 500		49 016 655		
Diposition according to decision by the AGM				-8 820 671	8 820 671
Result for the year					-10 483 500
Equity 2021-12-31	**3 318 346**	**68 409 773**	**164 712 421**	**-114 666 828**	**-10 483 500**
Opening balance 2022-01-01 (33 183 461 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	
Stock options			344 835		
Diposition according to decision by the AGM				-10 483 500	10 483 500
Result for the year					-13 810 029
Equity 2022-12-31	**3 318 346**	**82 226 190**	**165 057 256**	**-138 966 746**	**-13 810 029**

Proposal for Allocation of the Company's Profit or Loss

The Board of Directors proposes that unrestricted equity, 12 280 481 SEK, be appropriated so that 12 280 481 SEK is carried forward. No dividend will be paid to the shareholders.

Amounts in SEK	
Share premium reserve	164 712 421
Retained earnings	-138 621 911
Result for the year	-13 810 029
Total	**12 280 481**

Income Statement

(SEK)

GROUP	Not	2022-01-01 2022-12-31	2021-01-01 2021-12-31
Income			
Operating income		10 000	-
Other operating income	3	657 589	-
		667 589	**-**
Operating Expenses			
Purchased services		-8 884 613	-
Other external costs		-15 632 223	-
Personnel costs	4	-10 041 161	-
Capitalized expenses on own account		21 161 883	
Depreciation and impairment of tangible and intangible assets	5	-115 366	-
Other operating expenses	6	-1 006 742	-
			-
Operating Profit / Loss		**-13 850 633**	**-**
Interest income and similar profit/loss items		423	-
Interest expense and similar income items	7	-137 701	-
Profit/loss after financial items		**-13 987 911**	**-**
Profit / Loss Before Taxes		**-13 987 911**	**-**
Profit for the Year		**-13 987 911**	**-**

Balance Sheet

(SEK)

GROUP	Not	2022-12-31	2021-12-31
ASSETS			
Fixed Assets			
Intangible Fixed Assets			
Capitalized expenditure on development, patents licences and trademarks	8	105 051 108	-
Tangible Fixed Assets			
Equipment, tools and installations	10	46 068	-
Total Fixed Assets		**105 097 176**	-
Current Assets			
Current receivables			
Other receivables		1 936 905	-
Prepayments and accrued income	12	1 523 136	-
		3 460 041	**-**
Cash and bank balances		11 259 038	-
Total Current Assets		**14 719 079**	**-**
TOTAL ASSETS		**119 816 255**	**-**
SHAREHOLDER'S EQUITY AND LIABLITIES			
Shareholder's Equity			
Share capital		3 318 346	-
Other contributed capital		164 712 421	-
Other equity incl. profit/loss for the year		-70 385 545	-
Total Equity		**97 645 222**	**-**
Long-Term Liabilities			
Liabilities to credit institutions	13	1 552 795	-
Current Liabilities			
Liabilities to credit institutions		621 118	-
Advances from grants		7 960 800	-
Accounts payable		10 331 385	-
Tax liabilities		118 582	-
Other current liabilities		397 679	-
Accured expenses and deferred income	14	1 188 674	-
		20 618 238	**-**
TOTAL SHAREHOLDER'S EQUITY AND LIABILITIES		**119 816 255**	**-**

Cash Flow Statement

(SEK)

GROUP	Not	2022-12-31
Operating Activities		
Result after financial items		-13 987 911
Adjustments for non-cash items		113 453
Cash Flow From Operating Activities Before Changes in Working Capital		**-13 874 458**
Changes in Working Capital		
Change in current receivables		-535 941
Change in accounts payable		6 846 065
Change in current liabilities		184 185
Cash Flow From Operating Activities		**-7 380 149**
Investment Activities		
Investments in intangible assets		-23 757 229
Cash Flow From Investment Activities		**-23 757 229**
Financing Activities		
Warrants		344 834
Change in loans		-621 118
Cash Flow From Financing Activities		**-276 284**
Cash Flow for the Year		**-31 413 662**
Cash and Cash Equivalents at Beginning of the Year		**42 672 700**
Cash and Cash Equivalents at end of the Year		**11 259 038**

Notes to the cash flow statement - GROUP

Note Other disclosures to the cash flow statement

	2022-12-31
Adjustment for items not included in the cash flow etc.	
Depreciation and amortization	115 366
Unrealized exchange rate differences	-1 913
	113 453

Investments in Intangible Assets	**2022-12-31**
Expenses for the year	37 579 990
Acquisition of patents	1 483 507
Activated R&D grants	-7 345 468
Prepaid grants	-7 960 800
	23 757 229

Income Statement

(SEK)

PARENT COMPANY	Not	2022-01-01 2022-12-31	2021-01-01 2021-12-31
Income			
Operating income		10 000	-
Other operating income	3	657 589	541 858
		667 589	**541 858**
Operating Expenses			
Purchased services		-8 884 613	-10 640 995
Raw materials and consumables		-	-913 712
Other external costs		-15 454 340	-12 116 391
Personnel cost		-10 041 161	-5 621 541
Capitalized expenses on own account		21 161 883	18 754 868
Depreciation and impairment of tangible and intangible fixes assets	5	-115 366	-233 686
Other operating expenses	6	-1 006 743	-97 265
Operating Profit / Loss		**-13 672 751**	**-10 326 864**
Interest income and similar items		423	-
Interest expenses and similar items	7	-137 701	-156 525
Profit / Loss After Financial Items		**-13 810 029**	**-10 483 389**
Profit / Loss Before Taxes		**-13 810 029**	**-10 483 389**
Net Income for the Year		**-13 810 029**	**-10 483 389**

Balance Sheet

(SEK)

PARENT COMPANY	Not	2022-12-31	2021-12-31
ASSETS			
Fixed Assets			
Intangible Fixed Assets			
Capitalized expenditures for development and similar work	8	88 633 000	68 409 775
Capitalized expenditure for patents, licences and trademarks	9	-	4 993 788
		88 633 000	**73 403 563**
Tangible Fixed Assets			
Equipment, tools and installations	10	46 068	90 949
Financial Fixed Assets			
Shares in group companies	11	11 320 840	-
Total Fixed Assets		**99 999 908**	**73 494 512**
Current Assets			
Current receivables			
Other receivables		747 123	1 337 270
Prepaid expenses and accrued income		232 901	310 773
		980 024	**1 648 043**
Cash and bank balances		10 249 293	42 672 700
Total Current Assets		**11 229 317**	**44 320 743**
TOTAL ASSETS		**111 229 225**	**117 815 255**
SHAREHOLDER'S EQUITY AND LIABILITIES			
Shareholder's Equity			
Restricted equity			
Share capital		3 318 346	3 318 346
Fund for development expenditure		82 226 190	68 409 773
		85 544 536	**71 728 119**
Unrestricted Equity			
Share premium reserve		164 712 421	164 712 421
Retained earnings		-138 621 911	-114 666 829
Profit/loss for the year		-13 810 029	-10 483 500
		12 280 481	**39 562 092**
Total Shareholder's Equity		**97 825 017**	**111 290 211**
Long-Term Liabilities			
Other liabilities	13	1 552 795	2 173 913
Current Liabilities			
Liabilities to credit institutions		621 118	621 118
Advances from grants		7 960 800	-
Accounts payable		1 564 560	2 209 264
Tax liabilities		118 582	17 867
Other current liabilities		397 679	230 628
Accrued expenses and deferred income	14	1 188 674	1 272 254
		11 851 413	**4 351 131**
TOTAL SHAREHOLDER'S EQUITY AND LIABILITIES		**111 229 225**	**117 815 255**

Cash Flow Statement

(SEK)

PARENT COMPANY	Not	2022-12-31	2021-12-31
Operating Activities			
Result after financial items		-13 810 029	-10 483 500
Adjustment for non-cash items		115 366	233 686
Cash Flow from Operating Activities Before Changes in Working Capital		**-13 694 663**	**-10 249 814**
Changes in Working Capital			
Change in current receivables		668 019	-199 025
Change in accounts payble		-644 704	721 128
Changes in current liabilities		184 186	74 788
Cash Flow from Operating Activities		**-13 487 162**	**-9 652 923**
Investment Activities			
Shareholders' contributions		-11 320 840	-
Investments in intangible assets		-7 339 121	-19 587 414
Cash Flow From Investment Activities		**-18 659 961**	**-19 587 414**
Financing Activities			
New Share issue		-	63 480 012
Share issue expenses		-	-13 400 857
Warrants		344 834	-
Change in loans		-621 118	-621 118
Cash Flow From Financing Activities		**-276 284**	**49 458 037**
Cash Flow for the Year		**-32 423 407**	**20 217 700**
Cash and Cash Equivalents at the Beginning of the Year		**42 672 700**	**22 455 000**
Cash and Cash Equivalents at the end of the Year		**10 249 293**	**42 672 700**

Notes to the Cash Flow Statement - PARENT COMPANY

Note Other disclosures to the cash flow statement

Adjustment for items not included in the cash flow etc.	2022-12-31	2021-12-31
Depreciation	115 366	233 686
Investments Intangible Assets		
Expenses for the year	21 161 882	18 347 669
Acquisition of patents	1 483 507	1 239 745
Activated R&D grants	-7 345 468	-
Prepaid grants	-7 960 800	-
	7 339 121	**19 587 414**

Notes

Note 1 Accounting Principles

Amounts in SEK unless otherwise stated.

General Accounting Principles
The annual accounts were drawn up in accordance with the årsredovisningslagen [Annual Accounts Act] and the general guidelines of the bokföringsnämnden [Swedish Accounting Standards Board].
BFNAR 2012:1 Annual financial statements and consolidated financial statements (K3).

Consolidated Accounts

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 means having the right to design the financial and operating strategies of an entity in order to obtain economic benefits.

The accounting for business combinations is based on the unitary approach. This means that the acquisition analysis is prepared as at the date on which the acquirer obtains control. From this point onwards, the acquirer and the acquired entity are treated as a single unit of account. The application of the unitary approach means that all assets (including goodwill), liabilities, income and expenses are included in their entirety are included in their entirety even for partly owned subsidiaries.

The acquisition cost of subsidiaries is calculated as the sum of the fair value at the time of acquisition of assets with the addition of incurred and assumed liabilities and issued equity instruments, expenses directly equity instruments, expenses directly attributable to the business combination and any contingent consideration.

In the acquisition analysis, the fair value, with some exceptions, is determined at the date of the acquisition date of the identifiable assets acquired and liabilities assumed and the minority interest. Minority interests are measured at fair value at the acquisition date. From the acquisition date, the consolidated financial statements include the income and expenses of the acquired company,identifiable assets and liabilities and any goodwill or negative goodwill arising.

Valuation Principles, etc.
Assets, provisions, and liabilities have been valued based on their acquisition value unless otherwise specified.

In 2022, the patents have been reclassified to be part of the development expenses. Figures for the previous year has also been adjusted to ensure good comparability.

2022 is the first year in which consolidated reporting is prepared, so there are no comparative figures for the Group for the previous year.

Government Grants
A government grant that is not contingent on future performance is recognized as revenue when the conditions for the grant are met. A government grant that is associated with a requirement for future performance is accrued over the period to which it relates, and reduces the value of the intangible asset.

Intangible Assets

Research and Development Expenditure
The cost of the internally generated intangible asset consists of all directly attributable costs (e.g. materials, services and salaries).

- The intention is to complete the intangible asset and to use or sell it.
- Conditions exist to use or sell the intangible asset.
- It is probable that the intangible asset will generate future economic benefits. economic benefits.
- The necessary and adequate technical, financial and other resources are available to complete the development and to use or sell the intangible asset.
- The expenditure attributable to the intangible asset can be measured adequately.
- The cost of capitalized expenditure includes the cost of producing the asset. Directly attributable expenditure includes personnel costs incurred in the development work. The corresponding amount has been transferred to the Fund for development expenditure.

Internally generated intangible assets are recognized at cost less accumulated amortization and impairment. Patents are amortized over the life of the patent, patents acquired by the company are reported less accumulated amortization and impairment losses.

Amortization
Amortization is calculated on a straight-line basis over the estimated useful life of the asset. Amortization is recognized as an expense in the income statement. Capitalized development costs are amortized when the developed product is ready for use.

	Group %	Parent company %
The Following Amortization Periods are Applied:		
Internally generated intangible assets		
Capitalized expenses for development and similar work	0	0
Patents	12.50	12.50
Acquired intangible assets		

Tangible Fxed Assets
Tangible fixed assets are recognized at cost less accumulated depreciation and impairment losses. The cost includes not only the purchase price but also expenses that are directly directly attributable to the acquisition.

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 an asset's value is lower than its carrying amount. If there is such an indication, the recoverable amount of the asset is calculated. If the recoverable amount is less than the carrying amount, an impairment loss is recognized as an expense. An internally generated intangible asset that is not yet ready for use or sale at the balance sheet date is always tested for impairment. The recoverable amount of an asset or cash-generating unit is the higher of fair value less costs to sell and value in use. Fair value less costs to sell is the price the entity expects to obtain in a sale between knowledgeable, willing parties in an arm's length transaction. Deductions are made for costs that are directly attributable to the sale. Value in use consists of the future cash flows that an asset or a cash-generating unit is expected to generate. For the purpose of impairment testing assets are grouped into cash-generating units.

A cash-generating unit is the smallest identifiable group of essentially independent units. As a consequence, some assets are tested for impairment individually and some are tested at the cash-generating unit level. Goodwill is allocated to the cash-generating units that are expected to benefit from the synergies of the related business combinations and represents the lowest level at which goodwill is monitored. Impairment losses relating to cash-generating units first reduce the carrying amount of the goodwill allocated to the cash-generating unit. Any remaining impairment loss reduces proportionately the other assets of the cash-generating units. With the exception of goodwill, all assets are reassessed for indications that a previous impairment is no longer justified, see note 2.

Leasing - Lessees
All leases have been classified as financial or operating leases. A financial lease is a 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 lease that is not a finance lease.

Operating Leases
Lease payments under operating leases, including an initial rent increase but excluding services such as insurance and maintenance, are recognized as an expense on a straight-line basis over the lease term.

Foreign Currency
Monetary items denominated in foreign currencies are translated at the closing rate. Non-monetary items recognized at the exchange rate at the time of acquisition.

Cash Flow Statement
The cash flow statement is prepared using the indirect method. The reported cash flow includes only transactions resulting in cash receipts or payments.

Equity Capital
The equity of the company consists of the following items:
Share capital representing the nominal value of issued and registered shares. Share premium reserve which includes any premium received on the issue of new share capital. Any transaction costs associated with the issuance of new shares are deducted from the share premium, taking into account any income tax effects. The fund for development expenditure is increased annually by the amount capitalized for the company's own development work. The fund is reduced annually by the depreciation of the capitalized development work. Retained earnings and profit/loss result, i.e. all retained profits/losses and share-based payments for the current and previous periods and acquisitions of own shares.

In the Group's equity, other contributed capital is the share premium reserve. Other equity is the fund for development costs, retained earnings and profit/loss for the year.

Note 2 Estimates and Judgments

In preparing the financial statements, the Board of Directors and the Chief Executive Officer must, in accordance with the accounting and valuation principles applied, make certain estimates, judgments and assumptions that affect the recognition and measurement of assets, provisions, liabilities, income and expenses. The areas where such estimates and judgments can have a significant impact on the company, and therefore may affect the income statement and balance sheet in the future, are described below.

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

Capitalization of Intangible Assets
In order to assess the potential impairment of the intangible asset, a recoverable amount is calculated based on the expected recoverable amount is calculated based on the expected future cash flow with an expected start of sales in 2026 and then using an appropriate interest rate to discount the cash flow. In this assessment which extends a number of years into the future (up to 2031), there are uncertainties about future cash flows and the assessment of an appropriate discount rate.

However, the company's current is that, based on available information, the assessment is fair and probable. The valuation is based on the current plan for commercialization. The risk that exist would be significant delays in the approval from the medical authorities in the EU and the US. The price level seems reasonable as it is in line with the only similar product that is currently on the market and which, in our opinion, is based on old technology, and cannot be compared with our product in terms of user-friendliness, reliability and mobility.

Note 3 Other Operating Income

	2022-01-01 2022-12-31	2021-01-01 2021-12-31
Group		
Exchange rate gains on operating receivables/liabilities	649 929	-
Sick pay	5 235	-
Refund of surplus from insurance companies	2 425	-
Total	**657 589**	**-**
Parent Company		
Exchange gains on operating receivables/liabilities	649 929	16 253
Grants received	5 235	500 000
Sick pay	2 425	-17
Total	**657 589**	**516 236**

Note 4 Employees, Staff Costs and Directors' Fees

Average Number of Employees

	2022-01-01 2022-12-31	Of which men	2021-01-01 2021-12-31	Of which men
Parent Company				
Sweden	11	8	8	6
Total Parent Company	**11**	**8**	**8**	**6**
Subsidiary				
Australia	-	-	-	-
Total Group	**11**	**8**	**8**	**6**

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

	2022-01-01 2022-12-31	2021-01-01 2021-12-31
Group		
Depreciation and amortization according to plan broken down by asset		
Concessions, patents, licenses, trademarks	70 485	-
Equipment, tools and installations	44 881	-
	115 366	**-**
Parent Company		
Depreciation and amortization according to plan broken down by asset		
Concessions, patents, licenses, trademarks	70 485	45 535
Equipment, tools and installations	44 881	188 151
	115 366	**233 686**

Note 6 Other Operating Expenses

	2022-01-01 2022-12-31	2021-01-01 2021-12-31
Group		
Exchange losses on operating receivables/liabilities	529 047	-
Exchange rate difference	477 695	-
	1 006 742	**-**
Parent Company		
Exchange losses on operating receivables/liabilities	529 047	97 264
Exchange rate difference	477 695	-
	1 006 742	**97 264**

Note 7 Interest Expense and Similar Items

	2022-01-01 2022-12-31	2021-01-01 2021-12-31
Group		
Interest expense	136 238	-
Interest expense, accounts payable	1 426	-
Interest expense for taxes and duties	37	
	137 701	**-**
Parent Company		
Interest expense	136 238	155 222
Interest expense, accounts payable	1 426	743
Interest expense for taxes and duties	37	313
Exchange rate loss	-	247
	137 701	**156 525**

Note 8 Capitalized Expenditure for Development Work

	2022-01-01 2022-12-31	2021-01-01 2021-12-31
Group		
Accumulated acquisition values		
At the beginning of the year (parent company)	72 047 298	-
New acquisitions	37 579 990	-
Activated R&D grants	-7 345 468	-
Reclassification of patents, opening balance	5 318 981	-
Acquisitions of patents for the year	1 483 506	-
	109 084 307	**-**
Accumulated amortization		
At the beginning of the year (Parent company)	-3 637 521	-
Reclassification of patents, opening balance	-325 193	-
Amortization of patents for the year	-70 485	-
	-4 033 199	**-**
Carrying Amount at the end of the Year	**105 051 108**	**-**
Parent Company		
Accumulated acquisition values		
At the beginning of the year	72 047 298	53 699 627
New acquisitions	21 161 882	18 347 669
Activated R&D grants	-7 345 468	-
Reclassification of patents, opening balance	5 318 981	-
Acquisitions of patents for the year	1 483 506	-
	92 666 199	**72 047 296**
Accumulated amortization		
At the beginning of the year	-3 637 521	-3 637 521
Reclassification of patents, opening balance	-325 193	-
Amortization of patents for the year	-70 485	-
	-4 033 199	**-3 637 521**
Carrying Amount at the end of the Year	**88 633 000**	**68 409 775**

In 2022, patents have been moved to be included under the item Capitalized expenditure on development work. The patents are amortized during their term. For other capitalized expenses, amortization will will be amortized when the developed product can be used.

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

	2022-12-31	2021-12-31
Parent Company		
Accumulated acquisition values		
At the beginning of the year	5 318 962	4 079 237
New acquisitions	-	1 239 745
Reclassifications	-5 318 962	-
Accumulated amortization		
At the beginning of the year	-325 193	-279 659
Reclassifications	325 193	-
Amortization for the year		-45 535
Carrying Amount at Year-end	**-**	**4 993 788**

In 2022, Patents have been moved to be included under the item Capitalized expenditure for development work.

Note 10 Machinery and Other Technical Installations

	2022-12-31	2021-12-31
Group		
Accumulated acquisition values		
At the beginning of the year (Parent Company)	840 309	-
At the end of the year	840 309	-
Accumulated depreciation		
At the beginning of the year	-749 360	-
Depreciation for the year	-44 881	-
At the end of the year	-794 241	-
Carrying Amount at Year-end	**46 068**	**-**
Parent Company		
Accumulated acquisition values		
At the beginning of the year (Parent Company)	840 309	840 309
At the end of the year	840 309	840 309
Accumulated depreciation		
At the beginning of the year	-749 360	-561 209
Depreciation for the year	-44 881	-188 151
At the end of the year	-794 241	-749 360
Carrying Amount at Year-end	**46 068**	**90 949**

Note 11 Shares in Group Companies

	2022-12-31	2021-12-31
Accumulated acquisition values		
Company formation	78	-
Shareholder contributions	11 320 762	-
Carrying Amount at Year-end	**11 320 840**	**-**

Specification of the Parent Company's and Group's Holdings of Shares in Group Companies
The ownership share of the capital also corresponds to the share of the votes. The Parent Company has assessed that a controlling influence exists in the Subsidiary as the company is 100% owned.

			2022-12-31
Subsidiary / Company name / Registered office	*Shares*	*in %*	*Value*
Scandinavian Realheart Pty, reg. no. 629 303 788 Victoria, Australia	1 596 902	100	11 320 840

Note 12 Prepaid Expenses and Accrued Income

	2022-12-31	2021-12-31
Group		
Prepaid leasing fees	12 500	-
Prepaid insurance	9 374	-
Prepaid costs Hydrix	1 276 056	-
Other interim receivables	225 206	-
	1 523 136	**-**
Parent Company		
Prepaid leasing fees	12 500	31 250
Prepaid insurance	9 374	-
Other interim receivables	211 027	279 523
	232 901	**310 773**

Note 13 Other Liabilities to Credit Institutions

	2022-12-31	2021-12-31
Group		
Maturity date, 1-5 years from balance sheet date	1 552 795	-
	1 552 795	**-**
Parent Company		
Maturity date, 1-5 years from balance sheet date	1 552 795	2 173 913
	1 552 795	**2 173 913**

Note 14 Accrued Expenses and Deferred Income

	2022-12-31	2021-12-31
Group		
Accrued vacation pay	633 461	-
Social security vacation pay liability	199 033	-
Other items	356 180	-
	1 188 674	
Parent Company		
Accrued salaries		131 420
Accrued vacation pay	633 461	380 959
Social security vacation pay liability	199 033	119 697
Other items	356 180	640 177
	1 188 674	**1 272 253**

Note 15 Pledged Assets and Contingent Liabilities - Group

	2022-12-31	2021-12-31
Group		
Chattel mortgages	4 200 000	-
Total Pledged Assets - Group	**4 200 000**	**-**
Parent Company		
Chattel mortgages	4 200 000	4 200 000
Total Pledged Assets - Parent Company	**4 200 000**	**4 200 000**

In 2022, Patents have been moved to be included under the item Capitalized expenditure for development work.

Note 16 Significant Events After the end of the Financial Year

Research and Development Activities
During the year, Realheart has, together with KTH, developed a patient simulator that will allow for advanced tests of the control algorithm that controls Realheart's artificial heart, but also contribute to increase Sweden's competitiveness when it comes to assistive devices for cardiovascular disease in general.

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).

Financing
Warrants of series TO1 were also exercised, which provided the company with approximately 4.2 MSEK before the issuing costs.

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 inventory and work in progress / current liabilities.

Board of Directors

Christer Norström

Chairman

Holding: 8 555 shares

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

Patrick NJ Schnegelsberg

Board Member

Holding: -

Solveig Bergström

Board Member

Holding: -

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